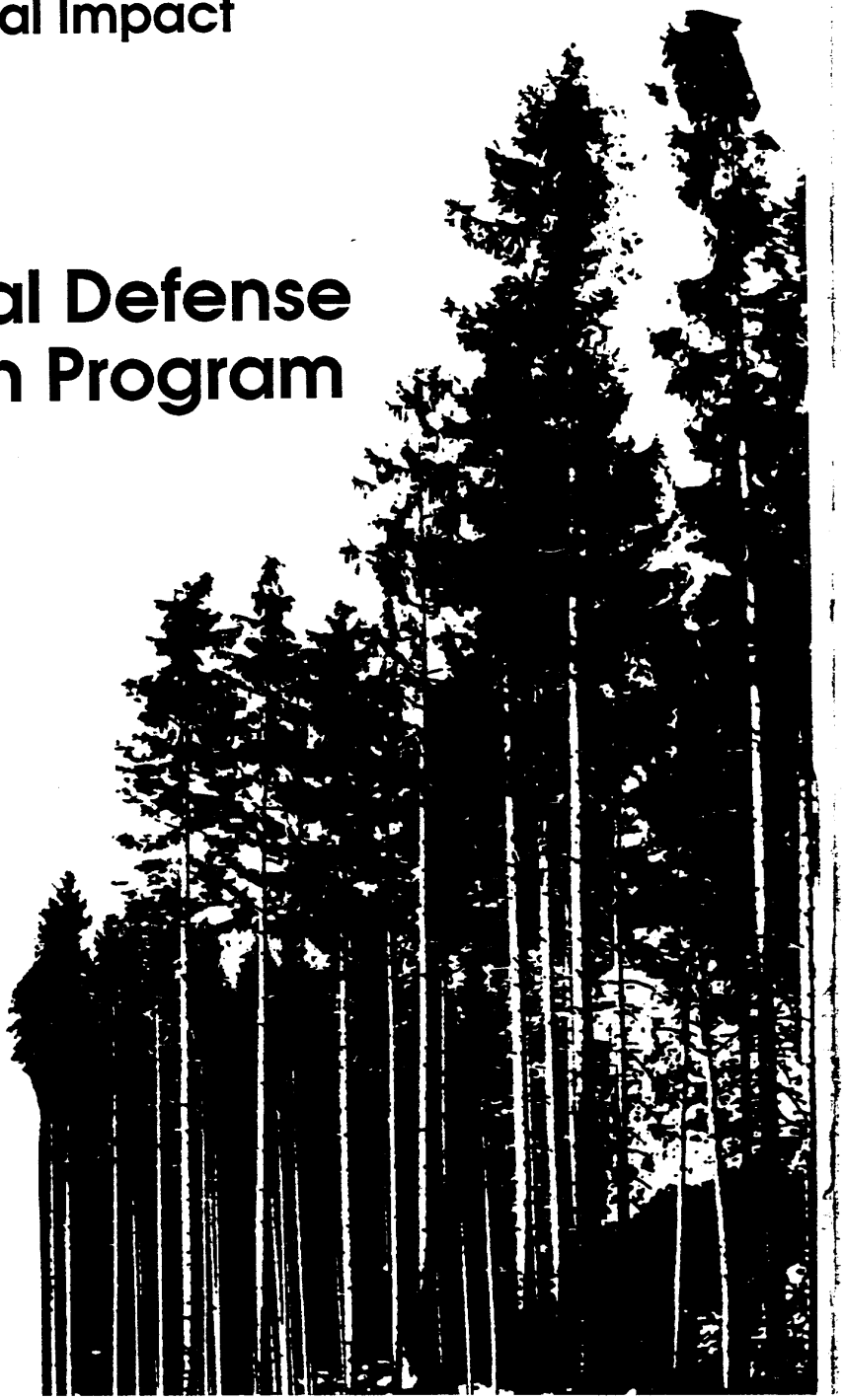
Linda S. Rowley

Final Programmatic Environmental Impact Statement

Biological Defense Research Program



April 1989

LEAD AGENCY: DEPARTMENT OF THE ARMY, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)

COOPERATING AGENCIES: None

TITLE OF PROPOSED ACTION: Biological Defense Research Program

AFFECTED JURISDICTION: Nationwide

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DOCUMENTATION DESIGNATION: Final Programmatic Environmental Impact Statement

ABSTRACT: The proposed action is to continue the Biological Defense Research Program (BDRP). The purpose and need for the BDRP is to maintain and promote a solid national defense posture with respect to potential biological warfare threats. A number of alternatives were evaluated and eliminated from further detailed study. The "no action" alternative (terminate the BDRP) and the "preferred" alternative (continue the BDRP) are evaluated in detail. Continuation of the BDRP would pose no unacceptable risks to the associated workforce and no significant risks to the public or to the environment. Termination of the BDRP would eliminate perceived risks and impacts associated with the BDRP, but would also eliminate significant scientific benefits derived from the program and significantly impair national defense.

REVIEW COMMENT DEADLINE: 4 May 1989

COMMENTS SHOULD BE ADDRESSED TO:
U.S. Army Medical Research & Development Command
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RCS DD-M (AR) 1327

EXECUTIVE SUMMARY

ES.1. PROPOSED ACTION

The proposed action, and subject of this Final Environmental Impact Statement (FEIS), is continuation of the Biological Defense Research Program (BDRP). The BDRP is a research, development, test and evaluation (RDT&E) program conducted by the Department of Defense (DoD), with the Department of the Army (DA) serving as the executive agent. This FEIS is programmatic in that it addresses the ongoing program and provides a basis for evaluating future BDRP activities.

The programmatic EIS provides an excellent approach for considering unscheduled, unidentified future implementing actions that may have environmental impact. Each proposed future BDRP action will be examined, in the context of the National Environmental Policy Act (NEPA), to ascertain whether it is covered adequately by this programmatic EIS. If the proposed future action is not covered, then a tiered approach to an environmental analysis will be undertaken. Future actions may range from those categorically excluded from further NEPA documentation to those with the potential to cause significant impacts on the quality of the human environment. Proposed future actions will thus be evaluated for their similarities to those in the existing BDRP; conformance to statutes, guidelines, and established practices; as well as for any site-specific considerations.

ES.2. DESCRIPTION OF THE BDRP

The objectives of the BDRP are to develop measures for detection, treatment, protection and decontamination of potential biological warfare threat agents. Development of medical defensive measures, such as prophylactic vaccines and drugs, therapeutic measures, and patient treatment and management protocols are important components of the program. The purpose of the BDRP is to maintain and promote a solid national defense posture with respect to potential biological warfare threats. The BDRP supports RDT&E efforts necessary for the maintenance and development of defensive measures and materiel to meet these threats. In addition to promoting the national defense posture, the BDRP benefits the scientific community in general through its research and development efforts, and benefits the global population in the development of diagnostic methods, and vaccine and drug therapies for the treatment of diseases. The BDRP does not include the development of any weapons, even defensive ones, nor does it attempt to develop new pathogenic organisms for any use. All work conducted under the BDRP is unclassified. However, results may be classified if they impinge on national security by specifying U.S. military deficiencies, vulnerabilities or significant breakthroughs in technology.

ES.3. CONDUCT OF THE BDRP

Management responsibility for the program is executed by three Army components:

1) U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) is the lead laboratory in medical defense against biological warfare threats. It is located at Fort Detrick, Frederick, Maryland.

2) U.S. Army Chemical Research, Development, and Engineering Center (CRDEC) manages and conducts research, development, and engineering activities to provide non-medical defense against biological warfare threats. It is located at U.S. Army Aberdeen Proving Ground, Maryland.

3) U.S. Army Dugway Proving Ground (DPG) is a major range and test facility which supports all DoD components. The Baker Laboratory Complex at DPG, located approximately 70 miles southwest of Salt Lake City, Utah, performs independent testing for the BDRP.

These three, USAMRIID, CRDEC and DPG, have been designated as primary sites in the BDRP FEIS. Under the auspices of the three primary organizations, the BDRP is conducted at other DoD laboratories, other government agencies, universities, and research organizations. Over 100 other sites, in 27 states and 8 foreign countries, are currently involved in some facet of the BDRP. These sites have been designated as secondary sites for the purpose of this FENS.

ES.4. CONTROVERSIAL ISSUES

The BDRP is both complex and controversial. The BDRP controversy primarily relates to concerns over, or opposition to, the program per se and/or to the inclusion in the program of research or testing with high hazard infectious organisms, genetically engineered microorganisms (GEMs), and aerosols. Other concerns center on a distrust for the military and apprehension that the BDRP could be used to foster the development of offensive weapons or would, in some manner, encourage other nations to engage in a biological weapons arms race. A portion of the controversy is apparently deeply rooted, especially within certain segments of the population opposed to research and development on GEMs. Other views and concerns may be based upon lack of information, misinformation, or misunderstandings about the BDRP.

Considerable effort has been devoted to present accurate information and explanations of the BDRP in this FEIS: what the BDRP is, as well as what it is not. The United States is fully committed to the Biological Weapons Convention (BWC) (Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their

Destruction). The BDRP is conducted in strict conformance with the provisions of the BWC, which explicitly permits the conduct of research and development for defensive purposes against potential biological warfare threats. The major portion of the BDRP is devoted to medical diagnosis, treatment and protection of military personnel. Perhaps full disclosure of program content and an explanation of the openness of the EDRP, along with a discussion of the stringency of the control measures employed and the safety history of the program, will alleviate much of the fear and controversy. However, because genetic engineering has been determined to be a vital research tool for all modern biomedical research and high hazard organisms must be used albeit in small quantities and under stringent safety standards) for the program to be effective, it is not anticipated that controversy will cease. The public review process for this EIS has provided a forum for all parties to examine the facts and conclusions reached, and to make their views known to the decision maker.

ES.5. ISSUES TO BE RESOLVED

The primary issue under consideration in this FEIS is the continuation of the BDRP. As stated above, there is controversy about the BDRP, but a number of the issues, such as those related to the appropriateness of research with GEMs, per se, are beyond the scope of this EIS. Perhaps the information presented in this FEIS will, however, resolve certain issues in the minds of some of the public. The BDRP is conducted under rigorous controls which serve adequately to protect the health and safety of the workforce and the quality of the human environment. As far as can be ascertained, all aspects of the BDRP are in compliance with applicable statutes, regulations, and guidelines; all necessary certifications, permits, and other entitlements are in place, and multiple stringent safety constraints are continually implemented.

ES.6. ENVIRONMENTAL CONSEQUENCES

Because the BDRP is ongoing, the impacts are either already manifested, are continuing, or could occur in the future. For example, it is possible that impacts to the environment could result from accidents or incidents. From this perspective, certain of the impacts can be observed while others (potential impacts) have to be projected. The analysis of impacts is complicated because of discrepancies between actual or credible (historical or reasonably anticipated) and catastrophic impacts as perceived by certain elements of the public. An Impact Analysis Matrix (JAM) was developed to assist in identifying and addressing environmental consequences. To further aid in the impact analysis, the BDRP is tiered into seven programmatic, or topic, categories based upon the potential risks or issues involved. Only three of the categories exhibit either potential for significant environmental consequences or are considered to be controversial. These are 1) high hazard organisms, 2) toxins, and 3) GEMs. The category GEMs is found to represent an issue

rather than a risk, even though it is perceived by some to present significant risks.

Using the IAM the entire ongoing BDRP is examined on the basis of the programmatic risk/issue categories and on the basis of selected specific sites. The three primary sites, and representative secondary sites selected from the highest risk/issue categories, are analyzed for potential site-specific impacts versus impacts arising directly from the program. These analyses, which consider normal operations with appropriate controls in place, reveal the following:

1) All significant issues relate to the existence of the program, not to specific sites.

2) No actual significant adverse impacts are identified.

3) No conflicts of resource use are identified.

Because of the controversy and perceived risks associated with the BDRP, a variety of maximum credible events, accidents, and incidents were postulated on the basis of credible scientific evidence and were analyzed for potential impacts. This examination found that even severe accidents would not create significant risk or impact upon the quality of the human environment. No catastrophic results that could lead to significant adverse consequences arising from the BDRP are identified in association with any site or activity.

ES.7. ALTERNATIVES

A number of options, including those suggested during public scoping and the DEIS comment period, were evaluated to determine those which were reasonable alternatives. The following were eliminated from consideration as viable alternatives:

1) Elimination of aerosol testing.

2) Placement of a moratorium on research involving GEMs.

3) Transfer of the management responsibility of the BDRP to a non-military agency.

None of the above options was found to be a reasonable alternative. It was determined that many other reasonable scoping suggestions and recommendations received in the form of public comments were already integral components of the ongoing program. No changes to the scope or location of BDRP activities were identified that offered significant improvements in the quality of the human environment. The alternatives considered reasonable reduced to the "preferred" alternative, continue the BDRP, and the "no action" alternative, terminate the BDRP, thus providing a clear choice to the public and the decision maker.

The "no action" alternative is the one that would alter the status quo and cause adverse impacts because the BDRP is an ongoing program. In summary, the tradeoffs associated with the two reasonable alternatives are:

ALTERNATIVE	TRADEOFFS
Continue BDRP (Preferred)	1. Controversy continues. 2. Perceived risks/impacts continue. 3. National defense posture and scientific benefit continue.
Terminate BDRP (No Action)	1. BDRP controversy eliminated. 2. GEM controversy continues in other government and non-government sectors. 3. Perceived risks/impacts eliminated. 4. National defense posture and scientific benefits lost.

Other secondary tradeoffs derive from those listed above but are considered to be of lesser consequence to environmental quality. For example, continuing the BDRP necessitates continuation of actual, though minor, adverse impacts, such as contributions to the waste stream and small risks to the health of the workforce. Existing controls reduce these impacts to a level of minor concern. Likewise, termination of the BDRP would create adverse economic impacts which would be locally significant, especially in Frederick County, Maryland, and the medical benefits to the global population, which are a secondary benefit of the BDRP, would be forfeited.

ES.8 FILING, DISTRIBUTION AND COMMENT ON THE DRAFT EIS

The Draft Programmatic EIS for the BDRP was filed with the Environmental Protection Agency on May 12, 1988, and distribution was made to governmental agencies, interest groups and others known to be interested in the proposed action. The notice of filing, notice of public availability and notice of public meeting were published in the *Federal Register* on May 17, 1988. More than 650 copies of the DEIS were distributed.

The public comment period was initially announced to end August 12, 1988. Two sessions of a public meeting were held on July 25, 1988 in Arlington, VA. Following this meeting, and in response to requests from public and private sectors in Utah, an additional public meeting was held September 19, 1988, at Tooele, UT. The public comment period was extended to October 4, 1988, to allow additional public input on the DEIS. A total of 59 oral and written comments were received within the overall review period. The comments are presented in Appendix 14, and the responses to the comments are presented in Appendix 15.

ES.9. CONCLUSIONS

The ongoing BDRP has been thoroughly analyzed in the NEPA context, using a systematic, interdisciplinary approach, and the public has been afforded the opportunity for review and comment. In recognition of the potentially hazardous nature of the type of research and development accomplished in the BDRP, the DoD, as well as the scientific community, has developed and implemented elaborate controls to assure adequate protection for the workforce and virtually total protection for the external environment. The history of the BDRP illustrates the effectiveness of these controls, and demonstrates how the conduct of activities with hazardous biological materials actually became safer over the years as better containment equipment and facilities became available and more effective biosafety protocols were developed. An inspection program has been implemented to further assure that facility standards are met at institutions performing BDRP research involving high-hazard organisms. The BDRP does not create significant adverse impacts on the quality of the human environment, and the perceived risks are considered to be very much exaggerated based on the credible scientific evidence and reasonably assumed circumstances. Because of the comprehensive mitigative measures, controls and monitoring already incorporated in the BDRP, and the lack of actual adverse consequences, additional mitigation was not found to be justified.

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SYMBOLS, ABBREVIATIONS, AND ACRONYMS

°	Degree
>	Greater Than
<	Less Than
%	Percent
°y	Lateral Dispersion Coefficient
°z	Vertical Dispersion Coefficient
ACDA	US Arms Control and Disarmament Agency
AMC	US Army Materiel Command
AQCR	Air Quality Control Region
APG	US Army Aberdeen Proving Ground
AR	Army Regulation
BATF	Biological Aerosol Test Facility
BD	Biological Defense
BDRP	Biological Defense Research Program
BG	Baci*llus subtilis* var. *niger*
BL	Biosafety Level
BW	Biological Warfare
BWC	Biological Weapons Convention
C	Celsius (or Centigrade)
CAR	Central African Republic
CB	Chemical/Biological
CBD	Chemical and Biological Defense
CBR	Chemical-Biological-Radiological (filter)
CDC	Centers for Disease Control
CEQ	Council on Environmental Quality
CERL	US Army Corps of Engineers Construction Engineering Research Laboratory
CFR	Code of Federal Regulations
CRDEC	US Army Chemical Research, Development and Engineering Center
d	Dose
D	Pasquill Atmospheric Stability Factor (neutral)
DA	Department of the Army
DEH	Directorate of Engineering and Housing
DEIS	Draft Environmental Impact Statement
DNA	Deoxyribonucleic Acid
DoD	Department of Defense
DOT	US Department of Transportation
DPG	US Army Dugway Proving Ground
DT	Developmental Testing
EA	Environmental Assessment
EICS	Environmental Impact Computer System
EIFS	Economic Impact Forecast System
EIS	Environmental Impact Statement
EPA	Environmental Protection Agency
F	Pasquill Atmospheric Stability Factor (stable)
FAR	Federal Acquisition Regulations
FDA	Food and Drug Administration
FEIS	Final Environmental Impact Statement
Ft.	Fort
9	Gram

GEMs	Genetically Engineered Microorganisms (or Material)
GPIPID	Guinea Pig Intraperitoneal Infectious Dose
HEPA	High-Efficiency Particle Arresting (filter)
HHS	US Department of Health and Human Services
HID	Human Infectious Dose
HIV	Human Immunodeficiency Virus
hr	Hour
HRLD	Human Respiratory Lethal Dose
HV1	Biological Containment Level (also HV2)
HV	Host-Vector
IAM	Impact Analysis Matrix
IBC	Institutional (or Installation) Biosafety Committee
ID	Infectious Dose
IP	Intraperitoneally
km	Kilometer
L,1	Liter
LCM	Lymphocytic Choriomeningitis Virus
LD	Lethal Dose
MCE	Maximum Credible Event
MICLD	Mouse Intracranial Lethal Dose
min	Minute
MIPLD	Mouse Intraperitoneal Lethal Dose
MIPR	Military Interagency Purchase Request
mg	Milligram
ml, mL	Milliliter
MRDC	Medical Research and Development Command
MRVS	Medical Research Volunteer Subject
NCI	National Cancer Institute
NEPA	National Environmental Policy Act
NIH	National Institutes of Health
NOI	Notice of Intent
NPDES	National Pollutant Discharge Elimination System
NRC	Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
pfu	Plaque Forming Unit
PHS	US Public Health Service
PRC	People's Republic of China
Q	Rate of Emission; units per minute
RAC	NIH Recombinant DNA Advisory Committee
RCRA	Resource Conservation and Recovery Act
r DNA	Recombinant DNA
RDT&E	Research, Development, Test and Evaluation
REC	Record of Environmental Consideration
RFP	Request for Proposals
RH	Relative Humidity
ROD	Record of Decision
ROK	Republic of Korea
rpm	Revolutions Per Minute
RVF	Rift Valley Fever (disease)
RVFV	Rift Valley Fever Virus
SIPRI	Stockholm International Peace Research Institute
SOP	Standard Operating Procedures
SoRI	Southern Research Institute, Birmingham, AL
SRI	SRI International, Menlo Park, CA

STD	Standard
TECOM	US Army Test and Evaluation Command
TRADOC	US Army Training and Doctrine Command
TSI-GSD	The Salk Institute-Government Services Division
U	Wind Speed, Meters per minute
UAB	University of Alabama at Birmingham
UK	United Kingdom
USACRDEC	US Army CRDEC
USADPG	US Army DPG
USAMRDC	US Army Medical Research and Development Command
USAMRIID	US Army Medical Research Institute of Infectious Diseases
USSR	Union of Soviet Socialist Republics
UV	Ultra Violet
VEE	Venezuelan Equine Encephalomyelitis
Vol	Volume

DEFINITION OF TERMS

The following terms are defined as they pertain to their use in this Environmental Impact Statement. Alternative definitions may exist that are not applicable to the intended usage in this document.

Credit is given for some definitions, or portions of them, to the Stockholm International Peace Research Institute (in "Biological and Toxin Weapons Today," E. Geissler, ed. Oxford University Press, New York, 1986); the New Riverside University Dictionary, Houghton-Mifflin Company, Boston, 1984; and Dorland's Medical Dictionary, 26th Ed, W.B. Saunders, Philadelphia, 1985.

Aerosol - A suspension or dispersion of small particles (solids or liquids) in a gas (such as air). The particles are so small, less than 10 microns in diameter, that they remain suspended for considerable periods of time instead of settling.

Airlock - A small room or passageway, similar to a foyer, used for access to a containment laboratory. The laboratory is maintained at constant negative atmospheric pressure relative to the airlock, such that the flow of air is always into the laboratory.

Anthrax - Disease from infection with the bacterium *Bacillus anthracis* .

Antibody - Any of the immunoglobulin proteins that are produced by lymphocytes in response to specific immunogens and that are capable of binding to, and often neutralizing, the immunogen.

Antigen - Any substance, usually a protein or carbohydrate that is bound specifically by immunoglobulins. The term is sometimes used as a synonym for "immunogen."

Antiserum - Serum containing antibodies specific for the antigen in question. Antisera are obtained from vertebrates, either experimentally immunized, or after a naturally acquired infection.

Arbovirus - Arthropod-borne virus; a virus transmitted to man by arthropods (e.g., mosquitoes and ticks).

Arthropod - Any member of the phylum of the animal kingdom composed of organisms having a hard, jointed exoskeleton and paired, jointed legs (e.g., insects, ticks).

Autoclave - An apparatus that completely sterilizes and/or decontaminates materials placed within by using gas or steam to generate high heat and pressure, or sterilizing gases.

Bacteria - Single-celled organisms that reproduce by simple division. Pathogenic bacteria are capable of producing disease in man, animals, or plants.

Bacteriophage - A virus that infects bacteria.

Baggy Filter - A biological filter that retains at least 95% of the particles, larger than 1.2 microns in diameter, passing through the filter.

Biological and Toxin Weapons Convention (BWC) - The full title is "Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction."

Biological Containment - See Host-Vector Containment.

Biological Warfare - The intentional use of living microorganisms or toxic biological products to produce sickness or death in man, animals, or crops.

Biosafety Level 1 (BL-1) - Practices, safety equipment, and facilities that are applicable for undergraduate and secondary school educational training and teaching laboratories in which work is done with microorganisms not known to cause disease in healthy adult humans (See Appendix 12).

Biosafety Level 2 (BL-2) - Practices, safety equipment, and facilities that are applicable to clinical, diagnostic, or teaching facilities in which work is done with a wide range of moderate-risk microorganisms (See Appendix 12).

Biosafety Level 3 (BL-3) - Practices, safety equipment, and facilities that are applicable for clinical, diagnostic, teaching, research, or production facilities for work with indigenous or exotic agents where the potential for infection is real, and the disease may have serious or lethal consequences; the safety features of a BL-3 laboratory are not as stringent as those of BL-4 (See Appendix 12).

Biosafety Level 4 (BL-4) - Practices, safety equipment, and facilities that are applicable to work with dangerous and exotic agents that pose a high individual risk of lifethreatening disease; the highest level in a series of four increasingly stringent designs developed by CDC/NIH (See Appendix 12).

Biotechnology - A general term relating to the technology that uses living organisms, generally microorganisms, or biomolecules to produce or modify useful products, to carry specific functions, or to change specific characteristics of other organisms.

Class I Biological Safety Cabinet - Open-fronted, negative pressure, ventilated cabinet; exhaust air is filtered by HEPA filters (See Appendix 11).

Class II Biological Safety Cabinet - Same as Class I above with a HEPA-filtered airflow within the work space (See Appendix 11).

Class III Biological Safety Cabinet - Totally enclosed, ventilated cabinet of gas-tight construction; operations are conducted through attached rubber gloves. Supply air is drawn through HEPA filters and cabinet exhaust air is filtered by two HEPA filters (See Appendix 11).

Clone - A group of cells, viruses, or nucleic acid molecules, all of which originated from a single common ancestor, and which, therefore, are identical.

Containment - The set of safe methods, established by the Centers for Disease Control and the National Institutes of Health, and facilities for managing infectious materials in a manner that will not endanger the laboratory worker, community, or the environment.

Cutaneous - Pertaining to, or affecting, the skin.

Decay Rate - The rate of loss of activity, toxicity, or infectivity over time.

Decontamination - The process of inactivating, by steam, gas, or chemical disinfectant, hazardous infectious organisms, toxins or other unwanted material from equipment and other materials. See also Sterilization.

Deoxyribonucleic Acid - A biomolecule consisting of a polymer of four different building blocks, the deoxyribonucleotides. DNA is the genetic material of all organisms and viruses, except for the small class of RNA-containing viruses.

Developmental Testing - Testing done during a research program to determine if the technical objectives are met.

DNA - See Deoxyribonucleic acid.

Effluent - Used or waste gases, liquids, or solids discharged from a process, laboratory, or building into the environment.

Electrophoresis - The technique of separating charged molecules or particles by differential movement through a liquid or porous matrix by application of an electric field.

Endemic - Present in a community or other defined area; within limited boundaries.

Enterotoxins - Toxins of bacterial origin that induce diarrhea! diseases in man or susceptible animals after oral ingestion by provoking an accumulation of water and electrolytes from the intestinal mucosa.

Enzootic - Constantly present in specific animal populations of a given area.

Epidemic - An outbreak of disease that affects many persons throughout an area at the same time.

Epizootic - An outbreak of disease that affects many animals throughout an area at the same time.

Extramural - BDRP activities conducted outside Army facilities by contract or other methods of funds transfer.

Etiological Agent - The cause of a disease or abnormal condition.

Fauna - The animal life characteristic of a given region.

Fomite - An inanimate object (e.g., instrument or clothing) that is capable of transferring infectious organisms from one individual to another.

Gene - The basic unit of genetic information and heredity. Biochemically, a sequence of DNA (or RNA in some viruses) in which unique information is encoded by a specific order of nucleotides. This unique sequence can be translated to form a unique protein that functions to express the information contained within the gene.

Genetic Engineering - A general term describing the intentional and directed modification of genetic information for some specific purpose (See Appendix 14).

Glove box - A sealed box in which workers, using gloves attached to and passing through openings in the box, can handle hazardous material safely from the outside.

Habitat - Natural living place of an animal or plant species.

HEPA filter - High-efficiency particle arresting filter that retains 99.97% of the particles, larger than 0.3 microns in diameter, passing into the filter.

Host - In epidemiology, an organism that harbors and allows the replication of another organism, such as a virus, bacterium, or rickettsia.

Host-Vector Containment - A measure of the degree of *biological* containment present in an experimental system. The levels are expressed as HV1 and HV2. "Containment" here means that the host and vector are selected specifically so that survival of the host and transmission of the vector to another host are deliberately either difficult (HV1) or extremely unlikely (less than 1 chance in 100 million -HV2).

Immunization - Intentional exposure of an animal or human to an immunogen with the intent of inducing a specific (usually protective) immune response.

Immunity - Resistance to a disease caused by a specific infectious agent, based on a prior exposure to the agent, a related agent, or a vaccine.

Immunogen - Any substance, usually a protein or a carbohydrate, that is recognized as "foreign" or "non-self" by an animal's immune system, and that provokes a specific immune response.

In Situ - In place; at the natural place where it is found.

Institutional Biosafety Committee (IBC) - The group of scientific, safety, community and medical personnel that has been established at an institution to review all procedures concerning proposed genetic engineering activities.

In Vitro - An experiment or other action carried out in a cellfree system (e.g., in *vitro* protein synthesis) or with isolated cells from higher organisms (e.g., in *vitro* transformation). In a culture tube or dish. Literally, "in glass."

In *viva* - In the living body of a plant or animal.

Insectary - Area in which insects are maintained in specially designed, screened cages.

Log (from logarithm) - The exponent that indicates the power to which a base number is raised to produce a given number (e.g., the log of 100 to the base 10 is 2). Colloquially used to mean "orders of magnitude larger or smaller," as in "5 logs greater than...."

Lyophilization - Process of preserving a substance by freeze drying.

Maximum Credible Event - The most severe accident or event whose originating conditions may be believed. A postulated event based on credible scientific evidence and the rule of reason (See Appendix 9).

Microorganism - An organism of microscopic size and therefore not visible to the naked eye.

Molecular Biology - The field of biology in which the structure and function of biological systems are analyzed in terms of the physics and chemistry of their molecular constituents.

Monoclonal Antibody - One of a group of identical antibodies able to react with one and the same antigen, produced by a clone of antibody-producing ("hybridoma") cells obtained by fusion of immortal tumor cells with stimulated lymphocytes.

Mycotoxin - Toxin produced by certain types of fungi.

Necropsy - Examination of an animal after death; analogous to an autopsy for a human.

Negative Air Pressure - Air pressure below the ambient atmospheric pressure; in terms of an enclosed room, the internal pressure is less than the external pressure such that, if a leak or puncture occurs in the containing walls, airflow is always from the outside to the inside.

Neurotoxin - A toxic substance that impairs the function of the nervous system.

Nonpathogenic - Incapable of causing disease.

Nonviable - Incapable of growth.

Nuclear, Biological, and Chemical Defense (NBC) - Actions, equipment, doctrine, etc., that protect military forces from the effects of nuclear weapons and/or chemical and/or biological agents. The technologies are different but the defense responses are similar. Thus, NBC is often used as a collective term. This report focuses on the biological portion.

Operational Testing - Testing done late in the RDT&E process with typical users as operators, crews, or units in a realistic, operational environment to provide data on utility, effectiveness, and suitability, plus other operational information.

Pasquill Stability Categories - Six categories or classes that relate atmospheric stability to plume dispersion according to weather conditions, especially surface wind speed, local insolation, and vertical temperature profile. A represents very unstable conditions;. B. moderately unstable; C, slightly unstable; D, neutral; E, stable; and F. very stable conditions.

Pathogen - Any disease-producing organism.

Pathogenesis - Sequence of events in the development of a given disease state.

Percutaneous Route - Through unbroken skin, as in absorption.

Plaque - In virology, a clear area within a confluent layer of cells grown in vitro caused by viral infection and subsequent destruction of the cells within the area.

Plaque-Forming Unit (PFU) - A unit of infectivity. Used when measuring the number of infectious particles in a viral suspension by counting the number of plaques the suspension can produce on a layer of susceptible cells.

Polypeptide - A polymer of numerous amino acid residues (usually more than 20), linked together by peptide bonds.

Positive-Pressure Protective Suit - A one-piece plastic suit maintained under constant positive pressure with an air hose. The suit contains one-way valves that allow air to exit but prevent room air from entering the suit.

Protein - A biopolymer of amino acid residues which are linked together by peptide bonds. A protein may consist of one or more polypeptides.

Q fever - Influenza-like disease caused by the rickettsia *Coxiella burnetii*.

Recombinant DNA (rDNA) - Literally, a single DNA molecule consisting of sequences originating from two (or more) DNA molecules joined by natural or experimental means. Often used to refer to DNA molecules produced by genetic engineering techniques.

Rickettsia - Any of several pathogenic microorganisms of the genus *Rickettsia* that are carried as parasites by many ticks, fleas, or lice. They are intracellular parasites which are intermediate between bacteria and viruses in size.

Simulant - Surrogate material that has physical, chemical, and/or biological characteristics similar to those of the threat material it mimics. Simulants are nonhazardous or very much less hazardous than the materials they simulate.

Slurry Concentration - A thick, semifluid suspension containing microorganisms and their growth substrate.

Spore - A dormant life form of some bacterial species which is much more resistant to heat, chemical, and physical stresses than the vegetative form.

Sterilization - The act of making something sterile; carries the meaning of the total elimination of all viability, rendering all organisms incapable of reproduction or growth. Autoclaving (q.v.) with heat and pressure is an example of sterilization. See also Decontamination.

Suspension - A system consisting of a solid dispersed in a liquid or gas, in particles larger than colloidal size.

Titer - Also agglutination titer. A measure of the functional activity of a given solution, suspension, or fluid, e.g., the number of infectious or toxic units, or the concentration of antibodies. See also Plaque Forming Unit.

10^x_ Where x may be either a positive or negative number. This is "Scientific Notation " which is read as "10 to the xth power." For example, $10^1 = 10$, $10^2 = 100$, $10^3 = 1000$, etc. For values of x less than zero (negative numbers), $10^{-1} = 0.1$, $10^{-2} = 0.01$, $10^{-3} = 0.001$, etc.

Toxin - A substance poisonous to other organisms produced by bacteria, fungi, reptiles, arthropods, algae and many other life forms.

Toxoid - A toxin that is modified to have reduced toxic properties but is still able to induce the formation of antibodies.

Tularemia - A disease caused by the bacterium *Francisella tularensis* .

Vaccination - Active immunization designed to induce immunity to specific diseases by prophylactic inoculation of attenuated or killed microorganisms, or immunogenic fractions of these agents or toxoids.

Vector - 1) In terms of transmission of disease, a carrier, such as an insect, that can transfer a pathogen from one organism to another. 2) In the context of genetic engineering, a small, autonomous piece of nucleic acid, such as a plasmid, used to transfer gene fragments between organisms.

Venezuelan Equine Encephalomyelitis (VEE) - A mosquito-borne viral disease endemic in various parts of the Western Hemisphere, which causes an acute, febrile disease in equines and man and which may affect the central nervous system.

Virus - Submicroscopic infectious organism, smaller than a bacterium, capable of passing through filters that will retain bacteria, and of multiplying only within a living susceptible host cell. Viruses differ from all other living entities by possessing only one kind of nucleic acid, either DNA or RNA.

Zoonotic Infection (zoonosis) - A disease, transmissible from animal to man, that can be maintained within an animal population (reservoir) in the absence of man as an essential link.

1. PURPOSE, NEED AND SCOPE

1.1 INTRODUCTION

Even though over 100 nations, including the United States (US) have signed the Biological Weapons Convention (BWC) (see section 2 and Appendix 1) and agreed never to develop biological organisms or toxins for offensive use, over 50 nations are not yet States Parties to the Convention. The unverifiable nature of the BWC and the relatively small resource base required to produce such biological weapons leave open the possibility that signatory nations could violate the articles of the convention, or that non-signatory nations could ignore it completely. Biological weapons constitute a potential component of an offensive arsenal that could be used by hostile parties either overtly or covertly. The Department of Defense (DoD) cannot ignore completely the possibility that BW threats exist, much less fail to provide a reasonable level of protection to US forces. Thus, defense against biological weapons is considered a vital component of the overall defense posture of the US and its allies. The Biological Defense Research Program (BDRP) provides this defense through the development of medical and physical protective strategies, products and materiel. The existence of a strong defensive program is considered in and of itself to be a significant disincentive to the development or use of biological weapons by hostile parties.

It is recognized that controversy exists concerning the need and appropriateness of the BDRP. Other issues related to the BDRP also cause concerns and evoke controversy. Later discussions in this Final Programmatic Environmental Impact Statement (FEIS) address many controversial issues in detail, and clearly delineate where differences of opinion exist and give the basis for positions espoused.

1.2 PROPOSED ACTION

The Proposed Action and subject of this FEIS is the continuation of the BDRP in the same manner as it is now constituted. The BDRP is a research, development, test and evaluation (RDT&E) program authorized and funded by the U.S. Congress and implemented through the DoD to provide protection for military personnel and materiel against potential biological warfare threats. Detailed descriptions of the activities conducted within the BDRP are presented in section 3.

1.3 PURPOSE

The purpose of the BDRP is to promote and maintain a solid national defense posture, in consonance with national policy, with respect to potential biological warfare threats. The mission objectives established in support of this goal are presented and discussed in section 2.

1.4 NEED

Simply stated, the need for the BDRP is to conduct necessary RDT&E of defensive measures and materiel with which to meet potential biological warfare threats. Although the BDRP has existed for a number of years, many challenges remain. There are needs for new and improved vaccines and drugs, as well as for more rapid and reliable diagnostics, field detection methods and better personal protective devices. Basic research helps foster a better understanding of the mechanisms of action of disease organisms and toxins of biological origin. The scientific advances afforded by the application of genetic engineering offer tremendous opportunities for improved diagnostic and treatment measures. Technological advances, improved laboratory equipment and more sophisticated techniques allow for the development of improved medical and physical protective measures. More importantly, the maintenance of a sophisticated technological base provides the capability to respond to unexpected threats and challenges and to prevent a technological "surprise."

While substantial gains in understanding potential BW agents have been made, and improved defensive measures continue to be developed, neither a complete solution to nor elimination of all threats has yet been realized. This is not a realistic expectation in any science. Therefore, an ongoing need for the BDRP will exist for the foreseeable future. The level of funding and effort may vary, and emphasis may change in response to new developments or circumstances, but the needs and purposes for the BDRP will continue. Congressional scrutiny and the reviews afforded by the appropriations process provide checks and balances to the system, thus assuring appropriate oversight of the DoD program by another branch of the Government. The management and implementation of the BDRP is entrusted to the Army because of its knowledge, expertise and experience.

The primary goal of the BDRP is to improve the effectiveness of the U.S. Armed Forces, especially in the area of biological defense, and to do so in a manner which reflects appropriate attention and sensitivity to environmental matters, including human health and safety. The BDRP is also to be conducted with due consideration to socioeconomic issues and concerns. The history of the BDRP and the reputation of the professionals engaged in its operation and management provide adequate evidence that this challenge has been and can continue to be met.

1.5 BENEFIT

Regardless of the controversial issues associated with the BDRP, certain aspects of the Program should be recognized as beneficial. Countermeasures developed to meet biological defense objectives, such as vaccines, drugs, diagnostic reagents, medical management methods, and detection devices, which are in and of themselves benefits, also create other benefits. The medical and scientific expertise developed through previous and ongoing

efforts have received worldwide acclaim. Additional benefits accrue to the research facilities and researchers receiving funding from the BDRP. For example, universities participating in the program receive funds for designated research and development activities. A large portion of the BDRP effort conducted under contract is for basic biomedical research and development. The presentation of these results to the scientific community provides further expansion upon the basic research data collected for the BDRP.

Each year the principal BDRP medical research laboratory at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) hosts talented postdoctoral fellows in the laboratories of internationally recognized BDRP investigators. For example, during fiscal year 1987, National Research Council postdoctoral fellows from the U.S., United Kingdom, the Republic of Korea, India, France, Sweden, the People's Republic of China, Japan, Senegal and Finland were hosted by the Institute. This type of educational experience is beneficial to the individuals involved and pays long term dividends to their respective nations and to the scientific community as a whole. In addition, the existence of the postdoctoral fellows program highlights the open nature of the biomedical research conducted within the BDRP.

The capable staff of the BDRP has proven its value many times over in responding to disease outbreaks in both civilian and military situations. For example, staff researchers provided valuable services in the diagnosis and control of epidemics of Venezuelan equine encephalomyelitis in the southern U.S. and Central America. They also actively participated in the efforts to understand and control the original outbreak of Legionnaires' disease in Philadelphia, and the outbreaks of Ebola fever, Lassa fever and Rift Valley fever in Africa. Medical support provided by BDRP physicians and researchers led to the rapid diagnosis and implementation of appropriate treatment in the recent occurrence of hemorrhagic fever with renal syndrome (Korean Hemorrhagic fever) among U.S. Marines training in the Republic of Korea (30). In these examples, staff scientists led or were members of the specialized teams, whose pooled expertise in infectious diseases resulted in successful diagnoses and, in some cases, countermeasures to outbreaks of epizootic diseases.

The BDRP scientists and other staff specialists serve as consultants and provide resources to other government agencies as well as to industrial laboratories, pharmaceutical houses and foreign governments, especially in the fields of disease pathogenesis, diagnosis, prevention and treatment. Staff members are also recognized for their experience and expertise in the design of biological containment laboratories and appropriate safety precautions and procedures. The scientific literature is replete with papers authored by the professionals affiliated with the BDRP. International symposia, lectures and other forums provide further opportunities for the open exchange of scientific information among BDRP scientists and the general scientific

community. Medical research and development efforts worldwide have been enhanced by the contributions of the competent and dedicated scientists engaged in BDRP activities. Emergency response, diagnostic services, consultation, technological advancements and technology transfer all represent important indirect benefits of the BDRP.

1.6 SCOPE OF ENVIRONMENTAL REVIEW

1.6.1 BACKGROUND

On April 8, 1987, pursuant to the National Environmental Policy Act (NEPA), the Department of the Army (DA) published in the Federal Register a Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) on the DoD's BDRP. An updated NOI and an announcement of public scoping meetings, held on August 12, 1987, in Tysons Corner, Virginia, were published in the July 20, 1987 Federal Register and in five major media and scientific publications. The scoping announcement explained that the EIS for the BDRP would be programmatic in nature, with an analysis of environmental impacts and alternatives on a programwide level. This FEIS addresses the overall program and its implications for the environment, although site specific issues are addressed where considered germane to complete inquiry into the potential significant environmental and socioeconomic consequences associated with the BDRP.

The ongoing BDRP has been analyzed to determine the degree to which actions [within the BDRP] may establish a precedent for future actions with significant effects or represent a decision in principle about a future consideration. It is recognized that if the program continues, changes in the program scope and location can be expected to occur. The BDRP is not static; scientific advances or breakthroughs have, in the past, and will, in the future, continue to influence research needs. Other factors, such as military intelligence, levels of funding, and technological improvements, also can influence the magnitude and direction of the program.

The programmatic EIS provides an excellent approach for considering unscheduled, unidentified future implementing actions that may have environmental impact. Each proposed future BDRP action will be examined, in the NEPA context, to ascertain whether it is covered adequately by this programmatic EIS. If the proposed future action is not covered, then a tiered approach to an environmental analysis will be undertaken. Future actions may range from those categorically excluded from further NEPA evaluation to those with the potential to cause significant impact on the quality of the human environment. Proposed future actions thus will be evaluated for their similarities to those in the existing BDRP; conformance to statutes, guidelines, and established practices; as well as for any site-specific considerations. As discussed subsequently, the Impact Analysis Matrix, developed especially for analyzing the potential

environmental impacts of the BDRP, can be utilized to assist in screening future actions for potentially significant effects (see Appendix 6). The potential for cumulative effects also will be addressed.

1.6.2 IDENTIFICATION OF ISSUES

As noted in the background discussion, Section 2.1, the BDRP has been conducted since the early 1940s, although program emphasis has shifted with time in response to changing situations and technological advances. President Nixon, in his August 19, 1970 message to the U.S. Senate (3), clearly stated the U.S. policy for biological defense research as follows:

> "Our biological and toxin programs will be confined to research for defensive purposes, strictly defined. By the example we set we hope to contribute to an atmosphere of peace, understanding and confidence between nations and among men. The policy of the United States Government is to support international efforts to limit biological and toxin research programs to defensive purposes."

The BDRP is conducted in strict adherence and compliance with this policy, as well as with the provisions of the BWC (See Appendix l). To avoid any possible misconceptions or misunderstanding, it must be clear that this FEIS addresses only those RDT&E activities and programs related to biological defense as defined in section 2.

It is recognized that by its very nature, the BDRP raises issues which are controversial and subject to differences of opinion. Terms such as terrorism, biological warfare, pathogens, infectious, viruses, toxins, genetic engineering and animal rights intensify concerns and raise questions about human health and safety. Potential risks may be real and/or perceived. Because the BDRP is by definition a research and development endeavor, the potential for additional controversy arises. Research implies exploration into the unknown with the expectation of discovery. Scientific advances, innovative approaches, technological improvements and increased knowledge and understanding are noteworthy products of research, but certainly there also may be elements of risk involved. Research involving more esoteric and potentially dangerous areas of investigation or inquiry adds further complexity to the situation. The BDRP is such a research and development program.

There are various reasons for opposition by special interest groups to the conduct of research involving toxins or genetic engineering. The basis for such opposition may be on scientific, religious, ethical, moral, emotional or philosophical grounds. Catastrophic events can be postulated, thus eliciting emotionally charged responses to perceived dangers. There may be concerns as to whether control measures are adequate to assure reasonable protection from the ongoing activities of the program. Even with

safeguards, there never can be absolute protection from "acts of God" or from multiple catastrophic systems failure. Special measures can be applied to minimize risk and provide protection. However, there are limits on what may be considered reasonable and rational safeguards.

In identifying the real or relevant environmental issues associated with the BDRP, two conditions were examined: a) "normal operations", where all physical and procedural control measures are intact and b) accidents or incidents, where one or more controls have been breached. It is from incident/accident scenarios that the most serious consequences of the program could arise. For example, it is at least theoretically possible that accidental occurrences such as an uncontained laboratory spill, escape of an infected animal, failure of a physical protection system or "act of God" (airplane crash, earthquake, etc.) could result in the release of potentially hazardous biological material to the environment. It is also within the realm of possibility that security and other control measures could be compromised by intentional actions of terrorists, special interest groups or disgruntled employees (see Appendix 9).

To place the above discussion in perspective, the BDRP and its potential impacts on the environment are analyzed in the context of what has occurred in the past, the types of activities presently conducted, the existing controls, and the extent to which one can predict, given existing knowledge and the application of scientific methodology, what can reasonably be expected to happen under specific circumstances. The facts surrounding the BDRP must also be considered in order to present a realistic assessment of the program. For example, the BDRP employs, and contracts with, competent professional scientists, many of whom are highly renowned in their areas of specialization. By training and experience, these scientists are sensitive to the potentially serious consequences to human health and safety that could arise from conducting research with toxins or pathogens.

The National Institutes of Health (NIB) studied the potential ramifications of genetic engineering and developed guidelines (4) for research involving recombinant DNA molecules. In accordance with these and other accepted guidelines (5), laboratory facilities handling hazardous biological materials have special containment provisions and protective measures, as well as security provisions, to guard against exposure to danger or unauthorized entry. Laboratory safety is emphasized and monitored closely at facilities where hazardous materials are present. In addition, security provisions commensurate with the potential hazards and liabilities are employed. Thus, many factors must be considered when assessing the likelihood that significant adverse environmental impacts might occur from continuation of the BDRP.

It should also be recognized that the BDRP represents only a

fraction of the biomedical research involving toxins, pathogens or genetic engineering conducted in the U.S. and throughout the world. Hundreds of universities and research institutions routinely conduct research with the same or similar toxins and organisms as those studied in the BDRP. In fact, many organizations are selected to support the BDRP under contract specifically because of their demonstrated capability to perform work with exotic or hazardous materials. They must demonstrate a satisfactory level of experience, expertise, and availability of adequate facilities to qualify for BDRP contracts. In most cases, the BDRP funding supports only a small portion of the total institutional research effort. The vast majority of work with hazardous biological materials with whatever associated risks may exist, would continue with or without the BDRP. The genetic engineering (biotechnology) research efforts supported by the BDRP are a minute fraction of such work conducted nationally by research institutions and commercial organizations. Genetic engineering offers significant opportunities for beneficial application, but is also the subject of considerable controversy to segments of the public (see Appendix 10).

To assure that the BDRP was subjected to a "hard look," the overall program and its principal components were examined carefully and probed for potential for adverse impacts using a systematic, interdisciplinary approach. To assure that the primary focus of this FEIS was directed at the real issues, information and insight were sought from a number of sources. Input from the public and the scientific community was obtained during the public scoping process in the form of oral and written comments (75). The information, opinions and questions presented helped highlight areas of concern to be scrutinized for validity and appropriate coverage in the EIS. Additional issues (see Appendix 6) were identified in: the Amended Complaint in the litigation Foundation on Economic Trends v. Weinberger et al (6); the EIS for the NIH Guidelines for Research involving Recombinant DNA Molecules (7); the litigation documents related to a challenge to prevent genetic engineering research at the National Cancer Institute (NCI) at Fort Detrick, Maryland (8); the DEIS for a Biological Aerosol Test Facility, Dugway Proving Ground, Utah (9); the unpublished Draft Environmental Assessment for a proposed (proposal not pursued) Medical Research Institute of Toxinology, Fort Detrick, Maryland (10); Working Paper Draft, Operational Environmental Assessment, Chemical Research, Development, and Engineering Center (CRDEC), Aberdeen Proving Ground, Maryland (11) and Centers for Disease Control (CDC) Guidelines, "Biosafety in Microbiological and Biomedical Laboratories (5)."

The NIH EIS on the recombinant DNA guidelines and the NCI litigation documents are especially enlightening on genetic engineering issues. NIH has issued a series of guidelines, the most recent in 1986 (4), to specify practices for constructing and handling recombinant DNA molecules and organisms containing recombinant DNA molecules. Considering the level of controversy

that exists, it is apparent that the use of genetic engineering techniques in the BDRP is a relevant issue. It is therefore addressed in this DEIS (See Appendices 4,6 and 10).

To further assist in identifying the complete spectrum of relevant environmental issues, the BDRP was subjected to analysis using the Environmental Impact Computer System (EICS) (12). This system was developed over the past 15 years by the U.S. Army Construction Engineering Research Laboratory (CERL), and has been widely utilized by both the government and civilian sectors as an appropriate analytical tool for the identification of potential environmental impacts arising from a broad range of activities. Areas of potential impact identified using the EICS were combined with those identified in the aforementioned documents and analyses, and a systematic examination of all identified issues and environments was undertaken. The result of this systematic overview was the development of the Impact Analysis Matrix (JAM) (See Appendix 6).

The IAM is designed to assure a thorough, systematic, interdisciplinary analysis of the potential effects of the BDRP activities on the human environment. It is used to identify the areas of significant environmental concern that are emphasized in the DEIS. It also identifies the issues that are not significant and are thereby eliminated from detailed study. Site-specific activities of the BDRP are evaluated at the primary sites and at selected secondary sites. The functional, or programmatic aspects of the BDRP, are grouped into seven risk and/or issue categories and subjected to IAM analyses.

1.6.3 DATA COLLECTIONS AND SUPPORT STUDIES

The nature of the BDRP and the circumstances surrounding the preparation of this FEIS create an unusual situation in the NEPA context. As mentioned previously, this EIS is being prepared for an ongoing RDT&E program. The activities are conducted in existing facilities; therefore, alterations to the natural environment normally associated with construction and development actions do not occur. The IAM process indicates that potentials for significant adverse impacts are related primarily to health or safety considerations, especially under accident conditions, and to the potential for environmental degradation from air emissions, wastewater discharges and disposal practices for solid wastes. Due to the existence of numerous environmental protection statutes such as the Clean Water Act, the Clean Air Act, and various laws and regulations at the federal, state and local levels addressing both non-hazardous and hazardous waste disposal, there are already many mechanisms to protect the environment from unacceptable levels of contamination or degradation. If these existing environmental protection provisions are reasonably effective, then unacceptable adverse consequences would be expected to occur only as a result of either noncompliance, or failure of treatment or containment systems. Again, these possibilities relate to accident or

incident situations, rather than to normal, controlled operations.

This does not imply that existing environmental protection measures are always perfectly applied. Obviously, more stringent controls, along with improved practices and technology, might provide an even greater level of environmental protection than currently exists. However, absent data to the contrary, it is reasonable to expect that a program or activity conducted in full compliance with the myriad of statutes, regulations and guidelines applicable to protection of the environment, including human health and safety, would not produce significant unacceptable adverse impacts. There is always the possibility that indirect, cumulative or synergistic impacts might become significant, so these too must be considered. The IAM process provides a mechanism to address identified impacts from an aggregate, or program-wide basis, and from a broad, overall perspective as well as on an individual basis.

The ongoing BDRP activities are conducted at a number of locations (See Appendix 3). As mentioned previously, while the BDRP-funded activities may represent a substantial part of the programs underway at a few locations, for the most part, BDRP funding and research are minor components of the programs at most organizations. In addition, BDRP research represents only a small part, much less than 1%, of the ongoing national activity in genetic engineering. The scientific literature abounds with discussions of issues and concerns related to BDRP activities. NEPA and other environmental oversight documents prepared for programs or facilities where similar research is conducted provide additional sources of information for an environmental evaluation of the BDRP. Thus, there exists a considerable information base on which to develop a systematic, interdisciplinary evaluation of the potential significant effects of the BDRP.

The data collection and studies performed in direct support of the preparation of this EIS can be categorized broadly as follows:

1. Scoping Process
    a. Obtained views
    b. Analyzed input
    c. Identified significant issues

2. Literature Searches
    a. Program records and files
    b. Program history
    c. Litigation documents
    d. NEPA and other environmental documents
    e. Scientific literature
    f. Congressional documents
    g. Social and environmental commentaries

h. Statutes, regulations and guidelines
i. Miscellaneous

3. Site Visits, Interviews, Meetings and Consultations.
a. Primary
b. Secondary sites
c. Experts and knowledgeable individuals
d. Agencies

4. Impact Analysis Process (Also a component of scoping process)
a. Environmental Impact Computer System Analysis
b. Impact Analysis Matrix (JAM) Development
c. IAM Application

5. Assessment of Accident/Incident Scenarios
a. Maximum Credible Event (MCE) Analysis
b. Evaluation of control and mitigation measures.

The above tabulation is not exhaustive, but rather provides an overview of the concepts and approaches employed to gather and analyze information. The interdisciplinary team involvement cannot be overemphasized. As noted in the list of preparers, (Section 8) a diverse group of professionals with considerable experience and expertise participated in the development of this DEIS. A core group responsible for intensive "hands on" involvement in the analyses and evaluations was established. This group included individuals with expertise and experience in biochemistry, veterinary medicine, bacteriology, biosafety, biotechnology, botany, virology, radiobiology, cell biology, molecular biology, aerobiology and environmental biology, planning and engineering. The blending of scientists from several disciplines, with various specialties, together with professionals with considerable experience in the NEPA process and the preparation of environmental documentation, created a multidimensional team. Thus, analytical tools for impact analysis were integrated with specialized scientific input to arrive at an in-depth evaluation of the BDRP, its relevant issues and significant impacts. The process was tailored to address the particular circumstances and concerns unique to the BDRP Close working relationships, dialogue, debate, scientific scrutiny and consensus building were elements which enabled the team to accomplish its task.

Three principal support studies, somewhat unique to this DEIS, are 1) The Impact Analysis Matrix; 2) analysis of risks associated with handling hazardous infectious organisms; and 3) assessment of accident/incident scenarios. Detailed explanations of the methodologies employed and the findings of these work products are presented in Appendices 6, 8 and 9, respectively. To the extent possible, objective measurable factors were utilized in the respective analyses; however, a number of issues were subjective in nature. The interdisciplinary team guided the deliberations and added an element of mutual informed judgment to the process. In these support studies, the interdisciplinary

team approach contributed substantially to the analyses by providing comprehensive coverage from a balanced perspective.

1.6.4 SIGNIFICANT ISSUES

The IAM approach (See Appendix 8) identified the following significant areas of relevant concern associated with at least some aspect of the BDRP:

a. Public Opinion - Insofar as controversial issues related to the BDRP are the subject of public debate.

b. Program Benefits - Benefits to the national defense posture and to the scientific community derived from the BDRP.

c Water - Surface water quality.

d. Air - Air quality with respect to potential biological contaminants.

e. Human Health - The health of the workforce in laboratories performing BDRP-supported studies.

f. Safety - Adequacy of the construction of containment facilities.

Additionally, several other areas were determined to be of minor relevance or importance as follows:

a. Economic Environment - The economic contribution of the BDRP to the labor force supported by the program

b. Human Health - The health the general population in the vicinity of BDRP sites.

c. Air Quality - Ambient standards of air quality with respect to recognized parameters.

d. Program Benefits - Benefits to the general public that derive from the BDRP.

The above summary represents the interdisciplinary team's evaluation of the potential impacts and relevant areas of concern for the BDRP with appropriate controls in place, i.e. normal operation.

It should be noted that some of the relevant concerns are based upon perceived risks or misunderstandings, as opposed to actual risks and credible scientific evidence. The issue of actual versus perceived risks or impacts is not unique to the BDRP, nor is it a new issue. In 1981, scientists from national laboratories, universities and other research organizations addressed this issue in the first annual meeting of the Society

for Risk Analysis (36). At this initial meeting (International Workshop on the Analysis of Actual vs. Perceived Risks), papers representing a variety of disciplines, including the health sciences, engineering, the physical sciences, the humanities, and the behavioral and social sciences, were presented. The following observations are drawn from the workshop proceedings:

a. Scientists tend to make what they consider to be rational choices about acceptability of risks based on available evidence, such as mortality tables.
b. Non-scientists tend to determine acceptability of risks based more on human values and human concerns than on factual information.
c. The priorities of scientists and lay people can be guise diverse and they can see the same facts from different perspectives.
d. Motivations or bias influences perception.
e. Unknowns foster apprehension, which can in turn create perceptions of risks.
f. Media can influence public perceptions, and distorted information can sway views.
g. Perceived risks of an option are often much larger than the actual risks.
h. There is a general distrust of experts i.e., credibility gaps exist.
I. When viewing benefits versus risks, value judgments tend to demand zero risks.
j. Philosophical, ethical, political and religious values are all inextricably woven into perceptions.
k. Preference is reason enough to drive action.
1. Perceptions drive societal responses.

None of the above statements are absolutes, but rather they reflect observations and insights from workshop participants. The issues involved are complex and there probably are no completely right or completely wrong answers to this dilemma.

In summarizing the workshop on actual versus perceived risks, Dr. Claud S. Rupert, Chairman, included the following in his remarks:

"In its own realm, Science provides effective methods for dealing with the unknown and the uncertain, for pooling informations and insights, and for moving toward resolution of disagreements. While scientists as individuals are just as ornery as anybody else, they do manage, within the framework of their profession, to add to each others' insight and information more often than they cancel out. Usually, however, this process requires that all participants keep track of a lot of small details painted in various shades of gray. As soon as people who cannot follow all those details become involved, the entire process changes. Matters then fall into the simpler black-and-white, true-or-false, good guilty-or-not-guilty categories characteristic of

adversary proceedings. Shades of gray are no longer detected. This tends to be the case with citizens' action groups which are often ill-equipped to deal with complicated options and simply have to be for something or against it. The scientists' taste for weighing fine shadings and factual complexities, such as have been discussed in this meeting, has some difficulty adapting to that situation. Yet we will have to deal with it, if we are going to interact with the public, rather then merely talk to ourselves and each other."

The BDRP is an unclassified military program which has been subjected to considerable scrutiny, internally and externally, over the past several years. Explanations and clarifications of the BDRP, what it is and what it is not, are presented in this DEIS to foster a clearer understanding of the issues. The public involvement process associated with this FEIS provides an opportunity for agencies and the public to make their views known and to comment on the information presented.

The IAM process allows identification of both real and perceived risks, and serves a dual purpose. It not only brings the relevant areas of concern into focus, but it is also useful in identifying topics which do not need to be addressed. For example, based on an analysis of both programmatic and site specific information, many areas of potential concern or impact that often are of significance in the NEPA context are found not to be relevant. For example, such resources of nationally recognized importance as endangered species, cultural resources (historical and archeological), wetlands and other types of fish and wildlife habitats are not measurably affected by the ongoing BDRP. There are two principal reasons why these are not affected. First, the BDRP activities are conducted at existing facilities, and, secondly, no physical expansions to facilities or new construction which would involve alteration to the biophysical environmental resources have been identified.

Relevant issues related to the overall BDRP are often viewed as being linked to site specific locations. For example, both Fort Detrick, Maryland and Dugway Proving Ground, (DPG), Utah have a long history of involvement in BW and ED activities. There are even misconceptions associated with these sites, such as the "contaminated building" at Fort Detrick (which was decontaminated long ago (14) and the death of sheep at DPG, erroneously attributed to biological agents (chemical agents, not biologicals were involved). These myths and other unsupported rumors contribute to the controversy surrounding the existence of the BDRP. Closer examination of the issues and the credible scientific evidence (facts) lead to the conclusion that the controversy actually surrounds the program, especially some of its more esoteric elements, such as work with hazardous infectious organisms and genetically engineered microorganisms (GEMs), not the specific sites. Thus it does not matter where the program activities are conducted; the opposition or concern is that they are conducted at all.

Other peripheral issues or concerns, such as an apparent distrust of the military, surfaced via the scoping process (75). The real motives for the program and the propriety of the Army management of the BDRP are questioned. There are questions or concerns about whether biological warfare threats really exist, or are merely fabricated or overstated to support the program. Apparently, there are also beliefs that the program should be terminated to avoid encouraging potential enemies from developing offensive weapons. A recent publication (15) by the Stockholm International Peace Research Institute (SIPRI) presents a discourse on the topic of biological warfare and biological defense programs which serves to highlight many of the areas of controversy. Perhaps an appreciation of the openness of the BDRP, coupled with a better understanding of the facts, and the awareness of close Congressional oversight, will alleviate some of these concerns and establish a greater level of public confidence in the program.

The term "significantly" as defined in CEQ regulations (40CFR 1508.27), "requires consideration of both context and intensity." The insignificant/relevant" issues for the BDRP are generally independent of the site or locale. While there are localized concerns, basically the concerns actually relate to particular aspects of the program as opposed to site-specific impacts. Therefore, the context component of the determination of significance is considered to be of broad scope relating to the program as a whole; i.e. a national concern or issue.

Intensity refers to the severity of a potential impact. For example, the CEQ indicates the following should be considered when evaluating the intensity of a proposed major federal action (40 CFR 1508.27(b).

1) Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial.

2) The degree to which the proposed action affects public health or safety.

3) Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.

4) The degree to which the effects on the quality of the human environment are likely to be highly controversial.

5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.

6) The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.

7) Whether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts.

8) The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.

9) The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.

10) Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

Because the BDRP is conducted at existing facilities, and no significant impacts have been identified at any of the sites where activities are underway, several of these considerations are not pertinent. For example; items 3), 8), 9) and 10) were considered in the IAM process and found only to involve insignificant impacts, if any (See Appendix 6). Items 3), 8) and 9) relate primarily to site-specific impacts. The BDRP, as currently defined, is an ongoing program without proposed construction* or expansion of facilities; thus no site-specific significant impacts were identified. Any future activities involving alteration to the physical environment would require appropriate examination of potential impacts on these areas of consideration. In regard to item 10), no violations or threats of violations of Federal, State or local law, or requirements imposed for the environment, were identified for the BDRP. On the contrary, in many instances, voluntary measures are undertaken to provide a level of protection beyond that required by regulatory controls or guidelines.

With regard to item 1) above, the IAM approach identified both potential beneficial and adverse impacts. An evaluation complexity arose, however, because virtually all of the

*The proposed construction of a Biological Aerosol Test Facility is evaluated for potential environmental impacts in a separate DEIS published February 1988.

significant adverse impacts were either perceived, rather than actual, or were associated with a potential accident or incident. Professional scientific scrutiny by the interdisciplinary team did not lend credence to the expressed fears or hypothetical risks. In contrast, the beneficial aspects of the program are more tangible and measurable.

For item 2), again, there are both beneficial and potential adverse consequences. There are documented instances where vaccines and other therapeutic methods developed in the BDRP have assisted in the control of disease outbreaks (see Section 1.5) while BDRP-related instances of serious illness to lab workers, especially in recent years, much less anyone outside, are nonexistent (see Appendix 8). Thus, the expressed concerns must either relate to perceived risks, or to low level actual risks under conditions where adequate controls are in place, operable and effective.

Item 4) is particularly pertinent to the BDRP. Once again, however, "the effects on the human environment", especially the adverse effects, are perceived rather than actual. Opposition to the program has been expressed in the form of concerns or impacts which are often utilized to discredit its worth or ability to operate safely. In any event, the BDRP, as well as its actual, perceived or imagined adverse effects, are "highly controversial", at least to some segments of the public.

The considerations discussed above bring item 5) into focus. Actual risks and documented effects present a different picture from those envisioned on the basis of perceived risks and potential catastrophic effects. There are also unique aspects of the BDRP related to GEMs, and to the hazards of research involving infectious organisms. Because adverse effects of any real severity have not been observed, an approach which analyzes maximum credible events is utilized (see Appendix 9) to put potential incidents or accidents into perspective.

Examination of the ongoing BDRP in regard to item 6) provides insight relevant to the programmatic nature of this DEIS. It is recognized that as an ongoing RDT&E activity, the BDRP is subject to change. Proposed future actions, with whatever type and level of significant effects they might contribute, will be evaluated in the NEPA context utilizing this programmatic EIS as a frame of reference. The tiered evaluation approach, based on risk/issue categories, will facilitate these evaluations by focusing their scope.

In regard to item 7), the potential for cumulative significant impacts was assessed and was found not to represent a major concern to the quality of the human environment. Three considerations influenced this finding. Under normal operating conditions, with controls in place and operable, no significant impacts were identified, and those minor concerns identified are not of the type with the potential to create additive,

synergistic, or cumulative impacts to any significant extent. Secondly, even under accident or incident circumstances, the characteristics of the facilities, the small quantities of hazardous biological materials involved, and the remote possibilities of failure, each contribute to alleviating any significant cumulative effects (see Appendix 9). Another consideration is the widespread nature of the program, with over 100 sites involved (see Appendix 3). The possibility of any significant cumulative impacts arising from interactions among these sites is extremely remote.

CEQ guidance (40 CFR Parts 1500.4(g), 1501.1(d), and 1501.7) encourages reduction of paperwork and narrowing of the scope of NEPA documentation. Agencies are to identify significant, but Reemphasize insignificant, issues, impacts or concerns. A dilemma exists when those opposed to a program, or aspect(s) of a program, raise issues where significance and relevance are a matter of opinion. Efforts have been made to focus on the real issues and also recognize that other viewpoints exist. Emotional issues involving conjecture and unknowns make the "significant" determination complex and somewhat subjective. Objectivity has been incorporated to the extent practicable in the scoping process, and in evaluation of consequences and alternatives to assure adequate treatment of the real and significant issues, impacts and concerns.

2. DEFINITION OF THE BIOLOGICAL DEFENSE RESEARCH PROGRAM (BDRP)

2.1 BACKGROUND

From the early 1940's, through World War II and until 1969, the United States conducted an offensive biological warfare research and development program. The U.S. formally renounced the "use of lethal biological agents and weapons, and all other methods of biological warfare" in National Security Decision 35, November 25, 1969. This decision stated further that "the U.S. will confine its biological research to defensive measures such as immunization and safety measures." In National Security Decision 44, dated February 20, 1970, the U.S. renounced "offensive preparations for the use of toxins as a method of warfare," and reiterated that "the U.S. will confine its military programs for toxins, whether produced by bacteriological or any other biological method or by chemical synthesis, to research for defensive purposes only, such as to improve techniques of immunization and medical therapy." (See Appendix 1 for excerpts of National Security Decisions.)

In 1972, the U.S. joined over 70 other nations in signing the Biological Weapons Convention (Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction)(Appendix 1). Signatories to this Convention pledge, in Article I, "never in any circumstances to develop, produce, stockpile, or otherwise acquire or retain: 1) microbial or other biological agents or toxins whatever their origin or method of production, or types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; 2) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes in armed conflict." This Convention was given the force of law in the U.S. by its ratification by the U.S. Senate in 1975, and its provisions are adhered to scrupulously within the BDRP.

In Articles I and X, the Convention specifically allows for the production of, and research on, biological agents for the purposes of "prophylactic, protective or other peaceful purposes." The Convention makes the clear distinction between defensive and offensive efforts by identifying the development of biological weapons delivery systems as a discrete and prohibited activity. No method of verification of compliance is specified in the Convention, nor have any methods of verification yet been developed.

Starting in the mid 1970's, two factors caused a resurgence of interest in research on defense against biological warfare (BOO) agents. One factor was the evidence that the U.S.S.R. continues to maintain an offensive BW capability (16). Specific examples include the accidental release of anthrax from the Sverdlovsk (U.S.S.R) Biological Warfare Facility in 1979 (17,18,76), and recent reports of the tactical use of toxins in

Southeast Asia and Afghanistan (19,20). Information supplied by the intelligence community further suggests that other countries, some of which are considered hostile to the U.S., are maintaining and developing offensive BW capabilities (21,77). Any classified information is provided to decision makers on a need-to-know basis. Other literature sources indicate that a real threat exists, and suggest the prudence of maintaining a level of preparedness against potential BW agents (22-28). While the detailed threat analyses provided by the intelligence community are classified, ALL WORK CONDUCTED UNDER THE BDRP IS UNCLASSIFIED. Those results which impinge on national security may be classified in accordance with Army Regulation (AR) 380-86, "Classification of Chemical Warfare and Chemical and Biological Defense Information."

The second factor which contributed to increased interest in the BDRP was the realization that new methods in molecular biology and genetic engineering potentially could be applied to the creation of novel BW agents, or to the production of specific agents (such as protein toxins) in quantities that far exceed their natural levels of biological availability. Thus, in the early 1980's, the Department of Defense reevaluated the Biological Defense Program in light of the available evidence of a BW threat and the potential for the existence of novel biological warfare agents. Emphasis was placed on improving the defensive posture in the areas of biological agent detection, treatment, protection and decontamination.

2.2 MISSION OBJECTIVES OF THE BDRP

The goal of the BDRP is to provide methods of detection for, and protective measures against, agents of biological origin that could be used as weapons against U.S. forces by hostile states or individuals. The specific program objectives that support this goal are:

A) Development of biological agent detection methods. Such detection methods include test procedures and reagents for agent identification in clinical or environmental specimens, as well as detectors and detector methodologies usable in a battlefield setting.

B) Development of treatment and protection capability. The development of treatment capabilities includes the development of prophylactic measures (vaccines, pretreatment drugs), therapies for specific groups of diseases or toxicoses, and patient treatment and management protocols. Included in this objective are efforts to ensure that protective masks, clothing, and shelters, which are developed primarily for protection against chemical threats, also provide protection against biological threats.

C) Development of decontamination capability. This objective, from the standpoint of the BDRP, includes assessment

of the decontamination capabilities developed for chemical agents for utility in decontamination of biological agents. Development of biological decontamination capabilities for personnel, materiel and equipment, and large scale items (shelters, transporters, etc.) is included in the overall chemical decontamination program.

2.3 PROGRAM MANAGEMENT

The Department of Defense (DoD) identified the Department of the Army (DA) as the Executive Agent for its research and development program on defense against biological warfare (DoD Directive 5160.5, 30 March 1976). The DA executes formal coordination with other armed services through the Joint Service Agreement, a Memorandum of Agreement with the Air Force, and the Joint Technology Coordinating Group of the Armed Services Biomedical Research, Evaluation and Management (ASBREM) Committee. The program is conducted by the U.S. Army Medical Research and Development Command (USAMRDC), a Field Operating Agency of the Office of the Surgeon General; the Chemical Research, Development and Engineering Center (CRDEC) (a component of the U.S. Army Armament, Munitions and Chemical Command); and the Dugway Proving Ground (DPG) component of the U.S. Army Test and Evaluation Command (TECOM). The annual DoD budget presentation to Congress specifically identifies the funds appropriated for the BDRP under Program 6, Research, Development, Test and Evaluation, as shown in Table 1. In addition, a report on the Biological Defense Research Program is submitted annually to Congress in accordance with PL 91-121, as amended by PL 91441.

2.4. PRIMARY SITES OF PROGRAM EXECUTION

2.4.1. U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)

The USAMRDC is responsible for conducting the Army medical RDT&E program, which includes surgical and dental research, medical materiel development, unique medical hazards associated with Army weapons and defensive systems, infectious disease hazards and medical biological defense research and development. The USAMRDC is composed of 11 subordinate commands, one of which, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), is designated as the lead laboratory in medical defense against biological warfare threats. The mission of USAMRIID is to conduct studies on the pathogenesis, diagnosis, prophylaxis, treatment, and epidemiology of infectious diseases and toxins that pose potential BW threats. Many of the infectious diseases studied are either "conventional BW agents" or disease hazards that are endemic in various regions of the world. In many cases, the disease-causing organisms "bacteria, viruses, and rickettsia) are sufficiently pathogenic that biological containment facilities (BL-3 or BL4)(29) are required to ensure the safety of the laboratory

TABLE 1. RDT&E Support for the BDRP

PROGRAM ELEMENT	DA PROJECT	TECHNICAL A
61102a, Defense Research Sciences	BS12, Science Base for Medical Defense Against Biological Warfare	S12/A, Basic Research in Medic Against Biological Warfare
	A71A, Research in Chemical/Biological Warfare Defense (Scientific area A, Research in Chemical and Biological Defense, Chemical Warfare and Obscurants)*	
67622A, Chemical and Smoke Munitions	A553, Chemical/Biological Defense and General Investigations	553/A, Chemical/Biological Thr Chemistry and Effects*
		553/C, Reconnaissance, Detecti Identification*
		553/F, Chemical/Biological Dec and Contamination Avoidance*
		553/G, Chemical/Biological Ant
		553/I, Chemical/Biological Simu Survivability and Systems Scien
62770A, Military Disease Hazards Technology	A871, Medical Defense Against Biological Warfare	871/A, Studies for the Preventic Treatment of BW Diseases
63763A, Nonsystems Medical Material Development	D807, Industrial Base for BW Vaccines and Drugs	807/A, Industrial Base for BW V and Drugs
63750A, Drug and Vaccine Development	D809, Drug and Vaccine Development for Medical Defense Against Biological Warfare	809/A, Development of Drugs a Against Diseases of BW Import
64758A, Drug and Vaccine Development	D847, Drug and Vaccine Development for Medical Defense Against Biological Warfare	847/A, Development of Vaccine Diseases of BW Importance
		847/B, Development of Antivira
		847/C, Development of Immune
		847/D, Development of Antibod Antitoxins
		847/E, Development of Rapid Ic and Diagnosis System.

*Note that biological and chemical defensive studies are not identified separately at the technical area level of the budget. Such discrete identification, if any, occurs only at the task of sub-task level.

workers. The toxins studied under this program are those produced by living organisms (as opposed to "chemical agents"), which often cause natural intoxications in specific scenarios; for example, food-borne botulism, paralytic shellfish poisoning, snake bites, etc. The portion of the program devoted to rapid identification and diagnosis has, as its goal, the development of reagents and techniques that will facilitate, in laboratory and field medical settings, the identification of disease-causing organisms and toxins in clinical specimens.

Traditional microbiological, immunological, and biochemical techniques, as well as the newer techniques of molecular biology and genetic engineering, are used in virtually all of the research efforts to provide improved medical defense against potential BW agents. For example, these techniques are used in the development of vaccines that are less reactogenic and more broadly protective than existing vaccines. A parallel effort is the "genetic engineering" of vaccinia virus (cowpox, the smallpox vaccine) so that it contains the requisite genetic information of other viruses important for producing immunity. The result will be a single vaccine that could confer immunity to several hazardous viral diseases. Gene cloning is used in the development of safe vaccines for several of the protein toxins; for example, anthrax toxin, botulinum toxin(s), and snake neurotoxins. The general approach is to identify the portions of the protein toxin responsible for eliciting immunity, as opposed to that portion of the molecule responsible for toxicity. The immunogenic portion of the molecule would then be cloned in order to produce a nontoxic antigen that could be used in a vaccine. The technologies of monoclonal antibody production and genetic engineering of specific proteins are implemented to obtain reagents (antibodies and antigens) for use in the development of rapid diagnostic assays.

With the recognition that the new techniques in "biotechnology" could be applied, by hostile entities, to the development of novel or "unconventional" biological warfare agents, efforts have been directed toward the development of drugs and vaccines that will provide therapy for, or immunity to, broad groups of potential threat agents rather than to only a single agent. The rationale for these "generic" approaches is that, while there are numerous different individual infectious organisms and toxins, many of these agents act through common mechanisms of action at the cellular level. For example, a goal of the antiviral drug discovery effort is to identify, and develop for human use, a broad-spectrum, antiviral drug (or drugs) that will be effective against viruses belonging to as many taxonomic families as possible. Similarly, for toxins, the focus is on development of generic therapies that would be effective against entire classes of toxins, for example, those that affect the electrically excitable sodium channel in neurons. The rationale for the generic approaches to development of antiviral or anti-toxin therapies is that while there are a large number of viruses and toxins that pose potential threats,

there are a finite number of cellular sites at which these viruses or toxins exert their effects (78-82).

The laboratory technique of aerosol challenge of experimental animals is utilized in testing the protective efficacy of vaccines and other potential biological therapies. Because airborne particles are considered the most likely manner in which a biological attack would be initiated, the protective efficacy of any vaccine or prophylactic therapy must be tested against this route of exposure. All such aerosol experiments are conducted within appropriate biosafety level biocontainment laboratories using special containment equipment. Such equipment permits the nose-only exposure of animals and thus allows the use of only very small quantities (on the order of teaspoons) of hazardous aerosols. Such aerosol experiments have, in the past, yielded the important observation that a vaccine that is protective against a parenteral (injection) exposure to a virus does not necessarily provide comparable protection against an aerosol exposure (83). Experiments requiring the aerosol exposure of animals are, like any other experiments, designed to answer a specific scientific question, and thus are conducted only infrequently and in the larger context of the goals of a particular project.

2.4.2 U.S. ARMY CHEMICAL RESEARCH, DEVELOPMENT AND ENGINEERING CENTER (CRDEC)

At the CRDEC, individual divisions within three Directorates: Research, Detection, and Physical Protection, participate in BDRP studies. The mission of CRDEC, in the context of the BDRP, is to manage and conduct research, development, and engineering activities to provide non-medical defense against biological warfare threats. Because the larger mission of this Center includes detection, protection, and defense against chemical weapons, the studies related to the BDRP are often subsumed in a combined chemical/biological detection or protection effort. The BDRP efforts conducted at CRDEC are: development of detection systems and technologies based on biological receptors, antibody binding reactions and analytical techniques, development of field detectors for biological threat agents, and development of methods for materiel and equipment decontamination. Aerosol studies, if required, are conducted with simulant or low hazard organisms, only in laboratories and only using special containment chambers.

Both microorganisms and biological toxins are used in the development of detection and decontamination systems. The organisms used are all either non-pathogenic, killed, or attenuated, and none require laboratory containment higher than biosafety level 2 (see Appendix 12 for definition of biosafety levels). The toxins used are obtained from other government laboratories or from commercial sources. Development of detection systems involves three broad approaches. One is the development of biosensor detection devices, where specific

receptor sites, isolated or derived from biological sources, are immobilized on synthetic supports and coupled to microelectronic signal processing equipment. The rationale for such a system is that many, if not all, receptors are the physiological target sites for many toxins and chemicals. Thus, receptor responses are the basis of the concept of "generic" detection of biological threat agents. Limited basic scientific studies on receptors are conducted in support of the biosensor development effort.

A second approach in detector development is the use of antibodies, especially monoclonal antibodies, designed to detect specific potential biological threat agents. This approach relies on the inherent specificity for a chosen antigen that antibodies possess by definition. Thus, this type of system would be useful in the unambiguous identification of selected organisms or toxins. The third approach employed in the development of detector systems is one based on sophisticated analytical instrumentation. The CRDEC is developing a mass spectrometer modified to allow for processing of a range of sample types.

The development of personal protective devices (e.g. masks) and materiel and equipment decontamination methods conducted by CRDEC is directed primarily at chemical agents, but toxins and non-pathogenic organisms are tested in both systems. Appropriate laboratory containment facilities are used for such tests; no open air field testing with biological materials is conducted at the CRDEC.

The CRDEC supports additional BDRP-related studies that involve only literature research and no laboratory work. Insofar as these endeavors relate to program management decisions, they are addressed as a program activity in the impact analysis matrix discussed in sections 1.5.3 and 6.2.

2.4.3 U.S. ARMY DUGWAY PROVING GROUND (DPG)

DPG is a DoD Major Range and Test Facility that supports all DoD components responsible for development, test, evaluation, and operation of chemical warfare equipment, obscurants and smoke munitions, and biological defense equipment. The DPG acts as an independent testing organization for all biological defense systems developed by the DoD. Its principal mission, as related to the BDRP, is to perform developmental and operational testing for biological defense materiel. Because the most realistic biological warfare threat is the delivery of hazardous agents by aerosol, the testing procedures performed at DPG focus on the delivery of test materials by this route. Laboratory studies requiring the use of aerosols are conducted only in response to specific equipment or materiel testing requirements and in the larger context of the goals of a particular project. Any such studies are conducted within appropriate biocontainment facilities in accordance with established controls.

Biological defense testing includes three broad, functional areas: test methodology development, laboratory assessment of suspected biological threat agents and their impact on materiel and operations, and operational and developmental testing. The actual proposals and requests for testing, including identification of the proposed challenge materials, are initiated by the individual equipment developer and transmitted through DPG's parent command to the DPG Materiel Test Directorate. Laboratory assessment of suspected biological threat agents will be determined by threat scenarios and information established by the intelligence and biological defense communities.

The Materiel Test Directorate at DPG is responsible for the design, performance and reporting of the results of biological defense testing. Aerosol testing with pathogenic or toxic challenge materials is performed only in biological containment laboratories using special containment equipment. Nearly all of the biological defense testing at DPG is done with simulant materials. Laboratory aerosol testing with live microorganisms and toxins is performed in those cases where simulants will not validate the materiel protection requirements or to verify that the simulants used represent the characteristics of the toxin or infectious material of interest. Outdoor field tests with simulants (non-pathogenic and/or non-toxic materials) are performed on an as-required basis after preparation of appropriate NEPA documentation. The materiel submitted to DPG for testing includes detectors, masks, protective clothing, and other protective devices. Decontamination systems are tested for efficacy, and the ability of equipment to perform to specifications after the contamination/decontamination cycle is assessed.

Biological stocks including sera, antigens, toxins, cultured cell lines and microorganisms are maintained at the Baker Laboratory area by Life Sciences Division personnel. The Life Sciences Division also prepares biologicals, simulants and tracers for required tests. Life Sciences Division's principal laboratory facility was designed for and operates at what today would be considered BL-3. However, laboratory activities are currently limited to those requiring BL-2 containment pending completion of routine maintenance and repair. Although the laboratory investigates new test methodologies and the development and validation of stimulants, no recombinant DNA studies ("genetic engineering") or work with genetically engineered microorganisms (GEMs) is performed or planned. Laboratory testing of organisms, toxins, tracers and simulants is conducted in order to ensure quality and consistency of data obtained in tests, as well as to validate the properties of the biological used in a given test from the standpoint of the test objectives. Laboratory functions include the use of standard microbiological techniques as well as the operation of specialized test equipment to expose test items to aerosols of biological materials.

In addition to performing biological defense testing, the Life Sciences Division is responsible for the preparation of NEPA documentation for all testing activities at DPG. Environmental monitoring programs are developed and implemented in support of NEPA documentation and overall ecological surveillance requirements. The Division is responsible for and initiates, develops, and executes a comprehensive test range environmental management program to ensure that the activities conducted by all divisions of the Materiel Test Directorate do not adversely affect the environment.

2.5 SECONDARY SITES OF PROGRAM EXECUTION

To execute fully the BDRP program missions, primary site organizations frequently seek the participation of "extramural" organizations to supplement existing internal facilities, personnel, equipment and expertise. Scientific support is sought from other DoD organizations, and from other government agencies, universities and research organizations outside the DoD. These organizations constitute the secondary sites of BDRP program execution. All program management responsibilities remain with the primary site organizations.

The mechanisms for support of secondary sites vary as a function of the type of organization. Support for work performed at other DoD organizations can be arranged by direct transfers of funds (funding authorization documents) from the primary site to the secondary site. The primary site retains program management responsibilities. An example of this type of secondary site is the Navy Medical Research Laboratory. This organization functions as secondary site for the USAMRDC, and performs basic research studies using only non-hazardous organisms in support of efforts to develop reagents for use in diagnosis and identification assays. Another mechanism by which support is provided to other DoD organizations is the Military Interagency Purchase Request (MIPR), which spells out performance requirements similar to those incorporated in research and development contracts. Funds can be awarded to support work at a non-DoD government organization by a similar instrument, the Interagency Agreement.

Secondary sites outside the federal sector are selected in accordance with procedures specified in the Federal Acquisition Regulations (FAR (48CFR 1.0 et seq.) (as supplemented by the Defense Acquisition Regulations and Army Acquisition Regulations). The primary sites publicly announce "areas of interest" in research and development through Requests for Proposals (RFP) and Broad Agency Announcements. Individual researchers, through their institutions, propose studies in response to these advertisements. Proposals are evaluated by review committees for the following factors: military and program relevance; the validity of the research objective; scientific feasibility; qualifications of the principal investigator and key personnel; adequacy of the facilities to be used in conduct of

the work; care, safety and compliance with regulations or guidelines with respect to the use of human subjects, animals or hazardous materials; budget; and environmental considerations. After this and other appropriate reviews and program management decisions, support is awarded to selected institutions in the form of contracts or grants. Research is then conducted in accordance with a stipulated scope of work and in compliance with various regulations and requirements identified in contract/grant clauses.

The utilization of secondary sites to support the BDRP enhances the scientific scope of the various subsidiary programs by enlisting the participation of established scientific specialists in universities and other research organizations. The support of program research efforts at secondary sites also allows for considerable flexibility in program and fiscal management. Particularly for basic and exploratory research efforts, utilization of secondary sites allows for the pursuit of multiple avenues of investigation that could not otherwise be conducted in a single effort. In addition, support for any one project at a secondary site is limited to one to five years, and is reviewed on a yearly basis. Thus, changes in program emphasis can be implemented relatively rapidly through judicious selection of secondary sites. Secondary sites supported by the BDRP as of January 1, 1988, are listed in Appendix 3.

3. DESCRIPTION OF THE PROPOSED ACTION

3.1 INTRODUCTION

In section 2, the BDRP was defined from the perspectives of the mission objectives, program management, and sites of program execution. The proposed action under consideration in this DEIS is the continuation of the BDRP. The purpose of this DEIS is to identify and evaluate potential environmental impacts that **might** arise from the proposed action, and to consider reasonable alternatives. To this end, the BDRP was subdivided into discrete, functional activities that could be evaluated individually for their potential impacts. Activities intrinsic to the conduct of research, development, test and evaluation, as well as activities intrinsic to program administration and management, were identified and are discussed below.

Program activities are conducted in the context of numerous operational, safety, security and regulatory controls. These controls, in essence, define the "normal operating conditions" of program activities. The program activities and their associated controls are an integral part of the Impact Analysis Matrix (JAM) (see Appendix 6), an analytical tool developed specifically for the identification of the potential environmental impacts of the BDRP. Although this FEIS evaluates a program, the program only has physical reality in the sites or facilities at which it is conducted. Thus, the primary and representative secondary sites of program execution were identified. The potential impacts of program activities as executed at various sites were evaluated by using the JAM. In addition, the potential impacts of program activities conducted in support of particular programmatic subject areas, the "Risk or Issue Categories," were analyzed similarly.

The program activities, controls, facilities and programmatic areas that constitute the BDRP are described here.

3.2 TYPES OF ACTIVITIES

3.2.1 RESEARCH, DEVELOPMENT, TEST AND EVALUATION

3.2.1.1 Laboratory Support Work

"Laboratory work" includes the handling of supplies and materials that are not unique to the particular subject of study in a given laboratory. This handling of supplies and materials, such as plasticware, glassware, non-hazardous chemicals and reagents, etc., is generally considered to be of very low intrinsic risk. The preparation of common reagents and solutions, such as culture media, buffer solutions, etc., is included in this activity. The maintenance of laboratory equipment either within a general use laboratory, or after appropriate decontamination and removal from a biosafety level 3 or 4 laboratory, is also included in this activity.

3.2.1.2 Storage of Chemicals, Biologicals, Supplies and Radioisotopes

Storage refers to the storage and maintenance of all laboratory supplies and materials in a BDRP facility. For items presenting little or no potential safety or environmental hazards, e.g. glassware, plasticware, spare parts, etc., ordinary storage units and practices are employed. Specific storage procedures and requirements are employed for particular classes of chemicals, such as heavy metal salts, acids, bases, organics, and chemicals subject to regulation as hazardous materials or RCRA hazardous wastes. Storage units, procedures, and practices for biological materials are tailored to requirements for maintenance of biological activity of the material in question, as well as to the biohazard classification of the material (30). The small quantities of radioisotopes used in BDRP studies are stored in a manner that will preserve the biological activity of the labeled compounds, as well as meet NRC regulatory requirements for storage and handling of radioisotopes.

3.2.1.3 Conduct RDT&E-Specific Procedures

This activity includes all use and handling of BDRP-specific microorganisms and toxins, from removal from storage through performance of experimental or test procedures, decontamination of the spent materials, the equipment and/or laboratory, and disposal of the biological materials. The transportation of biological materials into and out of the facility is included in this activity, because the special requirements for transportation of biohazardous organisms and toxins parallel the requirements governing their use in a laboratory.

3.2.1.4 Laboratory Animal Care and Use

This activity is segregated from the "Procedures" activity because the use of animals in biomedical research has been identified by the public as a controversial issue in and of itself, if not in relation to the BDRP. This activity includes all aspects of the use of laboratory animals in BDRP research and testing. The identifiable phases of laboratory animal use are: receipt and holding of animals, assessment of the health status of the animals, caging, feeding and watering of animals, use of the animals in experimental or test protocols, and disposal of animal remains and bedding.

3.2.1.5 Prototype Development of RDT&E Materials

A prototype is an operational model suitable for evaluation of the design, performance, or production potential of a particular item. The activity described here is the development of prototypes of all RDT&E materials related to the BDRP. This includes the development, for the purpose of protection from biological threat agents, of personal protective equipment, such as masks, and development of detector systems for identification

of biological agent threats. The development of protective vaccines or immunogens, and development of potential therapeutic drugs is also included in this activity.

3.2.1.6 Testing

Developmental testing of BDRP prototype materials is described by this activity. The biological material prototypes, such as vaccines, are tested in human volunteers. Such testing is conducted in full compliance with FDA and DA regulations governing the participation of human subjects in medical research. Equipment prototypes are tested within laboratory chambers for performance to operational specifications. Detection and personal protection equipment prototypes may be tested, as required, at the DPG in open-air tests with nonhazardous, non-toxic, biological simulants.

3.2.2 ADMINISTRATION AND MANAGEMENT

3.2.2.1 Facilities Operations and Maintenance

This activity includes operation, maintenance, and repair of all facility systems such as water, wastewater, steam, electrical, telephone, heating and air conditioning. Routine structural repairs and maintenance of the building and its grounds, including routine cleaning, are included. The operation and maintenance activities for facility operations within the BDRP are similar to common practices employed throughout the commercial and industrial medical field.

3.2.2.2 Waste Stream Management

This activity includes the management, treatment, control, and monitoring of effluents resulting from BDRP activities, regardless of source. Effluent air includes exhausts from buildings, laboratories, biosafety cabinets, heating, and incinerator discharge stacks. Management, control, treatment and monitoring of sanitary wastewater and contaminated laboratory wastes are included in this activity. Handling, storage, and disposal of liquid hazardous and toxic material are included as well. Liquid hazardous or toxic materials are as designated by the various states and by the U.S. Environmental Protection Agency. Sanitary wastewater includes general wastewater and noncontaminated laboratory wastewater. Contaminated laboratory wastewater results from procedures involving toxins or hazardous organisms, and includes shower, lavatory, and floor drain discharges from maximum containment laboratories. Management of the solid waste stream includes the handling, storage and disposal of refuse and discarded solid wastes generated by BDRP RDT&E activities. Discarded solid wastes include supplies, materials, chemicals, equipment, and animal wastes. Biohazardous wastes are decontaminated or detoxified before entry into the waste stream.

3.2.2.3. Planning and Designing Systems

This activity describes those BDRP efforts that involve the preparation of test methods for equipment, and the preparation of test methods for biological and biomedical research. It includes the planning and design of experimental and test methodologies for medical and physical protective systems as well as the overall planning of a project at the program task and sub-task levels. General planning activities include paperwork, idea formation, and activities requiring mental effort on the part of the professional staff.

3.2.2.4. Program Management

Activities in this category include management, accountability, and projection of the BDRP budget; administration of personnel and program activities; and review, analysis and planning of program objectives to achieve mission objectives. The primary sites are responsible for program management and implementation with respect to the secondary sites. Thus, an additional program management activity of primary sites is the administration of contracts and other instruments used to support the secondary sites. Program management includes administrative decision-making as it specifically applies to RDT&E operations and program development. The publication of program accomplishments and results in specialty publications, as well as in public documents, e.g. the Congressional Descriptive Summary, is identified as a program management activity.

3.3 CONTROLS

At least four major classes of controls govern the conceptual and physical conduct of activities comprising the BDRP. These operational, safety, security, and regulatory controls, described below, ensure the safe handling of potentially hazardous biological materials as well as compliance with federal, state and local laws, regulations and policies. The descriptions of these controls are not necessarily comprehensive, but are intended to indicate some of the types of controls in effect throughout every aspect of the BDRP.

3.3.1 OPERATIONAL

3.3.1.1 Physical Plant: The physical plant provides an important secondary barrier for protection of the environment from potentially hazardous biological materials used within a facility. Primary protective barriers are used within the individual laboratories and are addressed in the Safety section. The operational features of the physical plant that provides protection to the environment (both internal and external) include: air handling systems appropriate to the levels of the potential biological hazards used in the facility; emergency power backup systems that would serve to maintain equipment serving primary barrier functions during a power

failure; and the overall engineering of the facility, e.g. placement of air intakes and exhausts, adequacy of power systems, isolation of laboratory vacuum lines from other aspects of the air system, traps in the drainage systems, etc. Recommendations for the design of biological containment laboratories for biohazard levels 3 and 4 work are specified in detail in the publication "Biosafety in Microbiological and Biomedical Laboratories" (5). The most important features of containment laboratory design are the provision for controlled access, specialized ventilation systems, and sealed openings into the laboratory. The specialized ventilation systems maintain laboratory air pressure negative to the immediate surroundings (i.e. , air flow is into the laboratory rather than out of it), the exhaust air from the laboratory (BL-4) is filtered through HEPA filters or incinerated, and alarm systems provide immediate notification if air handling systems malfunction. Routine surveillance and maintenance of the facility's systems, and testing of backup systems, are required for effective functioning of the physical plant as a secondary barrier (see Appendix 12).

3.3.1.2 Waste Stream: Management of the solid and liquid waste streams in accordance with RCRA, Clean Air and Water Acts, and federal, state, and local standards is critical to protection of the environment. State or local governments often require that research and development facilities secure separate permits or certifications for discharge of their liquid and solid wastes. At a minimum, potentially hazardous laboratory wastes are segregated from sanitary waste to allow appropriate monitoring of the laboratory wastes. For work with biological materials that pose potential hazards to the environment, both solid and liquid laboratory wastes are routinely pretreated to render them nonhazardous. Pretreatment methods include autoclaving of solid and/or liquid wastes to heat-inactivate biologically hazardous materials, and chemical inactivation of liquid wastes (with appropriate subsequent consideration of disposal of the chemical agents used for decontamination). Monitoring and testing of pretreated wastes serve to assure that they have been rendered nonhazardous. Depending on the location of a given facility, laboratory solid wastes are disposed of either by incineration or burial in landfill (for disposal of certain materials, pathological incinerators, or hazardous materials landfills) operating under appropriate permits or licensure.

3.3.2 SAFETY

Since the preparation of the DEIS, the Director of Defense Research and Engineering issued a policy on DoD research activities in the BDRP. This policy formalized the requirement that all efforts in the BDRP be conducted in compliance with the CDC-NIH Guidelines: *Biosafety* in *Microbiological* and *Biomedical laboratories,* and further established the requirement that compliance with this guideline be included as a prerequisite in BDRP contracts. The USAMRDC, the only component of the BDRP

supporting work at secondary sites that requires the use of BL-3 or BL-4 laboratories, has implemented the DoD directive by establishing formal requirements in contracts for compliance with the Guidelines as well as for pre-award and post-award laboratory inspections.

The Army has initiated efforts to clearly identify the Army Safety Office, a subordinate function of the Office of the Chief of Staff, as the focal point for safety in the BDRP. In order to clarify and codify the responsibilities for safety throughout the program, the Army Safety Office has drafted two documents: an Army regulation on "The Army Biological Defense Safety Program," and a supporting Army Pamphlet that provides the technical information necessary for conduct of the safety program. The regulation will go into effect after formal review and approval.

3.3.2.1 Regulations: Numerous national and state regulations on the safe handling of specific hazardous materials apply to the BDRP. Occupational Safety and Health Administration (OSHA) regulations (29 CFR) apply primarily to employee safety with regard to ambient air quality and presence of toxic and/or carcinogenic materials. NIH Guidelines for Research Involving Recombinant DNA Molecules (31) have the force of law when the work conducted is supported by NIH funds. The DoD voluntarily adopted and mandated compliance with the NIH guidelines for all DoD-sponsored activities (DoD laboratories as well as contractors) involving genetic engineering (32). The Nuclear Regulatory Commission (10 CFR Ch. 1) regulates the use, handling and disposal of radioactive materials (primarily compounds containing very low energy isotopes) used in the BDRP. U.S. Food and Drug Administration guidelines and regulations (21 CFR) (for example, "Good Laboratory Practices") apply to research conducted in support of application for licensure of new drugs, vaccines or pharmaceuticals. The U.S. Department of Agriculture regulates the importation, possession, and use of animal and plant pathogens under authority of the Virus-Serum-Toxin Act (21 USC 151-158). The EPA, under the Toxic Substances Control Act, has ruled that genetically engineered microorganisms are chemical substances subject to the provisions of that Act for the purposes of manufacture, public distribution or significant new use. Other public laws and federal regulations govern the participation of human volunteers in biomedical research.

3.3.2.2 Institutional Approval: Certain institutional approval authorities are mandated by policy or regulation. These include, for example, an Institutional Biosafety Committee for review of research using recombinant DNA, and Radiation Safety Committees for review and approval of use of radioisotopes in biomedical research. Additional institutional approval authorities include committees governing the use of laboratory animals in research and research using human volunteers. The Institutional Biosafety Committees often have an extended mandate to review and approve all institutional research involving

potentially hazardous chemicals, organisms or toxins. Frequently, two separate biosafety and/or health and safety committees oversee recombinant DNA work and other work involving biohazardous materials, respectively. Periodic laboratory inspections for compliance with various regulations are conducted by internal or external reviewers, depending on the subject of the inspection. It should be noted that funding authorities, such as the NIH, DA, National Science Foundation, and numerous other private foundations that support biomedical research, all require requests for research support to be formally approved by authorized institutional officials. If work with animals, recombinant DNA, humans, or radioisotopes is involved, documentation of appropriate approvals must also be provided before any funds are awarded. Questions as to suitability of facilities or personnel are resolved by site visits prior to the award of funds.

3.3.2.3 Professional Standards: Professional standards and guidelines for the safe conduct of biomedical research are promulgated by various agencies and organizations. Examples of such standards are the NIH Laboratory Safety Monograph (33) and the CDC-NIH publication "Biosafety in Microbiological Laboratories" (5). Specialized areas in which individuals and/or laboratories must receive certifications before performing in a professional capacity include clinical laboratory technology, pathology, radiology, etc. In addition, many professional societies offer training courses and guidance in technical standards that are readily available to researchers at all levels. At the institutional level, compulsory employee orientations, provision of safety handbooks, and training in the use of isotopes, animals, specialized equipment, biosafety procedures, and emergency responses serve to promulgate and reinforce safe laboratory practices. On-the-job training of individuals involved in research and implementation of local standard operating procedures facilitate the maintenance and dissemination of professional standards. As appropriate to the level of biohazard work being conducted, worker protection is furthered by the provision of laboratory garments (lab coats, scrub suits, etc.), gloves, masks, respirators, and equipment (for example, automatic pipettors) designed to isolate the worker from the biological materials. Work conducted at the BL-3 or BL-4 level is conducted in a laboratory specifically designed and equipped to meet those biosafety standards (5). Thus, while there is no single codified set of professional standards applicable to the conduct of research in the BDRP, many specialized standards for the use of infectious organisms, and performance of various laboratory techniques and procedural methods exist and are accepted and followed throughout the biomedical research community.

3.3.2.4 Laboratory Design and Practices: The CDC-NIH publication "Biosafety in Microbiological and Biomedical Laboratories" (5) describes combinations of standard and special microbiological practices, safety equipment and facilities that

constitute Biosafety Levels 1-4 (BL 1-4), which are recommended for working with a variety of infectious agents in various laboratory settings (see Appendix 12). Two elements of containment for infectious agents are described. Primary containment, which is designed to protect personnel and the immediate laboratory environment, includes use of good microbiologial technique, i.e. maintenance of sterility and reduction of incidental aerosols, and use of appropriate safety equipment, e.g. Biosafety cabinets (see Appendix 11), sealed and vented centrifuges, etc. Secondary containment, designed to protect the environment external to the laboratory from biohazardous organisms, is provided by facility engineering features and operational practices.

In addition to these Biosafety guidelines, the Laboratory Safety Monograph (33) published by the NIH as a supplement to the NIH Guidelines for Recombinant DNA Research (34) describes detailed relevant laboratory practices, containment equipment, special laboratory design and roles and responsibilities. The guidelines for detailed laboratory practices include selection of laboratory techniques for biohazard control, personal hygiene habits and practices, protective clothing and equipment, housekeeping, decontamination and disposal, care and use of laboratory animals, and protection of vacuum systems when filtering biohazardous materials. The detailed descriptions of containment equipment include selection of biological safety cabinets and certification procedures. The details of special laboratory design include specifications for BL3 and BL4 facilities and their certification procedures. The roles and responsibilities section includes guidelines for the institutional Biosafety committee, the biological safety officer, emergency procedures, medical surveillance, and training aids, materials and courses. A book in preparation by the National Academy of Sciences, National Research Council titled "Biosafety in the Laboratory: Prudent Practices for the Handling and Disposal of Infectious Materials" presents comprehensive guidelines covering all facets of the operation of a laboratory in which human pathogens are handled. This peer-reviewed treatise incorporates the CDC-NIH guidelines and extends the recommendations in the Laboratory Safety Monograph (33) to all activities that involve infectious organisms other than those specifically involving recombinant DNA.

While the guidelines described above apply to work performed with infectious organisms, no similar set of national guidelines yet exists for the handling of toxins of biological origin. Standard Operating Procedures are developed locally for the handling, use and disposal of toxins, as appropriate. However, guidelines for the safe handling of botulinum toxin and the organism that produces it, *Clostridium botulinum,* are specifically described in the CDC-NIH Biosafety guide (5). (Recommended containment levels are BL-2 or BL-3 depending upon amounts of material used and specific procedures performed.) Because botulinum toxin is one of the most potent of the known

biological toxins, the principles of good laboratory biosafety and containment described for this toxin serve as good guidelines for laboratory work with other equally or less potent toxins.

3.3.2.5 Good Judgment: The essence of good judgment in any research activity is the protection of oneself, others in the laboratory, the environment (both internal and external), and lastly, the experimental material. Indeed, researchers and other laboratory personnel have a vested interest in their own health and safety. As a rule of thumb, when there is uncertainty as to the appropriate level of protective measures for a given situation, the highest available level of primary protective barrier is employed. An example of implementation of this policy is handling of a potentially hazardous blood sample in a biosafety cabinet while wearing surgical gloves, rather than handling such material on an open bench with bare hands. Good judgment extends also to conscious efforts to minimize the potential for accidents, and seeking guidance from standards or experts when confronted with unusual situations.

3.3.3 SECURITY

3.3.3.1 Laws and Regulations: Depending upon the location and ownership of a given facility, local, state and/or federal laws govern the security of that property. These laws and regulations pertain to trespass of unauthorized individuals, physical damage to property, theft of property, and violation of the owner's rights. Laws and regulations typically allow property owners to bar the general public from unauthorized entry to a facility and to place physical barriers for prevention of entry.

3.3.3.2 Enforcement: Depending upon jurisdiction, local, state or federal law enforcement officials uphold and execute the laws pertaining to property security for a given facility. In addition, personnel employed in a facility are charged with the responsibility to notify appropriate officials if they observe violations of relevant laws.

3.3.3.3 Physical security: Several levels of physical security, although implemented primarily to enhance property security, contribute to the overall safety of the BDRP. Many facilities have perimeter controls, where public access is regulated through manned gates. Facility doors are locked after working hours, on holidays, and weekends. Doors to laboratories are similarly locked during non-working periods. Biologically hazardous materials are stored in appropriate units (cabinets, refrigerators, freezers) to which access is controlled by a system of locks. Many facilities have implemented, or plan to implement, personnel access controls in the form of computer controlled facility access systems (such as magnetic card key systems), which only permit passage of an employee to designated areas, and further, provide an alarm system and audit trail for monitoring access violations. Guidelines for BL-3 and BL-4

laboratory operations contain additional specifications on control of access to the laboratory and access to hazardous infectious organisms (see Appendix 12).

3.3.4 REGULATORY CONTROLS

3.3.4.1 Controlled and Hazardous Substances: Federal regulations and common carrier tariffs have been enacted to ensure the safe transport of hazardous biological materials. U.S. Public Health Service (USPHS) regulations (42 CFR 72) specify packaging and labeling requirements for etiologic agents (see Appendix 2). The U.S. Department of Transportation (D.O.T.) regulations (49 CFR 173) contain additional requirements for packaging, and the U.S. Department of Agriculture (USDA) regulates animal (and plant) pathogens (9 CFR 122). The U.S. Food and Drug Administration (FDA) regulates the use, handling and shipment of biological products (21 CFR 312 and 600-800). In addition, U.S. Dept. of Justice, Drug Enforcement Administration, regulations (21 CFR Ch. II) list four classes of controlled substances for which use licenses are required, and to which specific DOT regulations apply.

3.3.4.2 Congressional: The U.S. Congress, through the budget authorization and appropriations process, controls all funds used to support the BDRP (see section 2.3 for discussion of program elements, projects, and tasks). An annual report on Chemical Warfare - Biological Defense Research Program Obligations is presented to Congress at the end of each fiscal year. In addition, an annual Research, Development, Test and Evaluation (RDT&E) Congressional Descriptive Summary, covering the various RDT&E DoD mission areas, is presented. The BDRP is identified discretely in the RDT&E achievements and fiscal analyses that are presented in this latter report.

3.3.4.3 National Policy and the Biological Weapons Convention: The U. S. formally renounced the "use of lethal biological agents and weapons, and all other methods of biological warfare" in National Security Decision 35, November 25, 1969. In National Security Decision 44, dated February 20, 1970, the U.S. renounced "offensive preparations for the use of toxins as a method of warfare," and reiterated that "the U.S. will confine its military programs for toxins, whether produced by bacteriological or any other biological method or by chemical synthesis, to research for defensive purposes only, such as to improve techniques of immunization and medical therapy." In 1972, the U.S. signed the Biological Weapons Convention (Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological "Biological) and Toxin Weapons and on their Destruction). Appendix 1 contains excerpts of these documents. The U.S. Senate ratified the Biological Weapons Convention in 1975. The BDRP is conducted in full cognizance of and compliance with these national policies and the BWC.

3.3.4.4 Army Regulations: Army Regulations (ARs) provide specific guidance and implementation of applicable federal regulations, public laws, and DoD policies. In addition to ARs, numerous technical bulletins and local implementations of ARs provide guidance on specific policies and procedures. Two major groupings of Army regulations (M s) contain individual regulations that govern, in whole or in part, various aspects of the BDRP. The two major AR series are Medical Services (AR 40 series) and Research, Development, and Acquisition (AR 70 series). The most important regulations from these two series, as well as miscellaneous pertinent regulations, are listed below.

AR 40 Series - Medical Services

40-1	Composition, Mission and Functions of the Army Medical Department
40-7	Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances
40-10	Health Hazard Assessment Program in Support of the Materiel Acquisition Decision Process
40-12	Medical and Agricultural Foreign and Domestic Quarantine Regulation for Vessels, Aircraft and Other Transports of Armed Forces
40-14	Control and Recording Procedures for Exposure to Ionizing Radiation and Radioactive Materials
40-24	Medical Laboratory Activities
40-38	Clinical Investigation Program
40-56	Introduction Requirements Determination and Publication of New Type Classified Medical Items Into the Department of Defense
40-60	Policies and Procedures for the Acquisition of Medical Materiel
40-61	Medical Logistics Policies and Procedures

AR 70 Series - Research, Development and Acquisition

70-1	Systems Acquisition Policy and Procedure
70-5	Grants to Nonprofit Organizations for Support of Scientific Research
70-6	Management of the Research, Development, Test and Evaluation Army Appropriation

70-10 Test and Evaluation During Development and Acquisition of Materiel

70-11 Dissemination of Scientific and Technical Information

70-14 Publication and Reprints of Articles in Professional Journals

70-17 System, Program, Project, Product Management

70-18 The Use of Animals in DoD Programs

70-25 Use of Volunteers as Subjects of Research

70-26 Department of the Army Sponsorship of Unclassified Scientific or Technical Meetings

70-35 Advanced Planning Information for Research and Development

70-59 Department of Defense Tactical Shelter Program

70-65 Management of Controlled Substances, Ethyl Alcohol and Hazardous Biological Substances in Army Research, Development, Test and Evaluation Facilities

70-69 Major Range and Test Facility Base

70-71 Nuclear, Biological and Chemical Contamination Survivability of Army Materiel

70-72 Production Management

70-74 Independent Research and Development

Miscellaneous

AR 190-50 Physical Security for Storage of Controlled Medical Substances and Other Medically Sensitive Items

AR 190-51 Security of Army Property at Unit and Installation Level

AR 190-52 Countering Terrorism and Other Major Disruptions on Military Installations

AR 385-10 Army Safety Program

AR 385-40 Accident Reporting and Records

AR 740-32 Responsibilities for Technical Escort of Dangerous Materials

3.4 FACILITIES SUPPORTING THE BDRP

3.4.1 Primary Sites

The primary DA sites at which BDRP activities are conducted are described in section 5.2.2 and Appendix 5. The RDT&E activities associated with the Program are conducted in specific laboratory facilities at each of these sites. Depending upon the types of microorganisms or toxins used, and the nature of the research or testing conducted, the individual facilities are specially designed and equipped to meet the biosafety level standards described in Appendix 12. For example, USAMRIID, the lead laboratory for medical defensive studies, contains laboratories designed and equipped at biosafety levels 1 through 4. The nature of the BDRP activities conducted by CRDEC requires laboratories that function only at biosafety levels 1 and 2. The Baker Laboratory Complex, DPG, currently performs laboratory developmental testing studies that require only biosafety level 2 facilities. The outdoor grid testing areas at DPG are used in tests with simulants in support of the BDRP only in response to specific materiel developer requirements, and only after preparation of appropriate NEPA documentation.

3.4.2 Secondary Sites

Representative secondary sites where BDRP studies are conducted are described in sections 5.2.3 and Appendix 5. Appendix 3 lists all secondary sites supported by the BDRP, current as of January 1, 88. Secondary sites supported by the BDRP all contain existing facilities appropriate for the particular BDRP studies conducted at that site. As a general policy, the BDRP does not support the construction of new facilities at secondary sites. Laboratory operations are conducted by established organizations within enclosed facilities where all waste streams are managed in compliance with existing laws and regulations. The majority of secondary sites provide only general laboratory facilities, where studies of microorganisms or toxins requiring only biosafety levels 1 or 2 containment are conducted. A small number of secondary sites provide biosafety level 3 laboratory facilities for performance of BDRP-supported studies.

3.5 POTENTIAL RISK/ISSUE CATEGORIES

The BDRP can be subdivided into several subject area categories relating to identifiable potential risks to the health and safety of the workforce or the environment, as well as to areas of public controversy. This programmatic perspective provides a useful and realistic basis for the analysis of potential impacts on the environment that might arise from the BDRP. A detailed discussion of each risk/issue category is presented in Appendix 4, and BDRP sites were identified according to these categories (by corresponding Roman numeral) in Appendix 3.

Many of the BDRP research and development efforts are similar, or parallel, to research and development efforts conducted in universities and research institutes throughout the U.S. and in other countries. At the level of the most basic research efforts, BDRP research is virtually indistinguishable from that conducted and sponsored by the National Science Foundation, National Institutes of Health (NIH), and the Centers for Disease Control (CDC). It is only when the research effort is carried into the phase of product development (e.g., vaccines, detectors) that the effort can be identified as one that is clearly of less general interest to the civilian sector than to the DoD. Nonetheless, both civilian and military biomedical product development involve the use of similar laboratory techniques and materials, including organisms, toxins, genetically engineered microorganisms (GEMs), etc. The general procedures, risks, safeguards, and potential environmental consequences are the same, regardless of the organization sponsoring the effort.

The NIH developed guidelines (34) for recombinant DNA research under the auspices of the National Environmental Policy Act (NEPA) (7,35) and other federal statutes. These guidelines established the minimum standards for laboratory safety, including procedures, equipment, and facilities appropriate for safe conduct of recombinant DNA research (33). The guidelines have been modified over the past decade (37-39) to reflect research experience and public input, which are incorporated in the most recent guidelines, published May 7, 1986 (31). The NIH and CDC jointly published guidelines that detail the laboratory procedures, safety equipment, and facilities design required for the safe conduct of research with pathogenic organisms (5). The DoD implementations of the NIH and CDC guidelines require laboratory procedures and containment facilities that meet or exceed these federal standards (32).

The most probable biological warfare threat to U.S. forces is an attack with aerosols of biological agents. Thus, the BDRP efforts differ from those conducted by most non-DoD organizations in the requirement for the use of aerosol challenges in the preclinical phase of vaccine and drug development, or aerosol testing in the development of protection, detection and decontamination systems. In the civilian sector, aerosol test systems are used primarily in the study of communicable diseases transmitted by the aerosol route, such as influenza, and in the development of aerosol forms of therapeutic drugs, for example, various aerosol asthma therapies and aerosol Virazole. for treatment of respiratory syncytial virus infection in infants.

3.5.1 High Hazard Organisms (I)

This subject category includes all laboratory activities with organisms for which biosafety levels 3 and 4 containment are recommended by the CDC-NIH guidelines (5). In addition, for laboratory procedures with BL-2 organisms that pose potentially greater risks to workers or the environment, e.g. possible

generation of aerosols or use of highly concentrated preparation" of organisms, the next higher biosafety level, BL-3, from that generally recommended for a particular organism is used and given consideration in this category.

3.5.2 Genetically Engineered Microorganisms (GEMs) (II)

GEMs do not constitute a programmatically defined category per se because genetic engineering is not a discrete object of study, but rather is considered a state of the art tool to be applied to attaining specific research objectives. This topic is given separate identification here primarily because of the public perception of special environmental risks associated with GEMs. In addition, segments of the BDRP can be identified as including, or potentially including, use of genetic engineering or genetically engineered microorganisms in the research and development endeavor. The NIH has published an environmental impact statement (7,35,37,38) specifically addressing the issue of GEMs and research involving recombinant DNA molecules. Thus, the analysis of the potential impact of GEMs and their associated methodologies on the environment presented in this DEIS is restricted to the context of the BDRP.

3.5.3 Toxins (III)

This category includes all toxins, as well as potentially toxic substances of biological origin such as bioregulators. Laboratory work with toxins may pose risks to an exposed individual, but unlike infectious microorganisms, toxins are not living entities and do not propagate themselves in a host or in the environment. Although there are no nationally recommended biosafety levels for work with toxins per se, the CDC-NIH guidelines (5) recommend biosafety level 2 for most work conducted with *Clostridium botulinum,* the bacterium that produces the potent botulinum neurotoxin. In addition, appendix F of the NIH Guidelines for Research Involving Recombinant DNA Molecules (31) addresses the appropriate levels of biosafety for use in cloning toxic molecule genes. For the most potent classes of toxins, biosafety levels 2 or 3 are recommended, depending upon the biological containment (host-vector) system used. Unless there are procedures that would pose an increased risk to the laboratory worker, such as potential for creation of aerosols or work with highly concentrated materials, work with toxins is appropriately conducted at biosafety level 2 (see Appendix 12). In the case of procedures with toxins or toxic molecules requiring more stringent containment measures and higher biosafety levels, consideration was given in the analysis under the high hazard organisms category.

3.5.4 Low Hazard Organisms (IV)

This subject area includes all low hazard organisms, which are defined by the CDC as including a broad spectrum of indigenous microorganisms present in the community and associated with human disease of varying severity (e.g., communicable

diseases), as well as organisms present in the environment and not known to cause disease in healthy adult humans (5). By definition, the low hazard organisms pose far less potential risk to the workforce and to the environment than the high hazard organisms. Organisms in this category are incorporated into the program whenever and wherever they can be used and still give meaningful results. Organisms used as simulants in testing of physical protective devices belong to this category.

3.5.5 Rapid Diagnosis and Detection (V)

This subject area was defined separately because it is a major identifiable program area that is of overall low-risk potential to either human health or the environment. The development and design of detection equipment, development of assay systems, and associated use of non-hazardous and non-toxic biological materials are considered in this category. Where development of reagents for testing of products and/or equipment would involve use of infectious agents or toxins, the analysis of environmental impact for this subject area was considered under those higher risk categories as appropriate.

3.5.6 Vaccine and Drug Therapy Development (VI)

This subject area is a major identifiable element of the BDRP in which the potential risks or impacts are of a markedly different nature than those evaluated under the high-hazard organisms or toxin categories. This subject area includes only the preclinical and clinical testing of anti-agent drugs, i.e. antiviral drugs, anti-toxin drugs, and vaccines. The other research and development aspects of drug and vaccine development involving use of infectious agents or toxins are covered under one or more of the other subject area risk categories.

Phase III human clinical testing of drugs or vaccines is conducted only where and when a target disease occurs naturally. Such human testing is conducted under appropriate controlled conditions meeting the human testing standards of the United States and of the country in which a study may be conducted. There is no introduction of an agent into the environment, and no additional risk to human or environmental health and safety over that which is a result of the occurrence of natural, endemic disease.

3.5.7 Other Program Research and Activities (VII)

This category includes those areas of the program that do not appropriately fit into one or more of the categories defined in sections 3.5.1-6, and that are likely to have imperceptible, if any, impact on the human or natural environment, and do not constitute discrete subject areas warranting separate consideration. Examples of these sorts of activities are literature studies, purification of immune plasma, and handling of non-hazardous biological laboratory materials.

4. ALTERNATIVES CONSIDERED

4.1 INTRODUCTION.

The treatment of alternatives is the heart of the EIS. For every choice among alternatives, there are trade-offs which must be considered. A goal of the alternatives presentation is to define clearly the issues to provide a basis for choice among options by the decision maker and the public (40CFR1502.14).

Two alternatives are readily identified:

a. Continue the BDRP (essentially as presently constituted) - This is considered to be the Preferred Alternative.
b.
b. Terminate the BDRP - This is designated as the "No Action" alternative.

It is important to note that termination of the BDRP has been designated as the "No Action" alternative, and that this is contrary to the manner in which "no action" may normally be interpreted. Maintenance of the status quo (unaltered environment) is usually inherent in the no action alternative. This would not be the case, however, because the BDRP is an ongoing program. Termination would definitely alter the status quo. This will be discussed further as the reasonable alternatives are compared.

Other possible alternatives relate primarily to different ways of conducting the BDRP or to selection of different locations for conducting research or testing activities. These options are grouped as "changes in the scope" or "changes in the location" of the program.

The primary reason for considering alternatives, in accordance with NEPA, is to provide reasonable alternatives to proposed actions that will avoid or minimize adverse effects of these actions on the quality of the human environment.

The degree to which the BDRP could affect the quality of the human environment is subject to debate or differences of opinion. The IAM process, utilized to assist in focusing on the truly relevant and significant issues, revealed that the perceived risks and associated impacts were, in many instances, quite different from the actual risks and the observed or realistically expected impacts (See Appendix 6).

4.2 ANALYSIS OF ALTERNATIVES

In addition to the two most obvious alternatives identified above, considerable effort was devoted to searching for other reasonable alternatives. The IAM assisted in the identification of relevant and significant areas of concern. This approach also provided a mechanism to identify any potential significant impacts and the resources that could be affected. The BDRP was systematically examined both on a programmatic and on a site specific basis. The IAM process led to the following conclusions for the ongoing BDRP (Preferred Alternative):

a. Negative or adverse considerations

(1) Public opinion, as manifested in the controversy surrounding the BDRP or portions of its content (such as genetic engineering), was identified as a relevant concern or issue. (Details on the controversial issues are presented in Section 5.2 and Appendix 10.)

(2) Impacts, perceived by elements of the public, on the following resources:

(a) Water quality

(b) Air quality

(c) Human health

(These perceptions are apparently based primarily upon distrust, lack of accurate information, or misunderstandings related to the adequacy of control measures and/or the nature of physical containment facilities.)

b. Positive or beneficial considerations

Contributions to the national defense posture and scientific benefits (See Section 1.5 for details).

The following conclusions are based on the consideration of alternatives and the identification of relevant and significant issues (See Appendix 6):

(1) All significant issues relate to the BDRP, and <u>not</u> to specific sites.

(2) The impacts of the BDRP fall into the category of <u>perceived</u> impacts; no <u>actual</u> significant adverse impacts were identified.

(3) No conflicts of resource use were identified.

4.2.1. ALTERNATIVES RECOMMENDED BY SCOPING

The Notice of Intent to prepare this EIS identified the proposed action as the continuation of the BDRP and solicited alternatives to be considered from other agencies and the interested public. In addition to suggestions that the BDRP be terminated (No Action alternative), the following alternatives (paraphrased) were suggested:*

a. Use innocuous agents or simulants in lieu of hazardous biological organisms for research or testing.

b. Environmental considerations should guide selection of location of research or testing sites.

c. Options to replace aerosol testing should be considered.

d. Place a moratorium on research involving genetic engineering.

e. Transfer the management of the BDRP to a non-military agency.

The first four suggestions represent modifications in the program scope, or potentially changes in locations, while the last would alter the present management authority. Each of these recommended alternatives was analyzed both in the NEPA context, and in the context of its possible effect on the BDRP, for its potential to alter conflicts in the use of available resources or to change (especially reduce) any significant impacts on the human environment. As discussed below, none of these alternatives, if implemented, would result in any significant changes in utilization of resources or in amelioration of any adverse impacts on the environment. Thus, these alternatives were eliminated from more detailed study and from further consideration in the identification of reasonable alternatives.

4.2.2 ANALYSIS OF SCOPING AND PUBLIC COMMENT RECOMMENDATIONS

a. Use innocuous agents or simulants in lieu of hazardous biological organisms for research or testing.

Maximum use of simulants is already part of the BDRP. It is standard practice to use lower hazard organisms or simulants, to the extent practicable, in the conduct of research and testing. Research design considers the objectives to be sought and seeks

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* It should be noted that each of these suggested alternatives was also identified in some fashion by various commentors in their comments on the DEIS (see Appendix 14).

to accomplish these objectives in a manner which is both safe and cost effective. If lower hazard organisms, or simulants, will meet the objectives, they are normally selected. Even so, the higher hazard organisms must be used for certain efforts, for example, in evaluating the efficacy of a vaccine or drug, and in the development of a diagnostic assay or of a detector. Vaccines or drugs must provide protection or therapy against a particular disease and must be tested in animal challenge studies against that disease to demonstrate their effectiveness. In the case of diagnostic assays, many experimental concepts can be and are developed using lower hazard organisms, but ultimately actual pathogens must be used in the laboratory in order to assure sensitivity and reliability. Similarly, in the development of detection systems, the detection paradigm can be developed using lower hazard organisms, but that paradigm then needs to be tested in the laboratory using higher hazard organisms in order to ensure sensitivity and reliability, especially in cases where a component of the detection system is based on a biochemical property unique to a specific organism. In the case of detection or protection systems based solely on a physical parameter, such as particle size, only simulants or lower hazard organisms are needed and therefore are used for those RDT&E efforts. In all cases, when the more hazardous materials must be used, test protocols are designed to use only small quantities of infectious organisms or toxins, and to incorporate appropriate procedures and containment to protect adequately the workforce and external environment. The IAM did not reveal significant adverse impacts to the environment nor conflicts in the use of resources arising from the use of higher hazard organisms in the BDRP. Thus, the alternative of increased or exclusive use of simulants in the program was not considered a viable alternative in the NEPA context.

b. Environmental considerations should guide selection of location of research or testing sites.

In regard to this second alternative recommended in scoping, environmental considerations can and do influence the location of some BDRP activities. Obviously, if there are no potential adverse environmental consequences which would differ from site to site, then the location is not a relevant area of consideration. Most of the potential impacts associated with BDRP activities have been determined to be site independent. There are circumstances, however, such as the selection of the remote DPG area for any open-air field tests with simulants which may be required, which are definitely dependent upon considerations of location (See Appendix 5). In addition, if potential accidents resulting from BDRP activities had been determined to threaten human or animal populations, then areas of sparse human population and poor habitat quality would need to be evaluated. This is not the case because no such threats are identified (See Appendix 9).

c. Options to replace aerosol testing should be considered.

The recommendation to eliminate aerosol testing would seem to provide an opportunity to reduce a few of the dangers or risks associated with BDRP activities. Transmission of infection through aerosols does represent one of the greatest risks to laboratory workers. However, most laboratory infections that have occurred in the past have been attributed to accidental or incidental aerosol release from other laboratory procedures and have not been associated with aerosol testing per se (5), and see Appendix 8). In addition, airborne particles (aerosols) are considered the most likely manner in which a biological attack would be initiated. Therefore, the design and testing of defensive materiel, such as protective devices and detectors, must address this factor. This preeminent consideration, together with the fact that a vaccine that is effective against disease transmitted by inoculation might not be effective against the same disease when transmitted by aerosol challenge (83), makes aerosol testing a necessary element of the BDRP. Studies requiring the use of aerosols are, like any other studies, designed to answer a specific scientific question, and thus are conducted only infrequently and only in the larger context of the goals of a particular project. Aerosol testing with all organisms (except those officially designated as simulants) is conducted only on very small scale, in sealed chambers, in biocontainment laboratories. Aerosol testing conducted in the BDRP is not large scale, and the potential risks associated with aerosol testing are mitigated by the use of special procedures, specially designed equipment, and appropriate levels of containment, which effectively reduce the risks and protect the work force and the external environment. Because the risk to human health and the environment are minimal, after consideration of mitigative measures, and because elimination of aerosol testing would make the BDRP ineffective, this alternative is not considered to be reasonable.

d. Place a moratorium on research involving genetic engineering .

Genetic engineering adds a significant research tool to the scientists' repertoire. It is a widely accepted scientific approach, albeit an area of concern to certain elements of the public. Genetic engineering, appropriately conducted, does not pose a significant risk to the workforce, nor does it threaten mankind. The scientific community is well aware of the possibilities for harmful effects and has responded by establishing stringent guidelines to minimize any impacts of genetic engineering on the human environment (See Appendix 10).

A moratorium on the use of genetic engineering as a research tool would probably alleviate at least a portion of the opposition to the BDRP, and might well also reduce some of the controversy. It would also eliminate some of the concerns for postulated catastrophic events, especially for those who envision

the uncontrolled spread of a novel hazardous organism. However, because the BDRP does not include any efforts whatsoever to produce novel hazardous organisms, this concern seems unrealistic. The elimination of genetic engineering would render a substantial portion of the BDRP scientifically ineffective and reduce the overall level of defensive "preparedness." Therefore, this recommended alternative is not considered to be reasonable.

e. Transfer the management of the BDRP to a non-military agency.

For those distrustful of the military, the fifth suggested alternative of transferring program management responsibilities to a non-military agency, for example the NIH, would appear to be an attractive option. It is also conceivable that another Federal agency, or perhaps a specially appointed board, could direct the BDRP. Such an approach might alleviate the criticisms of the military management of the BDRP, but it would not necessarily lessen the controversies or concerns related to such issues as genetic engineering, high hazardous infectious organisms, or aerosol testing. It is assumed that these issues would remain areas of concern because they are vital to the BDRP, regardless of the management authority. If BDRP type RDT&E efforts continued, it does not necessarily follow that there would be any reduced risks to the work force or the general populace. Different or additional management also would not necessarily improve the existing, excellent safety record of the BDRP. Thus, the transfer of management would not affect utilization of resources or environmental impacts.

A pertinent consideration to the "change management" alternative is that the BDRP is a vital component of the national defense posture. While certain scientific, programmatic, or research management responsibilities could possibly be transferred from the military, this is not the case for defense responsibilities. The DoD is responsible for recommending to the Congress adequate measures to defend the U.S. and its allies successfully. It would not be appropriate, even if it could be done institutionally, to transfer defense responsibility to another agency or organization.

In any event, it is not clear what would be gained from a transfer of management. Presumably, it might alleviate some of the fears of those who distrust the military. However, as for the BDRP, there are no clandestine objectives. The BDRP is an open UNCLASSIFIED program, however, results which impinge on National Security may be classified as described in Section 2.1. As discussed in Section 5.5, the participation of postdoctoral fellows from other nations is one example of this openness. In addition, independent scientists already review RDT&E activities and provide guidance on various aspects of the program, and a substantial portion of the research is conducted in non-military establishments (See Appendix 3). Finally, the U.S. Congress is provided a report on the BDRP annually. This

report, which is available for public scrutiny, informs the Congress of the objectives of ongoing and future BDRP efforts, accomplishments to date, and identified future needs. Certain aspects of the BDRP, especially safety, have also been evaluated by such external entities as the Government Accounting Office and a Congressional subcommittee (84, 85). With an appreciation of the openness of the program and the existing external oversight, along with an understanding of the need for military involvement, the benefits that would accrue to the nation, or the human environment, from a transfer of management are not apparent. In addition, it is anticipated that the efficiency of the program would decrease with the addition of another level of management, without any indication that new management would be better, or that the BDRP would be executed more cost-effectively or responsibly. Therefore, the option of transferring program management from the DoD to a non-DoD agency was rejected as not being a reasonable alternative.

4.3 COMPARISON OF REASONABLE ALTERNATIVES

The approach used in identifying the relevant and significant areas of concern has assisted in sharply defining the issues and in providing a clear basis for choice among alternatives. Based upon the preceding discussion, the alternatives have been narrowed to two, i.e. the preferred alternative (Continue the BDRP) and the no action alternative (Terminate the BDRP). Other possible alternatives were eliminated from consideration because they:

(1) Are already an integral part of the BDRP, and are thus fully incorporated in the preferred alternative.

(2) Would render the program ineffective.

(3) Would not materially improve the program, resolve conflicts in resource utilization or reduce impacts.

Early in the scoping process, it appeared that modification of the program scope, content, or location might be reasonable alternatives. Because no substantive approaches to improving or protecting the human environment were identified, these alternatives were also eliminated from further detailed study. *This* conclusion and the resultant narrowing of the issues should not be viewed as representing a complacent attitude. The ongoing BDRP has areas which can be improved and efforts are continually being made in this regard. For example, safety and security measures are the subject of intense oversight. Appropriate adjustments are implemented as needs or opportunities to upgrade or improve are recognized. Some changes have been incorporated and still others are proposed (see Section 3.3.2). While greater levels of safety may accrue, such adjustments in and of themselves do not constitute alternatives, nor do they materially affect any existing impacts arising from the BDRP.

Considerable sensitivity is also exhibited in managing GEM- activities in the BDRP. An active Institutional Biosafety Committee, which includes lay representatives from the local community, reviews all research protocols involving GEMs to assure that studies of recombinant DNA or genetically engineered organisms comply fully with the recommendations of the NIH guidelines. If there is any question as to the risk or propriety of a proposed study, external review and approval are sought through the NIH/RAC process, as specified by the NIH guidelines.

The concern for, and attention paid to, the safety, health, and welfare of the work force, as well as for protection of the external environment, are illustrative of the commitment on the part of the proponent to manage the BDRP responsibly. Thus, it was not considered necessary, nor appropriate, to develop a subset of alternatives which would merely reflect differing levels of emphasis or special attention to selected elements of the overall program.

Table 2 provides an overview of the significant issues, impacts, and tradeoffs associated with the two reasonable alternatives. The tradeoffs are basically between the amount or intensity of controversy and program benefits. The actual adverse impacts to the biophysical and socioeconomic environments associated with the BDRP are not significant and therefore cannot represent an area of consequential gain or loss. Termination of the BDRP would adversely affect individuals in the work force and would have an adverse effect on the local economy in the areas where BDRP efforts ceased. The greatest impact would occur to Frederick County, MD, where BDRP activities support about 3.5 percent of the county's total payroll. This would be within the range of economic impacts experienced over the past 12 years in the area, but would be considered locally significant. Other locales would be adversely affected to a much lesser extent depending upon the location and amount of funding involved.

It is clear that designating termination of the BDRP the "no action" alternative is a misnomer. The status quo would change as indicated in Table 2. It is also clear that any gains or positive contributions to the human environment associated with terminating the program are speculative, as opposed to tangible losses that would result from termination.

4.4 FUTURE CHANGES IN SCOPE, CONTENT OR LOCATION

No specific major changes in scope, content, or location are currently proposed, nor have any requirements (or advantages) for change been identified during the preparation of the FEIS. Relatively minor adjustments or refinements, within the context of the overall BDRP, are made on a routine basis. The review and approval of a new research proposal serves as an example. This could result in a change in program content and/or location. Each activity of this type is provided appropriate NEPA analysis and documentation, depending upon the circumstances and the

TABLE 2
COMPARISON OF REASONABLE ALTERNATIVES

ALTERNATIVE	IMPACTS/ISSUES	REMARKS
Continue BDRP (See Section 2 and 3 for Description). This is the Preferred Alternative.	1. The program evokes controversy among segments of the public which will continue along with the concerns and apprehensions.	1. This is an issue and not an impact per se. of BD research, along with the use of high haz organisms and genetic engineering in the prog primary areas of concern.
	2. Perceived adverse impacts related to: a. Water Quality b. Air Quality c. Adequacy of physical containment facilities. d. Health of the workforce.	2. The actual adverse impacts for these categ determined not significant for either normal o controls in place), or for accident/incident situ activities are in compliance with appropriate r (See Sections 5 and 6).
	3. Program benefits: a. National defense b. Scientific c. Public health benefit	3. It is the position of DoD that the defense a represents a vital component of the overall de Positive defense contributions accrue. This is impact. Tangible benefits accrue to the scienti community (See Section 1.5). The BDRP doe positive benefit on human health.
Terminate BDRP (This means that funding would be eliminated and all RDT&E activities halted.) This is the "No Action" Alternative.	1. The controversy and concerns related to BD research and development would be eliminated.	1. Because BD research is only a very small research and development involving genetic e controversy on this issue would continue. Res toxins and infectious organisms would contin military programs.
	2. Perceived impacts and risks would be eliminated.	2. No measurable improvement to the human be realized since the significant adverse effect rather than actual.
	3. Contributions to national defense and to the scientific community would be forfeited.	3. Greater vulnerability to enemy attack woul response capability to emergency situations w available and the contributions to basic scienc measures would not accrue.

potential for impacts. The tiering approach developed in this programmatic FEIS, based on programmatic risk/issue categories, provides a framework for future environmental review and documentation. Any proposed major change in the scope of the BDRP will be examined based on its own set of circumstances, including any site specific considerations which might exist. Likewise, a proposal for development/construction of new or expanded facilities would be expected to involve site specific considerations as well as programmatic issues. The general goals of resource conservation and environmental protection will certainly influence future proposals and actions. Assurance of appropriate environmental compliance will be an integral component of the review process for all future activities.

5. AFFECTED ENVIRONMENT

5.1. INTRODUCTION

The BDRP is an ongoing research program conducted in existing facilities. Therefore, the day-to-day conduct of the program activities does not require further alteration of either the biophysical or socioeconomic environment. Construction activities associated with the program have occurred on an infrequent basis, and if further needs arise, the proposed actions will be subjected to individual site specific evaluations, with appropriate NEPA documentation in accordance with 40 CFR 1500-1508 and AR 200-2. Air and water effluents and solid wastes emanating from the BDRP are subject to Federal, state, and local controls designed to protect against adverse impacts. Where appropriate, liquid waste streams from BDRP research facilities are pretreated (see Section 5.3), then discharged into established treatment facilities for final treatment before release to the environment.

This section of the DEIS provides a general description of only those aspects of the biophysical and socioeconomic environments that potentially could be affected by the BDRP. The environments described in this section correspond to the set of "Potential Areas Impacted" as displayed on each Impact Analysis Matrix (JAM) in the BDRP evaluations, displayed in full in Appendix 6. Through this evaluation process, decisions were made as to which aspects of any environment were relevant for consideration in the body of this EIS. Appendix 5 contains a fuller description of the environment, whether or not considered to be potentially affected, of the primary sites and of selected secondary sites.

Existing environments associated with specific research sites, and which were shown by the IAM to have some potential to be affected in a particular location, are described in section 5.3. The CEQ regulations (40CFR 1502.15) require that the presentation of these descriptions be sufficient to understand potential effects, and the data and analyses be commensurate with the importance of the impact. Less important material that requires inclusion in this presentation is summarized, consolidated or referenced. Because analyses performed for this study determined that the potential for effects was very small in many cases, treatment of those aspects of the environment is suitably brief. Considerable use is made of existing NEPA documentation (Environmental Assessments and EIS's) prepared for other purposes by the primary sites of BDRP execution.

5.1.1. Biophysical environment

5.1.1.1. Land Use. The general patterns of existing land uses on and surrounding the BDRP primary or secondary sites are evaluated in the following categories: agricultural, industrial, commercial, residential, recreational, wetlands,

floodplains, and unique geographical areas. Relevant land-use plans, policies, and controls, which could be affected by the BDRP activities are also considered.

5.1.1.2. Plant and Animal Ecology. The naturally occurring habitats surrounding the site are evaluated. Terrestrial and aquatic habitats, plant and animal populations, endangered or threatened species, and any designated critical habitats are the categories evaluated.

5.1.1.3. Geology. The land formations, soils, topography, and erosion characteristics of the soils in the area adjacent to the site are evaluated.

5.1.1.4. Water. Surface and ground water quality and quantity are evaluated in the area surrounding the site. Water use and supply are also evaluated.

5.1.1.5. Air Quality. Air quality of the area surrounding the site is evaluated. This includes a consideration of primary and secondary National Ambient Air Quality Standards and emission standards for "hazardous" air pollutants adopted under the Clean Air Act. The evaluation also includes consideration of appropriate biological and other parameters for which there are no standards.

5.1.1.6. Agriculture. Agricultural activities involving crops and livestock in the area surrounding the site are examined.

5.1.1.7. Cultural Resources. The existing districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places as well as other significant scientific, cultural, or historical resources are considered. The evaluation also includes the material remains of past human life and activities such as fossils, relics, artifacts, and monuments.

5.1.1.8. Energy Resources. The evaluation of energy resources includes depletable supplies such as oil, gas, and coal as well as renewable resources such as solar, wind, and water.

5.1.2. Socioeconomic Environment

5.1.2.1. Sociological Environment. The sociological environment of the area surrounding the site is characterized by its demographics, aesthetics, noise levels and odors.

5.1.2.2. Economic Environment. The economic environment in the area surrounding the site is characterized by the size of the labor force, personal income, business volume, and property values.

5.1.2.3. Public Opinion. Public opinion includes controversial issues such as laboratory animal care and use, infectious organisms, biotechnology, and existence of the BDRP in general. It also includes concerns such as socioeconomic wellbeing and other philosophical issues. Public opinion encompasses philosophical opposition to biotechnology in general, and the utilization of biotechnology in DoD-sponsored programs.

5.1.2.4. Program Benefits. The program benefits include the promotion of the existing posture of the United States with respect to defense against biological warfare threats. Potential general scientific and medical benefits include better methods of detection, treatment and prevention of various diseases, as well as increased understanding of basic biological and disease processes. It includes benefits to the public arising from the development of vaccines and drugs for naturally occurring animal and human diseases.

5.1.2.5. Transportation. The existing road, rail and air transportation systems are evaluated in the area surrounding the site. The existing traffic conditions on the roadways are also evaluated.

5.1.2.6. Human Health. Human health is considered for two distinct groups. The workforce at the site is evaluated as one group, since it is potentially at higher risk, especially the laboratory workers and medical research volunteer subjects. The other group is the general population of the area surrounding the site.

5.1.2.7. Safety. Safety considerations are evaluated at the site. This evaluation includes construction and occupational safety (OSHA activities) as well as consideration of past accident records.

5.2 NATIONAL ENVIRONMENT

The environmental impact analysis of the BDRP required an examination of all aspects of the program at the primary and secondary sites. Because several of the relevant areas of significant concern with the BDRP surfaced only from considerations of the total program, with little or no relationship to the sites of performance, the category "National Environment" was established to allow a meaningful discussion of these effects.

Appendix 6 lists all sites participating in the BDRP. Some of these locations are outside the United States. For a major action with the potential for effects outside the U.S., Executive Order 12114 (3CFR 356 (1980), as implemented by DoD Directive 6050.7 and AR 200-2, requires an examination of the potential to "significantly harm" the environment of another country. Although NEPA does not apply directly to BDRP sites outside the United States (as defined in AR 200-2), these sites were examined

for any potential harm under E.O. 12114. No potential was found to significantly harm any aspect of the environment of any other country, and no further examination of international participants in the BDRP, as distinct from other secondary sites, was conducted.

5.2.1 Relevant Areas of Significant Concern

Matrix analysis of the total BDRP revealed ten relevant areas of potentially significant concern which were not always intrinsically related to any one site. Seven areas of concern were associated with the biophysical or socioeconomic environment and three with program activities (see Appendix 6). The environmental areas potentially impacted are surface water, biological air quality, public opinion concerning controversial issues, program benefits with respect to the national defense posture, scientific benefit and public benefit, human health with respect to the workforce, and safety during construction. The program activity areas identified as most likely to be responsible for potential environmental impacts were program management, planning and designing the research, development and testing program, and the performance of procedures required for this research, development, and testing. Program activities are defined in Appendix 6.

5.2.1.1 Surface Water

The potential risk to surface water quality is perceived to be high by some special interest groups and individuals, but actually is low when one examines the stringency of the controls that are applied to the effluents entering wastewater streams from all sites performing BDRP activities (See section 3.3 and Appendix 6). The potential for effects on surface water quality caused by site-specific BDRP activities is discussed in sections 5.2.2 and 5.2.3, below.

5.2.1.2 Biological Air Quality

The potential risk to air quality as a result of possible release of biological toxins or infectious organisms during BDRP activities is perceived to be high by some members of the public, but actually is low or virtually non-existent when one examines the stringency of the controls that are applied to the exhaust air leaving the BDRP facilities. See section 3.3 and Appendices 6, 9 and 12 for a discussion of the many safety controls in place which serve to minimize any potential for release of hazardous materials into the air. The potential for effects on biological air quality caused by site-specific BDRP activities is discussed in sections 5.2.2 and 5.2.3, below.

5.2.1.3 Public Opinion

Controversial Issues

The operation of the BDRP for the study of hazardous biological organisms and toxins brings with it the potential for controversy (40-71). The development of defensive measures for neutralizing the current threat of biological weapon and toxin employment against U.S. soldiers or allies requires the use of the most modern scientific research techniques. Of all the biotechnology available today, perhaps the most controversial (see Appendix 10) is the use of recombinant DNA (rDNA) molecules (41,42) in the construction of genetically engineered microorganisms (GEMs). The facilities supporting the BDRP include microbiological laboratories with modern technological design and equipment. Basic (BL-1 and BL-2) and high-hazard (BL-3 and BL-4) containment capabilities supported by the BDRP represent the latest in functional concepts, laboratory design, and safety (see Appendices 11 and 12). Safety features built into these laboratories permit studies of pathogenic, disease causing organisms with minimal risk to research investigators and virtually no risk for the surrounding community.

Worldwide, USAMRIID is the one state-of-the-art containment facility which existed at the beginning of the genetic engineering era. USAMRIID's high-hazard containment laboratories are the model for the development of the physical containment recommendations in the first NIH Recombinant DNA Research Guidelines (34) and in its supplement, the NIH Safety Monograph (33). No member of the general public in any community has ever become infected with any natural or recombinant biological material as a result of research or test activities in the BDRP (Appendix 8). Since 1976, no BDRP laboratory worker has ever developed a disease as a result of infection with organisms studied in the BDRP laboratories. No resident of the surrounding community has ever developed a disease as a result of these research activities. Any allegation that the BDRP represents an actual community hazard at any location cannot be substantiated.

The BDRP currently includes research on high hazard microorganisms, GEMs, and biological molecules, including both high and low molecular weight toxins. The high molecular weight, or protein, toxins of interest include botulinum toxin, the staphylococcal enterotoxins, and several snake neurotoxins. The low molecular weight toxins include the trichothecene mycotoxins, algal toxins, marine, and various small, non-protein toxins such as saxitoxin and tetrodotoxins. All of these research and development activities are governed by the provisions of the Biological Warfare Convention (Appendix 1) and research results are routinely published in the open scientific literature. It may not ever be possible to eliminate totally some degree of public apprehension about a technically complex subject, such as research with infectious organisms, recombinant organisms, and toxins. However, BDRP research activities with these materials

is comparable, in terms of risks, organisms, and quantities of materials used, to scores of ongoing university and health department-sponsored biological and medical research programs in the U.S. and other countries.

5.2.1.4 Program Benefits

National Defense Posture

A positive impact from the research activities of the BDRP is the contribution these efforts have on the national defense posture of the United States. For a time after the signing of the 1972 Biological and Toxin Weapons Convention, which prohibits the use of BW (See Appendix 1), there was only limited interest in BW defense research. However, there has been increasing evidence that the Soviet Union and other countries have developed offensive BW capabilities. The nonverifiable nature of the 1972 BW treaty, and the realization that a realistic BW threat does exist, have renewed interest in defense against BW agents. Because BW is the only threat for which the U.S. possesses no capability for retaliation in kind, the existence of an active defensive research program serves as the only deterrent to potential adversaries in planning for indiscriminant use of bioweapons in operational war plans. The development of vaccines, prophylactic and therapeutic drugs, and diagnostic kits for biological agents and toxins, is believed to discourage our adversaries in their development of an effective, offensive, biological warfare arsenal.

Scientific Benefit

Other positive impacts from the research activities of the BDRP are the contributions these efforts have had in the prevention and treatment of bacterial and viral diseases throughout the world. The conventional approach to medical defense against BW has been based on the development of prophylactic and therapeutic drugs, vaccines, and diagnostic kits for specific, naturally occurring toxins and infectious disease organisms. Potential threat agents were identified principally on criteria related to their ease of production by a hostile country or terrorist organization, physical and biological stability, and infectivity or toxicity when delivered as an aerosol. Protective products derived from the BDRP during the past several years include vaccines for anthrax, tularemia, Venezuelan equine encephalomyelitis (VEE), Rift Valley Fever (RVF), Q fever, and toxoids against five types of botulism. While many of these products are not yet licensed for general public use, they are used to protect at-risk laboratory workers and are shared with other at-risk populations under certain disease outbreak conditions. Thus, the scientific breakthroughs and product developments arising from the BDRP contribute to the scientific community with advances in basic knowledge and potentially to the health status of certain populations at risk from endemic diseases.

5.2.1.5 Human Health

Workforce

The potential risk to the health of the workforce is perceived to be high by some members of the public, but actually is low when one examines the stringency of the controls that govern each BDRP workplace (see section 3.3 and Appendices 6 and 9). An examination of the potential for effects on the workforce is included in the examination of each site where any such potential could be identified (see sections 5.2.2.3 and 5.3, below).

5.2.1.6 Safety

Construction

There are currently no new construction activities supported directly by the BDRP, thus, this EIS does not address any potential risks resulting from the construction or operation of new facilities. The potential risk to construction safety is perceived to be high by certain public interests but actually is low when one examines the stringency of the controls which are applied to construction operations supporting the BDRP. The basic issue apparently relates to concerns about the adequacy of the design, construction, and operation of the physical containment facilities (see section 3.3). Appendix 12 also describes the requirements for construction of any new containment laboratory. In addition, a separate assessment and NEPA documentation must be prepared by the proponent prior to any new construction by a U.S. government agency.

5.2.1.7 Program Management

BDRP management is conducted openly under Congressional review and in full view of the public in order to minimize program controversy and to maximize program benefit. Through a combination of intelligence information and biotechnological advancements from the scientific community, the commanders of the three primary sites, USAMRDC, USACRDEC, and USADPG, and their professional staff are responsible for recommending a scientifically sound, economically efficient, safe and responsible research program that adheres to BWC and contributes to the protection of soldiers and the defense of the Nation.

The management of the BDRP is a relevant issue from the standpoint of both positive benefits and negative perception. Enhancements of the national defense posture and contributions to scientific advancement are benefits from the program. On the other hand, certain public interest groups espouse the opposing view that any research in biological defense leads both to destabilization of international political relationships and to the potential for a return to offensive biological weapons capabilities which would nullify the BWC. This divergence of

viewpoints and public perception establishes the controversy over the appropriateness of the BDRP.

5.2.1.8 Planning and Design

Planning and design differ from program management in that these are the activities in which BDRP scientists specifically develop test methods and design experiments. The actions are largely those of planning on paper and the development of procedural, health, and safety protocols on a project by project basis. It is at this stage that the course of the day to day laboratory work is determined, and appropriate safety precautions are included where necessary. Reference to appropriate safety standards and standard reference works is common. The health and safety protocols, animal use protocols, and human volunteer protocols are prepared at this stage and reviewed by the appropriate committees before any actual laboratory work is started.

5.2.1.9 Procedures

The relevant procedures are the sum of all the protocols, regulations, and requirements placed on the laboratory workers to regulate their day-to-day work. Essentially nothing is performed in a BDRP research laboratory without reference to project protocols or organizational standards. Procedures may be considered an important means whereby compliance with health and safety standards are assured.

5.2.2 Relevant Areas of Minor Concern

Matrix analysis of the total BDRP program revealed six relevant areas of minor concern, three associated with environmental areas and three with program activities (see Appendix 6). The potential areas affected include public opinion with respect to social concerns, program benefits in the area of public benefits, and the health of the general population. The program areas identified as most responsible for these potential impacts were testing, prototype development, and general laboratory work.

5.2.2.1 Public Opinion

Social Concerns

Four broad social concerns were examined. These concerns were: 1) That through genetic engineering, a deadly organism unknown to medicine or science could be produced and released (42-44,61,71); 2) That the research programs, especially at the primary sites, had the potential to involve many thousands of persons in a catastrophe caused by the release of an organism used in research (48,54,61,69,71); 3) That few, if any, controls existed to regulate the type of research being performed at either the primary or the secondary sites; and 4) That biological

warfare was so repugnant a concept that the U.S. should have nothing at all to do with consideration of even a defensive program with which to meet a potential threat (42,43,59,69,70,72). While these diverse feelings are grouped here under one heading, most have been discussed thoroughly as separate issues in other sections of this FEIS. We believe **that** each is closely related either to lack of accurate information about the BDRP or to strong personal convictions which are not likely to change even when the incorrectness of that misperception is strongly documented (72). Each will be examined briefly below.

Genetically Engineered Microorganisms -- Use of recombinant DNA procedures with pathogenic organisms and toxins is closely controlled at all locations, both within and outside the government. Development of a more virulent strain of a pathogen is specifically prohibited under any circumstance, and is not the goal of any BDRP effort. In fact, BDRP uses of recombinant techniques are with the goal of producing a less virulent strain which may be more safely used in the laboratory or for vaccine development. Section 3.3 and Appendix 10 discuss the many safeguards which preclude the development, let alone the release, of "deadly" recombinant organisms.

Catastrophic Accidents -- While a laboratory accident could potentially result in serious consequences to a member or members of the workforce (even one case of disease attributable to the BDRP would be considered serious), epidemic (i.e. a spread from person to person) resulting from organisms studied in the BDRP is technically and epidemiologically impossible. Appendices 7 and 9 describe some of the many reasons why major disease outbreaks are not a plausible consequence of the BDRP, even as a result of a laboratory accident. Appendix 9 discusses the most serious credible accidents. Appendix 8 describes the scope and magnitude of defensive biomedical research in perspective as compared to development of offensive biological weapons. Finally, it should be pointed out that while most of the organisms under study can cause human disease (otherwise they would not be considered a potential threat), most of the diseases studied are debilitating rather than deadly.

Controls on Research -- A discussion of the types of controls found to be in place at the primary and secondary sites visited during this study (a part of Appendix 5) indicates that controls on the conduct of research, development and testing are much more numerous and much more rigorous than is perceived by the general public. Section 3.3 and Appendices 1, 11 and 12 also describe some of the many levels of controls placed on the BDRP. Far from being almost unregulated, the program activities and procedures are heavily reviewed at every location where they are conducted.

Repugnance of Biological Warfare -- The U.S. government and the DoD share concerns over the potential consequences of

biological warfare. This is why the U.S. was a lead negotiator in the development of the Biological Warfare Convention, which renounced storage and use of, and even research into biological weapons. It would be extremely desirable to develop some means whereby all nations could be totally assured that biological weapons would never be developed and used. However, such means have not yet been developed, and they may never be developed. Many nations have not signed the BWC, and it is always possible that some signatories could ignore its provisions. Thus, there exists the finite possibility that the U.S. and its Allies may encounter enemy use of biological weapons when and if troops must be deployed. The DoD strongly believes that it is necessary to have some defense against such weapons. Appendix 1 contains the relevant portions of the text of the Biological Warfare Convention.

Overall, many of the concerns expressed during the scoping process (75) cannot be found to be based on the facts available. Strongly-held personal beliefs play an important role in shaping public concerns. Knowledge of the facts alone may not serve to alleviate every concern. To the extent that these concerns remain unresolved, they may be viewed as one specific form of public controversy, which has been discussed as an area of significant concern in sections 1.6.4 and 5.2.1, above, and acknowledged to be an area in which complete agreement may never be attained.

5.2.2.2 Program Benefits

Public Benefit

The infectious organisms and toxins of concern to the BDRP produce, or have produced, illness or death in naturally occurring episodes in one or more places throughout the world. BDRP developed drugs and vaccines thus have had, and can logically be expected to have, significant human and/or animal health and economic impacts, especially in those parts of the world where survival of food animals may mean the difference between life and death. Some recent examples are: BDRP developed VEE vaccine used in Central America, Mexico, and Texas (19691971) and Rift Valley Fever vaccine in Egypt and Central African Republic. In the epidemic of Venezuelan equine encephalomyelitis in the southern U.S. and Central America, the original outbreak of Legionnaires' disease in Philadelphia, and the outbreaks of Ebola fever, Lassa fever and Rift Valley fever in Africa, BDRP scientists led or were members of the specialized teams who pooled expertise in infectious diseases and coordinated the successful efforts that resulted in rapid and reliable diagnoses and, in some cases, countermeasures. In many of these outbreaks of enzootic disease, vaccines and/or hyperimmune plasma and/or antiviral drugs developed by the BDRP were used. BDRP-funded ribavirin (Virazole.) field trials are currently underway for treatment of naturally occurring hemorrhagic fever with renal

syndrome (in the Republic of Korea and the People's Republic of China) and for Argentine hemorrhagic fever (in Argentina).

5.2.2.3 Human Health

General Population

The belief that there is a clear health hazard to the general population in the vicinity of locations performing BDRP research is not uncommon in some groups. The problem area here is seen to be one of perception versus reality. No incident may be found of an infection of a person not working in the research laboratory or other "at-risk" position in the 45-year history of US Army offensive and defensive RDT&E work (Appendix 8). The reasonableness of any contention that a civilian sector epidemic could easily result from an accident involving small laboratory quantities is examined in some detail in Appendix 9. For a variety of reasons, there is virtually no likelihood that large numbers of people would be likely to acquire any disease, nor is a person-to-person (communicable disease) spread likely. An examination of available data on BDRP-associated illness, infections, and accidents (see Appendix 8) conducted for purposes of this EIS verified a total lack of credible hazard to the general public. The degree to which persons cannot be reassured of their personal safety represents an unresolved difference of opinion, which is examined is sections 5.2.1.3 and 5.2.2.1, above.

5.3 PRIMARY SITES

The primary sites of program execution are all located on active Army installations. They were identified (section 3.4) as those locations with either many ongoing efforts or with some responsibility for program planning and management or both. Examination of any site-specific topic at this programmatic level is restricted to relevant areas of environmental concern.

Further, certain areas of concern initially identified in this examination of the primary sites duplicated topics which have been examined above (section 5.2.1) as being correctly relevant only to the national environment. A more careful evaluation determined that these topics were a characteristic of the national environment, and were not actually generated by the site-specific actions. The site merely serves to focus some of the attention and concern created by the nationwide concerns and discussion. These topics were discussed in section 5.2.1 are identified here, and will not be individually examined again:

Program Management

Public Opinion: Controversial Issues

Program Benefits: National Defense Posture

Scientific Benefit
Public Benefit

5.3.1 USAMRIID

The U.S. Army Medical Research and Development Command's U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) is physically located in Buildings 1425 and 1412 on Fort Detrick, adjacent to the city of Frederick in Frederick County, MD. Their mission under the BDRP is that of research and development of medical defenses against biological weapons.

Examination of the environment in this section is limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. Areas of the environment not believed to have any possibility of being significantly affected are not discussed. See Appendix 5 for a more complete description of USAMRIID and its environment, including research-related health and safety provisions. See Appendix 6 for a complete examination of all relevant areas of potential concern.

5.3.1.1 Relevant Areas of Significant Concern

No unique areas.

5.3.1.2 Relevant Areas of Minor Concern

5.3.1.2.1 Surface Water

The water supply at Fort Detrick is good in terms of both quantity and quality. The current Fort Detrick Environmental Assessment (73) describes in detail the effect of daily post activities on the local water quality. Wastewater discharged from USAMRIID includes both laboratory and general wastewater discharges. Laboratory wastes are treated twice. They are first decontaminated before disposal in the laboratory and are then directed into a special collection and treatment system (see par 5.3.1.2.9 - Waste Stream Management) where they are sterilized prior to discharge to the installation sanitary sewer system. General wastewater discharge includes non-contaminated laboratory wastewater and sanitary sewer discharges. General wastewater, about 33% of the total wastewater from USAMRIID, is discharged directly into the Ft. Detrick sanitary sewer system for treatment in the installation wastewater treatment plant (73). See section 5.3.1.2.9, Waste Stream Management, for more details of wastewater treatment.

5.3.1.2.2 Biological Air Quality

The air quality at Fort Detrick is good, as is that of

Frederick County in general. The prevailing rural character of the area, and the lack of emissions from heavy industrial activities, are the principal reasons for the current air quality. The current Fort Detrick Environmental Assessment describes in detail the effect of daily post activities on local air quality (73).

Because of the use of research quantities of high hazard toxins and biological organisms in this facility, special filters and air handling capabilities are incorporated into the laboratory complex to ensure complete containment of and safe operations with these materials. The exhaust air from the high hazard containment laboratories is filtered through multiple high efficiency particulate air (HEPA) filters which remove minute particles from the laboratory air before it passes through the laboratory exhaust stacks. Filter chambers are designed for in situ decontamination prior to routine maintenance and replacement of the filters. This environmental control by HEPA filtration is described in detail in the CDC-NIH guidelines (5) and in Appendix 12.

Air emission limits for volatile organic, hazardous, and toxic compounds meet both Fort Detrick and Maryland state standards. The maximum spread of hazardous materials during an accident is calculated to remain within the walls of the USAMRIID buildings due to the state-of-the-art containment systems, biological safety cabinets, HEPA air filters, and the limited research quantities of hazardous materials on site (see Appendices 8 and 9. High hazard materials are handled at biosafety levels that meet or exceed all Federal and state guidelines.

Vehicular Emissions -- A potential source of adverse air emissions into the environment is the vehicular traffic associated with the research complex. USAMRIID is the destination of approximately 500 light-duty vehicles on any given work day. These vehicles are a minor component (10%) of the current Ft. Detrick traffic flow of approximately 5400 vehicles per day and even lesser component (0.6%) of the traffic flow in the immediate vicinity of Fort Detrick. Their effects on local and regional air quality are insignificant.

5.3.1.2.3 Economic Environment

Labor Force -- BDRP funding supports the full and part-time employment of 570 persons at USAMRIID, 277 civil service personnel and 293 military personnel. They represent approximately 14% of all persons assigned to or employed on Ft. Detrick. A large majority of these employees make their home in Frederick County, and most of those live in or near the city of Frederick. At any one time, approximately 40 additional persons work or study at USAMRIID under other sponsorship and funding, and their economic contributions are not calculated here.

Utilizing employment, income, and sales multipliers calculated for Frederick County, Maryland, by the Economic Impact Forecast System (EIFS) (74), the economic effect of the operation of USAMRIID is locally significant. The combined impact on the total of direct and indirect local sales volume is in excess of 39 million dollars, representing about 2.8% of the county total. Including both direct and secondary effects, USAMRIID employment represents about 2.3% of the Frederick County total of employed persons, and about 3.5% of the county's total payroll. This reflects the relatively high percentage of professional personnel, both military and civilian, employed by USAMRIID and their corresponding salaries.

5.3.1.2.4 Human Health

Workforce -- The basic research laboratory (biosafety levels 1 and 2) provides general space for work with viable organisms that are not associated with diseases in healthy adults or are organisms ubiquitous in the environment, and with compounds not requiring high-hazard containment. This type of laboratory is also appropriate for work with infectious organisms or potentially infectious organisms when the hazard levels are low and the research personnel are protected by standard laboratory procedures and by immunization if available. Most operations are carried out on the open bench with certain procedures confined to chemical fume hoods or biological safety cabinets.

Safety -- Worker safety is an essential and integral part of all research activities involving rDNA molecules, toxins, and highly hazardous infectious organisms. USAMRIID has developed a formal institutional safety program and extramural research safety requirements that adhere to both the specifics and the intent of federal, state, and local regulations governing all aspects of industrial, commercial, and investigational safety. This includes safety provisions of the NIH Guidelines, OSHA, the National Fire Protection Code, Fort Detrick regulations, Army Regulations, USAMRDC and USAMRIID regulations, and standard operating procedures.

Before undertaking a research project that involves the use of radioisotopes, recombinant DNA or the use of animals or volunteer human subject, USAMRIID investigators prepare a protocol which describes the manner in which the project will be carried out. Provisions for personnel and environmental safety, as well as compliance with laws and regulations, must be considered. Appropriate committees and authorized individuals review and approve the protocol before it is executed. Activities that generate recurring requirements may cite or refer to any of several standard references or previously prepared SOP's which have been prepared by or approved by the safety office. Activities covered by the provisions of the FDA Good Laboratory Practices Regulations (21 CFR 58) require preparation of a Standard Operating Procedure for each recurring activity to ensure reliability, reproducibility, and quality control.

5.3.1.2.5 Procedures

Physical Containment -- The safety record at Fort Detrick, since the advent of modern hazardous organism containment systems, has been excellent (see Appendix 8). So complete are the safety designs here that they served as the basis for the physical containment guidelines for rDNA research in the "Laboratory Safety Monograph" (34) published by the NIH in 1978. Construction of the USAMRIID BL-3 and BL-4 containment laboratories is in accordance with the provisions of that publication as well as the more recent joint publication from the CDC and NIH, "Biosafety in Microbiological and Biomedical Laboratories" (5), which describes combinations of standard and specialized facilities recommended for work with a variety of infectious organisms.

Thus, the environment is protected from any adverse impacts by three lines of defense. The first line of defense is the employment of a well-trained, safety-conscious research and support staff following all accepted laboratory practices; safe handling procedures for toxins and hazardous biological organisms; and aseptic microbiological techniques. The second line of defense is the availability and use of modern primary barriers for the chemical and physical containment of both routine laboratory procedures and potential laboratory accidents (e.g., biological safety cabinets, supply and exhaust air filtering systems, decontamination and sterilization systems, high-hazard containment suites) (see Appendices 11 and 12). The third line of defense is the use, in r DNA work, of the biological containment provided by enfeebled strains of host organisms and conjugation-crippled vector systems for the propagation of rDNA. These measures significantly reduce the probability that any escaped organisms will survive in the environment, infect a host, or transmit genetic information to other organisms (See Appendix 10).

5.3.1.2.6 Laboratory Animal Care and Use

The USAMRIID Laboratory Animal Care and Use Committee, which has representatives from all research divisions, reviews animal use proposals and oversees all animal usage and care. Maintenance and health care of laboratory animals is the responsibility of the Animal Resources Division, which has a trained staff of 35 to 40 persons. This division is headed by a veterinarian who is board certified in laboratory animal medicine, and has five to six other graduate veterinarians and 12 to 15 veterinary technicians at any one time. A veterinarian from the Animal Resources Division is assigned to each research division to assist in the preparation of animal use protocols for each project. All animals are held, and used in research, in strict accordance with the requirements of the "Guide for the Care and Use of Laboratory Animals" (NIH Pub 85-23) and the Animal Welfare Act (7 USC 2131-2156 and 9 CFR 1-4), and other applicable federal, state and Army regulations (AR 70-18). The USAMRIID

animal care facilities have been accredited by the American Association for Accreditation of Laboratory Animal Care since 1971, and have received six on-site visits by an accreditation team, the most recent in 1986. The remains of test animals are autoclaved prior to being incinerated, as are infectious animal wastes and bedding. Remains of test animals used in research requiring BL-4 containment are autoclaved twice before incineration.

5.3.1.2.7 Prototype Development

USAMRIID develops prototype vaccines, prophylactic and therapeutic drugs, and diagnostic reagents designed to support medical defense against biological organisms and toxins. The program involves basic research in bacteriology, rickettsiology, virology, and toxicology. This research supports the evaluation of both protective epitopes for vaccine design and unique organism characteristics for rapid diagnosis. Basic research in macromolecular structure and function supports the drug development program. The antiviral drug development program investigates and develops broad-spectrum, anti-viral drugs to augment the viral vaccine development program. These drugs, vaccines, and other protective and diagnostic items are the end products of the USAMRIID portions of the BDRP. After successful testing, they will be turned over to other organizations or contractors for production and/or further development.

5.3.1.2.8 Testing

This activity in the BDRP is viewed to be a relevant area of concern because its impacts are directly reflected in the area of scientific benefit which was discussed previously (See section 5.2.1.4). USAMRIID must test the prototype products (vaccines, drugs, diagnostic kits) for safety and efficacy in accordance with FDA requirements prior to transferring the medical technology to contractors for larger-scale manufacture of the medical products. Pre-clinical studies performed with animals are accomplished in the research divisions or by contract. The Medical Division of USAMRIID accomplishes clinical testing through its clinical laboratory and the medical research volunteer program (MRV). Tests with human volunteers are carefully regulated by the USAMRIID Human Use Review Committee and the U.S. Army Surgeon General's Human Subjects Review Board, in accordance with the regulations in 45 CFR 46 and AR 70-25. These clinical protocols are limited to determination of the safety of the vaccine or drug, and the measurement of antibody production and other forms of immunity or protection. No tests of protective devices or equipment take place at USAMRIID, nor have any outdoor tests for any purpose ever been a part of the program conducted at USAMRIID.

5.3.1.2.9 Waste Stream Management

Solid Waste -- The current Fort Detrick Environmental Assessment (73) details solid waste disposal practices. Approximately 525 cubic yards of non-hazardous solid waste is generated by USAMRIID per month, 8 percent of the Fort Detrick total generations. It is picked up by the Fort Detrick Directorate of Engineering and Housing (DEH) Disposal is primarily through incineration, and is regulated by established Fort Detrick, Maryland, and Federal standards (73) Non-burnable solid waste is disposed of in a landfill. The landfill is operated under a letter of permit from the State of Maryland, and is subject to regular and unannounced monitoring for potential groundwater contamination. No sampling has detected any material in excess of established standards.

Incinerators are operated within legal limits for stationary emission sources as detailed in Federal, state, and local regulations, and conform to the requirements and intent of the Clean Air Act of 1963 [42 USC 7401-7642] and its amendments in 1970 [Public Law (PL) No. 91-604, 84 Stat 1676] and in 1977 [PL No. 95-95, 91 Stat 685]. The function of the incinerators is as a mode of volume reduction rather than for the purpose of decontaminating any wastes. They are computer-controlled with interlocks to prevent loading of waste before the correct temperatures (at least 1700 to 1800 degrees F) are reached. Secondary combustion is provided to assure that any partially consumed products of the first stage are further reduced to water and carbon dioxide. The incinerators are also equipped with scrubbers to remove sulfur and nitrogen compounds and particulate matter. Scrubber residue and ash are disposed of in a landfill. Scrubber and ashpit washwater is routed to the laboratory special treatment sewer system.

The USAMRIID research facilities have been designed to ensure safe and secure storage, handling, use, and disposal of hazardous materials. The disposal of any hazardous wastes meet applicable Federal, state, local, and Fort Detrick regulations. USAMRIID contributes minimally to installation hazardous waste generations (estimated 335 pounds during Calendar year 1987), accounting for about 8% of the demand on the Fort Detrick hazardous waste program. All collection and ultimate disposal of hazardous wastes is by civilian contractors licensed by the state for that purpose, and no disposal of hazardous wastes takes place on the installation itself. Internal hazardous waste management precautions are specified in Fort Detrick regulations, and these meet all environmental provisions necessary for safe and lawful operation of the facility, and for the disposal of hazardous waste that is generated. USAMRIID is a conditionally exempt small quantity generator under 40CFR 261.5(9) and is in full compliance with the Resource Conservation and Recovery Act, its implementing regulations, and other applicable state and local requirements.

Liquid Waste -- The primary level of laboratory wastewater management at USAMRIID is the in situ decontamination and chemical neutralization of research wastes at the laboratory bench. Before research projects with any toxin or hazardous biological organism are started, small quantities are tested to determine the most efficacious method of decontamination. Safe handling and waste treatment procedures are then written for each toxin or hazardous organism. At the end of each experiment, any residual toxin or organism is treated, following these established procedures, to detoxify the residues. The most common chemical used for treatment is sodium hypochlorite (chlorine bleach). Such pre-treated wastewater is then neutralized to approximately pH 7.0 and discharged into the isolated laboratory wastewater system.

All liquid effluents from the laboratory sinks, biological safety cabinets, floors, autoclave chambers, shower rooms, and toilets within biological containment areas discharge into the specially designed Fort Detrick isolated laboratory sewer system. This sewer system is a series of 8-, 10-, and 12-inch cast iron mains encased in concrete through which the potentially contaminated wastewater flows to one of several 50,000 gallon holding tanks at the Decontamination Facility. Collected wastewater is periodically pumped to a heat exchanger system, which utilizes steam injectors to raise the temperature of the wastewater to approximately 270 degrees F for 20 minutes. Automatic controls prevent the discharge of any batch of wastewater which has not reached the required temperature for the proper time. Sterilized and cooled wastewater is discharged into the sanitary sewer system, and passes into the normal wastewater treatment system, where standard treatment for biological and chemical demand is carried out. USAMRIID discharges into this system are about 2 million gallons per month, or about 26% of the Ft. Detrick flow.

The USAMRIID sanitary sewer system consists of a network of gravity-flow, 8-inch concrete piping discharging into the Fort Detrick sanitary sewer system (73). In a typical month, USAMRIID generates about 1 million gallons of non-laboratory domestic wastewater, about 4.5% of the Ft. Detrick total flow. These discharges into the Fort Detrick sewer systems do not affect the capability of the sewage treatment plant to continue providing an effluent water quality which meets state water quality standards and is significantly better than the ambient water in the Monocacy River, into which it is discharged.

5.3.2 CRDEC

The U. S. Army Chemical Research, Development and Engineering Center (CRDEC) is located in the Edgewood Area of Aberdeen Proving Ground, in Harford County near Edgewood, MD, about 25 miles northeast of downtown Baltimore. It is the largest of several Army tenants of this portion of the installation, and occupies laboratory, office, and storage space

in over 200 buildings. Their mission under the BDRP is one of developing detection and protection equipment for use by troops on the battlefield.

Examination of the environment in this section is limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. See Appendix 6 for a complete examination of all relevant areas of potential concern. Areas of the environment not believed to have any possibility of being significantly affected are not discussed. See Appendix 5 for a more complete description of CRDEC and its BDRP research-related health and safety provisions.

5.3.2.1 Relevant Areas of Significant Concern

No unique areas

5.3.2.2. Relevant Areas of Minor Concern

5.3.2.2.1 Economic Environment

Labor Force -- There are 19 persons employed full or part- at CRDEC under the funding of the BDRP, including 18 civil service and 1 military personnel. In total, they represent approximately 1.3% of the approximately 1400 CRDEC employees, about 0.1% of the almost 18,000 Aberdeen Proving Ground employees, and, according to the Economic Impact Forecast System (74), their income generates somewhat less than 0.075% of the personal income of Harford County.

5.3.2.2.2 Testing

No outdoor tests conducted at the CRDEC facilities on Aberdeen Proving Ground involve biological materials. Limited indoor tests involving small quantities of toxins and biological simulants, such as non-pathogenic bacteria and pre-killed viruses, are performed. Laboratory-scale testing of technology for detector and warning devices requires use of extremely small amounts of certain toxins. All indoor testing uses minimal quantities of the materials, and takes place in biological safety cabinets equipped with high efficiency particulate filters. The filters are decontaminated with paraformaldehyde prior to disposal. No cumulative effects are known for any of the BDRP- testing carried out at CRDEC, and no interreaction is known to exist between biological and chemical testing.

5.3.2.2.3 Prototype Development

Prototype devices under development at CRDEC that fall within the scope of the BDRP are detection and monitoring systems intended to provide early warning of possible enemy use of a biological weapon in a combat situation. Protective masks, designed primarily for protection against chemical agents, are also tested to determine their suitability for protection against

biological agents. No infectious organisms or toxins are used by CRDEC for this purpose, but non-hazardous bacteria and bacterial simulants and small quantities of commercially-purchased or government-supplied toxins are used in the research and development process.

5.3.2.2.4 Procedures

The CRDEC has developed extensive protocols for personal and environmental safety in the handling of chemical weapons materiel, and their laboratory and test personnel may be considered well experienced in managing safety procedures. SOPs have also been developed for laboratory bench and hood work with microbiological organisms, and for storage and handling of biological toxins. These SOPs undergo periodic review and revision.

5.3.3 DPG

The Baker Laboratory Complex, which houses the Life Science Division of the Materiel Test Directorate, is located on the Dugway Proving Ground (DPG), in Tooele County, and is about 70 miles southwest of Salt Lake City, UT. This Directorate is the organization that carries out tests of detectors and equipment as part of the BDRP. The installation includes more than 800,000 acres in Tooele County, of which about 800 developed acres are devoted to Army uses such as housing and testing facilities. The remainder of the land area is used for a variety of tests and for military training unrelated to the BDRP.

Examination of the environment in this section is limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. See Appendix 6 for a more complete examination of all relevant areas of potential concern. Areas of the environment not believed to have any possibility of being significantly affected are not discussed. See Appendix 5 for a more complete description of Dugway Proving Ground and its BDRP-related health and safety provisions.

In February 1988, DPG filed a Draft EIS covering a proposal to construct a small test facility which would have the capability to test detectors and protective devices against hazardous infectious organisms and toxins presented in the form of aerosols. The studies carried out in this chamber, if it is constructed, will be test activities within the BDRP. The Biological Aerosol Test Facility DEIS is an excellent source of additional information about the DPG environment and the nature of their testing activity.

5.3.3.1 Relevant Areas of Significant Concern

No unique areas.

5.3.3.2. Relevant Areas of Minor Concern

5.3.3.2.1 Economic Environment

Labor Force - There are approximately 1100 civilians and 325 military personnel employed full or part-time by the Army or by contractors at Dugway Proving Ground. Of these, approximately 26 are supported partly under the funding of the BDRP. This represents about 1.8% of the total Dugway military and civilian personnel, and, including multiplier effects, about 0.1% of the personal income of Tooele and Juab counties (74).

5.3.3.2.2 Facilities Operations and Maintenance

The many actions necessary to operate even a small military installation are here considered as one activity area. Management of installation wastes has been a recent problem which the installation is striving to correct. These are not, however, related to the waste products of BDRP or any other tests. This area of interest is not, then, actually related to the BDRP efforts in any direct manner. All wastes resulting from tests are inactivated at the individual laboratory level before any disposal is made to DPG collection and treatment systems.

5.3.3.2.3 Testing

Testing of chemical materiel and of chemical and biological defense equipment is the primary mission of the Dugway Proving Ground. Field testing of biological detection and defense devices is a small, but important part of this program. Tests which utilize living infectious organisms and toxins are limited to indoor facilities specifically designed for the purpose, and are further confined to gas-tight, isolated safety cabinets inside those laboratories. All outdoor testing which is a part of the BDRP utilizes only non-pathogenic simulants. No field test of any type may be performed until a test-specific environmental evaluation has been performed and documentation prepared. The IAM (see Appendix 6) did not identify cumulative or synergistic effects associated with any biological test procedures.

5.3.3.2.4 Laboratory Animal Care

DPG maintains an animal holding facility for a small number of domestic rabbits, guinea pigs, and white mice to support testing activity. All animals are held, and used in testing, in strict accordance with the requirements of the "Guide for the Care and Use of Laboratory Animals" (NIH Pub 85-23) and the Animal Welfare Act (7 USC 2131-2156 and 9 CFR 1-4), and other applicable federal, state and Army regulations (AR 70-18).

5.3.3.2.5 Procedures

The DPG has an active Installation Biosafety Committee (IBC). Since no recombinant DNA research is performed at DPG,

the focus of the IBC is on general laboratory biosafety. All aspects of the BDRP fall within the charge of this committee. The Life Sciences Division has developed eight SOPs that cover the different health and safety aspects of use and storage of hazardous biological materials.

5.4 REPRESENTATIVE SECONDARY SITES BY POTENTIAL RISK CATEGORY

These secondary sites were selected from among the approximately 100 sites that are a part of the BDRP. All primary and secondary sites are listed in Appendix 3. The selection of representative sites was made utilizing the classification of research according to the potential for risk or generation of controversy, as discussed in sections 2.5 and 3.5.

The official records for each secondary site were reviewed in order to determine the nature of the BDRP work performed at each site as well as to identify any unique concerns that might be associated with that site. During the course of the examination of risk associated with BDRP research at secondary sites (see Section 3.5), it was determined that no credible risk or significant controversy which could be linked to a specific site was associated with the majority of the secondary research sites. Selection of secondary sites to be examined further was thus limited to those where research involved one or more of the higher risk or issue categories. These were determined to be: 1) High Hazard Organisms; 2) Genetically Engineered Microorganisms; and 3) Toxins. The institutions examined below represent approximately 25% of all secondary sites conducting research in one of these areas of interest. Appendix 3 indicates the nature of the research being performed at each of the secondary sites based on the risk/issue categories established in section 3.5.

Several areas of potential environmental concern which have been already discussed in section 5.2.1 were identified through the completion of the Impact Analysis Matrix (Appendix 6) as being associated with one or more of these secondary sites. Further examination, however, determined that these were the localized expression of a nationwide concern rather than being caused directly by the local activity or facility. The following topics were so identified, have been discussed in section 5.2.1, and will not be further examined in this section.

Program Benefits:	National Defense Posture Scientific Benefit Public Benefit
Public Opinion:	Controversial Issues

5.4.1 High Hazard Organisms

(BL-3 and BL-4 Containment Levels)

Please refer to section 3.5.1, above, and Appendix 4 for a discussion of the meaning of this category of research risk.

5.4.1.1 Southern Research Institute, Birmingham, AL

Contract Title: Research in Drug Development Against Viral Diseases of Military Importance (Biological Testing)

Descriptive Summary:

The Southern Research Institute (SoRI) supports the USAMRIID Antiviral Drug Discovery Program by performing extensive experimental testing of candidate drugs for activity against a number of viruses of interest to the BDRP Standardized assays of viral activity in cultured cells or in animals are used to test approximately 1000 compounds per year. The viruses against which drugs are tested include adenovirus, vesicular stomatitis, vaccinia, Venezuelan equine encephalomyelitis, Pichinde, Punta Toro, Hantaan Japanese encephalitis B and yellow fever.

Environmental Setting:

BDRP-related work is conducted in urban, single-use buildings devoted entirely to biomedical research. Two separate buildings are involved, one containing general laboratory and office space, where BL-2 laboratory facilities are maintained, and one containing the BL-3 laboratories. The building with the BL-3 laboratories is located on the campus of the University of Alabama at Birmingham (UAB). It was constructed in 1980-82, specifically for biomedical research on recombinant DNA materials, and was further modified in 1986-1987 to be used for the work with infectious viruses. The building has no classroom or general office space, and no areas are open to the public.

Examination of the environment in this section is limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. Areas of the environment not believed to have any possibility of being significantly affected are not discussed. See Appendix 5 for a more complete description of the Southern Research Institute and its BDRP-related health and safety provisions.

5.4.1.1.1 Relevant Areas of Significant Concern

None

5.4.1.1.2 Relevant Areas of Minor Concern

Surface Water Quality:

The SoRI buildings are connected to the Birmingham municipal sewer system. No living materials of any type are disposed of in the sanitary sewer system.

Provisions for pre-treatment of BDRP-related wastes prior to discharge into the sanitary sewer include inactivation with strongly alkaline solutions and/or autoclaving to kill living organisms. No potentially infectious material is disposed of without such treatment.

Biological Air Quality:

Biological safety cabinets are used for all potentially hazardous operations. They are certified by personnel from the UAB Department of Occupational Safety and Health when initially installed, when moved, and every six months while in use.

Air from containment areas is double HEPA-filtered before being released to the external environment. Potentially hazardous areas are kept at a negative pressure differential in relation to surrounding rooms. Air from animal holding areas is HEPA filtered prior to exhaust. Air from general laboratory areas (where BL-2 practices apply) is not specifically treated. Used filters are decontaminated with paraformaldehyde prior to removal, and are then bagged and autoclaved prior to disposal.

5.4.1.2 The Salk Institute, Government Services Division, Swiftwater, PA

Contract Title: Development of Special Biological Products

Descriptive Summary:

This facility provides support to the medical portion of the BDRP in the form of pilot production of investigational vaccines, diagnostic materials, and antibodies. The organisms used at this facility vary over time, but include the vaccine and, in some cases, native strains, of the following: chikungunya, western equine encephalitis, eastern equine encephalitis, Venezuelan equine encephalomyelitis, Rift Valley fever, and Junin viruses; *Coxiella burnetii* (Q fever) rickettsia, and *Francisella tularensis (* tularemia) bacteria.

Environmental Setting:

The setting in which this work is being carried out is a rural, single-use building, with associated support buildings originally constructed for this purpose. The Institute occupies approximately nine acres in Pocono Township, Monroe County, PA near the town of Swiftwater. It is, in turn, one of a group of

biomedical research and production facilities on a 50+ acre complex devoted to this purpose. The other facilities in the complex are operated by Connaught Laboratories, Inc., which also provides some support services to the Salk laboratory.

Examination of the environment in this section is limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. Areas of the environment not believed to have any possibility of being significantly affected are not discussed. See Appendix 5 for a more complete description of the Salk Institute, Government Services Division, and its BDRP research-related health and safety provisions.

5.4.1.2.1 Relevant Areas of Significant Concern

No unique concerns.

5.4.1.2.2 Relevant Areas of Minor Concern

Surface Water Quality -- The institute's wastewater treatment is performed under contract by the Connaught Laboratories wastewater treatment plant. That plant utilizes tertiary treatment technology and has a current NPDES permit from the State of Pennsylvania. The permit requires periodic measurement of 12 characteristics of the wastewater stream. After treatment, no specific contribution of the Salk (TSI-GSD) waste stream may be separately identified, but all parameters of the waste flow meet state and federal requirements.

BDRP-related infectious liquid waste which may enter the laboratory drains is inactivated by heat treatment prior to discharge. Laboratory wastes are collected in a separate sewer system connected only to the containment areas. Liquid wastes in this system are directed to one of two 5000 gallon tanks which, when full, is heated to 220 degrees F for six hours. The heat treated waste is then discharged into the Connaught treatment plant lines for removal of remaining biological and chemical materials.

Biological Air Quality -- Vertical laminar flow biological safety cabinets are required for use in all procedures involving handling of infectious materials and tissue cultures. Their operation is certified annually, or after they are moved, by Salk personnel who have been specifically trained in this procedure. Filters are decontaminated with paraformaldehyde prior to disposal.

Procedures that require the handling of larger quantities of infectious organisms are carried out in containment suites that meet BL-3 standards in accordance with the NIH-CDC guidelines (30). The air supply to these BL-3 containment areas is HEPA filtered before being drawn in, and the exhaust air is HEPA filtered before being released to the external environment. Air

moves through in a "single pass" without being recirculated for any other purpose. Other potentially infectious waste material, e.g., contaminated glassware, is autoclaved before removal from containment areas.

Ambient Air Quality -- A pathological waste incinerator operated under a state permit is used for the disposal of test animals, their wastes, and bedding. Animal remains and wastes are autoclaved prior to the incineration.

Labor Force -- The Government Services Division of the Salk Institute employs approximately 57 persons full- or part-time under their contract with the BDRP Including both direct and indirect effects as calculated by the EIFS model, this activity generates approximately 0.28% of the employment available in Monroe County, and the payroll generates, directly and indirectly, approximately 0.23% of the county business volume.

Human Health (Workforce) -- Management of general laboratory safety hazards is the responsibility of a safety committee, which is headed by a professional employee with an advanced degree. The committee, itself, has representation from every operating department, and has prepared and distributed a 40 page general safety manual. This manual specifically addresses potential problems associated with the operation of a vaccine production facility, and much of the content is directed to biological safety issues.

In compliance with the FDA Current Good Manufacturing Practices Regulations (21 CFR 58), the institute has prepared over 250 SOPs which cover every recurring activity in the operation of the laboratory. Of these, 20 deal specifically with minimization of any potential for environmental effects from operation of sterilizers, disposal of wastes, and shipment of vaccines and cultures. Standard Operating Procedures (SOPs) established for employee health and safety require that personnel **who** may come in contact with an organism, either in the form of a vaccine or in its virulent form, must be immunized against that disease in all cases where an immunization is available.

There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations either in general or as they may relate to materials used in the performance of the Biological Defense Research Program.

5.4.2 Genetically Engineered Microorganisms (GEMs)

Please refer to section 3.5.2 and Appendix 4 for a discussion of the meaning of this category of research risk/issue.

5.4.2.1 Scripps Clinic and Research Foundation, LaJolla, CA

Contract Title: Synthetic Vaccines for the Control of Arenavirus Infections

Descriptive Summary:

Lymphocytic choriomeningitis virus (LCM), a mouse arenavirus, is used as a model for developing the approaches for identification of the critical viral glycoproteins that would serve as good immunizing agents to protect against arenavirus infections. The laboratory work performed in this project includes the use of cultured cells, biochemical techniques, cloning, and immunization of mice and rabbits.

Environmental Setting:

The setting in which this work is being carried out is a suburban, single-use building having appropriate construction and use permits for the types of research performed. It is located among a series of research facilities extending for several thousand feet along the California coast in the northwestern part of La Jolla, an area specifically designated for institutions devoted to biomedical research. The Salk Institute is in the same area, within one-half mile of the Scripps location.

There were no relevant areas of environmental concern (see Appendix 6) that had the potential to become significant. See Appendix 5 for a more complete description of the Scripps Clinic and Research Foundation, and its BDRP research-related health and safety provisions.

5.4.2.2 Salk Institute, La Jolla, CA

Contract Title: Human Hybridomas for Exotic Antigens

Descriptive Summary

The objective of this work is to develop *in vitro* methods to generate human monoclonal antibodies to selected antigens (toxins or viral proteins). White blood cells are isolated from fresh blood samples and fused with "immortal" cultured cells. The resulting hybrids are tested for production of antibody to specific toxins. The research use of hybridomas is an example of advanced biotechnology rather than of genetic engineering, per se, but has been included under that heading solely for convenience in this EIS.

Environmental Setting:

The setting in which this work is being carried out is a suburban, single-use building having appropriate construction and use permits for the types of research performed. It is located

among a series of research facilities extending for several thousand feet along the California coast in the northwestern part of LaJolla, an area specifically designated for institutions devoted to biomedical research. The Scripps Clinic and Research Foundation is within one-half mile of the Salk Institute.

There were no relevant areas of environmental concern (see Appendix 6) that had the potential to become significant. See Appendix 5 for a more complete description of the Salk Institute, and its BDRP research-related health and safety provisions.

5.4.2.3 University of Massachusetts, Amherst, MA

Contract Title: Genetic and Physiological Studies of *Bacillus anthracis* Related to Development of an Improved Vaccine

Descriptive Summary:

The objective of this research is to develop an improved vaccine for protection from *Bacillus anthracis* (anthrax). The techniques used in these studies are those of classical microbial genetics, and involve bacterial mating, plasmid exchange, and spontaneous genetic recombination. The strains of *B. anthracis* used in these studies are attenuated and non-virulent because they each lack at least one critical genetic determinant of virulence or toxicity.

Environmental Setting:

The setting in which this work is being conducted is an urban, multiple-use building, containing offices, laboratories and classrooms. The Morrill Science Building houses the Microbiology Department and four other departments. The university has about 30,000 students, and the town of Amherst has a permanent population of approximately 25,000.

There were no relevant areas of environmental concern (see Appendix 6) that had the potential to become significant. See Appendix 5 for a more complete description of the University of Massachusetts, and its BDRP research-related health and safety provisions.

5.4.2.4 Wadsworth Center for Laboratories and Research, NY State Department of Public Health, Albany, NY

Contract Title: Genetically Engineered Poxviruses and the Construction of Live Recombinant Vaccines

Descriptive Summary:

The objective of this work is to develop the methods and approaches for using the vaccinia virus (smallpox vaccine virus) as a carrier of specific genetic information from other viruses, so that the recombinant vaccinia virus could be used as a

"multiple" vaccine that would provide protection against two or more viruses in a single immunization.

Environmental Setting:

The setting in which this work is being carried out is an urban, mixed-use building, containing laboratories and offices. The Corning Tower complex is located in downtown Albany. It is a 42-story building housing 20,000 employees. The New York State Department of Public Health occupies 14 floors. The Wadsworth Center for Laboratories and Research occupies three floors and is the largest state public health laboratory in the U.S. Approximately 600 persons work in the laboratories, 2,000 in Health Department administrative offices, and 17,000 to 18,000 are employed in other government offices in this and other buildings.

There were no relevant areas of environmental concern (see Appendix 6) that had the potential to become significant. See Appendix 5 for a more complete description of the Wadsworth Center for Laboratories and Research, and its BDRP research related health and safety provisions.

5.4.3 Toxin Research

Please refer to section 3.5.3, above, and Appendix 4 for a discussion the meaning of this category of research risk.

5.4.3.1 Jefferson Medical College, Philadelphia, PA

Contract Title: A Core Facility for the Study of Neurotoxins of Biological Origin

Descriptive Summary:

This contract supports several individual projects all dealing primarily with protein neurotoxins, such as botulinum toxin and snake venom toxins, as well as toxins that affect nerve ion channels. Small animals (rats, mice) and cultured cell lines are used throughout these studies. The overall goals of this project are to define the mechanisms of action of several of the potent neurotoxins and to develop approaches for the prevention and/or therapy of intoxications with these materials.

Environmental Setting:

Jefferson Medical College is a unit of Thomas Jefferson University, a major educational institution located in the urban center city of Philadelphia, PA. The campus occupies 13 buildings and covers over four city blocks. Approximately 10,000 full and part-time faculty, staff, and students are present on campus in any one working week, with fewer than half present at any one time. The buildings in which the research is performed were designed, issued building permits, built for, and are

devoted to, teaching and research related to medicine, drugs, and disease.

Examination of the environment in this section is limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. Areas of the environment not believed to have any possibility of being significantly affected are not discussed. See Appendix 5 for a more complete description of the Jefferson Medical College, and its BDRP research-related health and safety provisions.

5.4.3.1.1 Relevant Areas of Significant Concern

None

5.4.3.1.2 Relevant Areas of Minor Concern

Human Health (Workforce)

The university has a Safety Committee which is separate from the Institutional Biosafety Committee required under NIH guidelines. The safety committee is subdivided into groups specifically charged with considerations of Radiological Health and Safety, General Laboratory Safety, and Animal Care and Use.

Management of general laboratory safety hazards is the responsibility of a general laboratory safety committee. They have prepared guidelines and requirements which cover all university-wide activities and common practices. Each unit of the University prepares more-specific safety guidance which is appropriate to that division, and each individual department and major subdivision supplements this guidance with laboratory- and project-specific protocols.

To protect against illness which might result from a laboratory accident involving the most potent toxin studied, botulinum toxin, all laboratory personnel are immunized with pentavalent botulinum toxoid. Further, limits are placed on procedures that require toxin solutions to be used in syringes, minimizing opportunities for inadvertent self-injection. There has never been such an accident in this laboratory.

5.4.3.2 SRI International, Menlo Park, CA

Contract Titles: 1) Active Antitoxic Immunization Against Ricin Using Synthetic Peptides; 2) Synthesis and Testing of Tetrodotoxin and Batrachotoxin Antagonists; 3) Research in Drug Development for Therapeutic Treatment of Neurotoxin Poisoning: Studies on Conotoxins

Descriptive Summary:

The common objective of the toxin research projects supported at SRI International is to develop compounds for the

prevention and/or therapy of certain intoxication. Researchers are attempting to synthesize fragments and analogs of two types of toxins that would be useful for immunization against the corresponding toxin or treatment of toxin exposures. The procedures used include organic syntheses, peptide synthesis, in vitro assays of animal neuronal tissues, and immunization and toxin challenge of mice.

Environmental Setting:

The setting in which this work is carried out is an urban, single-use building, containing research laboratories and associated offices. The SRI campus consists of 76 acres in the city of Menlo Park, is surrounded by residential, commercial and municipal development. Approximately 2600 persons are employed at the Menlo Park offices, and they occupy over 1,300,000 square feet of office and laboratory space.

There were no relevant areas of environmental concern (see Appendix 6) that had the potential to become significant. See Appendix 5 for a more complete description of SRI International, and its BDRP research-related health and safety provisions.

5.4.3.3 Wright State University, Dayton, OH

Contract Title: Freshwater Cyanobacteria (Blue-Green Algae) Toxins: Isolation and Purification

Descriptive Summary:

The objectives of this study are to develop methods to grow several different blue-green algae in the laboratory, to isolate and chemically characterize the various toxins, to study and understand their mechanisms of action and toxicity, and to develop methods for toxin detection. The toxins studied under BDRP support are microcystin, a liver toxin, and anatoxin, a neurotoxin.

Environmental Setting:

The setting in which this work is being carried out is a building on a suburban, planned-development, university campus. The Life Sciences building is a multiple-use building containing laboratories, offices, and classrooms. All extraction and purification of algal culture materials takes place in research laboratories in this building. In addition, algal culture and growth takes place in laboratory space in a dedicated research building operated by Antioch College in Yellow Springs, OH, approximately 10 miles from the main campus. Growth of 15 liter algal cell cultures takes place in the Yellow Springs laboratory, and unpurified cells are concentrated and dried there.

There were no relevant areas of environmental concern (see Appendix 6) that had the potential to become significant. See

Appendix 5 for a more complete description of Wright State University and its BDRP research-related health and safety provisions.

6. ENVIRONMENTAL AND SOCIOECONOMIC CONSEQUENCES

6.1 INTRODUCTION

The purpose of this section is to present the scientific and analytical basis for comparing the alternatives identified in section 4. Evaluation of reasonable alternatives for the BDRP, as discussed in section 4, revealed no unresolved conflicts concerning available resources, and identified no significant effects upon the quality of the human environment sufficient to warrant considering additional mitigation to supplement the elaborate controls and procedures that are already in place.

The BDRP has been an ongoing program for a number of years, and, as such, has been subject to continuous internal and external review processes to ensure that all BDRP activities are conducted in a manner that protects the health and safety of the workforce and the external environment. Throughout this period of operation, the BDRP developed the present-day set of effective procedures, controls (section 3), and guidelines that mitigate impacts on the human environment. This section presents results of the analytical methodology (JAM, Appendix 6) used to identify relevant impacts and issues of the program. The rationale for identification of the alternatives considered to be reasonable, which include the preferred action (continue the BDRP) and the no-action (terminate the BDRP) alternatives, is presented in section 4. Because the BDRP is ongoing, the actual impacts associated with the program are identified in section 5, Affected Environment. The discussion of environmental and socioeconomic consequences addresses these impacts as well as perceived impacts.

The following sub-sections describe the impacts of consequence and the relevant areas of concern resulting from the discrete elements of the BDRP as identified through application of the matrix analysis. Descriptions of the discrete elements of the BDRP, primary sites, secondary sites, and programmatic categories, are presented in section 3. Program management is discussed in section 2.3. Primary sites are defined as DoD facilities having prime BDRP managerial responsibilities (sections 2.4 and 5.3). The secondary sites (sections 2.5. and 5.4 and Appendix 3) are other governmental laboratories and contractor facilities engaged in biological defense research activities. The total BDRP is managed (section 2.3.) from three primary sites: the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD; the U.S. Army Chemical Research, Development and Engineering Center, Edgewood Area, Aberdeen Proving Ground, MD; and U.S. Army Dugway Proving Ground, Dugway, UT.

Nine representative secondary sites were selected for detailed evaluation and analysis because the work performed at these sites involved organisms or toxins belonging to the three highest perceived risk/issue groups: high hazard organisms,

toxins, or genetically engineered microorganisms (GEMs) (sections 3.5, 5.4 and Appendices 4 and 10). Within these three risk/issue groups, the selected sites were considered also to have the greatest potential for generating impacts. Thus, The Salk Institute - Government Services Division (TSI-GSD) at Swiftwater, PA, and Southern Research Institute (SoRI) at Birmingham, AL, conduct work on agents requiring BL-3 containment; Wright State University, Dayton, OH; Jefferson Medical College, Philadelphia, PA; and SRI, International, Menlo Park, CA, conduct BDRP work on toxins. The University of Massachusetts, Amherst, MA; New York State Department of Public Health Research Laboratories, Albany, NY; and Scripps Institute, LaJolla, CA, conduct BDRP studies categorized as genetic engineering. The Salk Institute, LaJolla, CA conducts studies of human hybridoma cells; this biotechnology was grouped with GEMs because many of the issues associated with this type of work are similar to those identified for work with GEMs.

The other secondary sites where BDRP work is performed were evaluated thoroughly, but in less detail. This was deemed appropriate because the in-depth evaluations, including site visits and interviews, served to verify the application of the programmatic tiering (based upon the IAM evaluations by risk/issue category) as a reasonable and reliable approach for impact analysis. The other BDRP secondary sites were evaluated individually on this basis utilizing available information 1) on the work involved, 2) the adequacy of facilities, 3) implementation of control measures, and 4) past performance history. Where appropriate, consultation was used to obtain needed information. The other secondary sites were also examined to determine if there were any unique circumstances that would affect the application of this approach. The results of this analysis confirmed that, in all cases, the potential impacts were either similar to, or of lesser consequence, than those examined at representative sites (See Appendix 3). Consideration was also given to any potential for cumulative or synergistic impacts. None were identified.

6.1.1 PROGRAMMATIC CATEGORIES

A more detailed discussion of these categories is presented in Appendix 4.

High Hazard Organisms: This category includes all program laboratory activities with organisms requiring biosafety levels 3 and 4 containment (See Appendices 11 and 12). Significant areas of concern associated with this activity include surface water, biological air quality, controversial issues, and the health of the workforce. When site-specific activities are considered, safety, regulatory and other controls adequately address the concerns for the biophysical environment and the risks of these organisms to public health and the environment become minor.

Benefits resulting from this category include maintenance of the national defense posture and contributions to scientific knowledge.

Low Hazard Organisms: This category includes simulants and low hazard infectious agents requiring biosafety levels BL-1 and BL-2 containment (See Appendices 11 and 12). Reducing the need to use high hazard organisms through the use of simulants and less pathogenic organisms is considered to be a positive impact upon the health of the workforce. A significant benefit from this category of activity is the contribution to the national defense posture. There are no significant relevant areas of concern associated with this category.

Toxins: Inclusion of toxins in the BDRP may be perceived as a controversial issue. The potential for impacts upon surface water by activities in this category is considered a relevant area of concern, but controlled disposal methods prevent adverse impacts. Activities in this category contribute significantly to the national defense posture and to the scientific community.

Genetically Engineered Microorganisms (GEMs): The inclusion of genetic engineering methodology into the BDRP is critical to developing appropriate defense measures, and therefore makes a significant contribution to the national defense posture and, at the same time, to the scientific community. GEMs are the object of controversy within certain segments of the population, and the potential environmental impacts arising from their use have been addressed comprehensively by the NIH (See Appendix 10).

Rapid Diagnosis and Detection: The rapid diagnosis and detection research, development, and testing efforts are integral to maintaining the national defense posture. There are no relevant areas of concern perceived for this element of the BDRP.

Drug Therapy: The development and testing of potential therapeutic drugs and vaccines provide benefits to the global public health, to the scientific community, and make a significant contribution to the national defense posture as an integral part of the BDRP. There is a minor concern associated with the use of medical research volunteer subjects, but, historically, this is a well-controlled activity and there have been no adverse impacts reported.

Other Program Research and Activities: Activities of this category include those subject areas of the program that do not appropriately fit into other defined categories and do not constitute discrete subject areas warranting separate consideration. These activities are integral to the overall contribution of the BDRP to national defense, but involve insignificant risks or potential for adverse impacts. There are no detrimental relevant areas of concern perceived for this element of the program.

6.1.2. PRIMARY SITES

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID): There are no significant environmental consequences associated with activities at USAMRIID. Controversial issues, national defense posture, and scientific benefit were identified as the three relevant areas of significant concern by the impact Analysis Matrix (See Appendix 6). Since these areas relate to the program-wide issues, they are addressed in section 5.2.1, national environment. Surface water, biological air quality, labor force, public benefit and workforce were identified as relevant areas of minor concern. Due to the high hazard nature of many organisms studied at USAMRIID, potential risk to the surface water is perceived to be high, but is actually low when one examines the stringency of controls that are applied to effluents entering wastewater streams (See 5.2.2.1). The incorporation of special filters and air-handling capabilities into the laboratory complex ensures containment of, and safe operations with, these high hazard agents (See 5.2.2.1). The nature of research conducted at this institute may potentially present a minor concern for the health and safety of the workforce involved. However, personnel are protected by adherence to rigid safety protocols, application of specific laboratory procedures, use of biocontainment laboratories and equipment, and by immunization. Thus, safe conduct of this research in compliance with the standard operating procedures, guidelines, and controls will have no potentially significant consequences.

Effects of the labor force and public benefit were identified as two positive relevant areas of minor concern. The labor force at USAMRIID consists of approximately 570 people. This represents about 14% of all persons employed on Fort Detrick. Since most of the people who work at USAMRIID make their home in or near Frederick County, their employment, representing about 3.5% of the county's total payroll, has a significant positive effect on the local community (See 5.2.2.1). The positive impacts from the research activities performed at USAMRIID and their benefit to the public are discussed as part of the considerations for the national environment in section 5.2.1.

U.S. Army Chemical Research, Development and Engineering Center (CRDEC): The examination of CRDEC's activities under the BDRP revealed no significant environmental consequences. National defense posture was identified as a positive relevant area of significant concern (See Appendix 6), and is discussed as one of the national environment considerations in section 5.2.1. Effects of the labor force were identified as a positive relevant area of minor concern. The employment of 19 persons, many part-time, at CRDEC under BDRP funding represents about 1.3% of the total CRDEC employees, and about 0.075% of the regional personal income (See 5.2.2.2). Thus, the economic impact of the

labor force associated with the BDRP at this facility is very small.

U.S. Army Dugway Proving Ground (DPG): The examination of DPG's activities under the BDRP revealed no significant environmental consequences. Controversial issues and national defense posture were identified as relevant areas of significant concern, and are discussed as part of the national environment considerations in section 5.2.1. Labor force was identified as a positive relevant area of minor concern. The employment of 10 persons under the funding of the BDRP represents about 0.7% of the total DPG personnel, and about 0.1% of the regional personal income (See 5.2.2.3). Thus, the economic impact of the labor force associated with the BDRP at this facility is small.

6.1.3 SECONDARY SITES

Nine representative BDRP secondary sites were selected for in-depth analysis. IAM evaluation concentrated on the portion of the work performed under the BDRP sponsorship at each site. Consideration was given to any aspects of the site, or other ongoing activities, which would influence the potential for any BDRP related impacts to become significant as a result of cumulative or synergistic effects. A list of all secondary sites is provided in Appendix 3. Eight of the nine secondary sites examined, utilizing the IAMB, indicated no relevant areas of significant concern (See Appendix 6). The IAM for the Salk Institute, Government Services Division, identified national defense posture as a positive relevant area of significant concern. This is discussed as part of the national environment in section 5.2.1.

Nine relevant areas of minor concern were identified for one or more of the secondary sites (see Appendix 6). These are: surface water, ambient air quality, biological air quality, labor force, controversial issues, national defense posture, scientific benefit, public benefit and workforce.

Surface water and biological air quality were identified as relevant areas of minor concern at the Salk Institute, Government Services Division, and the Southern Research Institute (SoRI). Research at both of these institutions is conducted with organisms requiring BL-3 containment facilities, thus providing a potential for minor impacts. However, due to the control measures and safety features inherent in the structural and operational characteristics of these facilities (See 5.2.3.1), the potential for environmental consequences on surface water and biological air quality becomes insignificant. Ambient air quality was identified to be a potentially relevant area of minor concern at the Salk Institute, Swiftwater, PA. This is attributed to the disposal of test animals and their wastes by autoclaving, followed by incineration of these wastes. However, these procedures are performed in compliance with the requirements of a state permit, which minimizes the potential for

any consequences to the environment. A potential minor impact on the health of the workforce was identified at both the Salk Institute, Government Services Division, and at the Jefferson Medical College. A safety committee at both of these facilities manages general laboratory safety hazards and requires laboratory personnel to follow specific guidelines that cover recurring activities in the operation of the laboratory {see 5.2.3.1 and 5.2.3.3). The laboratory personnel who may come in contact with high hazard organisms or toxins used in research are immunized for their maximum protection.

Economic effect of the labor force was identified as a positive relevant area of minor concern for the Salk Institute, Government Services Division. The employment of approximately 55 persons under the BDRP sponsorship at this institute represents 0.23% of the regional personal income (see 5.2.3.1). Thus, the economic impact of the labor force associated with the BDRP in the region of this facility is positive, but minor. National defense posture, scientific benefit, and public benefit were identified as relevant areas of minor concern by the IAMs for several secondary sites. These benefits are discussed as site independent national considerations in section 5.2.1. Controversial issues related to GEMs were identified as a relevant area of minor concern for the Wadsworth Center for Laboratories and Research, New York State Department of Public Health. These issues are discussed as part of the national environment considerations in section 5.2.1.

The remainder of the secondary sites were analyzed on the basis of their respective risk/issue categories. Appropriate checks were made to assure that the facilities were adequate for the ongoing research or testing activities. In addition, an examination of the control measures and environmental compliance requirements was conducted to verify that appropriate measures were in place to protect the workforce and the external environment. Additional safety policies relevant to secondary sites were initiated after the publication of the DEIS and are described in Section 3.3.2. The potential for cumulative effects was also examined. The overall analysis of all secondary sites indicated no significant adverse impacts on the human environment, either on an individual basis, or cumulatively.

6.1.4 SITES OUTSIDE THE UNITED STATES

The BDRP sites located outside the United States are also included in Appendix 3. Requirements for NEPA evaluation of sites abroad are discussed in Section 5.2. No potential was found to significantly harm any aspect of the environment of any other country; thus no further examination of international participants in the BDRP was conducted.

6.2 SUMMARY OF IMPACTS

In summary, analyses of individual and cumulative effects of

the BDRP revealed the beneficial effects of the program are: maintenance of the national defense posture, contributions to scientific knowledge, and benefits to the global population by development of vaccines and drugs for naturally occurring animal and human diseases.

Relevant areas of concern are associated with the potential for impacts on: surface water, air quality, human health of the workforce and contiguous populations, economic impacts of the BDRP expenditures, social concerns, safety during construction phases, and controversial issues. With regulatory and other controls in place, risks to the environment and workforce become minor. All other environmental and socioeconomic impacts were determined to be insignificant or non-existent. No significant cumulative or synergistic adverse impacts were identified.

The program activities identified as most responsible for the potential impacts were: program management, planning and designing the research, the development and testing program, and the actual procedures required for research, development, and testing. In all cases, the potential for impacts was found to be based upon perceptions that were not supported by actual data or experiences.

Analysis of the BDRP identified no conflicts in alternative uses of resources, or land-use plans or policies. In addition, there were no short-term uses of the environment that materially affected the maintenance and enhancement of long-term productivity. No BDRP activities produced adverse impacts on the natural ecosystem balance at any location, either from the programmatic or site-specific perspectives. The program utilizes depletable, non-renewable energy resources, such as natural gas, coal, and fuel oil, but the quantities consumed are small and result in insignificant impacts. Use of financial and energy resources are the only areas where measurable commitments, though minor, of irreversible or irretrievable uses of resources were identified. There were no activities identified as producing adverse or significant impacts on cultural or natural resources, such as historic or archaeological sites, unique geographical areas, or ecosystems. The BDRP is an ongoing, in place, research program that will have no effect on cultural resources. All current BDRP experimentation takes place in established research laboratories. Future BDRP construction projects that may affect cultural resource sites will be addressed under separate NEPA documentation when such projects are proposed. No endangered species or designated critical habitat would be affected.

6.3 CONSEQUENCES OF THE ALTERNATIVES CONSIDERED

The identification of alternatives considered and the basis for eliminating non-relevant alternatives are discussed in section 4.

6.3.1 ALTERNATIVE TO CONTINUE THE BDRP

The preferred alternative is continuation of the BDRP. Under this alternative, the benefits and contributions that the BDRP makes to the national defense posture, scientific knowledge, and to the global public health would continue. Controversy over the development of defensive measures for biological warfare threats and the use of genetic engineering methodologies in the program will also continue with this alternative.

In addition to the controversial issues, there is a perception by segments of the population that events external to the controls of the program, such as a catastrophic accident or an act-of-nature, may cause a serious outbreak of an uncontrollable disease. The types of acts-of-nature or catastrophic incidents proposed include seismic or climatic disturbances, fire, explosions, falling meteorites, airplane crashes, terrorism, riots, and sabotage. The potential for release of contaminated test materials or infectious organisms outside of the laboratory through any number of means, such as escape of infected animals, accidental spills of infectious organisms, contagious laboratory workers, uncontrolled vectors, uncontrolled open-air testing, and purposeful direct releases to the environment, are perceived by certain segments of the population as a constant threat or risk. This aura of concern about events which have never occurred will no doubt persist if the BDRP is continued.

The potential consequences associated with extraordinary catastrophic, unpredictable events, should they occur, are evaluated in Appendix 9. Although occurrence of an extraordinary event is theoretically possible, the probability of such an occurrence at any given time is considered to be remote. The opportunity for an infectious disease to spread uncontrollably as a result of an extraordinary event has been evaluated and found to be immeasurably small (see Appendix 8). Considering the maximum quantity of infectious disease organisms or toxins contained at any one of the BDRP locations, the worst credible event that could result from the above mentioned catastrophes would create a potentially infectious or hazardous environment only within a few meters of the origin, and the duration of the hazard would be on the order of minutes to hours. Considering the nature of the organisms used, if any humans or animals should become infected as a result of such an incident, it would be highly unlikely that a disease would spread from man to man, animal to animal, or animal to man, because these routes are not the normal mode of transmission of these organisms (see Appendices 7 and 9). The majority of humans or animals initially infected could be treated effectively, and even without treatment, a disease would probably spread no farther than the initial infected contacts. The type of catastrophic event discussed here pertains to all real life endeavors without regard to location or time, and are beyond the reasonable control of the BDRP or any other agency. Within the DoD, the capability exists

to respond effectively to any of the aforementioned incidents. However, because of the highly speculative and improbable nature of such events occurring, it is not believed to be necessary to modify or terminate the BDRP in order to eliminate the potential occurrence of these remote and unlikely events, which must then be followed by other, equally unlikely, events in order to **cause** even localized adverse consequences.

Within the BDRP as in virtually any endeavor in the biological sciences, there is the unavoidable potential for injuries or infections resulting from accidents in any phase of the program. Since the inception of the BDRP, there have been no fatalities or untreatable injuries for any reason associated with the BDRP (see Appendix 8). Accidents which have occurred in the past include needle sticks, laboratory spills, equipment breakage, punctures from broken laboratory ware and animal bones, animal bites, and cuts during necropsy procedures. In all cases, appropriate monitoring and treatment were provided to affected personnel, and no overt disease has ever developed in either close personal contacts of the laboratory worker or in the community. It is anticipated that, regardless of the level of preventive efforts and controls, these types of accidents will inevitably continue at a low frequency. The overall safety record of the BDRP has been exemplary; with the special attention devoted to occupational and biosafety, the safe conduct of the program is expected to continue.

6.3.2 ALTERNATIVE TO TERMINATE THE BDRP

Termination of the program (no action alternative) would eliminate the perceived and potential impacts of the BDRP on the workforce, the general population, and the biophysical environment. The actual minor adverse impacts would also cease. It has been determined that none of these significantly affect the quality of the human environment. Objections to the study of potential biological warfare agents and development of defensive measures against them would be eliminated, but the objections of special interest groups and individuals to the existence and use of genetic engineering as a biomedical technology would continue. The genetic engineering efforts in the BDRP represent a very minute portion of the usages of genetic engineering by the total biomedical research and development community on a national or worldwide scale. Termination of the program would forfeit the program benefits of maintaining the national defense posture, contributions to the scientific community, and to the global population. The positive economic impacts of the workforce on local economies would be lost as well. While not of a major national consequence, these types of impacts are significant locally.

6.4 MITIGATION AND MONITORING

Mitigation of potential adverse impacts resulting from normal operational activities such as biocontainment, waste

discharge and disposal, and accidents is accomplished by the implementation of operational, safety, security, and regulatory controls (Section 3.3) which are established based upon federal, state, and institutional criteria. Because of the nature of the BDRP, there will always exist an element of risk. Appropriate concern for the inherent risks is properly expressed through the implementation of adequate measures to protect the workforce and the environment. Continuous monitoring and surveillance of all phases of the BDRP by each institution and by appropriate Federal and state authorities have effectively eliminated significant adverse impacts to the biophysical environment and to human health. The controls in effect throughout every aspect of the BDRP are adequate, and implementation of more stringent monitoring, or development of new criteria to provide, in theory, further protection for the workforce or the external environment, are not considered to be necessary.

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Appendix 1 Excerpts from official documents, specifically National Security Decision Memorandum, the Biological Weapons Convention and other related texts, pertinent to the BDRP are presented here.

Document

1. White House press release November 25, 1969 (Excerpts)

2. National Security Memorandum 35, November 25, 1969 (Excerpts)

3. Memorandum for the Deputy Secretary of Defense, December 27, 1969, Subject: Implementation of the President's Decision on Chemical Warfare and Biological Research Programs (Excerpts)

4. White House press release, February 14, 1970 (Excerpts)

5. National Security Memorandum 44, February 20, 1970

6. Arms Control and Disarmament Agreements Texts and Histories of Negotiations, Convention on the Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

7. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

8. Memorandum for the Secretary of Defense, January 16, 1976, Subject: United States Compliance with the Biological Weapons Convention (Excerpts)

9. Memorandum for the President, January 24, 1976 (Excerpts)

   Subject: United States Compliance with the Biological Weapons Convention

1. WHITE HOUSE PRESS RELEASE NOVEMBER 25, 1969 (EXCERPTS)

[Subject: United States Policy on Chemical Warfare Program and Bacteriological/Biological Research Program]

"The United States shall renounce the use of lethal biological agents and weapons, and all other methods of biological warfare.

The United States will confine its biological research to defensive measures such as immunization and safety measures.

The DOD has been asked to make recommendations as to the disposal of existing stocks of bacteriological weapons."

2. NATIONAL SECURITY MEMORANDUM 35, NOVEMBER 25, 1969 (EXCERPTS)

"3. With respect to Bacteriological/Biological programs:

a. The United States will renounce the use of lethal methods of bacteriological/biological warfare.

b. The United States will similarly renounce the use of all other methods of bacteriological/biological warfare (for example, incapacitating agents).

c. The United States bacteriological/biological programs will be confined to research and development for defensive purposes (immunization, safety measures, et cetera). This does not preclude research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required."

3. MEMORANDUM FOR THE DEPUTY SECRETARY OF DEFENSE, DECEMBER 27, 1969, SUBJECT: IMPLEMENTATION OF THE PRESIDENT'S DECISIONS ON CHEMICAL WARFARE AND BIOLOGICAL RESEARCH PROGRAMS (EXCERPTS)

"This memorandum assigns responsibilities within the Department of Defense for implementation of each of the President's decisions on Chemical Warfare and Biological Research Programs."

"a. The term "Chemical and Biological Warfare (CBW)" will no longer be used. Secretaries of the Services, the Chairman of the

Joint Chiefs of Staff, Assistant Secretaries of Defense, and other agency heads will inform their personnel that henceforth reference should be to these two categories separately - the Chemical Warfare Program and the Biological Research Program."

"c. With respect to the Biological Research Program:

(1) The President has renounced the use of lethal and other methods of bacteriological/biological warfare, including incapacitating agents, and all supervisors will instruct their personnel to adhere to this policy."

"(2) The Director, Defense Research and Engineering, is responsible for developing, in coordination with the Military Departments, a research and development program in biological research which will ensure that the U.S. bacteriological/biological program will be confined to research and development for defensive purposes (immunization, detection and warning, safety measures, etc.). The plans will not preclude research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required should they be used against us."

4. WHITE HOUSE PRESS RELEASE, FEBRUARY 14, 1970 (EXCERPTS)

The United States renounces offensive preparations for and the use of toxins as a method of warfare;

The United States will confine its military programs for toxins, whether produced by bacteriological or any other biological method or by chemical synthesis, to research for defensive purposes only, such as to improve techniques of immunization and medical therapy.

The President has further directed the destruction of all existing toxin weapons and of all existing stocks of toxins which are not required for a research program for defensive purposes only."

5. NATIONAL SECURITY MEMORANDUM 44, FEBRUARY 20, 1970, *SUBJECT:* UNITED STATES POLICY ON TOXINS (EXCERPTS)

Following a review of United States military programs for toxins, the President has decided that:

1. The United States will renounce the production for operational purposes, stockpiling and use in retaliation of toxins produced either by bacteriological or biological processes or by chemical synthesis."

2. The United States military program for toxins will be confined to research and development for defensive purposes only."

6. Arms control and Disarmament Agreements Texts and Histories of Negotiations, pp. 120-123.

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

Biological and chemical weapons have generally been associated in the public mind, and the extensive use of poison gas in World War I (resulting in over a million casualties and over 100,000 deaths) led to the General Protocol of 1925 prohibiting the use of both poison gas *and* bacteriological methods in warfare. At the 1932-1937 Disarmament Conference. unsuccessful attempts were made to work out an agreement that would prohibit the production and stockpiling of biological and chemical weapons. During World War II, new and more toxic nerve gases were developed. and research and development was begun on biological weapons. Neither side used such weapons. President Roosevelt, in a statement warning the Axis powers against the use of chemical weapons, declared:

> Use of such weapons has been outlawed by the general opinion of civilized mankind. This county has not used them, and I hope we never will be compelled to use them. I state categorically that we shall under no circumstances resort to the use of such weapons unless they are first used by our enemies.

In the postwar negotiations on general disarmament, biological and chemical weapons were usually considered together with nuclear and conventional weapons. Both the United States and Soviet Union, in the 1962 sessions of the Eighteen-Nation Disarmament Committee (ENDC), offered plans for general and complete disarmament that included provisions for eliminating chemical and biological weapons.

An issue that long hindered progress was whether chemical and biological weapons should continue to be linked. A British draft convention submitted to the ENDC on July 10, 1969. concentrated on the elimination of biological weapons only. A draft convention proposed in the General Assembly by the Soviet Union and its allies on September 19 dealt with both chemical and biological Weapons. The Soviet representative argued that they had been treated together in the Geneva Protocol and in the General Assembly resolutions and report, and should continue to be dealt with in the same Instrument. A separate biological weapons convention, he warned, might serve to intensify the chemical arms race.

The United States supported the British position and stressed the difference between the two kinds of weapons. Unlike biological weapons, chemical weapons had actually been used in modem warfare. Many states maintained chemical weapons in their arsenals to deter the use of this type of weapons against them, and to provide a retaliatory capability if deterrence failed. Many of these nations, the United States pointed out, would be reluctant to give up this capability without reliable assurance that other nations were not developing, producing, and stockpiling chemical weapons.

While the United States did not consider prohibition of one of these classes of weapons less urgent or important than the other, it held that biological weapons presented less intractable problems, and an agreement on banning them should not be delayed until agreement on reliable prohibition of chemical weapons could be reached.

Shortly after President Nixon took office, he ordered a review of U.S. policy and programs regarding biological and chemical warfare. On November 25. 1969 the President declared that the United States unilaterally renounced first use of lethal or incapacitating chemical agents and weapons and unconditionally renounced all methods of biological warfare. Henceforth the U.S. biological program would be confined to research on strictly defined measures of defense. such as immunization. The Department of Defense was ordered to draw up a plan for the disposal of existing stocks of biological agents and weapons. On February 14. 1970, the White House announced extension of the ban to cover toxins (substances falling between biologicals and chemicals in that they act like chemicals but are ordinarily produced by biological or microbic processes).

The American action was widely welcomed internationally, and the example was followed by others. Canada, Sweden and the United Kingdom stated that they had no biological weapons and -`d not intend to produce any. It was generally recognized. However that unilateral actions could not take the place of a binding international commitment. A number of nations. including the Soviet Union and its allies. continued to favor a comprehensive agreement covering both chemical and biological weapons.

Discussion throughout 1970 in the General Assembly and the Conference of the Committee on Disarmament (CCD)—as the ENDC was named after its enlargement to 26 members in August 1969—produced no agreement. A breakthrough came on March 30, 1971, however, when the Soviet Union and its allies changed their position and introduced a revised draft convention limited to biological weapons and toxins. It then became possible for the co-chairman of the CCD—the U.S. and Soviet representatives—to work out an agreed draft , as they had done with the non-proliferation and the seabed treaties. On

August 5, the United States and the Soviet Union submitted separate but identical texts.

On December 16, the General Assembly approved a resolution, adopted by a vote of 110 to 0, commending the convention and expressing hope for the widest possible adherence.

The French representative abstained, explaining that the convention, though a step forward, might weaken the General Protocol ban on the use of chemical weapons and he did not consider that adequate international controls were provided. He announced. however that France would enact domestic legislation prohibiting biological weapons and this was done in June of the next years

The People's Republic of China did not participate in the negotiations on the convention and did not sign it. At the 1972 General Assembly its representative attacked the convention as a "sham," and criticized it for not prohibiting chemical weapons.

The convention was opened for signature at Washington, London, and Moscow on April 10, 1972. President Nixon submitted it to the Senate on August 10. calling it "the first international agreement since World War II to provide for the actual elimination of an entire class of weapons from the arsenals of nations." The Senate Foreign Relations Committee delayed action on the convention, however, holding it for consideration after resolution of the herbicide and riot-control issues involved in the Geneva Protocol (see section on the Geneva Protocol).

In the latter part of 1974 the Ford Administration undertook a new initiative to obtain Senate consent to ratification of both the Geneva Protocol and the Biological Weapons Convention, and ACDA Director Fred Ikle testified with respect to both instruments before the Senate Foreign Relations Committee on December 10. Soon thereafter the Committee voted unanimously to send the two measures to the Senate floor and on December 16 the Senate voted its approval also unanimously.

President Ford signed instruments of ratification for the two measures on January 22, 1975.

Under the terms of the convention, the parties undertake not to develop, produce, stockpile, or acquire biological agents or toxins "of types and in quantities that have no justification for prophylactic, protective, and other peaceful purposes," as well as weapons and means of delivery. All such materiel is to be destroyed within 9 months of the convention's entry into force. In January 1976, all heads of Federal departments and agencies certified to the President that as of December 26, 1975, their respective Departments and agencies were in full compliance with the convention.

The parties are to consult and cooperate in solving any problems that arise. Complaints of a breach of obligations may be lodged with

the Security Council. and parties undertake to cooperate with any investigation the Council initiates. If the Security Council finds that a state has been endangered by a violation the parties are to provide any assistance requested.

Nothing in the convention is to be interpreted as lessening the obligations imposed by the General Protocol and the parties undertake to pursue negotiations for a ban on chemical weapons

In addition. articles provide for exchange of information on peaceful uses. amendment and review and accession and withdrawal The convention is of unlimited duration.

7.

The 1972 Biological Weapons Convention

CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

Signed at London, Moscow and Washington on 10 April 1972
Entered into force on 26 March 1975
Depositaries: UK, US and Soviet governments

The States Parties to this Convention,

Determined to act with a view to achieving effective progress towards general and complete disarmament, including the prohibition and elimination of all types of weapons of mass destruction, and convinced that the prohibition of the development, production and stockpiling of chemical and bacteriological (biological) weapons and their elimination, through effective measures, will facilitate the achievement of general and complete disarmament under strict and effective international control,

Recognizing the important significance of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925, and conscious also of the contribution which the said Protocol has already made, and continues to make, to mitigating the horrors of war,

Reaffirming their adherence to the principles and objectives of that Protocol and calling upon all States to comply strictly with them,

Recalling that the General Assembly of the United Nations has repeatedly condemned all actions contrary to the principles and objectives of the Geneva Protocol of June 17, 1925,

Desiring to contribute to the strengthening of confidence between peoples and the general improvement of the international atmosphere,

Desiring also to contribute to the realization of the purposes and principles of the Charter of the United Nations,

Convinced of the importance and urgency of eliminating from the arsenals of States, through effective measures, such dangerous weapons of mass destruction as those using chemical or bacteriological (biological) agents,

Recognizing that an agreement on the prohibition of bacteriological (biological) and toxin weapons represents a first possible step towards the achievement of agreement on effective measures also for the prohibition of the development, production and stockpiling of chemical weapons, and determined to continue negotiations to that end,

Determined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,

Convinced that such use would be repugnant to the conscience of mankind and that no effort should be spared to minimize this risk,

Have agreed as follows:

Article I

Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:

1. Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

2. Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

Article II

Each State Party to this Convention undertakes to destroy, or to divert to peaceful purposes, as soon as possible but not later than nine months after the entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, which are in its possession or under its jurisdiction or control. In implementing the provisions of this article all necessary safety precautions shall be observed to protect populations and the environment.

Article III

Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any

way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in article I of the Convention.

Article IV

Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

Article V

The States Parties to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention. Consultation and cooperation pursuant to this article may also be undertaken through appropriate international procedures within the framework of the United Nations and in accordance with its Charter.

Article VI

1. Any State Party to this Convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council.

2. Each State Party to this Convention undertakes to cooperate in carrying out any investigation which the Security Council may initiate, in accordance with the provisions of the Charter of the United Nations, on the basis of the complaint received by the Council. The Security Council shall inform the States Parties to the Convention of the results of the investigation.

Article VII

Each State Party to this Convention undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention.

Article VIII

Nothing in this Convention shall be interpreted as in any way limiting or detracting from the obligations assumed by any State under the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925.

Article IX

Each State Party to this Convention affirms the recognized objective of effective prohibition of chemical weapons and, to this end, undertakes to continue negotiations in good faith with a view to reaching early agreement on effective measures for the prohibition of their development, production and stockpiling and for their destruction, and on appropriate measures concerning equipment and means of delivery specifically designed for the production or use of chemical agents for weapons purposes.

Article X

1. The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so shall also cooperate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention of disease, or for other peaceful purposes.

2. This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

Article XI

Any State Party may propose amendments to this Convention. Amendments shall enter into force for each State Party accepting the amendments upon their acceptance by a majority of the States Parties to the Convention and thereafter for each remaining State Party on the date of acceptance by it.

Article XII

Five years after the entry into force of this Convention, or earlier if it is requested by a majority of Parties to the Convention by submitting a proposal to this effect to the Depositary Governments, a conference of States Parties to the Convention shall be held at Geneva, Switzerland, to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, including the provisions concerning negotiations on chemical weapons, are being realized. Such review shall take into account any new scientific and technological developments relevant to the Convention.

Article XIII

1. This Convention shall be of unlimited duration.

2. Each State Party to this Convention shall in exercising its national sovereignty have the right to withdraw from the Convention if it decides that extraordinary events, related to the subject matter of the Convention, have jeopardized the supreme interests of its country. It shall give notice of such withdrawal to all other States Parties to the Convention and to the United Nations Security Council three months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme interests.

Article XIV

1. This Convention shall be open to all States for signature. Any State which does not sign the Convention before its entry into force in accordance with paragraph (3) of this Article may accede to it at any time.

2. This Convention shall be subject to ratification by signatory States. Instruments of ratification and instruments of accession shall be deposited with the Governments of the United States of America, the United Kingdom of Great Britain and Northern Ireland and the Union of Soviet Socialist Republics, which are hereby designated the Depositary Governments.

3. This Convention shall enter into force after the deposit of instruments of ratification by twenty-two Governments, including the Governments designated as Depositaries of the Convention.

4. For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Convention, it shall enter into force on the date of the deposit of their instruments of ratification or accession.

5. The Depositary Governments shall promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification or of accession and the date of the entry into force of this Convention, and of the receipt of other notices.

6. This Convention shall be registered by the Depositary Governments pursuant to Article 102 of the Charter of the United Nations.

Article XV

This Convention, the English, Russian, French, Spanish and Chinese texts of which are equally authentic, shall be deposited in the archives of the Depositary Governments. Duly certified copies of the Convention shall be transmitted by the Depositary Governments to the Governments of the signatory and acceding States.

Source: *Treaties and Other International Acts, Series 8062* (US Department of State, Washington, D.C., 1975)

8. MEMORANDUM FOR THE SECRETARY OF DEFENSE, JANUARY 16, 1976, SUBJECT: U.S. COMPLIANCE WITH THE BIOLOGICAL WEAPONS CONVENTION (EXCERPTS)

> "(1) All programs of the Department of the Army in which any biological agents or toxins are retained are completely oriented toward medical research, protective and defensive measures, and vulnerability studies and research, and
>
> (2) All quantities of such materials retained are reserved or committed solely to those programs noted above which are in full compliance with the President's determination of "prophylactic, protective, and other peaceful purposes," and
>
> (3) The destruction of all stockpiles of biological or toxin agents maintained in support of operational plans and their associated munitions was completed on October 18, 1972, and the destruction or conversion of all delivery systems designed to use biological agents or toxins was accomplished on January 21, 1974."

9. MEMORANDUM FOR THE PRESIDENT, JANUARY 24, 1976, (EXCERPTS)

> "(1) All programs of the Department of Defense in which any biological agents or toxins are retained are completely oriented toward medical research, protective and defensive measures, and vulnerability studies and research, and
>
> (2) All quantities of such materials retained are reserved or committed solely to those programs noted above which are in full compliance with your determination of "prophylactic, protective, and other peaceful purposes," and
>
> (3) The destruction of all stockpiles of biological or toxin agents maintained in support of operational plans and their associated munitions was completed on October 18, 1972, and the destruction or conversion of all delivery systems designed to use biological agents or toxins was accomplished on January 21, 1974."

Appendix 2

Shipment of Etiologic Agents

1. Background

2. Packaging

   2.1 Introduction
   2.2 Description of Current Packaging Standards
   2 3 Packaging Reliability

3. Shipment of Etiologic Agents within the BDRP

4. Conclusions

5. References

APPENDIX 2 Shipment of Etiologic Agents

1. Background

Clinical specimens, cultures and samples of many types of biological materials must often be transported between the primary and secondary sites of program performance, as well as between BDRP sites and other cooperating or collaborating laboratories. Other government biomedical laboratories, for example, the Centers for Disease Control (CDC) and the National Institutes of Health (NIH), as well as almost every major biomedical research organization in the country, initiate and/or receive similar shipments. Within the U.S., transportation of potentially hazardous infective materials and toxins, termed "etiologic agents," is highly regulated. Title 42 of the Code of Federal Regulations (CFR) establishes the pertinent regulations, which uniformly apply to all military, government and nongovernment organizations (1). In addition to restrictions on the domestic shipment of organisms which are potentially hazardous to humans, the U.S. Department of Agriculture regulates the importation, use, and interstate shipment of non-indigenous pathogens of livestock and poultry.

Regulations on the shipment of etiologic agents are designed to meet two objectives. First, it is vital to both the shipper and the receiver that the specimens and cultures be delivered intact, and in viable condition if they are living materials. Second, the carrier must be assured that there is only an extremely small risk to all those persons who might handle the package in transit. This latter consideration includes the general public, as well as those non-laboratory personnel within the sending and receiving organizations who must handle the package when it is not within the laboratory itself. Both objectives have common elements. For example, a package that adequately cushions its contents against breakage will also assure that there can be no escape of potentially hazardous materials. Similarly, the sealed packaging of the specimen or organism sample helps assure the viability of the shipped material as well as ensure against leakage.

The regulations at 42 CFR 72, published by the Public Health Service (PHS), provide for three types of control of these etiologic agents. First, the bacteria, fungi, viruses and rickettsia that are subject to these requirements are listed (42 CFR 72.3). Second, the actual packaging and shipping requirements are specified (42 CFR 72.3 a-d). These packaging requirements reflect closely the requirements of the US Department of Transportation (DOT), which describes them in detail at 49 CFR 173. (DOT is the agency charged with setting the packaging standards for most interstate shipments of all commodities.) Third, a list is given of those etiologic agents for which shipment by "registered mail or equivalent system" is

required (42 CFR 72.3f). Many of the organisms used within the BDRP are classified as etiologic agents for the purposes of shipment. Several of the organisms studied in BDRP laboratories are identified on the list of organisms requiring shipment by "registered mail or equivalent system." In addition, to the requirements described above, the regulations specify procedures for notification of the Centers for Disease Control in the event that any package bearing the "Etiologic Agents/Biomedical Material" label (see figure A2-2) is damaged or shows evidence of leaking, or in the event that a sender does not receive a notification of delivery within five days following anticipated delivery of the package.

2. Packaging

2.1 Introduction

Army examination of safe means of packaging biological specimens and cultures was initiated over 30 years ago at Ft. Detrick (2,3,5). This was at approximately the time (May, 1956) that a large bottle of living poliomyelitis culture, shipped by a non-DOD organization, broke while in transit on a commercial airliner. This incident is usually cited as the origin of the first PHS regulation of interstate shipment of etiologic agents (42 CFR 72.25, 15 March 1957) (note that the CFR section numbering has changed over the years). Research on packaging conducted by Ft. Detrick involved field tests of various combinations of inner and outer containers to determine if leakage to the outside environment could be totally prevented (2). Tests included standard drop test from 4, 10 and eventually 40 feet to concrete; penetration tests with steel rods; crushing tests; and wetting tests where boxes were soaked in a shower prior to the drop and penetration tests. The packaging configurations ultimately developed met all of these tests with no failures, and were approved for shipments of up to one US gallon (3787 ml) per container (2,3). These data still provide a basis for our present standards (5).

2.2 Description of Current Packaging Standards

In general, the current standards for shipment of etiologic agents require three separate, nested containers (1,3,4). The innermost one holds the actual specimen. It must be impervious, watertight, and sealed with waterproof tape or other positive seal <u>in addition to</u> the normal lid or cover of the container. The outside of this closed vial or tube is treated with bleach and/or ultraviolet light so that it is free of hazardous materials. Then, an absorbent material such as cotton or corrugated, absorbent paper towels or "wipes" must be wrapped around the culture vial in sufficient quantity that it could totally absorb the culture if necessary. The wrapped vial is then placed in a <u>metal</u>, screw-cap can. The can is closed and then placed in a larger fiber or metal can, which has either a metal screw cap or a crimped metal rim closure similar to a

sealed can of soup. This outer can may be used as a shipping container for small specimens (50 ml or less) if chilling of the specimen is not necessary. If chilling is required, this can is placed in a foamed plastic box, braced against movement, and the box is filled with dry ice or cold packs; the entire box then is sealed in a heavy-duty fiberboard box sized to fit the foam box. Larger samples (up to 1000 ml) can be prepared in a similar manner with appropriately-sized cans and boxes. A total of 4000 ml may be enclosed within one outer shipping carton if each 1000 ml portion of the total is completely self-contained in appropriate primary and secondary containers 11).

2.3 Packaging Reliability

The packaging standards described above are designed to provide protection against spillage during a disaster. During testing, containers as large as several gallons were subjected to many different types of simulated hazards (2,3). "Drop challenges" from many different heights were performed, in addition to the "standard" tests for packaging specified by the DOT. The basic DOT standards require no exterior leakage following a drop of 30 feet to a hard surface, which corresponds to "rough handling" during shipping (3). The Ft. Detrick tests added falls from 40 feet, and later included drops from 1000 and 1500 feet to concrete, and from 2000 and 4000 feet to hard soil. In cooperation with the Air Force and Navy, aircraft crash tests and rocket sled acceleration tests were used to simulate the combined conditions of other types of disasters (2).

The proposed packaging for small quantities (10 to 1000 ml) passed all tests with no external leakage, and with only one instance of breakage of the innermost container (2,3). Many variants on larger container systems were also studied, and several types of packaging for sizes up to 15 gallons were also tested successfully (2). Following this series of tests, the Army applied for permission from the PHS to utilize the packaging developed for air shipments of biological materials. This permission was received in written opinions from the US Surgeon General on February 19 and April 1, 1968 (2). The containers now used for shipment of specimens and cultures by all biomedical research organizations correspond to those tested, and the packaging, which meets the small-quantity requirements of 42 CFR 72.3(a), is shown in Figure A2-1. In addition to the requirements for the package itself, a distinctive label is required. The size, design and color of the label is specified in 42 CFR 72.3d, and is shown (in black and white) in Figure A2-2.

Fire is another possible disaster which must be considered in the context of shipment of etiologic agents. Unlike reactive chemicals, the very small quantities of biological materials which are typically shipped for BDRP purposes cannot add to the intensity of a fire. One value of the metal can which forms the second container is that it would not be **consumed in a fire until** temperatures reached more than 1000 degrees F. Long before that

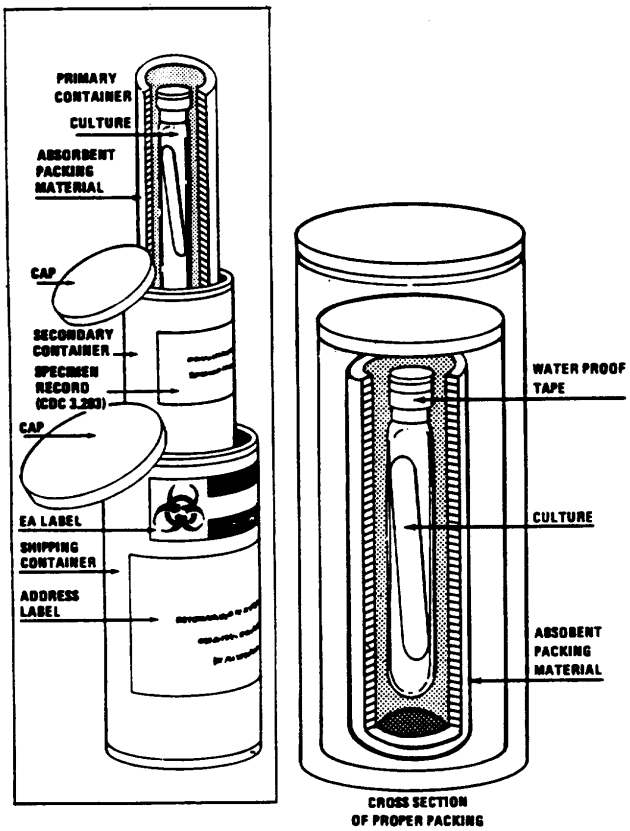

Figure A2-1. Required packaging for Etiologic Agents when shipped in quantities of less than 50 ml

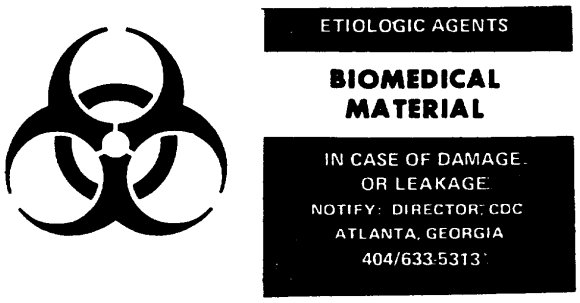

Figure A2-2. Required label for shipments of Etiologic Agents. (All printing is red on white background)

time, the heat of a fire would serve to raise the temperature of the culture in the innermost vial to the boiling point. This would be adequate in itself to inactivate the organisms rapidly. Continued heat would raise the inner temperature above boiling, and create higher heat as well as pressure. The metal secondary container could rupture if this pressure were high enough, but all biological activity of the sample would have ceased long before this point. The culture would thus be sterilized. With small quantity shipments (less than 10 ml), the volume of liquid may not be adequate to create this rupturing pressure, so the sterilized contents would remain inside the can.

3. Shipment of Etiologic Agents within the BDRP

What is the actual number and *f*requency *of* shipments of these regulated materials in the conduct of the BDRP? The activities of USAMRIID, the largest and most active primary site in the BDRP, serve as a good example. In 1987, USAMRIID made 50 shipments of etiologic agents to other institutions and organizations, an average of approximately one per week. The two largest shipments, those over 100 ml, were both urine samples sent for analysis at contract test laboratories. Aside from these large shipments, the mean size of a shipment was 6.9 ml, or about one and a third teaspoons. The median size of a shipment, i.e. the size in the middle-25 larger and 25 smaller, was 2 ml, less than one-half of a teaspoon. USAMRIID standard operating procedures also require that three professional employees, the investigator, the Division Chief and the Safety Officer, must concur on the classification of the material to be shipped and the corresponding packaging requirements that will be followed.

All 1987 shipments were made by overnight express package services, which do not utilize passenger aircraft. The choice of this mode of shipment is for reasons of greater certainty of timely arrival of the specimens, rather than for any particular safety goal. Shipment of cultures and specimens through the US Postal Service is legal, and is regularly used by many clinics and laboratories where the sample is adequately stabilized against degradation for several days.

BDRP-associated shipments of etiologic agents are thus actually rather infrequent even in the most active organization. There is no way to count accurately the number of shipments of such materials by all persons nationwide, but, taking into account hospitals, clinical laboratories, commercial suppliers of organisms, universities and other research institutes, there are certainly hundreds, if not thousands per day. The majority of these are clinical specimens, and are likely to be of low potential hazard. Scores, possibly hundreds, of shipments per week, however, are made of higher hazard cultures and organisms, including many of HIV-infected blood. Many shipments to and from the various CDC and NIH laboratories, and from the American Type Culture Collection, are of materials with potential risk levels similar to those shipped as a part of

the BDRP. Thousands of university and foundation researchers regularly ship cultures and specimens between laboratories under the regulations of 42 CFR 72. The BDRP shipments probably constitute no more than a small fraction of one percent of all shipments of etiologic agents initiated in the U.S.

4. Conclusions

The question of the safety of shipments of BDRP-related cultures and specimens is a reasonable one. Upon examination, we see, however, that the shipment of the etiologic agents has been regulated closely by the PHS and the DOT, as well as by DoD and the Army, for decades. In the 1960s, the Army assisted PHS and DOT in developing and testing the standards for shipments of all types of biomedical materials. These standards are universally followed within the BDRP, and provide very large margins of safety for the shipper and for the public. Packages, especially those used for the very small vials in which frozen cultures are shipped, are literally able to survive an aircraft or highway crash undamaged, and have been performance-tested for this capability. Packages will not survive an intense fire intact, but the packaging is such that the biological material is rendered harmless before the secondary container opens.

Shipping standards and practices are monitored by many parties. The packing requirements provide for many levels of protection, and the overwhelming majority of shipments contain very small volumes, usually less than a teaspoonful. USAMRIID and the other primary and secondary sites are all regulated by the same PHS and DOT requirements that apply universally throughout the U.S. The concerns over safety in transportation of potentially hazardous biological materials thus appear to have been addressed adequately many years ago, through interagency cooperation in rule making. Present standards ensure that the potential for hazard to the public arising from shipment of etiologic materials such as those used in the BDRP is miniscule.

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5. References:

1. Code of Federal Regulations, Title 42, Part 72, "Interstate Shipment of Etiologic Agents," Final rule published 21 Jul 80.

2. Glick, Charles A. and Arnold G. Wedum, 1970, "Military Packaging Standards for Shipment of Biological Material/Etiologic Agent/Infectious", Technical Memorandum 215, Department of the Army, Ft. Detrick. MD. Available from DTIC under AD 874347.

3. Glick, Charles A. and Arnold G. Wedum, 1970, "Shipping Containers for Less than One Gallon of Etiologic Agent, Tested Under Standards Suggested by the Department of Transportation," Technical Manuscript 641, Department of the Army, Ft. Detrick, MD.

4. US Department of Health and Human Services, 1984, "Biosafety in Microbiological and

Biomedical Laboratories," a joint publication of the Public Health Service, Centers for Disease Control and the National Institutes of Health.

5. Department of the Army, 1977, "US Army Activity in the US Biological Warfare Programs," Information paper for the Congress of the United States, 2 Volumes. Vol 2, Annex J. details the history of the development of packaging for potentially hazardous biological materials.

APPENDIX 3 INSTITUTIONS PERFORMING BDRP RESEARCH

All primary and secondary BDRP sites were evaluated to determine the appropriate risk/issue category of the work conducted at each site. For discussion of primary and **secondary** sites, see Sections 2.4 and 2.5. Reports, records, statements of work and proposals of each secondary site were reviewed to identify the nature of the work performed by risk/issue category. Representative secondary sites were selected **from** those risk/issue categories that theoretically might give rise to the greatest environmental concern or be the most contentious (Categories I, II, III). Consideration was also given to diversity of geography, type of institution and environmental setting, e.g.-, rural, urban or suburban. The IAM was applied and potential impacts analyzed (Sections 3.4, 5.3, 5.4, 6.1 and Appendix 6). Primary and selected secondary sites performing BDRP research were visited specifically for this EIS and site visit reports prepared (Appendix 5).

The risk/issue categories are described in section **3.5 and** Appendix 4 and are coded here as follows:

Code	Risk/Issue Category
I	High Hazard Organisms
II	Genetically Engineered Microorganisms
III	Toxins
IV	Low Hazard Organisms
V	Rapid Diagnosis and Detection
VI	Vaccine and Drug Therapy Development
VII	Other Program Research and Activities*

Based on the results of the IAM analysis of the applicable specific risk/issue category(s), each of the secondary **sites that** was not visited was evaluated as appropriate to determine if: 1) any unique circumstances or extraordinary conditions exist; 2) adequate facilities are available 3) there is evidence of implementation of the appropriate controls that mitigate any areas of concern identified in the risk/issue JAM; and 4) appropriate environmental compliance measures are in place. No

*Includes either very low risk or non-risk activities which do " not fit into the above categories.

problems of non-compliance were identified, and no environmental risks associated with the

BDRP were identified.

The risk/issue tiering approach described in this programmatic EIS establishes a frame of reference for examination of both ongoing and future activities. This approach involves a screening process which focuses attention on the components of the BDRP with the greatest potential for significant environmental impacts, while also assuring that all actions are addressed. As the potential for adverse effects increases, appropriate mitigation measures, generally in the form of physical facilities, special procedures and other controls, are necessary to assure that significant adverse impacts do not occur. Therefore, each activity must be examined based upon its risk/issue category(s) and any special requirements needed for safety and/or environmental protection. The following discussion describes how this approach was applied to the remaining secondary sites of the BDRP as well as how it can be applied to future activities. Future proposed actions and sites can be evaluated to determine the potential for significant impacts, on an individual and cumulative basis. This approach applies to activities conducted at existing facilities. Proposed actions involving expansion, new construction or other activities that would involve potential impacts to the biophysical or socioeconomic environment would require appropriate NEPA documents.

Because the IAM did not identify any relevant areas of concern for activities in categories IV, V, VI, and VII, no further evaluations are deemed necessary for secondary sites that only perform work within these categories and for which the work possesses no unique characteristics warranting further analysis.

For secondary sites that performed BDRP work in category II, evidence of Institutional Biosafety Committee approval (conformance to the NIH guidelines on recombinant DNA (1) is required. For secondary sites that perform work with high hazard infectious organisms (Category I), evidence of the availability and use of appropriate BL3 or BL4 facilities, procedures and equipment is required. Annual safety inspections are required for BL-3 facilities, and semiannual inspections for BL-4 facilities. These examinations are performed by the professional safety staff of the primary site. For those secondary sites whose work involves the study of toxins (Category III), the mitigating requirement is to show that toxin waste materials will be adequately inactivated before discharge into effluent systems. This inactivation can be accomplished by several means, e.g., the actual laboratory procedures can result in destruction of the toxin; the quantities of toxin in use can be of such low risk (a function of the toxicity of the toxin and quantity in use) that no further treatment is required; or chemical or thermal detoxification processes can be utilized (see Appendix 13).

Research efforts by risk/issue category are noted for each BDRP site. For organizations conducting work in multiple potential risk/issue areas, the lower risk categories may not be listed as they are subsumed in the higher risk/issue category.

ORGANIZATION	LOCATION	RISK ISSUE CATEGORY
PRIMARY SITES		
US ARMY CHEMICAL RESEARCH DEVELOPMENT AND ENGINEERING CENTER	MD, EDGEWOOD AREA ABERDEEN PROVING GROUND	III, IV, V, VII
US ARMY DUGWAY PROVING GROUND	UT, DUGWAY PROVING GROUND	III, IV V
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES	MD, FT DETRICK, FREDERICK	I, II, III, IV, V, VI, VII
SELECTED SECONDARY SITES		
GOVT SERVICES DIVISION SALK INSTITUTE	PA, SWIFTWATER	I, VI
HEALTH RESEARCH INC.	NY, ALBANY	II, VI
JEFFERSON MEDICAL COLLEGE	PA, PHILADELPHIA	III
MASSACHUSETTS, UNIVERSITY OF	MA, AMHERST	III, IV
SALK INSTITUTE FOR BIOLOGICAL STUDIES	CA, LA JOLLA	II, VII
SCRIPPS CLINIC AND RESEARCH FOUNDATION	CA, LA JOLLA	II, IV, VII
SOUTHERN RESEARCH INSTITUTE	AL, BIRMINGHAM	I, VII
SRI INTERNATIONAL	CA, MENLO PARK	III
WRIGHT STATE UNIVERSITY,	OH, DAYTON	III
OTHER SECONDARY SITES		
ALABAMA, UNIVERSITY OF	AL, BIRMINGHAM	III
APPLIED PHYSICS LAB	MD, COLUMBIA	V

ORGANIZATION	LOCATION	RISK ISSUE CATEGORY
AUBURN UNIVERSITY	AL, AUBURN	III
BENDIX	MD, TOWSON	V
BIOMETRIC SYSTEMS, INC.	MN, EDEN PRAIRIE	III
BIONETICS RESEARCH INC.	MD, ROCKVILLE	III
BIRMINGHAM, UNIVERSITY OF	UK, BIRMINGHAM	VII
BRIGHAM YOUNG UNIVERSITY	UT, PROVO	II
CALIFORNIA, UNIVERSITY OF	CA, LOS ANGELES	III
CENTERS FOR DISEASE CONTROL	GA, ATLANTA	I
CENTERS FOR DISEASE CONTROL	SIERRA LEONE	VI, VII
CHILDREN'S HOSPITAL CORPORATION	MA, BOSTON	VII
COLORADO STATE UNIVERSITY	CO, FORT COLLINS	III
COLUMBIA UNIVERSITY	LIBERIA	VII
DEPARTMENT OF ENERGY	WA, RICHLAND	III
FOOD AND DRUG ADMINISTRATION	MD, ROCKVILLE	III
FLORIDA, UNIVERSITY OF	FL, GAINESVILLE	III
GEORGETOWN UNIVERSITY	DC, WASHINGTON	VII
HAHNEMANN UNIVERSITY, SCHOOL OF MEDICINE	PA, PHILADELPHIA	III
HARVARD UNIVERSITY	MA, CAMBRIDGE	IV, VII
HAWAII, UNIVERSITY OF	HI, HONOLULU	III
HAWAII BIOTECHNOLOGY GROUP, INC.	HI, AIEA	III
HAZELTON BIOTECHNOLOGY CO.	VA, VIENNA	VII
HINES VA HOSPITAL	IL, CHICAGO	III, VII

ORGANIZATION	LOCATION	RISK ISSUE CATEGORY
HUBEI MEDICAL COLLEGE	PRC, WUCHANG, HUBEI	VI
ILLINOIS, UNIVERSITY OF	IL, CHAMPAIGN/URBANA	III, VII
IMPERIAL COLLEGE OF SCIENCE AND TECHNOLOGY	UK, LONDON, SOUTH KENSINGTON	III
INSTITUT PASTEUR	CAR, BANGUI	IV, VII
INTEGRATED CHEMICAL SENSORS	MA, NEWTON	V
IOWA, UNIVERSITY OF	IA, IOWA CITY	VII
JK RESEARCH	MT, BOZEMAN	IV, VII
JOHNS HOPKINS UNIVERSITY	MD, BALTIMORE	VII
KANSAS STATE UNIVERSITY	KS, MANHATTAN	III
KOREA UNIVERSITY, COLLEGE OF MEDICINE	ROK, SEOUL	I
LETTERMAN ARMY INSTITUTE OF RESEARCH	CA, SAN FRANCISCO	III
LITTON BIONETICS, INC.	MD, ROCKVILLE	IV, V
MARYLAND, UNIVERSITY OF	MD, BALTIMORE	III
MIAMI, UNIVERSITY OF	FL, CORAL GABLES	III
MINNESOTA, UNIVERSITY OF	MN, ST PAUL	III, VII
MOLECULAR GENETICS, INC.	MN, MINNETONKA	II, VII
MOUNT SINAI SCHOOL OF MEDICINE	NY, NEW YORK	IV
NATIONAL INSTITUTES OF HEALTH	MD, BETHESDA	VII
NATURAL ENVIRONMENTAL RESEARCH COUNCIL	UK, WILTS, SWINDON	I
NAVY MEDICAL RESEARCH INSTITUTE	MD, BETHESDA	IV, V
NAVAL RESEARCH LABORATORY	DC, WASHINGTON	III, V

ORGANIZATION	LOCATION	RISK ISSUE CATEGORY
NEW ENGLAND MEDICAL CENTER HOSPITALS	MA, BOSTON	III
NEW YORK, STATE UNIVERSITY OF	NY, ALBANY	III
NEW YORK, STATE UNIVERSITY OF	NY, SYRACUSE	VII
NORTH CAROLINA STATE UNIVERSITY	NC, RALEIGH	II, IV
OHIO UNIVERSITY	OH, ATHENS	VII
OHIO MEDICAL COLLEGE	OH, TOLEDO	VII
ORD INC.	MA, NAHANT	V
PAN AMERICAN HEALTH ORGANIZATION	ARG, PERGAMINO	VI
PATHOLOGY ASSOCIATES, INC.	MD, IJAMSVILLE	VII
PENNSYLVANIA, MEDICAL COLLEGE OF	PA, PHILADELPHIA	VII
PHARMATEC	FL, ALACHUA	VII
PHARM-ECO LABORATORIES, INC.	CA, SIMI VALLEY	VII
RESEARCH FOUNDATION OF SUNY	NY, ALBANY	III
RHODE ISLAND, UNIVERSITY OF	RI, KINGSTON	VII
ROCHESTER INSTITUTE OF TECHNOLOGY	NY, ROCHESTER	VII
ROSWELL PARK MEMORIAL INSTITUTE	NY, BUFFALO	VII
SAN FRANCISCO, UNIVERSITY OF	CA, SAN FRANCSICO	VII
SOUTH CAROLINA, UNIVERSITY OF	SC, COLUMBIA	IV, VII
SOUTHERN BIOTECHNOLOGY ASSOCIATION INC.	AL, BIRMINGHAM	VII
SOUTHERN ILLINOIS UNIVERSITY	IL, CARBONDALE	III

ORGANIZATION	LOCATION	RISK ISSUE CATEGORY
SOUTHWEST FOUNDATION FOR BIOMED RESEARCH	TX, SAN ANTONIO	III
ST&E INC.	CA, LIVERMORE	VII
TECHNASSOCIATES, INC.	MD, ROCKVILLE	VII
TELEDYNE	CA, SANTA CLARA	V
TEXAS, UNIVERSITY OF	TX, GALVESTON	I, VII
TEXAS, UNIVERSITY OF	TX, SAN ANTONIO	III
TRANS AMERICAN IMMUNOLOGY	MA, NORTH QUINCY	VII
UNIFORMED SERVICES UNIVERSITY OF HEALTH SCIENCE	MD, BETHESDA	III
UNIVERSAL SENSORS	LA, NEW ORLEANS	V
US ARMY HUMAN ENGINEERING LABORATORY	MD, ABERDEEN PROVING GROUND	VII
US ARMY BIOMEDICAL RESEARCH & DEVELOPMENT LABORATORY	MD, FT DETRICK, FREDERICK	III
US ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY	MD, FT DETRICK, FREDERICK	VII
US ARMY MEDICAL RESEARCH & DEVELOPMENT COMMAND	MD, FT DETRICK, FREDERICK	VII
US ARMY MEDICAL RESEARCH INSTITUTE OF CHEMICAL DEFENSE	MD, EDGEWOOD AREA ABERDEEN PROVING GROUND	III
US ARMY RESEARCH OFFICE	NC, RESEARCH TRIANGLE PARK	VII
UTAH STATE UNIVERSITY	UT, LOGAN	IV, VII
VETERANS ADMINISTRATION MEDICAL CENTER	AZ, TUCSON	IV
VETERANS ADMINISTRATION MEDICAL CENTER	PA, PITTSBURGH	III
VIRGINIA, UNIVERSITY OF	VA, CHARLOTTESVILLE	III

ORGANIZATION	LOCATION	RISK ISSUE CATEGORY
WASHINGTON, UNIVERSITY OF	WA, SEATTLE	III
WASHINGTON UNIVERSITY	MO, ST. LOUIS	II, IV
WISCONSIN, UNIVERSITY OF	WI, MADISON	III
WISTAR INSTITUTE	PA, PHILADELPHIA	IV
WALTER REED ARMY INSTITUTE OF RESEARCH	DC, WASHINGTON	III
WYOMING, UNIVERSITY OF	WY, LARAMIE	III
YALE UNIVERSITY	CT, NEW HAVEN	I

REFERENCES

1. "Department of Health and Human Services, National Institutes of Health, Guidelines for Research Involving Recombinant DNA Molecules" Federal Register (1986) Vol. 51, No. 88, pp 16958-16985.

APPENDIX 4 - ANALYSIS OF PROGRAMMATIC RISKS/ISSUES
CONTENTS

SECTION

1. High hazard organisms

2. Genetically engineered microorganisms

3. Toxins

4. Low hazard organisms

5. Rapid diagnosis and detection

6. Vaccine and drug therapy development

7. Other program research and development activities

1. High Hazard Organisms

1.1 Introduction

A number of factors influence the determination of an appropriate biosafety level for work with a particular organism. Among the factors that must be considered for a given organism are: virulence, pathogenicity, biological stability, route of spread, communicability, nature or function of the laboratory, the procedures and manipulations involving the organism, quantity and concentration of the organism, endemicity of the agent, and availability of effective vaccines or therapeutic measures.

The assignment of microorganisms to the category requiring BL-3 practices, safety equipment, and facilities is based on one of the following criteria, as stated in the CDC-NIH guide (1):

overt laboratory-associated infections have occurred by aerosol route if protective vaccines are not used or are unavailable; or laboratory experience with the organism is inadequate to assess risk and the natural disease in humans is potentially severe, life threatening, or causes residual damage. Similarly, the assignment of an organism to the category of agents requiring BL-4 containment is based on documented cases of severe and frequently fatal naturally occurring human infections and aerosol-transmitted laboratory infections.

The data upon which these classifications of organisms are based were accrued over years of operation of microbiological research and clinical laboratories throughout the world. Since the early 1900's, reports of laboratory-acquired infections have been published in the biomedical literature. Several systematic surveys of laboratory-acquired infections have been conducted in the past 40 years. Efforts initiated under the auspices of the World Health Organization in the late 1950's to codify the taxonomic relationships of the arthropod-borne viruses resulted in the ongoing publication of the "International Catalog of Arboviruses Including Certain Other Viruses of Vertebrates" by The American Society of Tropical Medicine and Hygiene (ASTMH). This Catalog provides descriptions of those viruses biologically transmitted by arthropods in nature (or thought originally to be transmitted by arthropods), and actually or potentially infectious for humans or domestic animals. A subcommittee of ASTMH, the Subcommittee on Arbovirus Laboratory Safety (SALS), assessed documented arbovirus infections of laboratory workers. In 1980, SALS published recommended levels of practices and containment for all viruses listed at that time in the Catalog (I). The SALS committee activities are ongoing; information on newly discovered viruses is evaluated so that appropriate biosafety levels for work with those viruses can be determined.

Certain bacteria and rickettsia are classified as BL-3 or BL-4 organisms on the basis of criteria similar to those applied to viruses, i.e., known laboratory infections, infectivity by the

aerosol route, stability, etc. For virtually all of the bacteria and rickettsia of interest in the BDRP, BL-2 containment and practices are recommended for handling quantities on the order of those used in routine clinical diagnostic procedures. However, BL-3 containment, equipment, and practices are recommended for handling of the same organisms in procedures that potentially create aerosols, or when handling larger quantities.

The viruses, rickettsia, and bacteria used in the BDRP are capable of causing infections in humans, but these infections are not classified as communicable diseases because their natural mode of transmission is not from human to human (see Appendix 7). Representative organisms belonging to the groups classified as requiring BL-3 or BL-4 containment and procedures, for some of the types of procedures conducted with them in the BDRP, include the following:

Rickettsia:	Coxiella burnetii (Q fever)
Bacteria:	*Francisella tularensis* (tularemia, "Rabbit fever") *Bacillus anthracis* (anthrax) *Clostridium botulinum* (produces botulinum toxin)
Viruses:	Chikungunya, tick-borne encephalitis, Hantaan, Rift Valley fever, Venezuelan equine encephalomyelitis, Yellow fever, Junin, Ebola, Crimean-Congo hemorrhagic fever, Lassa, Machupo.

1.2 Types of Studies Conducted Using High Hazard Organisms

Basic research studies of disease pathogenesis of both *in vitro* and animal models are conducted using the organisms described above. In addition, efforts to develop vaccines for these organisms range from basic research to human clinical trials of safety and efficacy. The development of antiviral drugs and therapies similarly involves studies from the basic research level through human clinical trials for efficacy in treatment of viral diseases. Laboratory testing of personal protective materiel, decontamination systems detector methodologies, and rapid identification and diagnosis methodologies requires the limited use of high hazard organisms to verify specificity.

1.3 Rationale for the Use of High Hazard Organisms in the BDRP

Because the primary concerns, from the standpoint of potential biological warfare threats, are organisms such as those listed above, and exposure by small particle aerosol, defensive research and development efforts must employ small quantities of the actual biological materials in order to develop and test the efficacy of vaccines, drugs, and therapies. A vaccine to a simulant or to a "model," low hazard organism or toxin would be of no value to the national defense posture. Similarly, the

ability to detect or to protect against a harmless organism is of little value.

1.4 Environmental, Health and Safety Considerations

As required by the nature of the procedures being performed, studies of high-hazard organisms are conducted in BL-3 and BL-4 laboratory facilities, described in Appendix 12. These "maximum laboratory containment" facilities, equipment, and procedures are recommended in the CDC-NIH guide to biosafety (1), and are explicitly intended to provide protection to the laboratory worker as well as to the human environment in general.

The following vaccines are available (1) and are used to immunize at-risk laboratory personnel:

Q fever vaccine, tularemia vaccine, anthrax vaccine*, pentavalent botulinum toxoid (serotypes ABCDE), Rift Valley fever vaccine, Venezuelan equine encephalomyelitis vaccine (TC-83 and TC-84), Yellow fever vaccine* (17D), vaccinia*, tick-borne encephalitis.

Immune globulin, antibiotics, or antiviral drug treatments are available for use (1,4) in treatment of Q fever, tularemia, anthrax, botulinum intoxication, hemorrhagic fever with renal syndrome (caused by Hantaan virus), Junin hemorrhagic fever, and Lassa fever.

1.5 Waste Materials

A detailed description of the elaborate procedures required for removal and disposal of materials from BL-3 and BL-4 laboratories is presented in Appendix 12. All infectious or potentially infectious materials are killed by autoclaving prior to disposal. All residual botulinum toxin or toxin-containing materials are inactivated with alkali prior to disposal.

1.6 Security

Seed stocks or cultures of BL-3 and BL-4 organisms are stored in multi-walled, leak-proof containers in locked freezers which are in locked rooms located in locked biocontainment laboratories to which access, even to the outer room, is limited to authorized personnel. The security provisions for BL-3 and BL-4 laboratories, described in Appendix 12, apply to the general security for laboratory procedures with "working cultures" of the high hazard organisms.

* Licensed in the US. The other vaccines are available for use as Investigational New Drug (IND) products. Additional vaccines, e.g. Chikungunya (3), are in various stages of development.

1.7 Accidents and Incidents

Handling of highly infectious, pathogenic or exotic organisms always poses a potential risk to laboratory personnel. Thus, biosafety facilities, procedures and equipment, and vaccines, have been developed to minimize these risks. Since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BL-3 and BL-4 BDRP laboratory facilities, although in 1980, one focal infection with F. *tularensis* occurred at the site of a puncture wound. There have been laboratory accidents that resulted in potential exposures; however, prior immunization or immediate treatment with the appropriate therapy have averted the possible development of clinical disease (see Appendix 8). There have never been any occurrences of infections in non-laboratory workers or in the general community arising from organisms handled in BL-3 or BL-4 facilities associated with the BDRP.

1.8 Program Benefits

The development of vaccines, drug therapies, detector methodologies, and rapid identification and diagnosis methodologies for potential biological warfare threat agents enhances the national defense posture with respect to these threats. Because many of the threat agents are also endemic disease hazards in certain areas of the world, the development of protective and therapeutic approaches for these diseases enhances the health status of peacetime forces stationed in such areas. For example, the development of an antiviral therapy for treatment of hemorrhagic fever with renal syndrome (Korean hemorrhagic fever), will potentially contribute significantly to the health and well-being of the local populace as well as to U.S. soldiers stationed in areas of the world where this disease is endemic. The results of the BDRP efforts with high-hazard infectious organisms contribute to a better understanding of the pathogenesis of many exotic diseases on the part of the general scientific community, and to the peoples living in areas of endemic disease caused by these organisms.

2. Genetically Engineered Microorganisms (GEMs)

2.1 Introduction

Genetically engineered microorganisms are derived in the laboratory by removing a fragment of genetic information, a gene, from one organism and "cloning" this fragment into another organism, called the host, which is usually a bacteria or yeast. Cloning refers to a sequence of steps in which the gene of interest is inserted, using special enzymes, into a special, non-chromosomal piece of DNA called a plasmid, or vector. The vector, containing the foreign gene, is introduced into the host cell. Plasmid vectors are not part of the host cell genetic information, but when the host cell divides, the plasmid divides also. Under ideal conditions, the foreign genetic information

carried in the plasmid is then transcribed into RNA, translated into protein, and secreted from the host cell. Another approach is to clone gene fragments of interest into a vaccine virus. Commercial applications of genetic engineering have resulted in the production of biomedical products, such as the hepatitis B subunit vaccine, human growth factor, human insulin, tissue plasminogen activator (TPA), interferon, and diagnostic antibodies, as well as veterinary and agricultural products, such as the swine pseudorabies vaccine and the frost-free *Pseudomonas* bacteria.

Because genes carry information which can be transcribed and expressed as a particular protein, only products that are protein in nature can be cloned. Thus, it is not currently possible to clone molecules that belong to other biochemical classes, such as steroids, alkaloids, fatty acids, carbohydrates, etc. These classes *of* compounds are synthesized in complex series *of* enzymatic reactions and are not simply the product of a single gene.

2.2 Types of Studies Conducted Using GEMs

Within the BDRP, genetic engineering is used in efforts to develop safer and more efficacious viral and bacterial vaccines as well as vaccines *for* protection against protein toxins, such as snake neurotoxins and botulinum neurotoxin. Through years of intensive effort, immunologists have discovered that antibodies, the molecules that fight infections and other foreign compounds introduced into the system, are extremely specific and can recognize even minute portions of a larger foreign molecule. Further studies have revealed that only small portions of the proteins on the surface of a virus, or small portions of a protein toxin, are necessary for the production of antibodies to that virus or toxin. *Thus,* vaccine development efforts focus on identification of those small portions of the viral, bacterial, or toxin proteins responsible for immunity, and on cloning those small immunogenic portions (these are called epitopes) in order to produce quantities that would be useful in the research, development, and testing of new vaccines. Another approach, also used in the BDRP, is to clone the gene fragments coding for important epitopes into the vaccinia virus (smallpox vaccine virus) in the hope of developing a genetically engineered vaccinia vaccine that would confer immunity to two or more other viruses or toxins.

The following organisms and toxins are representative of the focus of BDRP efforts in genetically engineered vaccine development: Rift Valley fever virus, Lassa virus, lymphocytic choriomeningitis virus, yellow fever virus, anthrax (bacteria), botulinum toxin, crotoxin, staphylococcal enterotoxin.

2.3 Rationale for the Use of GEMs in the BDRP

Traditional vaccines used by both the military and civilian medical community fall into one of three categories: live, attenuated vaccines, killed organism vaccines, and inactivated toxin vaccines (toxoids). All three types of vaccines have intrinsic deficiencies. Live, attenuated vaccines cause an asymptomatic infection after administration, but for some vaccines, the rate of subacute and acute infection is undesirably high (e.g., influenza vaccines often produce a mild to serious flu-like syndrome in some recipients). Vaccines prepared from killed organisms often do not produce a highly effective immune response. Inactivated toxin vaccines, or toxoids, are generally prepared from crude materials and many of them are undesirably "reactogenic," meaning that they produce local reactions such as swelling, redness, and soreness at the site of injection. Thus, BDRP scientists use the modern approaches and techniques of genetic engineering in an effort to develop vaccines that obviate the difficulties and deficiencies of the traditional vaccines.

2.4 Environmental, Health, and Safety Considerations

The NIH, in the course of developing of the Guidelines for Research Involving Recombinant DNA Molecules (5,6), published an environmental impact statement (7) and environmental assessments (8) of the potential impacts of research with GEMs (see Appendix 10). In addition, the Recombinant Advisory Committee and other scientists have published documents dealing with risk assessment of the use of recombinant organisms. The conclusions of these assessments and studies are that genetic engineering techniques and GEMs, when utilized under the conditions recommended in the NIH guidelines, present no risk to the human environment. Appendix I of the NIH guidelines (6) describes the physical and biological containment levels recommended for use in recombinant DNA studies; these are also described in Appendix 10. Depending upon the nature of the gene being cloned, and the host-vector system employed, the recommended biocontainment levels for recombinant DNA work are either BL-2 or BL-3. These biosafety levels, discussed in Appendix 12, specify the laboratory facilities, procedures, and equipment appropriate for protection of laboratory workers and the environment from exposure to GEMs.

2.5 Waste Materials

A detailed description of the procedures required for removal and disposal of materials from BL-2 and BL-3 laboratories is presented in Appendix 12. All infectious or potentially infectious or toxic materials are killed by autoclaving or chemical inactivation prior to disposal.

2.6 Security

Seed stocks or cultures of BL-3 organisms used in BDRP studies involving genetic engineering are stored in multi-walled,

leak-proof containers in locked freezers which are in locked rooms located in locked biocontainment laboratories to which access, even to the outer room, is limited to authorized personnel. The security provisions for BL-3 and BL-2 laboratories, described in Appendix 12, apply to the general security for laboratory procedures with "working cultures" of the high and low hazard infectious organisms.

2.7 Accidents and Incidents

Handling of highly infectious, pathogenic, or exotic organisms, including GEMs, always poses a potential risk to laboratory personnel. Thus, biosafety facilities, procedures, and equipment, and vaccines, have been developed to minimize these risks.- Since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BL-2 and BL-3 BDRP laboratory facilities. Although in 1980, one focal infection with F. *tularensis* occurred at the site of a puncture wound. There have been laboratory accidents that resulted in potential exposures; however, prior immunization or immediate treatment with the appropriate therapy have averted the possible development of clinical disease (see Appendix 8). None of these potential exposures have involved GEMs. There have been no occurrences of infections or illness in non-laboratory workers or in the general community arising from infectious microorganisms, toxins or GEMs handled in BL-2 or BL-3 facilities.

2.8 Program Benefits

The development of vaccines effective against potential biological warfare threat agents enhances the national defense posture with respect to these threats. Because many of the threat agents are also endemic disease hazards in certain areas of the world, the development of improved protective vaccines through the use of genetic engineering potentially enhances the health status of peacetime forces stationed in such areas as well as that of the local population. The results of the BDRP efforts with GEMs contribute to the scientific community in the area of vaccine development in general, and specifically in the area of development of vaccines for and understanding the pathogenesis of exotic diseases or toxins.

3. Toxins

3.1 Introduction

The toxins studied in the BDRP are all derived from natural sources, and are thus designated "toxins of biological origin." Unlike many of the non-naturally occurring toxins, those that exist only as a result of chemical synthesis, the toxins of biological origin all exist in some ecological niche. In addition, these toxins are bioorganic molecules. Some are proteins or peptides; others are small alkaloid-like molecules.

All are susceptible to degradation, denaturation or decay, whether within an organism or upon exposure to heat, acids, bases, enzymes or, in some cases, simple dilution. Laboratory work with toxins may pose risks to an individual who becomes exposed accidently to toxic material, but unlike organisms, toxins are not living entities and do not propagate themselves in a host or in the environment. Thus, unlike disease-causing organisms, toxins cannot be transmitted from person-to-person (or animal or insect) (see Appendix 9).

3.2 Types of Studies Conducted Using Toxins

Various toxins are used throughout research, development, and testing activities. Studies conducted include basic research to elucidate the mechanism of action of a particular toxin, preparation of antibodies to a toxin, structural analyses to identify the parts of a toxin responsible for immunity, production of toxoids (inactivated toxins which are not toxic but can elicit an immune response) in support of vaccine development efforts, testing of decontaminants to determine efficacy against toxins, development and testing of methodologies with cellular receptors or antibodies for detection and identification of toxins, and testing of personal protective devices for effectiveness when exposed to toxins.

Representative toxins used in the BDRP include the following: botulinum toxin, anthrax toxin, staphylococcal enterotoxins, plant toxins such as ricin, toxins derived from snake and arachnid venoms, toxins produced by blue-green algae and other marine and fresh water organisms, tetrodotoxin, and trichothecene mycotoxins. Physiologically active compounds, particularly peptide hormones and neuromodulators, are included for consideration in the toxin category because excesses of these compounds can cause physiological imbalances similar to those caused by some toxins.

3.3 Rationale for the Use of Toxins in the BDRP

Toxins have traditionally been identified as significant biological threat agents (9) and thus are the focus of BDRP efforts to develop defensive measures such as vaccines, drugs, and protective materiel.

3.4 Environmental, Health and Safety Considerations

Because toxins are non-living and cannot establish themselves in the natural environment, they pose very little threat to the environment outside of the laboratory. BDRP laboratory workers who handle anthrax or botulinum toxins (or the organisms that produce them) in quantities larger than those which would be encountered in a typical clinical or diagnostic laboratory are immunized with the appropriate toxoid (botulism) or vaccine (anthrax). Although there are no nationally recommended biosafety levels for work with toxins per se, the

CDC-NIH guidelines (1) recommend biosafety level 2 for work conducted with *Clostridium botulinum,* the bacterium that produces the potent botulinum neurotoxin. In addition, appendix F of the NIH Guidelines for Research Involving Recombinant DNA Molecules (6) addresses the appropriate levels of biosafety for use in cloning toxic molecule genes. For the most potent classes of toxins, biosafety levels 2 or 3 are recommended, depending upon the biological containment (host-vector) system used (see Appendix 10). Unless there are procedures that would pose an increased risk to the laboratory worker, such as potential creation of aerosols or work with highly concentrated materials, work with toxins is appropriately conducted in biosafety level 2 laboratories.

3.5 Waste Materials

All laboratory materials containing or exposed to toxins are decontaminated, either chemically or with high heat, prior to disposal.

3.6 Security

Stock quantities of toxins are maintained in locked freezers or refrigerators. For those toxins that are studied within BL-3 laboratories, additional security is provided by the overall security provisions and access restrictions for such areas (see Appendix 12). Most of the toxins studied in the BDRP are available from commercial chemical/biochemical companies that sell research, diagnostic, and clinical reagents to biomedical laboratories. The quantities of any given toxin that are marketed and shipped are marked with appropriate warnings regarding potential biohazards, and are sold only to institutions which appropriately identify themselves as legitimate biomedical organizations.

3.7 Accidents and Incidents

The handling of toxins known to cause disorders in humans always poses a potential risk to laboratory personnel. These risks are minimized by the use of special biosafety facilities, equipment and procedures for those activities that would otherwise cause a high potential for exposure. In laboratories performing basic research studies with toxins, only minute quantities of a particular toxin are in use at any given time, and these small quantities pose virtually no risk to the laboratory workers. While some of the toxins studied, for example, botulinum toxin or tetrodotoxin, are sometimes lethal to man even with medical treatment, most of the toxicoses caused by other toxins can be treated successfully with supportive care and/or drugs which antagonize the action of the particular toxin.

There has been no occurrence in any laboratory worker associated with the BDRP of intoxication or poisoning as a result of handling toxins of biological origin.

3.8 Program Benefits

The development of vaccines and therapeutic drugs for potential biological warfare threat toxins enhances the national defense posture with respect to these threats. The basic research conducted to understand the mechanism of action of many of these toxins contributes to the general scientific community. Methods of detection developed for toxins of interest in the BDRP have many potential applications in the public health arena, where food borne toxins (such as saxitoxin, enterotoxins, botulinum toxin, mycotoxins) often cause serious economic and medical problems. It is of interest to note that one of the most potent toxins known to man, botulinum toxin, has been used successfully as a specific treatment for a disorder of the eye muscles known as blepharospasm. There are active efforts on the part of the biomedical community to develop methods for "targeting" toxins to cancerous cells and tumors, thus harnessing the potent toxicity of these materials for a positive effect.

4. Low Hazard Organisms

4.1 Introduction

The group of microorganisms designated "low hazard" by the CDC includes a broad spectrum of indigenous microorganisms present in the community and associated with human disease of varying severity (e.g., communicable diseases), as well as organisms present in the environment and not known to cause disease in healthy adult humans (1). By definition, the low hazard organisms pose far less potential risk to the workforce and to the environment than the high hazard organisms. Organisms in this category are incorporated into the program whenever they can be used and still give meaningful results. Organisms used as simulants in testing of physical protective devices belong to that class not known to cause disease in healthy adult humans. In addition, the live, attenuated vaccine strains of various hazardous viruses or bacteria are classified as low hazard organisms.

4.2 Types of Studies Conducted with Low Hazard Organisms

Basic research studies of disease pathogenesis using both in vitro and animal models are conducted with many of the low hazard organisms. Laboratory development and testing of personal protective materiel, detector methodologies, and rapid identification and diagnosis methodologies are most often conducted with the low hazard organisms. Clinical trials of live, attenuated vaccines or of the efficacy of an antiviral drug involve the use of low hazard organisms with human volunteers. Such clinical trials are conducted only after a thorough scientific and human use committee review and approval, and only under conditions of informed consent.

Representative low hazard organisms used in the BDRP are: Punta Toro virus, Pichinde virus, Dengue viruses, the live vaccine strains of yellow fever and Venezuelan equine encephalomyelitis viruses (17D and TC83, respectively), Sandfly fever virus, the live vaccine strain of *Franciscella tularensis,* and attenuated strains of *Bacillus anthracis.*

4.3 Rationale for the Use of Low Hazard Organisms in the BDRP

Low hazard organisms are used in BDRP research, development, and testing when the results obtained with such organisms will adequately address the questions posed. Development of experimental and test methodologies is often performed with the low hazard organisms prior to testing with higher hazard organisms. The low hazard organisms require less rigorous containment facilities, equipment, and procedures than the high hazard organisms. Thus, their use allows for reservation of BL-3 or BL-4 facilities and equipment for appropriate uses. The low hazard organisms also, by definition, pose less risk to the workforce and environment, and thus are more safely handled by laboratory staff.

4.4 Environmental, Health and Safety Considerations

The low-hazard organisms are appropriately studied in BL-1 or BL-2 facilities. The recommendations that these organisms and/or strains can be studied safely at Biosafety Levels 1 or 2 are based on adequate historical laboratory experience which indicates that a) no overt laboratory-associated infections have been reported, or b) infections resulted from exposures other than to infectious aerosols, or c) if aerosol exposures are documented, they represent an uncommon route of exposure. It must be reiterated that many organisms that can be handled safely at BL-2 in small quantities by routine procedures still are classified as requiring BL-3 facilities, equipment, and procedures for studies that involve handling of larger quantities of organisms or which potentially generate aerosols. In addition, it is recommended that laboratory workers be immunized with the live, attenuated vaccine strains such as TC-83 (VEE), 17D (yellow fever) or LVS (tularemia) when they are handling these organisms in BL-2 laboratories.

4.5 Waste Materials

Biological wastes of low hazard organisms are routinely killed, inactivated, or decontaminated either by autoclaving (high temperature sterilization) or by chemical decontamination (bleach or Lysol solutions).

4.6 Security

The access restrictions for BL-1 and BL-2 laboratories are described in Appendix 12. Because the low hazard infectious

organisms present only minimal risk to laboratory workers or to the environment, extraordinary security precautions are not warranted.

4.7 Accidents and Incidents

Handling of organisms capable of causing infections in humans always poses a potential risk to laboratory personnel. Thus, biosafety facilities, procedures, and equipment, and vaccines, have been developed to minimize these risks. Since 1971, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BL-1 and BL-2 BDRP laboratory facilities. There have been laboratory accidents which resulted in potential exposures; however, prior immunization-or immediate treatment with the appropriate-therapy have averted the possible development of clinical disease (see Appendix 8). There have never been any occurrences of infections in non-laboratory workers or in the general community arising from organisms handled in BL-1 or BL-2 facilities associated with the BDRP.

4.8 Program Benefits

The development of detector methodologies, rapid identification and diagnosis methodologies, and personal protective materiel for potential biological warfare threat agents enhances the national defense posture with respect to these threats. The results of the BDRP efforts with low hazard organisms contribute to a better understanding of the pathogenesis of many exotic diseases on the part of the general scientific community, and to the development of defensive methodologies and materiel.

5. Rapid Diagnosis and Detection

5.1 Introduction

The development of rapid diagnosis and detection methodologies and equipment is a major identifiable program area that is of overall low risk potential to human health and the environment. The development and design of detection equipment, development of assay systems, and associated use of non-hazardous and non-toxic biological materials is considered in this category.

5.2 Types of Studies Conducted for Rapid Diagnosis and Detection Efforts

Efforts conducted in support of development of rapid diagnosis procedures and detection equipment include the development of prototypes of assay systems, detection methodologies based on biological materials, and remote sensor detection equipment. In the development of assay systems and detection methodologies, efforts are directed toward the

development of reagents, including antibodies, antigens, nucleic acid probes, or receptors attached to inert substrates, and toward the development of sensor systems with the capabilities to detect minute amounts of sample. The reagents, methodologies, and procedures are developed with the goal of detecting potential biological threat materials in clinical specimens as well as in field specimens. The development of rapid diagnosis and detection prototype methodologies and equipment only requires the use of non-infectious materials, for example, antigens (proteins) purified from an organism, or other purified biological materials such as receptors, because the methodologies used do not depend on the growth of an organism. During the development phase, toxoids (inactivated and detoxified toxins) are used to test methods, procedures, and sensitivity of detection systems-. All of the work conducted in support of this program effort is safely conducted in BL-1 or BL-2 facilities.

5.3 Rationale for BDRP Rapid Diagnosis and Detection Efforts

A good defensive posture against potential biological warfare threats includes the development of methods to detect such threats in a field setting, as well as the development of diagnostic systems that could be used to determine, in a timely manner, whether such an attack has occurred. In the case of biological threats that could cause severe disease or toxicosis, the ability to detect or diagnose the threat agent in a timely manner could potentially be a significant consideration to the personnel at risk.

5.4 Environmental, Health and Safety Considerations

Because the development efforts described here do not involve the use of either toxic or infectious materials per se, laboratory workers involved in the rapid diagnosis and detection programs are exposed to little risk beyond that associated with the ordinary commercial or industrial workforce. There are no significant or minor environmental or safety considerations associated with these development efforts.

5.5 Waste Materials

The non-infectious, non-toxic waste materials generated in laboratories involved in rapid diagnosis and detection are disposed of in accordance with routine, accepted procedures for the disposal of general laboratory wastes. Any potentially infectious or toxic materials would be disposed of only after proper sterilization or decontamination as described for low or high hazard organisms, or toxins in the preceding sections.

5.6 Security

The access restrictions for BL-1 and BL-2 laboratories are described in Appendix 12. Because the reagents and materials

used in the development of rapid diagnosis and detection procedures and systems present only minimal risk to laboratory workers or to the environment, extraordinary security precautions are not warranted.

5.7 Accidents and Incidents

There have been no accidents or incidents among laboratory workers, their close associates, or the general community from the biological materials used specifically in the development of rapid diagnosis and detection systems.

5.8 Program Benefits

The development of rapid identification and diagnosis methodologies, and remote and laboratory detection equipment for potential biological warfare threat agents enhances the national defense posture with respect to these threats. The results of the BDRP efforts in rapid diagnosis are of benefit to the general population, as these efforts have resulted in the development of sensitive assays for the identification of various exotic, endemic diseases in clinical specimens. Scientists associated with this portion of the BDRP have, on numerous occasions, shared their expertise, methodologies, and reagents with health scientists in other countries where outbreaks of diseases such as Rift Valley fever have occurred. BDRP scientists provided diagnostic reagents and expertise to assist in the diagnosis and management of a recent outbreak, in U.S. troops stationed in the far East, of hemorrhagic fever with renal syndrome.

6. Vaccine and Drug Therapy Development

6.1 Introduction

This subject area is a major identifiable element of the BDRP in which the potential risks or impacts are of a markedly different nature than those evaluated under the other categories. This subject area includes only the preclinical and clinical testing of potential therapeutic compounds, i.e. antiviral drugs or anti-toxin drugs, immunomodulators, antibodies and vaccines. The other aspects of drug and vaccine development involving use of infectious organisms or toxins are covered under one or more of the other subject area risk/issue categories.

6.2 Types of Studies Conducted in Vaccine and Drug Therapy Development

Preclinical drug or vaccine testing, as the term "preclinical" implies, involves testing only in animals or with *in vitro* laboratory experimental systems. Any "challenge studies", where the efficacy of a drug or vaccine is tested against the disease or toxin of interest, are considered for the purposes of the IAM analysis under the appropriate risk/issue category, i.e. high hazard organisms, low hazard organisms, or

toxins. Phase I clinical trials involve small numbers of human medical research volunteers; the object of a phase I clinical trial being to establish the safety of the drug or vaccine of interest and the appropriate dose ranges. Phase II clinical trials are conducted with relatively small numbers of human volunteer subjects (on the order of tens of individuals) to obtain initial estimates of efficacy by measuring immunogenicity. Phase III clinical trials are conducted in larger numbers of volunteers (on the order of hundreds to thousands) in order to establish statistically significant efficacy data. This phase of testing is not performed at the BDRP primary sites.

Phase III clinical testing of drugs or vaccines is only conducted where and when a target disease occurs naturally. Such human testing is conducted under appropriate controlled conditions meeting the human testing standards of the United States and of the country in which a study may be conducted. There is no introduction of an organism into the environment, and no additional risk to human or environmental health and safety over that which is a result of the occurrence of natural, endemic disease.

Representative vaccines in various stages of development in the BDRP include: the live, attenuated Chikungunya and Junin viral vaccines, an improved anthrax vaccine, an improved Q fever vaccine, and an improved Rift Valley fever vaccine. Efforts to improve the efficacy of existing vaccines or toxoids include developmental studies of microencapsulated vaccine and other immunogen delivery systems. The development effort for drugs effective against viral diseases has advanced to the point where one antiviral drug is in phase II clinical trials. The development effort for drugs effective against the various toxins of interest is still in its infancy, with the effort focused on basic and exploratory research.

6.3 Rationale for BDRP Vaccine and Drug Therapy Development

The goal of the drug development efforts conducted in the BDRP is to identify and develop, for human use, broad-spectrum therapeutic and prophylactic drugs and immunomodulators that would be effective against viruses and toxins. The pharmaceutical industry has, over the years, developed numerous antibiotics, and many of these are effective in treatment of the bacterial and rickettsial diseases studied in the BDRP. The development of antiviral and anti-toxin drugs is in its infancy in comparison to the status of antibiotic development. In addition, the pharmaceutical industry does not place a high priority on development of drugs for treatment of diseases that do not have a significant incidence of occurrence in the United States or other western countries. Thus, the drug discovery effort for the diseases and toxins of interest in the BDRP, which are primarily naturally occurring diseases found in other parts of the world, is undertaken within the BDRP.

Similar considerations pertain to vaccine development. The U.S. pharmaceutical industry is primarily interested in the development of vaccines for communicable diseases prevalent in the United States. The biomedical communities of many of the countries where the viral diseases of interest are endemic are in no position to undertake vaccine development efforts. Because the goal of the BDRP is to provide protection against potential biological warfare threats as well as against endemic diseases to which troops may be exposed, efforts to develop effective vaccines for selected viral diseases are an important part of the program.

6.4 Environmental, Health and Safety Considerations

There is always a finite element of risk involved in testing experimental drugs or vaccines in human volunteers. For this reason, such testing is closely regulated by the NIH, the Food and Drug Administration, and within the DoD. There is no known significant risk to the environment arising from RDT&E activities conducted in support of vaccine and drug therapy development.

6.5 Waste Materials

The only waste materials that could be of concern in vaccine and drug development, other than materials covered in other risk/issue categories such as high and low hazard organisms, would be live, attentuated organism vaccines. Such materials are killed by autoclaving or by chemical inactivation before disposal. Syringes, needles, and other medical supplies that have had direct contact either with bodily fluids or biological materials are disposed of in accordance with standard procedures, i.e. in puncture-proof receptacles, closed waste containers, and autoclaved before disposal.

6.6 Security

Any drugs or vaccines used in studies designed to support an application to the FDA for exemption as an investigational new drug (IND) (or biologic product) are closely controlled, monitored, and accounted for. Access to these materials is limited solely to authorized investigators, and all use of the test materials must be documented thoroughly. An additional security consideration unrelated to environmental issues is that patient medical records and medical records from clinical trials are subject to the provisions of the Privacy Act.

6.7 Accidents and Incidents

There have been no accidents or incidents among laboratory workers, their close associates, or the general community from the biological materials used specifically in vaccine and drug therapy development.

6.8 Program Benefits

The availability of useful drug therapies for treatment of diseases or toxicoses that could be caused by potential biological warfare threat agents would be a great benefit to the national defense posture. The public benefits of this effort are the potential discovery and/or development of vaccines and treatments for diseases and toxicoses that are significant public health problems in many less developed parts of the world.

7. Other Program Research and Development Activities

7.1 Introduction

This category includes those subject areas of the BDRP that do not appropriately fit into one or more of the categories defined previously, that are likely to have imperceptible, if any, program-unique impact on the human or natural environment, and were not discrete subject areas warranting separate consideration.

7.2 Types of Studies Conducted

Examples of the sorts of activities included in this category are literature studies, purification of antibodies from immune plasma or hybridoma cells, growth of cultured animal or insect cells for use in experimental studies, manipulation of mouse spleens and cultured non-human cell lines for the creation of hybridoma cell lines that secrete monoclonal antibodies, purification of proteins or enzymes after isolation from cultures of various organisms, and light and electron microscopy (Microscopy samples are chemically inactivated and embedded in wax or plastic resins). Also included in this category are activities involving the chemical synthesis of potential therapeutic compounds in support of the Vaccine and Drug Therapy Development program area. These efforts are conducted in organic or medicinal chemistry laboratories, and are not considered to be significant or program-unique in that the BDRP-related fraction of this effort on a national scale is infinitesimally small. In addition, the BDRP-supported chemical synthesis efforts are no different in nature from those supported by the pharmaceutical industry, and are many orders of magnitude smaller.

7.3 Rationale for other BDRP Research and Development Activities

Most, if not all, of the activities identified above can be viewed as "support" efforts for the other program areas of the BDRP. As such, they are integral components of the program but do not play a discrete role in defining the BDRP.

7.4 Environmental, Health and Safety Considerations

With the exception of specific considerations for certain laboratory chemicals and reagents employed in these "other activities," there are no BDRP-specific environmental, health or safety considerations that differ in any way from the general considerations for these areas that apply in the public, commercial arena. Certain chemicals used in biomedical studies are classified as explosive, oxidants, flammable, toxic, irritant, corrosive, or biohazardous. The quantities of such materials used within the BDRP are extremely small, on the order of milligrams or grams, or liters, per year. These quantities are on the order of millions of times smaller than those employed in the chemical and pharmaceutical industries, and therefore represent a proportionally miniscule hazard. None of the chemicals used within the BDRP is classified as Surety Materials and therefore do not require coverage by DA chemical surety regulations.

7.5 Waste Materials

Laboratory materials that are non-toxic, uninfectious, and not biohazardous are appropriately disposed of in the ordinary waste stream. Chemicals or substances subject to coverage in the Resource Conservation and Recovery Act (RCRA) regulations (40 C.F.R. 261.5(g) et seq.) are collected, identified, manifested, and disposed of by private contractors specifically licensed under applicable state programs to perform such disposal.

7.6 Security

The facility security provisions employed for the protection of real and personal property provide the appropriate level of security for the materials and activities identified in this program category. Specific storage requirements for volatile or explosive chemicals are mandated by OSHA and NFPA regulations and implemented through institutional safety offices.

7.7 Accidents and Incidents

By and large, the accidents or incidents related to this category of activities are the same sorts as one would encounter in everyday life, for example, getting a cut from broken glass. As described above, the quantities of potentially hazardous chemicals used within the BDRP are so small that only extremely localized effects could arise from any accident or incident. The only possible hazard would be to the laboratory worker.

7.8 Program Benefits

In that the activities described here support other BDRP functions, they contribute to the overall benefits of the BDRP in the areas of national defense posture, contributions to the scientific community, and to public health.

References Cited in Appendix 4

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APPENDIX 5 - SITE SPECIFIC INFORMATION

1. Environment of Affected Locations

2. Primary Sites

2.1 USAMRIID
2.2 CRDEC
2.3 DPG

3. Secondary Sites

3.1 Jefferson Medical College
3.2 Salk Institute (Govt. Services Div.)
3.3 Scripps Clinic and Foundation
3.4 Salk Institute
3.5 Southern Research Institute
3.6 SRI International
3.7 University of Massachusetts
3.8 Wadsworth Center for Laboratories & Research
3.9 Wright State University

Reference Materials Consulted

APPENDIX 5: SITE SPECIFIC INFORMATION

1. The Environment of Affected Locations

1.1 Introduction

The primary focus of this FEIS is on the BDRP as a program. As an ongoing program, however, site specific information about the sites of program execution is desirable in order to address potential impacts which may vary depending upon site characteristics. This information serves to assist a reviewer to relate more closely to the actual conditions at a specific location. For example, unique characteristics of a geographic area would be important if BDRP activities, or the absence thereof, could have an impact on the resources identified as being sensitive or otherwise important. Site specific information may also be used to establish the basis for absence of need for concern at a particular locale. It is in this context that site specific information is presented on selected areas where BDRP activities are conducted.

Information about selected aspects of the environment of the locations individually examined in this FEIS was presented in Sections 5.3 and 5.4. There, it was stated that "Examination of the environment in this section is limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. Areas of the environment not believed to have any possibility of being significantly affected are not discussed." This appendix provides a more complete presentation of the environmental setting of the primary and selected secondary locations where BDRP research is conducted. The paragraphs following will present additional information about the environments of BDRP research, and will include many elements of the environment which are not likely to be affected by any BDRP activities.

1.2 Primary vs. Secondary Sites

For the purposes of this EIS the sites have been categorized as primary sites and secondary sites. The primary sites are existing Department of Army Facilities which have been involved in various aspects of the BDRP for a number of years and would be expected to remain as part of the program if it continues. Program management responsibilities reside with the Primary sites. The secondary sites generally represent less integral components of the BDRP. In addition, the secondary sites change frequently because they are supported by extramural funding arrangements lasting from one to five years.

The secondary sites selected for examination are representative of the range of sites which conduct research and development studies classed on the risk/issue categories high hazard organisms, genetically engineered microorganisms, and toxins. (See section 3 and Appendix 3 for discussion of these categories).

The secondary site program activities are conducted at existing facilities which will continue to operate with or without BURP funding. In some situations, funding from other sources might be required to keep certain facilities operational; however, in most instances the BDRP represents a very minor component of the overall funding levels and research efforts underway at the various locations associated with the program. Therefore, more information is presented on the Primary sites than on the Secondary sites. If more detailed information is desired for a particular location, it is available in referenced documents or other publications available to the general public.

2. Primary Sites

The three primary sites are: 1) U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Maryland; 2) U.S. Army Chemical Research, Development, and Engineering Center (CRDEC) Aberdeen Proving Ground (APG), Maryland; and 3) U.S. Army Dugway Proving Ground (DPG), Utah.

2.1 USAMRIID

This organization is physically located in Buildings 1425 and 1412 on Fort Detrick in Frederick, MD. The relevant areas of concern which are believed to have some possibility of being affected are discussed in section 5.3.1. The material below describes USAMRIID's general environment, including many aspects not believed to have any likelihood of being affected.

2.1.1 Land Use -- The existing land use pattern at Fort Detrick conforms to the future plans for development within Frederick County (1). The Fort Detrick Environmental Assessment (2) discusses the current and projected land use policies on post. Fort Detrick is not located in any floodplain or wetland area of the state. The nature of the area surrounding Fort Detrick is agricultural, commercial, and residential. There are recreational facilities on post for the use of military and civilian personnel and athletic teams from the Frederick county community. USAMRIID is not in conflict with local land use policy.

2.1.2 Plant and Animal Ecology -- A more complete description of the natural habitat of Fort Detrick is given in the current Fort Detrick Environmental Assessment {2) and in the Fort Detrick Natural Resources Management Plan (3). There have been no identified endangered species at Fort Detrick. USAMRIID therefore exerts no adverse impacts on any species listed as endangered or threatened by the U.S. Department of the Interior.

2.1.3 Geology -- The current Fort Detrick Environmental Assessment (2) provides additional information concerning soils, topography, and erosion for Fort Detrick. USAMRIID has no impact on the soils and geology of the area.

2.1.4 Water -- The water quality and quantity at Fort Detrick is good. The current Fort Detrick Environmental Assessment (2) describes in detail the effect of daily post activities on the local water quality. Waste water from USAMRIID includes both laboratory and general waste water discharges. Laboratory wastewater includes all drainage from containment laboratories and associated preparation areas. It is heattreated to remove all biological activity. General waste water discharge includes non-contaminated laboratory waste water and sanitary sewer discharges. General waste water, about 35 per cent of the total waste water, is discharged directly into the Ft. Detrick sanitary sewer system. USAMRIID research operations have no significant adverse effect on surface or ground waters.

2.1.5 Air Quality -- The air quality at Fort Detrick is good, as is that of Frederick County in general. The prevailing rural character of the area, and the lack of old industrial areas in the region, are principal reasons for the current air quality. The city and installation are located in the Mid Maryland Air Quality Control Region (AQCR), which is presently meeting all ambient standards. The current Fort Detrick Environmental Assessment describes in detail the effect of daily post activities on local air quality. Incinerators are operated within legal limits for stationary emission sources detailed in Federal, state, and local regulations and conform to the requirements and intent of the Clean Air Act of 1963 [Title 42 U.S. Code 7401-7642] and its amendments in 1970 [Public Law (PL) No. 91- 604, 84 Stat 1676] and in 1977 [PL No. 95-95, 91 Stat 685]. Approximately 500 cubic yards of burnable waste is generated for incineration per month from the USAMRIID facility.

Because natural gas is available for use in firing boilers, there is a reduced level of particulate emissions from the stacks as compared to coal- and fuel-oil fired boilers used in the past at Fort Detrick. The boilers operate within legal limits for new stationary emission sources detailed in Federal, state, and local regulations and conform to the requirements and intent of the Clean Air Act and its amendments. Stack emissions are well below the levels requiring a permit in the state of Maryland.

The exhaust air from the high hazard containment laboratories is filtered through double high efficiency particulate air (HEPA) filters which remove minute particles from the air passing through the laboratory exhaust stacks. Filter chambers are designed for in situ decontamination prior to routine maintenance and replacement of the filters. Such environmental controls by HEPA filters at USAMRIID serve as a model for all facilities of this type in the world today. The safety record at USAMRIID and Fort Detrick is testimony to the excellence in maintenance and operation of these containment facilities "Appendices 8 and 12).

Air emission limits for volatile organic, hazardous, and toxic compounds meet both Fort Detrick and Maryland state

standards. The Maximum Credible Event (MCE) line remains within the walls of the USAMRIID due to the modern containment systems, hoods, HEPA air filters, and limited research quantities of hazardous materials on site (Appendix 9). High hazard toxins and recombinant and natural biological organisms are handled at the highest levels of safety and containment meeting or exceeding all Federal, state, local, and post regulations.

Vehicular Emissions -- A potential source of adverse air emissions into the environment is the vehicular traffic in the vicinity associated with the research complex. USAMRIID is the destination of approximately 500 light-duty vehicles on any given day. These vehicles are a minor component (10%) of current on post traffic flow of approximately 5400 vehicles per day and about 1% of the traffic flows in the immediate vicinity of Fort Detrick. These are approximately 41,000 vehicles per day on U.S. Highway 40, 45,000 on U.S. Highway 15, 15,000 on Rosemont Avenue, 7500 on Yellow Spring Road, and 2900 on Opossumtown Pike. The environmental impact of the USAMRIID traffic and the concomitant vehicular emissions in the Fort Detrick area is insignificant.

2.1.6 Agriculture

Frederick County is an active participant in the Maryland Agricultural Land Preservation Program, with 81 farms totaling over 13,000 acres included as of 1987. The closest of these parcels is approximately two miles direct distance from Ft. Detrick, with considerable intervening residential and commercial development.

a. Crops -- USAMRIID research operations under the BDRP involve no crops or plant pathogens.

b. Livestock -- USAMRIID operates a large-animal farm to support research requirements. Research on these animals is not conducted at this location.

2.1.7 Cultural Resources

a. Historical -- There are four facilities on Fort Detrick officially entered on the National Register of Historic Places. A discussion of these is included in the current Fort Detrick Environmental Assessment (2). The USAMRIID research complex is located more than one-quarter mile from any of the historic features on Fort Detrick.

b. Archaeological -- An archaeological survey has not been performed on Fort Detrick. No sites of archaeological importance have been uncovered on post in the course of past construction and maintenance activities. Uncovering of archaeological artifacts in this area would seem unlikely since the land was farmed for almost 200 years prior to establishment of Detrick Field in 1930.

2.1.8 Energy Resources -- Depletable resources consumed include natural gas, fuel oil, and electricity. USAMRIID uses natural gas directly in its research laboratories. Indirectly heat is provided from a central Fort Detrick boiler facility which is fired by natural gas and fuel oil. The Fort Detrick Environmental Assessment (2) describes this boiler facility. The source of electricity used to operate the USAMRIID physical plant is Potomac-Edison.

2.1.9 Sociological Environment

a. Demographic -- Frederick County had a reported 1980 population of 114,792, and a 1987 estimated population of from 132,500 (35) to about 138,700 (18) depending on the source of the estimate. Proportions of population by race in 1980 were: White - 93.6%; Black - 5.5%; Asian, Native American and others not recorded - 0.8%. There are approximately 45,000 households in Frederick County, with an average annual income of $36,000 per household estimated for 1987 by the Economic Impact Forecast System (EIFS) system (35).

According to a 1987 projection, the City of Frederick has increased in population to about 36,000, an increase over the 1980 census of about 30% (18). Population increases have averaged 3% to 4% per year for the period 1983 to present (18). The three census tracts immediately surrounding Ft. Detrick are estimated to have averaged more than 25% increase in population between 1980 and 1987, and are also estimated to have added more than 1500 new households during this 7 year period (35).

b. Aesthetics -- Any assessment of visual or aesthetic effects is, by its very nature, subjective. Factors influencing such an assessment include the existing viewscape of the site, the nature of the proposed change to the visual environment, and the sensitivity of the surrounding area. The USAMRIID building complex construction criteria included design considerations which conformed to post expansion plans and the architectural style of both existing and projected structures.

2.1.10 Noise -- Vehicular noise generation is insignificant, with approximately 500 vehicles per day in the USAMRIID research complex. Noise during facility operations is produced by generator and air handling equipment. The initial design of the USAMRIID physical plant and its operational control, coupled with the significant distance to residential and other governmental activities, effectively mutes any significant operational noise.

2.1.11 Odors -- The Fort Detrick Environmental Assessment (2) describes current local conditions. USAMRIID odor-generating activities, such as chemical decontamination of containment laboratories, autoclaving of contaminated culture media, and handling of animal wastes and bedding, are restricted to the areas within the research laboratory and animal holding

areas of the facility. Because the design of the building facilitates a directed airflow, odors do not permeate the atmosphere outside these areas. Also, because normally decontamination operations are scheduled after regular duty hours when possible, employee exposure to odors within these areas is minimized. USAMRIID does not generate uncontrollable, objectionable odors during research operations.

2.1.12 Economic Environment

a. Labor Force -- The number of employed persons in the immediate region (Frederick County) has been increasing in recent years, both through increased opportunity for local employment and through increased commuter access to the Washington, DC area. The employment level is approximately 69,000 persons according to the US Bureau of Labor Statistics and the State of Maryland (36). This number has varied considerably from year to year from 1969 to the present, with a loss of 3.8% in 1975 and a gain of 4.9% in 1978. In 1985, however, almost 20,000 persons were added to the official count through a combination of changes in the definition of an employed person and actual population growth, an increase of over 40%. The county unemployment rate was 3.1% in December, 1987, slightly above the average for the Maryland portion of the Washington, DC area (2.7%), but comparing favorably to the figures for the entire state of Maryland (4.2%) and the U.S. total (6.3%) (36).

b. Economic Activity -- Local personal income, as reported by the EIFS (35), is approximately 1.5 billion dollars. County non- farm business volume reported by the EIFS is approximately 600 million dollars annually.

c. Property Values -- The county had a pool, in 1980, of about 39,500 housing units. This has since been substantially supplemented. The (1980) aggregate value of al} owner-occupied units was $1.4 billion, an average of slightly less than $63,000 per unit. (35)

2.1.13 Public Opinion

a. Controversial Issues -- The general discussion for this impact area has been covered previously under the BDRP national environment (section 5.2.1.3). There are no site-specific controversial issues related to USAMRIID apart from the existence of the total program. A historical perspective of the BDRP is presented in the definition of the program in section 2, and in Appendix 8. The precedence for defensive (medical) hazardous biological organism and toxin research by the U.S. Army Medical Department has its origin with the creation on 20 June 1956 of a small medical research unit which is now known as USAMRIID. USAMRIID's mission is to develop strategies, products, information, procedures, and training for medical defense against

biological warfare agents and naturally occurring diseases of military importance.

To support that mission with the most modern research facility available at the time, Building 1425 was constructed and became operational in December 1971. This facility, which contains modern laboratory suites with BL-3 and BL-4 high-hazard containment capabilities, represented the latest in functional concepts, laboratory design, and safety. Safety features built into these laboratories permit studies of these pathogenic disease organisms with minimal threat to research investigators and technicians, and complete safety for the surrounding community. Among the many safety features are the six, sealed biological safety cabinet systems, ultraviolet light barriers, personnel safety suits, autoclaves, differential negative air balance systems, redundant high efficiency filtration of exhaust air, and special clothing change rooms. The special feature microbiological laboratories provide a unique resource among laboratories in the free world for the safe study of highly virulent diseases. USAMRIID has grown in stature over the past 20 years into a nationally and internationally recognized center for military medical and biological research. The USAMRIID high hazard containment facilities were the model used in the development of the physical containment recommendations in the NIH Guidelines for Recombinant DNA Research.

Currently, USAMRIID has active infectious organism and toxin research programs investigating both high and low molecular weight toxins. The high molecular weight toxins of interest include botulinum toxin, the staphylococcus enterotoxins, and snake neurotoxins from the cobra and the rattlesnake. The low molecular weight toxins include the trichothecene mycotoxins, blue green algae, and the marine toxins (saxitoxin and tetrodotoxin). All of these research activities are governed by the provisions of the BWC, and research results are routinely published in the open scientific literature.

USAMRIID has become a center for excellence in toxin research and for developing diagnostic reagents, vaccines, and prophylactic and therapeutic compounds. With the experience of the research and safety staff at USAMRIID to draw upon for the careful design of experiments and with the review of r DNA research protocols by the USAMRIID IBC, operation of the facility according to the requirements and the intention of the BWC is assured. Relatively small, justifiable quantities of toxins (from several milligrams to a few grams) are required for the physical, biochemical, pharmacological, toxicological, immunological, physiological, and microbiological studies designed to determine the structure, function, and mode of action of the toxins and the efficacy of materiel and compounds developed for rapid detection, prophylaxis, and therapy. These toxins are extracted from the appropriate biological samples or synthesized, either at USAMRIID or by contractors, if not already available for purchase from commercial sources. Any

transportation of toxin or toxin containing biological materials to or from USAMRIID conforms to the requirements and intent of all applicable U.S. Department of Transportation, state, and local regulations governing the shipment of hazardous materials See Appendix 2.

b. Social Concerns -- The hazardous wastes currently generated by Fort Detrick research activities include radioactive liquids and solids, infectious pathological materials, chemicals, solvents, and toxins. The Fort Detrick Environmental Assessment (2) details the method of disposal and the effect of these activities on the environment.

The USAMRIID research facilities have been designed with criteria to ensure safe and secure storage, handling, use, and disposal of hazardous wastes. The disposal of hazardous wastes meet applicable Federal, state, local, and Fort Detrick regulations. USAMRIID contributes minimally to the hazardous waste inventory (estimated 28 pounds per month), and consequently does not significantly increase that inventory at Fort Detrick. Hazardous waste management operations are specified in Ft. Detrick safety regulations and these meet all environmental provisions necessary for safe and lawful operation of the facility and for the disposal of hazardous waste that is generated. USAMRIID complies with the specifics and the intent of the Resource Conservation and Recovery Act regulations governing conditionally exempt small quantity generators (40 CFR 261.5(g), and all applicable state and local requirements.

2.1.14 Transportation

a. Road -- Ft. Detrick is located on the northern side of the present city of Frederick, northwest of the older city center. Several minor arterial streets, including 7th Street, Rosemont Ave. and Opossumtown Pike provide access to the installation from three sides.

b. Rail -- The city of Frederick is served by the CSX lines which provide connections for freight to the North American rail net. No passenger rail service is available in the immediate vicinity of Frederick or Ft. Detrick. Passenger trains on the State of Maryland MARC line and Amtrak passenger service run through the extreme southern end of Frederick County, providing service at Brunswick and Point of Rocks to the Washington, DC area and Harper's Ferry, WV, and beyond.

c. Air -- Commercial airline service is indirectly available to the Frederick area through the massive service provided for the Washington, DC metropolitan area. Frederick is approximately equidistant from Dulles Airport, Chantilly, VA, Baltimore- International Airport, and Washington National Airport. Each is roughly one-hour's travel time, and the actual highway distances are from 45 to 60 miles.

d. Traffic -- The transportation needs of Ft. Detrick are well served by the existing highway access system with three primary points of entry to the post, at the northern, southern, and eastern boundaries. Frederick County has made plans to improve existing roads and to build new roads to meet the current and anticipated needs of the region.

Of particular interest to Fort Detrick was the upgrading of Opossumtown Pike to a major arterial from Frederick to Bethel in the north. Rosemont Avenue continues to serve as a minor arterial for areas north of the post with a new connection to Oppossumtown Pike near Bethel. Shookstown Road is also planned to be a minor arterial for developing residential areas north and west of post. No new entrances to Ft. Detrick are planned and traffic patterns to and from post will not change significantly.

The USAMRIID building complex brings approximately 500 light-duty vehicles to the area daily. These vehicles have a minimal effect upon the traffic patterns on Fort Detrick and the adjacent communities.

2.2 CRDEC

The U. S. Army Chemical Research, Development and Engineering Center (CRDEC) is located in the Edgewood Area of Aberdeen Proving Ground (APG) in Harford County near Edgewood, MD, about 25 miles northeast of downtown Baltimore. It is the largest of several Army tenants of this portion of the installation, and occupies laboratory, office and storage space in over 200 buildings. The BDRP portion of the CRDEC mission is to develop detection and personal protection equipment for use by troops in the battlefield.

Examination of the environment in Section 5.3.2 was limited to those areas determined, by examination of the nature of the research, to have some potential to be affected by the BDRP. Areas of the environment not believed to have any possibility of being significantly affected were not discussed. Here in Appendix 5 is a somewhat more complete description of CRDEC and its BDRP research-related health and safety provisions, including many aspects of the environment which are not believed to have any potential whatsoever to be affected.

Significantly more information and analysis on the APG environment and CRDEC activities may be found in two separate documents specifically prepared to meet other NEPA requirements. They are the Operational Environmental Assessment for CRDEC, which was published in September, 1988 (33) and the Installation Environmental Impact Assessment prepared by Aberdeen Proving Ground in March, 1978 (32). The operational EA examines, in considerable detail, the ongoing activities of CRDEC, including those related to the BDRP. Much of the biophysical environment of the area is stable, and is adequately examined in the APG EA.

2.2.1 Land Use -- CRDEC utilizes more than 200 buildings in the Edgewood area of APG, and is the largest of several tenants in this area (33). The peninsula that forms the Edgewood area is low-lying, generally less than 50 feet above sea level. Most structures are placed at the northern (landward) portion of this peninsula. The southern (lower) portion is largely unbuilt, and is used only for tests or storage. No use is made of these fields for any BDRP purpose.

2.2.2 Plant and Animal Ecology -- The less-used portions of the Edgewood area support a relatively rich flora and fauna. Habitats available may be characterized broadly as open fields, tidal marsh, swamp, and moist deciduous forest. All upland areas were severely disturbed in the 18th and l9th centuries, and all forested areas are probably third-growth at best. Plants and animals are typical of those in abandoned or reversion habitats along Chesapeake Bay. With one exception, no endangered or threatened species is known to inhabit the APG (32,33). One pair of bald eagles nests in a remote portion of the Edgewood area, and other eagles have been observed feeding and roosting along the shoreline.

2.2.3 Geology -- This portion of the state is seismically uninteresting. Deep layers of sediments cover the bedrock, and major earth movements are unknown. Soils of the region are well-drained to saturated, and may be characterized as loams and silt loams (33).

2.2.4 Water -- APG water is obtained from a combination of surface water and wells. The Edgewood area uses surface water treated in a government-owned plant. The production is approximately 2.5 million gallons per day, with considerable reserve capacity available (32,33).

2.2.5 Air Quality -- The installation is located in the Greater Baltimore AQCR. The region, as a whole, has had problems meeting ambient standards for photochemical oxidants. APG is several miles from the edge of the metropolitan area, and does not contribute significantly to this problem. No activities associated with the BDRP appear to be related to air quality problems of the installation or the region.

2.2.6 Agriculture

a. Crops -- The western portions of Harford County retain considerable agricultural activity. The portions south and east of I-95, within 2 to 4 miles of APG, have been mostly urbanized, and crops are now only a small portion of the local economy.

b. Livestock -- A few, very small herds of livestock are still located relatively close to APG. Continued development and

urbanization has largely driven this type of industry out of business or to the northwest part of the county.

2.2.7 Cultural Resources

a. Historical -- The general Harford County area contains more than 100 registered historic sites, reflective of the rich heritage of that part of Maryland. Two listed structures are located within the Edgewood area of APG (32,33); neither is used or affected by CRDEC activities in any way other than the possibility that an officer posted to CRDEC might be assigned to the Quite Lodge, which is used for officer's housing.

b. Archaeological -- The shores of the Chesapeake Bay are rich in evidence of past cultures. Many of the oldest are imprecisely known, while pre-Colonial and Colonial period artifacts are abundant. Some specific, professional reconnaissance has been made of the sites with the most potential. No activities of CRDEC which may be related to the BDRP have the potential to affect any known sites (32,33).

2.2.8 Energy Resources -- The major consumption of energy is as electricity and heat. All electricity is purchased from the Baltimore Gas and Electric Company. Heat is provided by numerous boiler plants through all areas of the installation. These plants burn low-sulfur #2 fuel oil (32). CRDEC is the major consumer of both types of energy in the Edgewood area.

2.2.9 Sociological Environment

a. Demographic -- Harford County had a 1980 population of 145,930 persons, 38,654 families, 46,547 households, and a pool of 49,346 housing units. Distribution by race was White -90%; Black - 8.3%: Asian - 0.8%; and others, including Native Americans and those unrecorded - 0.7%. A 1983 update continues a pattern from 1978-83 of small annual gains in population following a period (1966-78) of much larger regular gains (35).

b. Aesthetics -- The APG natural setting, especially in the Edgewood Area, is one of low-lying fields and forest bordered by the waters of Chesapeake Bay. Historically, the area was one of small, poor farms, many of which had been abandoned. Much of the older facility construction was expedient, and remains functional, and in good repair, if architecturally uninspiring. Army policy calls for replacement of older structures as allowed by budgetary constraints, and newer construction is considerably more pleasing to the eye. A large proportion of the APG setting, however, has never been significantly disturbed by Army uses, and remains attractive and tranquil. Water views are generally superb, regardless of the season.

2.2.10 Noise -- The many test and evaluation activities of the APG generate considerable impulse and machine noise during the times when testing is active. Artillery and tank gunnery

tests are obtrusive to locally disturbing at times, especially in the Aberdeen area. Engine noise from tested vehicles is more localized and somewhat less obtrusive. Both types of activity are less evident in the Edgewood area where CRDEC is located, and none of these types of noise generating activities are related to the BDRP.

2.2.11 Odors -- No BDRP activities routinely generate objectionable odors.

2.2.12 Economic Environment

a. Labor Force -- The number of employed persons in Harford County was estimated in 1984 to be over 55,000, with a pat-tern of steady increase after a 1980 slump (35).

b. Economic Activity -- County business volume, the total of all goods and services produced, was about $782 million per year in 1983. The pattern over 1965-83 is generally steady, with a large increase in volume in 1983 as compared to a large loss in 1979. Personal income has showed similar fluctuations, with variations of + or - 5% per year common (35).

c. Property Values -- The 1980 census showed a total of over 49,000 housing units in the county, and about 2,800 vacancies. Owner-occupied homes had an aggregate value of over S1.7 billion, and an average valuation at that time of about $65,000 (35).

2.2.13 Public Opinion

Controversial Issues -- The Aberdeen Proving Ground has been the site of chemical development, testing and instruction for many decades. It is acknowledged that the standards considered suitable in past decades for disposal of many of these chemical waste products are now unacceptable in many cases. Several issues not intrinsically related to the BDRP have recently received attention. One of these is the Record of Decision following the Final EIS for the disposal of the stockpile of chemical weapons. This decision defined destruction in place as the Army's preferred alternative. One of the locations with a stockpile is APG, thus focusing considerable attention on the location in early 1988.

Another area of concern involves recent actions by the State of Maryland, which have categorized the residues of chemical detoxification as hazardous wastes. Disposal of wastes has traditionally been by incineration in a CRDEC incinerator maintained specifically for this purpose. Under state regulations, this is no longer possible; neither is continued storage of the residues an option. CRDEC, APG and Maryland officials are examining several possible short- and long-term solutions. Additionally, several locations on APG have been identified where past chemical contamination, including some due to past disposal of chemical wastes, is potentially a source of

contaminated surface and groundwater. One area has been listed on EPA's National Priorities List, and will be cleaned up under the Defense Environmental Restoration Program. Other sites are still under detailed examination to determine the type and extent of the problem. None of these problems is related in any way to BDRP activities.

b. Social Concerns -- No outdoor tests conducted at the CRDEC facilities on Aberdeen Proving Ground involve biological materials. Limited indoor tests involving small quantities of toxins and biological simulants, such as non-pathogenic bacteria and killed viruses, are performed. Laboratory-scale testing of technology for detector and warning devices requires use of extremely small amounts of certain toxins. All indoor testing uses minimal quantities of the materials, and takes place in biological safety cabinets equipped with high efficiency particulate filters.

2.2.14 Transportation

a. Road -- The APG area is abundantly served by some of the most-traveled highways in northeast Maryland. US 40 crosses Harford county, roughly paralleling the northwestern edge of APG, but at a distance of 2 to 4 miles. Interstate 95 lies northwest of US 40. Both provide long-distance northeast-southwest access to all major metropolitan areas in the United States. APG, itself, has six access roads, all corresponding to improved state highways. A majority of these trend roughly northwest, crossing and providing commuting access to US 40, I-95, and the western part of Harford County.

b. Rail -- Extensive rail service is available via Conrail main lines paralleling US 40. Freight service is available to APG on Army-owned tracks, with yard space for about 50 cars (32). Limited Amtrak passenger service is available from Aberdeen on the northeast corridor between Washington, DC and Boston.

c. Air -- Commercial passenger service is provided by Baltimore-Washington International Airport, about 40 miles southwest of APG and 14 miles south of Baltimore. Military aircraft use two airfields on APG, one in the Aberdeen area and one in the Edgewood area (32)

d. Traffic -- There are no traffic flow problems in Harford County that require immediate remediation. Traffic flows through the six entrances to APG range from about 15,000 vehicles per day on Maryland Route 22 down to about 2,100 per day on Maryland Route 152, near the Edgewood area.

2.2.15 Human Health

a. Workforce -- The CRDEC has developed extensive protocols for personal and environmental safety in the handling of

chemicals, toxins and hazardous materials, and their laboratory and test personnel may be considered well experienced in managing safety procedures. SOPs have also been developed for laboratory bench and safety cabinet procedures with microbiological organisms, and for storage and handling of biological toxins. All SOP's undergo continuous review and revision.

b. General Population -- The location of CRDEC in the Edgewood area, away from the largest adjacent population centers, provides a large measure of separation between Army activities and civilian populations(33). In any case, activities related to the BDRP do not involve hazardous pathogenic organisms, use only minute quantities of toxins, and are totally conducted within biological safety cabinets within enclosed buildings. There can be only the slightest health risk to CRDEC personnel actually conducting research and tests, and none at all to the general public.

2.3 DPG

The Life Sciences Division of the Materiel Test Directorate (MTD) of Dugway Proving Ground (DPG) has facilities located in the Baker Laboratory Complex. Dugway Proving Ground is under the command of the U.S. Army Test and Evaluation Command (TECOM). The discussion which follows relates either to the entire Army installation, of which the MTD is one component, or to the facilities of the MTD, itself. A Draft EIS for a proposed Biological Aerosol Test Facility, released in February, 1988, contains considerable additional detail on the DPG environment (19).

The purpose, or mission, of DPG is to perform developmental testing on 1) Chemical Warfare (COO) equipment, 2) flame, incendiary and smoke obscurant systems, and Chemical-Biological Defense (CBD) equipment. Of these, only the biological aspects of the CBD equipment testing fall within the scope of this DEIS. DPG is the only DoD testing facility in the United States equipped to perform these tasks on the large scale considered necessary to assure reliable testing under realistic conditions.

2.3.1 Land Use

a. Setting -- The Baker Laboratory Complex is located about 70 air miles southwest of Salt Lake City, UT, in Tooele County. The DPG encompasses slightly more than 800,000 acres. This is a sparsely populated region, averaging only approximately six people per square mile (19,20). The area exhibits the dominant environmental conditions of a Great Basin, high-altitude desert with hot dry summers and cold dry winters. Development on DPG is relatively limited, with only 299 acres improved for use for resident housing and facilities (English Village) and 536 acres which are semi-improved land. The remaining land is in its natural state except where disturbances, generally minor and

temporary in nature, have occurred due to troop training and maneuvers or testing activities.

b. Background -- Early in 1942, in response to an identified need to test military weapons as part of the war effort, DPG was established on lands withdrawn from the public domain. Facilities were constructed expeditiously and testing commenced in the summer of 1942. Biological warfare facilities were established in 1943. Following World War II, DPG was essentially inactive for a few years until reactivated in 1951 (20). Additional biological facilities were added and various improvements have been instituted over the ensuing years. Tests conducted specifically for biological purposes have been, since 1968, only a very small part of the ongoing mission of the DPG.

2.3.2 Plant and Animal Ecology -- Even though initial site selection was made many years prior to the enactment of NEPA, concern for protection of the populace and sensitivity to environmental matters were exhibited by the selection of a remote site with a relative scarcity of wildlife that could be adversely impacted by testing activities. An active ecological epidemiological surveillance program has been in effect since 1952 for the express purpose of detecting any adverse effects which might have resulted from the tests which were carried out (19).

From a biological perspective, the scientific evidence supports the conclusion that there have been no effects. Long term comprehensive investigations have been conducted on selected aspects of the flora and fauna of the DPG environs to ascertain what effects testing activities, including BD, may have created or induced. For example, the comparative incidences of selected diseases in various animals were statistically analyzed utilizing both on-and off-site data. In general, the incidence of disease was similar for both populations. Exceptions that did occur may be attributable to natural causes. Also, black-tailed jack rabbit *(Lepus californicus)* population dynamics have been studied in great detail in recent years. These studies demonstrate that military activities have not measurably influenced changes in jack rabbit population density. Information is also available on disease vectors and zoonotic infection (diseases transmissible between animals and from animals to humans).

A series of investigations has revealed no adverse trends in wildlife diseases. In fact, the incidence of zoonotic infection at DPG has been extremely low. For example, tularemia (rabbit fever) was 4 to 10 times less prevalent in Utah than in the states of Arkansas, Missouri, and Oklahoma over a recent five year period. Consideration of the biophysical characteristics of the area, in concert with data on diseases, provides insight as to the effect biological testing over the past 45 years may have produced (19,20). No relatable adverse implications are apparent.

2.3.3 Geology -- DPG is located within the Great Basin, where the main features are north-south trending mountains with broad, shallow valleys. Elevations in the Dugway Valley are in the range of 1300 to 1500 meters (about 4300 to 5000 feet) above sea level. Mountains to the west and east rise to about 3500 m (11,000 feet) and 3300 m (10,000 feet), respectively. The Great Salt Lake Desert lies directly north of the western portions of DPG. The mountain ranges are of fault-block origin, and dip slightly to the west (19,20).

Soils of the area are typically poor, dry and saline. Many playas and claypans are found in zones of internal drainage where salts have collected as temporary ponds evaporated. Higher elevation soils may be coarser and relatively free from salts. Over large portions of the area, a crust of hardened, fine particles bound with clay covers the surface much of the year.

2.3.4 Water -- There are no major surface water areas in this arid region. Surface water in the desert evaporates rapidly. Waste streams are treated to meet state water quality standards. Some degradation of ground water quality in localized wells has been observed. The nature of the degradation is an increase in concentrations of naturally occurring chemical constituents, such as salts, and is not related to BDRP activities. Because of the importance of the ground water resources, special action was taken to rectify the situation and to minimize the possibility of any increase in such problems.

2.3.5 Air Quality -- The air quality of the Dugway area, within the Wasatch Front AQCR, meets primary ambient air quality standards. Air pollution from the Salt Lake City area, which enters the Tooele Valley during periods of air stagnation, and which causes periodic violations of SOx standards, rarely reaches DPG. The laboratory biological chambers contain specially designed filter systems to prevent air contamination with biohazardous materials. Filters which have become clogged are treated with paraformaldehyde to kill any residual organisms, then burned in a solid-waste incinerator.

Biological simulants have not been used for testing since 1986, and the simulants which were previously used **were** biodegradable. The relatively pollution-free atmosphere at DPG has a capacity to rapidly dilute airborne material. No air pollution problems have been observed from the release of test material into the atmosphere.

2.3.6 Agriculture

a. Crops -- The lands in the immediate vicinity of DPG are all poorly suited to any type of agriculture. Less saline soils several miles to the north in Skull Valley are planted to alfalfa for use as winter livestock feed. Elsewhere in the state, where groundwater supplies are adequate, soils similar to these better types support irrigated potato and alfalfa crops.

b. Livestock -- Ranching has been a traditional industry in this area for over 100 years. A recent USDA census of livestock showed about 27,000 cattle and 25,000 sheep and lambs on ranches in Tooele and Juab counties. Grazing has not been permitted at DPG. Adjoining the installation at the extreme southeast, over 10 miles from the Baker Laboratory Complex, is an area owned by the Bureau of Land Management, which is available for grazing, and with specific permission, for use by DPG.

2.3.7 Cultural Resources

a. Historical -- There are several historic sites in the vicinity of DPG, including Pony Express stations and other 19th century structures. Only one structure, the Lincoln Memorial Highway Bridge, a relic of the first transcontinental highway, is located on the installation itself.

b. Archaeological -- At least a score of relatively well documented sites of previous cultures have been identified. As many as hundreds of other minor sites may exist. Most are small and of modest interest, but some indicate potential for register eligibility. All those so classed and those known but unevaluated are marked for avoidance during Army activities.

2.3.8 Sociological Environment

a. Demographic -- The total population of the Juab-Tooele region was enumerated in the 1980 census as 31,563 persons (35). Bureau of Economic Analysis estimates for 1983 show an increase to approximately 34,400 persons. About 93% of the 1980 population is classified as white, 1.3% as Native American, 0.5% Black, 0.4% Asian and 4.7% of other races or not recorded by race. In 1980 there were 9,673 households in the region; 10,459 dwelling units, and 5,850 of these were owner-occupied (35).

b. Aesthetics -- Beauty is in the eye of the beholder. The immediate DPG vicinity is one of almost unbroken Great Basin natural landscape. Off the installation, human activity often appears to have had almost no effect. Occasional ranch houses, fenced corrals and windmills at watering troughs in favorable sites are normally the only evidence that settlers ever visited the area. As such, vistas are superb, but unrelieved. The facilities on the installation are the largest man-made complex for about 40 miles in any direction.

2.3.9 Noise

In the almost undisturbed rural setting of Dugway Proving Ground, few noise sources other than Army activities are caused by humans. Natural sound sources, including elements such as the wind and night animal noises, predominate at most times. Occasional artillery firing or aircraft operations may cause short-term disturbance, as will construction activities.

2.3.10 Odors

The predominant smells are those of natural vegetation. No activities take place that create objectionable odors that have more than very local, transient effects.

2.3.11 Economic Environment

a. Labor Force -- The labor force of the region is small and highly dependent on government employment. Over 50% of the employed persons work for the federal, state or local government (19,35). The number of employed persons has been stable, at 13 , 000 to 14,000 persons, for almost 10 years (35). Many persons are underemployed in part-time farming, ranching or mining.

b. Economic Activity -- Total regional business (volume of goods and services produced and sold) in this two-county (Tooele and Juab) area has been relatively unchanged for several years, and is approximately $230 million annually (35). Historic deviation from the mean has been relatively large, reflecting the ups and downs of the mining, construction and ranching sectors. Total personal income for the region has been about $300 million, and has varied less than has business volume (35).

c. Property Values -- The 5,850 single-family houses in the region had an aggregate value in 1980 of $293 million dollars, or a mean value of $50,182 per unit (35). At that time, the vacant units had a mean value of $50,836, indicating that vacancies were not due to serious oversupply. Similarly, the mean rentals of the occupied and unoccupied units were $191 vs. $189, also indicating that the vacant units were not substantially better or poorer quality than the occupied ones.

2.3.12 Public Opinion

a. Controversial Issues -- The Army has proposed to construct and operate a Biological Aerosol Test Facility (BATF) at the Baker Laboratory Complex on DPG. A DEIS for the proposed BATF was prepared and made available to the public in February, 1988 (19). It should be noted, however, that the decision on the proposed BATF remains separate from a decision on the BDRP. The DEIS for the BATF incorporates and references extensive background information on the DPG area and the Baker Laboratory Complex, and thus serves as an excellent source document for site specific information on this Primary Site.

b. Social Concerns -- In response to requirements of the developer of an item of equipment, BD related testing using simulants may be performed in the field (open-air), but only after appropriate NEPA consideration and documentation (19). Testing with aerosols is conducted because it is considered the most likely form of biological attack (19), though all outdoor testing involves only simulants.

Even with these provisions for specific environmental precautions, testing and related activities at DPG evoke controversy. In addition to opposition to the BDRP in general, aerosol testing is probably considered the most controversial issue, followed by the use of biological simulants for open-air testing. If open-air testing is required, it is conducted on designated test grids (19).

2.3.13 Transportation

a. Road -- Road access to DPG is by means of one of two highways (one state-maintained and one county-maintained) that meet at the entrance gate. One is routed to the north through the Skull Valley, and connects with I-80 about 37 miles from DPG and about 41 miles west of Salt Lake City. The second highway provides a connection to the towns of Tooele and Grantsville, and
is routed to the northeast through Johnson's Pass over the Stansbury mountains. The distance to Tooele is about 45 highway miles. Both are two-lane rural highways in generally good condition.

b. Rail -- There is no rail access to DPG. The closest point of transfer is at Tooele, where the Tooele Army Depot has major rail yards connecting to the Western Pacific track system.

c. Air -- The closest scheduled commerical airline service to DPG is in Salt Lake City. Michael Army Airfield is located on the installation, and is available for cargo and passenger operations involving military aircraft.

d. Traffic -- Existing access roads are generally adequate for the needs of DPG. During periods of commuting to and from work, vehicle counts may reach a peak rate equivalent to several hundred movements per hour in one direction, effectively utilizing most of the capacity of the roadway. Traffic at most other hours is light to very light. Travel over Johnson's Pass toward Tooele and Grantsville may be hazardous in winter storms. Very infrequently, snowfalls are sufficient to isolate the installation for a period of time.

2.3.14 Human Health

a. Workforce -- The level of containment, special controls, and other precautionary measures employed are commensurate with the hazard level and potential risk involved. For example, DPG operates a "Biotron" complex equipped with two Class III biosafety cabinets (See Appendix 11) connected by stainless steel ducts. This complex is designed to test systems for sampling and detection of aerosols of pathogenic microorganisms. Five types of safety are built into the complex: 1) The complex is at a negative pressure with regard to the other rooms in the building. 2) The safety cabinets are sealed, as certified by leak testing with Freon vapor, with access provided by glove ports. 3) Air from the complex passes through a HEPA filter, which removes

99.97 percent of the particle sizes of most interest, which are in the range of 1 to 2 microns (general size of infectious bacteria). 4) The filtered air then passes through an air incinerator chamber. 5) The complex is operated only during hours of daylight, when ultraviolet radiation will accelerate the inactivation of any pathogens that may possibly survive the incinerator, although it is highly unlikely that such an event could occur. After use, the chamber is saturated with paraformaldehyde fumes for a specified period of time to kill any living organisms.

Management of the DPG safety program occurs at several administrative levels. A division biosafety officer provides close oversight. An installation biological safety officer manages a biosafety program as an integral part of the overall safety program. Also, an Installation Biosafety Committee (IBC) develops and implements biosafety policies and provides general biosafety review and oversight of all biohazardous operations.

b. General Population -- An Installation Environmental Assessment (EA) for DPG was prepared in 1982 (20). As a matter of policy, every project (proposed test) is evaluated for its potential for adverse environmental impact. A number of EAs and other forms of environmental documentation have been prepared to address the potential impacts of BDRP-related testing activities. In addition, a substantial amount of baseline environmental data has been collected, analyzed and reported for the DPG area. The DEIS for the BATF presents the most recent information and references on environmental matters and resources at DPG. Protection of employee health and safety is recognized as a crucial aspect of the BDRP related activities. Likewise, adversely affecting protection of the external environment from any hazardous materials is a high priority effort.

3. Secondary Sites

The selection of secondary sites to be examined was made, as discussed in Sections 3.5 and 5.4 of the EIS, and in Appendix 3, on the basis of participation in research activities in the risk/issue categories of higher concern. Those locations which do not work with high-hazard infectious organisms, GEMs or toxins are assumed to be of less concern, and are not examined further. Appendix 4 also discusses the method of evaluation in some detail. The conclusion of these sections is that the secondary sites here included constitute a representative sample of the locations at which the BDRP is performed.

The treatment of these sites in Section 5.4 of the body of the EIS was limited to those aspects of the environment which the application of the IAM (Appendix 6) determined had some significance to the nature of the research and which might have the potential to be affected by the BDRP. Thus, many aspects were not mentioned in detail and others were not discussed at all. In the text which follows, the nine secondary sites of BDRP

execution are examined in some detail. Also incorporated is a site-specific examination of the maximum credible event. This is parallel to the discussion of maximum credible events found in Appendix 9.

3.1 Jefferson Medical College, Philadelphia, PA

Contract Title: A Core Facility for the Study of Neurotoxins of Biological Origin

3.1.1 Descriptive Summary:

This contract supports several individual projects all dealing primarily with protein neurotoxins, such as botulinum toxin and snake venom toxins, as well as toxins that affect nerve ion channels. The types of studies conducted include: using metabolic and radioisotope mapping to study the effects of neurotoxins in the brain, neurophysiology techniques to study the effects of toxins on cultured neuronal cells and animal tissues, biochemical studies to elucidate the mechanism of action of the various toxins in cultured cells, protein chemistry analyses to understand the structure-function relationships between toxicity and immunogenicity, and immunological studies to develop antibodies that will potentially be useful for therapeutic applications. Small animals (rats, mice) and cultured cell lines are used throughout these studies. The overall goals of this project are to define the mechanisms of action of several of the potent neurotoxins and to develop approaches for the prevention and/or therapy of intoxications with these agents.

3.1.2 The proportion of all research at this institution represented by the BDRP-funded work is:

a. Percentage dollar value: c 5%
b. Percentage person-hours: < 5%
c. Percentage space allocation: < 5%
d. Work with toxins is approximately 15% BDRP-funded.
e. Work with toxins at this institution would continue in the absence of BDRP funds.

The personnel employed under BDRP contract generate about 0.001% of the employment in Philadelphia, and generate, directly and indirectly, about 0.002% of the local business volume.

3.1.3 Jefferson Medical College is a unit of Thomas Jefferson University, a major educational institution located in the urban center city of Philadelphia, PA. The campus occupies 13 buildings and covers over four city blocks. Approximately 10,000 full and part-time faculty, staff and students are present on campus in any one working week, with fewer than half present

at any one time. The buildings in which the research is performed were designed, issued building permits, built for, and are devoted to, teaching and research related to medicine, drugs and disease.

3.1.4 Environmental, Health, and Safety Compliance

a. *The* university has a Safety Committee which is separate from the Institutional Biosafety Committee required under NIH guidelines. The safety committee is subdivided into groups specifically charged with considerations of Radiological Health and Safety, General Laboratory Safety, and Animal Care and Use.

b. No cloning or generation of recombinant organisms takes place at this site under the BDRP sponsorship.

c. Management of general laboratory safety hazards is the responsibility of a general laboratory safety committee. They have prepared guidelines and requirements which cover all university-wide activities and common practices. Each unit of the University prepares more specific safety guidance which is appropriate to that division, and each individual department and major subdivision supplements this guidance with laboratory- and project-specific protocols.

d. There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations either in general or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.1.5 Waste discharges

a. The institution is connected to the Philadelphia sanitary sewer system, and all discharges to that system are in compliance with university operating regulations, city ordinances and rules, and the provisions of other applicable federal, state and local regulations.

b. Pre-treatment of BDRP-related wastes, such as toxins, is performed with alkali and detergent solutions, which are allowed to stand in contact for 1 to 30 days before disposal. The treated wastes are periodically assayed for residual toxin activity, and are also examined microscopically for possible bacterial contamination. No living or toxic residues remain after this pre-treatment.

c. Biological safety cabinets are used for all manipulations of toxins in this laboratory. They are inspected and certified when placed and recertified annually thereafter by contractors who are trained to perform the procedures.

d. There are no containment areas used for BDRP-sponsored work at this location which utilize BL-3 or BL-4 precautions, and the nature of the research does not require them.

e. Dead test animals and cage bedding materials are incinerated according to medical standards for hazardous substances or for potentially pathogenic wastes, whichever is the more applicable in a particular case. This also serves to eliminate any possibility of introduction of toxins into the ecosystem or surrounding human or animal populations.

3.1.6 Security Provisions

a. Toxins are stored in locked refrigerators to which only one key has been made. Furthermore, they are inside a locked room to which no general issue of keys has been made and whose locks are outside the institutional master key system. If a key must be issued to a security guard to investigate a possible security violation, the key must be signed out from a separately locked cabinet under the charge of the guard captain. No maintenance or custodial personnel are allowed to enter these rooms without supervision by responsible persons working on the research program.

b. Institutional security provisions which aid laboratory security include the use of 24-hour guard service, presence of locked and alarmed exterior doors both during and after working hours, and visitor sign-in requirements.

3.1.7 Accidents and Incidents

a. The most serious credible accident involving laboratory personnel involves inhalation of toxin solutions following a spill or breakage of laboratory glassware, or self-injection of toxins while working with laboratory animals. To protect against illness which might result from these accidents, all laboratory personnel are immunized against the toxins used in research. Further, limits are placed on procedures that require toxin solutions to be used in syringes, minimizing opportunities for inadvertent self-injection. There has never been such an accident in this laboratory.

b. There is no credible means whereby other occupants of the building, other members of the university population, or the community at large could be endangered by the materials used in the conduct of the BDRP.

c. There is no history of accident, death or injury at Jefferson Medical college related in any way to materials now a part of the biological defense program.

3.1.8 Research Benefits

The effects at the cellular level of several of the most potent neurotoxins, such as botulinum toxin, and snake venom toxins are not yet understood. Intoxications with these toxins can only be treated with supportive care. The anticipated benefits of the BDRP-sponsored research performed at this site are a) discovery of the mechanism of action of botulinum neurotoxin and b) identification of potential therapies or treatments for various potent toxins, including botulinum neurotoxin. Potential public health benefits are obvious, since virtually every year there is focal episode of botulinum toxin poisoning as a result of improperly preserved food. Because botulinum toxin is considered to be a potential biological weapons threat, the military would benefit greatly from having a useful therapy for botulinum and other neurotoxins available.

3.2 The Salk Institute, Government Services Division), (TSI- Swiftwater, PA

Contract Title: Development of Special Biological Products

3.2.1 Descriptive Summary:

This facility provides support to the medical portion of the BDRP in the form of pilot production of investigational vaccines, diagnostic materials and antibodies. Several viral, rickettsial and bacterial vaccines, all of which are licensed as investigational materials for human use by the Food and Drug Administration, are produced on a demand basis and tested for safety and potency in animals. The diagnostic materials are primarily "spot slides", i.e. microscope slides on which preserved samples of various viruses, etc. are dried in small droplets. The USAMRDC submits hybridoma cell lines that produce particular monoclonal antibodies of importance to the program, and these are grown further in mice or rats to produce large quantities of fluids containing the monoclonal antibodies. The organisms used at this facility vary over time, but include the vaccine and, in some cases, native strains, of the following: chikungunya, western equine encephalitis, eastern equine encephalitis, Venezuelan equine encephalomyelitis, Rift Valley Fever, and Junin viruses; *Coxiella burnetii* (Q fever) rickettsia, and *Francisella tularensis (* tularemia) bacteria.

3.2.2 The proportion of all research at this institution which is represented by the BDRP-funded work is:

a. Percentage dollar value. ca 90%
b. Percentage person-hours. ca 90%
c. Percentage space allocation. ca 90%

d. Work with infectious organisms at this institution would continue in the absence of BDRP funds.

The persons employed under BDRP contract generate about 0.27% of the employment in Monroe County. Their income and spending, including both direct and indirect effects, generate about 0.28% of local business sales volume.

3.2.3 The setting in which this work is being carried out is a rural, single-use building, with associated support buildings originally constructed for this purpose. The institute occupies approximately nine acres in Pocono Township, Monroe County, PA, near the town of Swiftwater. It is, in turn, one of a group of biomedical research and production facilities on a 50+ acre complex devoted to this purpose. The other facilities in the complex are operated by Connaught Laboratories, Inc., which also provides some support services to (TSI-GSD)

3.2.4 Environmental, Health, and Safety Compliance

a. TSI- GSD has prepared an Environmental Assessment (EA) of their ongoing activities. The EA was originally prepared in 1986 and was last updated in January 1988. In this examination, two general types of risks were identified: 1) the storage and handling of hazardous chemicals, and 2) the maintenance of seed stocks of the microorganisms required for the preparation of the vaccines, which is currently the main mission of TSI-GSD. The hazardous chemicals identified were chloroform, methanol, acetone and formaldehyde. Wastes of the first three are manifested for shipment as hazardous waste for disposal at approved facilities under Pennsylvania DER rules. Formaldehyde gas is exhausted to the atmosphere after decontamination operations, but even local outdoor concentrations are reported in the EA to be less than 1 ppm following dilution in the exhaust air stream.

b. TSI-GSD has a state charter to perform activities of the type for which the facilities are being used. It is properly identified as a hazardous waste generator, has a certificate of occupancy from the state Department of Labor and Industry, and a series of licenses for operation of its several steam boilers and autoclaves.

c. Management of general laboratory safety hazards is the responsibility of a safety committee, which is headed by a professional employee with an advanced degree. The committee, itself, has representation from every operating department, and has prepared and distributed a 40 page general safety manual. This manual specifically addresses potential problems associated with the operation of a vaccine production facility, and much of the content is directed to biological safety issues.

d. In compliance with the FDA Current Good Manufacturing Practices Regulations the institute has prepared over 250 Standard Operating Procedures (SOP's) which cover every recurring

activity in the operation of the laboratory. Of these, 20 deal specifically with minimization of any potential for environmental effects from operation of sterilizers, disposal of wastes, and shipment of vaccines and cultures.

e. There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations, either in general or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.2.5 Waste discharges

a. The institute's wastewater treatment is performed by the Connaught Laboratories wastewater treatment plant on a contractual basis. That plant utilizes tertiary treatment technology and has a current NPDES permit from the State of Pennsylvania. The permit requires periodic measurement of 12 characteristics of the wastewater stream. After treatment, no specific contribution of the Salk (TSI-GSD) waste stream may be separately identified, but all parameters of the waste flow meet state and federal requirements.

b. BDRP-related liquid waste that enters the laboratory drains is inactivated by heat treatment prior to discharge. Laboratory wastes are collected in a separate sewer system connected only to the containment areas. Liquid wastes in this system are directed to one of two 5000 gallon tanks which, when full, is heated to 220 degrees F for 6 hours. The heat-treated waste is then discharged into the Connaught treatment plant lines for removal of remaining biological and chemical materials.

c. Vertical laminar flow biological safety cabinets are required to be used for all procedures involving handling of infectious materials and tissue cultures. Their operation is certified annually, or after they are moved, by Salk personnel who have been specifically trained in this procedure. Filters are decontaminated with paraformaldehyde prior to disposal.

d. Procedures which require the handling of larger quantities of infectious organisms are carried out in containment suites which meet BL-3 standards in accordance with the NIH-CDC guidelines. The air supply to these BL-3 containment areas is
HEPA filtered before being drawn in, and the exhaust air is HEPA filtered before being released to the external environment. Air moves through in a "single pass" without being recirculated for any other purpose. Other potentially infectious waste material, e.g., contaminated glassware, is autoclaved before removal from containment areas.

e. The disposal of test animals, their wastes and bedding is by autoclaving, followed by incineration in a pathological waste incinerator operated under state permit and in compliance with the permit requirements.

3.2.6 Security Provisions

a. A security regulation prepared by TSI-GSD provides specifically for special handling procedures for all biological materials. Infectious materials are kept in locked freezers, **whose** keys, in turn, are kept in a secure location with restricted access.

b. The institutional security regulations provide for 24hour guard service, with general access even to the parking lots restricted to employees during the day. After-hours access is limited to persons with special needs, and requires personal identification. This access is logged and becomes a part of the security records.

3.2.7 Accidents and Incidents

a. Standard Operating Procedures (SOP's) established for employee health and safety require that personnel who may come in contact with an organism, either in the form of a vaccine or in its virulent form, must be immunized against that disease if an immunization is available. The most severe credible accident with respect to hazards to laboratory personnel is that of exposure to a disease-causing organism to which the person is not supposed to come in contact. To do so, a person intentionally would have to enter (and be allowed to enter) a containment laboratory suite to which they did not have authorized access, and be present at the time that an accidental spill or glassware breakage took place, and receive an infectious dose into the bloodstream, respiratory tract, or mucous membranes. None of this series of events is totally impossible, but their simultaneous occurrence has an extremely low probability, and, in fact, has never taken place at TSI-GSD.

b. To create a hazard to the external natural environment and surrounding human population centers, several independent events must take place. First, one must assume that a living animal that has been challenged with a virulent and exotic organism is intentionally or unintentionally released to the environment. Then, the animal must survive and provide a source of infection that a suitable vector of transmission, such as a tick or insect, may utilize for transfer to native or domestic animals or to humans. While any of these conditions is possible, their individual probability is low, and their combined probability extremely low. Appendix 9 examines in some detail the likelihood of such a chain of events.

Much of the potential for hazard in this situation depends on exactly which organism might be involved in the hypothetical incident. The diseases and vaccines used vary over time, depending on contract requirements. Thus, even if an exotic and dangerous species such as Rift Valley fever virus were to "escape" and become established -- remembering that this is,

itself, extremely unlikely -- vaccines are available to protect surrounding animal and human populations, should this become necessary. Some of the other diseases which are the focus of vaccine production and testing, such as tularemia, are widespread in the surrounding environment as a result of natural endemic infection unrelated to BDRP research.

3.2.8 Research Benefits

TSI-GSD performs work that supports the BDRP in the form of production of trial vaccines and diagnostic reagents on a scale that could not be accomplished with existing facilities and personnel resources within DA. These vaccines and reagents are of benefit to the mission to provide improved military defense against potential biological warfare threats. The vaccines are used to protect at-risk laboratory workers in various areas of the BDRP and thus represent a significant mitigation of potential personnel health risk. The public benefit of these efforts is the availability, on a limited scale, of vaccines and diagnostic reagents for exotic diseases that present rare, but significant, public health problems in the U.S., and for which physicians and public health officials have no alternative source.

3.3 Scripps Clinic and Research Foundation, LaJolla, CA

Contract Title: Synthetic Vaccines for the Control of Arenavirus Infections

3.3.1 Descriptive Summary:

Lymphocytic choriomeningitis virus (LCM), a mouse arenavirus which is widespread in North America, is used as a model for developing the approaches for identification of the critical virus glycoproteins that would serve as good immunizing agents to protect against arenavirus infections. Synthetic peptides (short pieces of the larger virus glycoproteins) are tested for their ability to elicit protective antibodies. The DNA coding from the most effective peptides is then cloned into the vaccinia virus (smallpox vaccine virus), and this recombinant vaccine tested in cultured cells and mice. The techniques developed using LCM virus are applied to the human arenavirus, Lassa. Starting material used in the Lassa studies is always non-infective fragments of single strands of the viral nucleic acid which have been prepared and safety tested at USAMRIID. The laboratory work performed in this project includes the use of cultured cells, biochemical techniques, cloning, and immunization of mice and rabbits.

3.3.2 The proportion of all research at this institution which is represented by the BDRP-funded work is:

a. Percentage dollar value: 0.45%

b. Percentage person-hours: < 1.0%

c. Percentage space allocation: < 1.0%

d. Research work recombinant DNA is approximately 10% BDRP

e. Work with recombinant DNA and infectious organisms at this institution would continue at virtually the same level in the absence of BDRP funds.

The persons employed under BDRP contract account for about 0.001% of the employment in the county and also generate, directly and indirectly, about 0.001% of the county's personal income and business volume.

3.3.3 The setting in which this work is being carried out is a suburban, single-use building having appropriate construction and use permits for the types of research performed. It is located among a series of research facilities extending for several thousand feet along the California coast in the northwestern part of La Jolla, an area specifically designated for institutions devoted to biomedical research. The Salk Institute is in the same area, within one-half mile of the Scripps location.

3.3.4 Environmental, Health, and Safety Compliance

a. The institution has an active Institutional Biosafety Committee for oversight of recombinant DNA work as required by the 1986 NIH guidelines. The committee's mandate includes general biohazards in addition to recombinant DNA research. A memorandum explaining and defining biohazards, and requiring their registration with the institutional committee, was prepared and distributed in 1987, and is undergoing minor revision at this time.

b. Under these guidelines, a Microbiological Hazard Registration Form must be filed and approved prior to working with an infectious organism. The form must indicate amounts to be used, storage locations, personnel in contact, decontamination procedures, waste treatment, prophylaxis, and guidelines for medical treatment, if it should be required.

c. Cloning, and growth of recombinant organisms, falls within guidelines established by NIH and is specifically identified and approved through registration documents and memoranda of understanding submitted to and approved by NIH in 1980 and 1984.

d. Management of general laboratory safety hazards is the responsibility of the Environmental Health and Safety Division. They have prepared and distributed a manual entitled "Safety Program for Laboratories." The most recent revision of this manual is dated September 1986.

e. There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations either in general or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.3.5 Waste discharges

a. The institution has a separate Industrial User Discharge Permit from the City of San Diego Water Utilities Department that identifies 20 characteristics of the permitted flow, and requires periodic sampling for seven parameters.

b. Provision for pre-treatment of BDRP-related wastes prior to discharge into the sanitary sewer takes the form of hypochlorite treatment and/or autoclaving of cultures prior to discharge. All cultures of all organisms are treated in this manner. No potentially infectious material is poured into drains without such treatment.

c. Biological safety cabinets are used for all potentially hazardous operations. They are certified annually by contractors.

d. Air from containment areas is HEPA-filtered before being released to the external environment. Potentially hazardous areas are kept at a negative pressure differential in relation to surrounding rooms. Air from animal holding areas is HEPA filtered prior to exhaust. Air from general laboratory areas (where BL-2 practices apply) is not specifically treated.

e. Remains of test animals, their wastes, and bedding are autoclaved before disposal. If radioisotopes have been used, animal remains are disposed of as radiation wastes.

3.3.6 Security Provisions

a. The local safety program requires posting of known hazards, and informing employees of required procedures prior to use of potentially hazardous materials.

b. General building and institutional security provisions require screening, badging, and escort of all visitors during working hours. After hours, access to buildings is controlled by security guards, and requires employee photoidentification badges. No outside door keys are issued. Hazardous materials are kept in locked freezers or incubators in locked rooms. Interior doors have combination locks

3.3.7 Accidents and Incidents

a. The most serious credible accident which may be envisioned with respect to laboratory personnel is that aseptic

meningitis may be acquired by an individual who fails to follow personal protection guidelines and becomes infected with LCM virus. This virus disease is treatable when symptoms appear, and full recovery is anticipated. LCM virus use represents an intentional substitution of a treatable arenavirus for more virulent and less easily treatable renaviruses--a form of the use of simulants.

b. There is no credible means by which this organism could escape the laboratory to the external natural environment and surrounding human population centers. Even if such an "escape" were to take place, the LCM virus is already endemic in mouse populations in many areas of North America, and little or no added human health hazard is envisioned.

c. One laboratory technician became infected with LCM and developed aseptic meningitis within the last two years. The exact infecting incident is unknown, but several prior breaches of personal protective procedures were identified when the infection was confirmed. The person recovered fully and is at work in the same laboratory at this time. During followup investigations of this employee's family, it was determined that no family members or household pets had developed antibodies to LCM, i.e. had not become infected with the virus, and none became ill. Followup education and training for laboratory workers was given, and the need for precautions was reinforced.

3.3.8 Research Benefits

Arenaviruses, especially those which are found throughout parts of Africa and South America, cause a group of severe diseases called hemorrhagic fevers. If this research succeeds, all or some of the following benefits may be realized: 1) development of synthetic vaccines that will protect against this family of viruses, 2) development of monoclonal antibodies that would be useful in treating disease, and 3) development of various molecular probes, such as antibodies and nucleic acid fragments, that could be used in diagnosing hemorrhagic fevers caused by arenaviruses. Public health benefits would apply largely to Third World countries, where these diseases present significant health problems.

3.4 Salk Institute, La Jolla, CA

Contract Title: Human Hybridomas for Exotic Antigens

3.4.1 Descriptive Summary:

The objective of this work is to develop *in vitro* methods to generate human monoclonal antibodies to selected antigens (toxins or virus proteins). The advantage of such antibodies is that they could be produced at will using cultured cells rather than isolated from the serum of immune individuals. In addition, the *in vitro* system will allow for antibodies to be produced to almost any antigen, whereas donor human immune serum is only

available for use against a few diseases. All of the studies are performed with cultured human cell lines and cells derived from. human blood. White blood cells are isolated from fresh blood samples and fused with "immortal" cultured cells. The resulting hybrids are tested for production of antibody to specific toxins. This is a use of advanced biotechnology that provides a tool similar to that which might be provided by genetic engineering, although recombinant DNA techniques are not **utilized** here directly. The toxins used to develop these techniques are actually in the form of toxoids (vaccines) with which virtually everyone in the U.S. has been immunized (diphtheria and **tetanus** toxoids, a.k.a. DT or DPT shots).

3.4.2 The proportion of all research at this institution which is represented by the BDRP-funded work is:

a. Percentage dollar value: 0.9%

b. Percentage person-hours. < 1%

c. Percentage space allocation. < 1%

d. Work with human hybridomas at this institution would continue in the absence of BDRP funds, and was in existence prior to Army support.

The persons employed under BDRP contract account for about 0.001% of the employment in the county and also generate, directly and indirectly, about 0.001% of the county's personal income and business volume.

3.4.3 The setting in which this work is being carried out is a suburban, single-use building having appropriate construction and use permits for the types of research performed. It is located among a series of research facilities extending for several thousand feet along the California coast in the northwestern part of La Jolla, an area specifically designated for institutions devoted to biomedical research. The Scripps Institute and Clinic are within one-half mile of the Salk Institute.

3.4.4 Environmental, Health, and Safety Compliance

a. The institution has an active Institutional Biosafety Committee for oversight of recombinant DNA work as required by the 1986 NIH guidelines. Its mandate includes other biohazards in addition to recombinant DNA research.

b. No cloning or duplication of recombinant organisms which falls within the purview of the NIH guidelines takes place at this location as a result of BDRP-sponsored research. The human cell hybridomas are made using a technology of cell fusion developed over 25 years ago, and no DNA manipulation or "engineering" is a part of this work.

c. Management of general laboratory safety hazards is the responsibility of the Occupational Health and Safety Division. This unit has several full-time staff members, and the director possesses the Ph.D. degree.

d. There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations, either in general or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.4.5 Waste discharges

a. The institution has a separate Industrial User Discharge Permit from the City of San Diego Water Utilities Department that identifies 20 characteristics of the permitted flow, and requires periodic sampling for seven parameters.

b. Pre-treatment of BDRP-related wastes takes the form of inactivation through use of sodium hypochlorite and autoclaving of all discarded cultures of all organisms prior to disposal. No potentially infectious organisms are used in BDRP-sponsored research.

c. Biological safety cabinets are used for all potentially hazardous operations. They are certified annually by in-house personnel who have completed specific training in this procedure.

d. There are no containment areas used for BDRP-sponsored work at this location that require BL-3 or BL-4 precautions.

e. Test animals and their wastes and bedding are autoclaved, followed by appropriate disposal according to whether or not radioactive or hazardous substances were used in the experimental procedures. If so, disposal is as hazardous or radioactive waste, and follows all procedures required for that type of waste. Potentially pathogenic wastes are incinerated in a pathological waste incinerator. Other animals and wastes are considered non-hazardous, and are handled, after autoclaving, as solid waste. No test animals are used, however, in any research project under BDRP sponsorship.

3.4.6 Security Provisions

a. The institution, as a matter of policy, has no potentially hazardous research activities that require biohazard precautions above the BL-2 level. No infectious organisms are used in BDRP-sponsored research.

b. The research buildings are staffed with 24 hour guard services. Visitors are required to be escorted. All buildings are locked after hours. Access is controlled by coded magnetic card.

3.4.7 Accidents and Incidents

The most serious credible incident which may reasonably be envisioned with respect to potential for effects on laboratory personnel involves the hazards related to virus diseases, including human immunodeficiency virus which, unknowingly, may be present in incoming samples of human whole blood. The potential exists for laboratory workers, as a result of manipulation of these samples, to become infected with any of several blood-borne diseases, including AIDS. This hazard is comparable to that experienced in thousands of hospital laboratories, and established guidelines for worker protection, such as the wearing of surgical gloves, are implemented. There is no BDRP-related component in this hazard.

Because no reproducing organisms capable of living outside culture facilities are used, no credible series of events may be postulated whereby the external natural environment and surrounding human population centers could be affected by BDRP sponsored research efforts.

3.4.8 Research Benefits

Passive immunization, or transfer of antibodies, is a time honored medical approach to the prevention and treatment of various diseases. For example, use of gamma globulin to prevent hepatitis or of RH-immune serum to prevent fetal defects in RH- mothers is a part of standard medical practice. However, donor human immune serum is only available for use against a few diseases, is in limited supply, and its use carries the risk of inadvertent transmission of other blood-borne diseases. If this research is successful, it will provide the methods and techniques for the production of potentially useful human antibodies to virtually any disease or toxin for which immunotherapy is desirable. In addition, the amounts of antibody that could be generated by the in *vitro* techniques far exceed those that would be available from donor serum. For both the military and civilian populations, such developments promise better protection and medical care for a broad spectrum of diseases and toxicoses.

3.5. Southern Research Institute, Birmingham, AL

Contract Title: Research in Drug Development Against Viral Diseases of Military Importance (Biological Testing)

3.5.1 Descriptive Summary:

The Southern Research Institute supports the USAMRIID Antiviral Drug Discovery Program by performing extensive experimental testing of candidate drugs for activity against a number of viruses of interest to the military. Standardized assays of viral activity in cultured cells or in animals are used to test approximately 1000 compounds per year. Compounds that

appear promising are further tested in more detail in animal models. The viruses against which drugs are tested include: adenovirus, vesicular stomatitis, vaccinia, Venezuelan equine encephalomyelitis, Pichinde, Punta Toro, Hantaan Japanese encephalitis B and yellow fever.

3.5.2 The proportion of all research at this institution represented by the BDRP-funded work is:

a. Percentage dollar value: 4.7%

b. Percentage person-hours: < 5%

c. Percentage space allocation: < 5%

d. Research work with infectious diseases requiring BL-3 containment is approximately 66% BDRP-funded.

e. Work with infectious diseases at this institution would continue in the absence of BDRP funds.

The persons employed under BDRP contract account for about 0.01% of the employment in the county and also generate, directly and indirectly, about 0.014% of the county's personal income and 0.012% of the local business volume.

3.5.3 The setting in which this work is being carried out is one of urban, single-use buildings devoted entirely to biomedical research. Two separate buildings are involved, one containing general laboratory and office space, where BL-2 facilities are maintained, and one containing the BL-3 facilities. The building with the BL-3 laboratories is located on the campus of the University of Alabama at Birmingham (UAB). It was constructed in 1980-82 specifically for biomedical research on recombinant DNA materials, and was further modified in 1986 and 1987 to be used for the work with infectious viruses. The building has no classroom or general office space, and no areas are open to the public.

3.5.4 Environmental, Health, and Safety Compliance

a. Both the Southern Research Institute (SoRI) and the UAB maintain Institutional Biosafety Committees as required by the CDC-NIH guidelines. These committees also have responsibility for oversight of infectious disease research as well as of projects using recombinant DNA. In addition, the UAB Infectious Disease Committee also has oversight responsibility for all activities involving potential human pathogens, and regularly examines both structural features of the facility and procedural adequacy in terms of their health hazard.

b. No cloning or generation of recombinant organisms takes place at this site under the BDRP sponsorship.

c. A manual covering general laboratory safety has been prepared by the institutional safety committee. This committee also oversees the work of a full-time professional safety staff responsible for administration of these safety requirements and SoRI management of hazardous wastes.

d. A Standard Operating Procedure (SOP) was prepared for all activities which were to take place in the BL-3 containment laboratories prior to their first use. This SOP has been revised, most recently in December, 1987.

e. All animals are held, and used in research, in strict accordance with the requirements of the "Guide for the Care and Use of Laboratory Animals" NIH Pub 85-23) and the Animal Welfare Act (7 USC 2131-2156 and 9 CFR 1-4), and other applicable federal and state regulations. SoRI animal care facilities are accredited by AALAC and by the USDA.

f. There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations either in general, or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.5.5 Waste discharges

a. The SoRI buildings are connected to the Birmingham municipal sewer system. No living materials of any type are disposed of in the sanitary sewer system.

b. Provision for pre-treatment of BDRP-related wastes prior to discharge into the sanitary sewer takes the form of inactivation with strongly alkaline materials and/or autoclaving to kill living organisms. No potentially infectious material is poured into drains without such treatment.

c. Biological safety cabinets are used for all potentially hazardous operations. They are certified by personnel from the UAB Department of Occupational Safety and Health when initially installed , when moved, and every six months while in use.

d. Air from containment areas is double HEPA-filtered before being released to the external environment. Potentially hazardous areas are kept at a negative pressure differential in relation to surrounding rooms. Air from animal holding areas is HEPA filtered prior to exhaust. Air from general laboratory areas (where BL-2 practices apply) is not specifically treated. Used filters are decontaminated with paraformaldehyde prior to removal, and are then bagged and autoclaved prior to disposal.

e. Remains of test animals, their wastes and bedding are autoclaved twice before disposal in a pathological waste incinerator.

3.5.6 Security Provisions

a. All entrance into the building where the BL-3 laboratories are located is by electronic key card. No public access is possible. All windows and doors are alarmed, with notification at a 24-hour manned police department which has proven, rapid response to the site. Authorized visitors must be accompanied by employees who have proper access privileges. Entrance into the containment suites is by an additional keyed lock. Issue of both key cards and suite keys is restricted to employees whose duties require entrance. No general issue of either key has ever been made.

b. Within the containment rooms, entrance into the room (s) where virus seed stocks are held is by coded electronic key pad lock. This room also has additional intrusion alarms. The biological materials are stored in a locked freezer. It is believed that accidental contact with the viruses is not possible, and that forceful intrusion, while not absolutely impossible, could not be made prior to response by police and security personnel.

3.5.7 Accidents and Incidents

Because all at-risk personnel in the BL-3 facility are immunized against the materials with which they are working, the most serious credible accident which may be envisioned with respect to most laboratory personnel is that a very large infective dose might override this immunity. Such a dose is most likely to be acquired through accidental injection of a hand or finger or inhalation of droplets from a spill or splash. No such accident has actually taken place at this facility. If such an infection should take place, treatment is available and full recovery is expected.

There is no immunization available for Hantaan virus. Special precautions are used for assays involving this organism as a means of minimizing potential for worker infection. No animals are used to test drug efficacy, and all work is done in culture only. Thus, no needles are ever used in association with Hantaan virus. Further, only plastic culture dishes are used, which minimizes the possibility of glass breakage and a subsequent cut. The one technician who works with this organism is highly skilled, specially trained, experienced, and closely monitored. If an infection should develop in spite of these precautions, the resulting disease can be treated with supportive care and/or experimental drug therapy.

3.5.8 Research Benefits

The benefit derived from successful execution of this work will be the identification of potentially useful new drugs with which to treat various viral diseases. Because a number of the viruses tested in this drug screening effort do not cause

diseases that are of socioeconomic importance in the U.S., pharmaceutical firms do not necessarily devote resources to development of effective therapeutic drugs for these diseases. For the military, however, many of these more exotic viral diseases are endemic disease hazards for troops stationed in various parts of the world, and some present potential biological warfare threats. Therefore, development of drugs effective against these viruses would be of great benefit to the military, and potentially to the inhabitants of endemic disease areas.

3.6. SRI International, Menlo Park, CA

Contract Titles: 1) Active Antitoxic Immunization Against Ricin Using Synthetic Peptides; 2) Synthesis and Testing of Tetrodotoxin and Batrachotoxin Antagonists; 3) Research in Drug Development for Therapeutic Treatment of Neurotoxin Poisoning: Studies on Conotoxins

3.6.1 Descriptive Summary:

The common objective of the toxin research projects supported at SRI International is to develop compounds for the prevention and/or therapy of certain intoxication. Researchers are attempting to synthesize fragments and analogs of two types of toxins which would be useful for immunization against the corresponding toxin or treatment of toxin exposures. One group of toxins includes those that poison nerve conduction at the site of the nerve sodium channel. Another group of toxins block nerve transmission at the nerve terminal acetylcholine receptor. The preventive approach is being used in the development of peptide fragments of the potent protein toxin ricin. The goal is to identify inherently non-toxic subfragments of the toxin that would cause an immune response, and thus provide protection against exposure to the whole toxin. The procedures used include organic syntheses, peptide synthesis, in vitro assays of animal neuronal tissues, and immunization and toxin challenge of mice.

3.6.2 The proportion of all research at this institution represented by BDRP-funded work is:

a. Percentage dollar value: 0.17%

b. Percentage person-hours. < 0.25%

c. Percentage space allocation. < 0.25%

d. Research work with toxins is entirely BDRP-funded at this time.

e. Work with toxins at this institution would continue in the absence of BDRP funds as an element of basic research into protein structure.

The persons employed under BDRP contract account for about 0.004% of the employment in the county and also generate, directly and indirectly, about 0.005% of the county's personal income and 0.003% of the local business volume.

3.6.3 The setting in which this work is carried out is an urban, single-use building, containing research laboratories and associated offices. The SRI campus consists of 76 acres in the city of Menlo Park; is surrounded by residential, commercial and municipal development; and occupies facilities that were originally the site of an Army hospital complex constructed late in WW II. An extensive construction program is underway to upgrade the remaining older structures with newer facilities. Approximately 2600 persons are employed at the Menlo Park offices, and they occupy over 1,300,000 square feet of office and laboratory space. The mix of space usage is approximately 50% offices, 25% "wet" laboratory, 10% dry laboratory, and 15% support and common use facilities such as libraries and conference rooms.

3.6.4 Environmental, Health, and Safety Compliance

a. SRI has prepared an Environmental Impact Report (EIR) detailing the probable environmental effects *of* its operations. The EIR was originally prepared in 1975, and has been updated regularly, most recently in June, 1987. The primary purpose of this report is to keep the city of Menlo Park informed about the nature of the work being carried out at SRI, and to help alleviate possible anxiety about the unknown. The SRI site is included in the Menlo Park comprehensive land use plan as an area for "Professional and Administrative Offices," and the area is zoned for Administrative, Professional, Research and Development use.

One conclusion of the EIR was that traffic congestion due to employee commuting was one of the most locally significant effects of SRI operations. Contribution to regional air emissions was also higher than most other employing entities, but was consistent with the size of the work force. Region-wide, stationary air pollution sources are minor in comparison with vehicular emissions. Other, minor, effects were seen on urban services and utilities. A positive effect on local government income is identified.

b. No cloning or generation of recombinant organisms takes place at this site under the BDRP sponsorship.

c. Laboratory use of hazardous materials is under the review of the Hazardous Materials Control Board, which consists of six professional scientists and legal counsel. Their charge includes "...Cognizance of all activities with biological agents and extremely toxic materials... " and "...Assurance that safeguards and controls are established...to protect the health of staff members and residents of the adjacent community..."

Each outgoing proposal by a staff member involving work with BDRP-related sponsored hazardous materials is reviewed for an understanding of the chemical and biological hazards, including carcinogenicity, of any organisms or chemicals required to complete the proposed work. A safety sheet is prepared for each approved project, and a central "safety notebook" is kept by the Health and Safety Department. The safety sheet for conducting studies with ricin, for example, requires use of two pairs of surgical gloves, gowns and respirators. These are incinerated as potentially hazardous after one wearing.

d. Management of general laboratory safety hazards is the responsibility of the Health and Safety Department. They have prepared and distributed manuals entitled "Health and Safety Manual, Hazardous Materials Control Manual," and "Radiation Safety Manual." The "Hazardous Materials Control Manual" contains specific sections on biologically hazardous materials, toxic chemicals, and potential carcinogens.

e. There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations, either in general, or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.6.5 Waste discharges

a. The institution has a separate Industrial User Discharge Permit from the West Bay Sanitary District. Wastewater flows from the SRI campus average under 200,000 GPD, approximately 65% of the quantity allocated to SRI by the sanitary district. Periodic sampling of SRI's waste stream is required, and it has not shown unacceptable levels of permitted materials or the presence of contaminants not allowed by the permit.

b. Pre-treatment of BDRP-related wastes is performed by inactivation with sodium hypochlorite or mercaptoethanol or sodium hydrobromide prior to disposal, depending on the characteristics of the toxin. Cultures and media are autoclaved prior to disposal.

c. Biological safety cabinets are used for all potentially hazardous operations. The safety protocol for the research with ricin, for example, requires use of the safety cabinet for all work with test animals. Safety cabinets are certified annually by contractor personnel.

d. There are no containment areas used for BDRP-sponsored work at this location that require BL-3 or BL-4 precautions.

e. BDRP-sponsored research on batrachotoxins is entirely in vitro, and no test animals are used. For other toxin research involving test animals, all animals are autoclaved prior to incineration in a pathological waste incinerator. After exposure

of animals to ricin, all bedding and waste from cages is autoclaved and incinerated. For other animal tests, bedding is autoclaved prior to disposal as ordinary solid waste.

3.6.6 Security Provisions

a. Access restrictions appropriate to the nature of the biohazard are a part of the hazardous materials control program. Toxins present in sufficient quantity to present a human health hazard are required to be kept in locked containers in rooms to which access is specifically restricted to authorized persons. However, only small quantities (e.g., no more than 5 mg of ricin) are ever kept on hand.

b. The entire facility is fenced, and gates and building doors are locked after working hours. Building access after hours is limited to regular employees whose magnetic card allows entrance to a particular building. Security personnel personally examine all after hours personnel entries and confirm the identities of persons found in laboratories with their photographic identification cards.

3.6.7 Accidents and Incidents

a. The most serious credible accident which may reasonably be envisioned with respect to potential for effects on laboratory personnel involves the accidental injection of a toxin into the finger or hand of the researcher while injecting a test animal. The safety protocols developed for these experiments specifically address this hazard by limiting the amount of toxin allowed to be taken into the syringe to less than 5% of a human lethal dose of the toxin involved. Thus, even if the full contents of the syringe were injected...and this rarely happens in this type of accident...little or no hazard to the worker is anticipated.

b. There have never been any accidents, incidents, or "scares" involving breakage, spillage, or other loss of BDRP related toxins at SRI. No personnel exposure incidents have occurred.

c. There is no credible route whereby other workers in the building and persons resident or working in the surrounding community may be placed at risk as a result of any materials used in BDRP-sponsored research. The restrictions on maximum quantities of toxins which may be held, and the conditions under which they may be kept, are a part of the biosafety plan prepared for each proposed project.

3.6.8 Research Benefits

The anticipated benefits from the BDRP-sponsored research performed at SRI are the development of potentially useful therapeutic compounds for treatment of certain neurotoxin poisonings (tetrodotoxin, batrachotoxin and conotoxin), and the

development of a potentially useful candidate vaccine for protection against ricin poisoning. While these specific benefits have been identified as priorities in medical defense against potential biological warfare threats, they would benefit the scientific community in general by contributing to an increased understanding of the toxins themselves and of the sites at which they exert their toxic effects.

3.7. University of Massachusetts, Amherst, MA

Contract Title: Genetic and Physiological Studies of *Bacillus anthracis* Related to Development of an Improved Vaccine

3.7.1 Descriptive Summary:

The objective of this research is to develop an improved vaccine for protection from *Bacillus anthracis* (anthrax). The approach is to manipulate the pieces of genetic information (plasmids) that carry genes coding for the three proteins which form the anthrax toxin. The goal is to obtain plasmids that would code for the protective antigen component of the toxin, as well as for immunogenic protein fragments of the other two components, so that the resulting protein products would cause production of protective antibodies, but not toxicity. The techniques used in these studies are those of classical microbial genetics, and involve bacterial mating, plasmid exchange, and spontaneous genetic recombination. These events occur naturally in many species of bacteria. The strains of B. *anthracis* used in these studies are attenuated and non-virulent because they each lack at least one critical genetic determinant of virulence or toxicity.

3.7.2 The proportion of all research at this institution represented by BDRP-funded work is:

a. Percentage dollar value: Approximately 0.25%
b. Percentage person-hours: Approximately 0.20%
c. Percentage space allocation: Approximately 0.20%

d. Work with infectious organisms and with recombinant organisms at this institution would continue in the absence of BDRP funds, and was in place prior to inception of BDRP support.

The persons employed under BDRP contract account for about 0.006% of the employment in the county and also generate, directly and indirectly, about 0.008% of the county's personal income and 0.009% of the local business volume.

3.7.3 The setting in which this work is being conducted is an urban, multiple-use building, containing offices, laboratories and classrooms. The Morrill Science Building houses the Microbiology Department and four other departments. The

university has about 30,000 students, and the town of Amherst has a permanent population of approximately 25,000.

3.7.4 Environmental, Health, and Safety
Compliance

a. The university's safety program includes an Institutional Biosafety (recombinant DNA) Committee and a biological hazards committee. The Principal Investigator is a member of both of these committees. There is also a radiation safety committee, a laboratory animal use committee, and a human use committee. The university's grants and contracts office forwards all proposals to each of these committees for review to assure compliance with their published guidelines and applicable Federal guidelines (NIH and CDC guidelines). Review is documented with a cover sheet for the appropriate signatures from committee reviewers.

b. There is a community recombinant DNA oversight committee, formed during the initial period of public concern over the development of the original NIH guidelines that reviews, at the local level, research on recombinant DNA. They were very active in the l970s but are less so today.

c. No cloning or generation of recombinant organisms involving *Bacillus anthracis* genetic material takes place at this site. All recombinant work under BDRP sponsorship is of a nature such that it is considered totally safe and is exempt under the NIH Guidelines.

d. Management of general laboratory safety hazards is the responsibility of the Environmental Health and Safety office of the University Health Services. They have a professional, fulltime staff which includes trained personnel with advanced degrees. The Biological Safety Officer possesses a Ph.D. in bacteriology, has several years' experience in laboratory research in bacteriology, and has completed a training course in institutional biosafety. The Health Services Division has prepared a general "Employee Health and Safety Guide" and "Guidelines for the Management of Hazardous Wastes." The employee guide contains specific sections on chemical, biological and radiation safety practices. A biosafety manual is currently being prepared.

e. The university has a coal-fired power plant. The Massachusetts Department of Environmental Quality and Engineering cited the university with a Notice of Violation in 1981. It was determined to be an administrative and not a physical violation. There is no other organizational history of noncompliance with any environmental, health and safety, or pollution control regulations either in general or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.7.5 Waste discharges

a. There is a municipal waste water treatment facility located in Northampton-Hadley, a few miles west of the university. Several municipal, public and private institution, and small industrial waste water streams feed into this facility. There have been disruptions to treatment plant operation which have not been traceable, but have more likely been due to university physical plant operations, such as boiler cleanout, than to laboratory activities.

b. Sodium hypochlorite is used to inactivate and decontaminate cell residues, laboratory glassware and other research materials. Live cultures and reusable glassware are autoclaved after use. Wastes that cannot be decontaminated are incinerated in a pathological waste incinerator. No test animals are used under the Army research contract.

c. A laboratory biological safety cabinet is used when workers scrape bacteriophage preparations from soft agar plates. Biosafety cabinets are certified by a contractor on a yearly basis or when moved or when the filters are changed.

d. There are no BL-3 or BL-4 containment areas involved in the research, and the nature of the work does not require them.

3.7.6 Security Provisions

a. The local biosafety guidelines do not require any specific security provisions or access restrictions for this research, which is considered to involve non-infectious organisms. The largest culture used in this research effort is 25 ml, or about one ounce.

b. At 10 p.m. daily and on weekends and holidays, the outside doors to the Morrill Science Building are locked. Doors to laboratories are locked when unoccupied.

3.7.7 Accidents and Incidents

a. The most serious credible accident that may be envisioned with respect to both laboratory personnel safety and community health involves the potential for an error during conduct of a *Bacillus anthracis* mating experiment. A phase of this research involves the transfer of plasmids between different *Bacillus* types using different fertility plasmids as physical mediators. If a strain of *Bacillus anthracis* which already contained the toxin-formation plasmid were mated with a strain carrying the capsule-formation plasmid (or vice-versa), there is the potential to restore to the progeny strain of *Bacillus anthracis* both the toxin-producing and capsule-forming factors. However, even if a virulent form were to result, the only potential risk would be to the laboratory workers. Should they accidentally sustain a puncture wound, and it were contaminated

with such a reconstituted virulent strain, the result could be cutaneous anthrax, which is treatable with antibiotics. If aerosolized, a far greater number of spores would be required to infect a human than would be present in the small volumes worked with in this laboratory.

For release of a potentially hazardous organism to the environment to occur, a flask containing the restored culture would have to be inadvertently discarded into the drain without being autoclaved or treated with bleach. Both procedures are routinely followed for all discarded cultures, even those which are not potentially virulent. Sporulation would then have to occur (before or after entering the sanitary sewer system), followed by release in the treated stream or from sludge disposal. The consecutive occurrence of such events is highly unlikely. Anthrax spores are widely dispersed throughout New England in the natural environment, although at relatively low concentrations in any one area. Actual cases of the disease are rare.

To preclude such an occurrence, part of the experimental design process involves the conscious review of the genetic background of all bacterial components of a given experiment with respect to plasmid contents. Present laboratory operating procedures require the examination of all proposed matings for the capability for restoration of virulence and toxin production in each case, even if these factors are not the object of the study. No unintended mating resulting in restoration of either toxin production or spore formation has taken place in over 10 years of laboratory work with B. *anthracis* under BDRP or any other sponsorship, nor has it been intentionally prepared for any purpose.

b. There has never been an accident or incident involving breakage, spillage, or other loss of BDRP-related organisms or cultures.

c. No case of infection of a researcher or laboratory worker has taken place in the course of either BURP or non-BDRP research activities at this location.

3.7.8 Research Benefits

The current, licensed human anthrax vaccine is used to protect laboratory workers and, in some areas, meat and leather processors and wool mill workers. However, this vaccine often causes painful local site reactions and must be administered repeatedly over a long period of time before affording protection. If this research is successful, those laboratory and animal processing workers who require immunization to anthrax to maximally protect them from potential exposure would have available an improved, less painful and potentially more effective vaccine. Ideally, the military benefit would be the availability of a vaccine that could be used to protect large

numbers of troops should protection against anthrax ever be identified as a military medical priority.

3.8. Wadsworth Center for Laboratories and Research New York State Department of Public Health, Albany, NY

Contract Title: Genetically Engineered Poxviruses and the Construction of Live Recombinant Vaccines

3.8.1 Descriptive Summary:

The objective of this work is to develop the methods and approaches for using the vaccinia virus (smallpox vaccine virus) as a carrier of specific genetic information from other viruses, so that the recombinant vaccinia virus could be used as a "multiple" vaccine that would provide protection against two or more viruses in a single immunization. USAMRIID has supplied the nucleic acid fragments coding for "protective" proteins from several viruses. Studies in this laboratory are devoted to manipulating the vaccinia virus nucleic acid so that the vaccinia virus remains viable after insertion of these nucleic acid fragments. The success of the cloning manipulations, as determined by the growth of virus and expression of the cloned genes, is assessed in cultured cells, and promising recombinant vaccinia strains are provided to USAMRIID for any further testing.

3.8.2 The proportion of all research at this institution which is represented by the BDRP-funded work is:

a. Percentage dollar value: 0.6%

b. Percentage person-hours: < 1%

c. Percentage space allocation: < 1%

d. Research work with recombinant DNA and gene fragments is approximately 7.5% BDRP-funded.

e. Work with recombinant DNA and infectious organisms at this institution would continue in the absence of BURP funds, and was established prior to the existence of an Army research contract.

The persons employed under BURP contract account for about 0.004% of the employment in the county and also generate, directly and indirectly, about 0.006% of the county's personal income and 0.006% of the local business volume.

3.8.3 The setting in which this work is being carried out is an urban, mixed-use building, containing laboratories and offices. The Corning Tower complex is located in downtown Albany.

It is a 42-story building housing 20,000 employees. The New York State Department of Public Health occupies 14

floors. The Wadsworth Center for Laboratories and Research occupies three floors and is the largest state public health laboratory in the U.S. Approximately 600 persons work in the laboratories, 2,000 in Health Department administrative offices, and 17,000 to 18,000 are employed in other government offices in this and other buildings.

3.8.4 Environmental, Health, and Safety Compliance

a. The Wadsworth Laboratory safety program includes an Institutional Biosafety Committee, a Chemical Safety Review Committee, a Radiation Safety Committee, an animal welfare committee, a General Safety Committee, and a General Safety Review Committee. Management of laboratory safety is performed by a full-time safety office of four persons, many of whom have advanced degrees. The Safety Office has prepared and distributed a comprehensive safety manual containing specific sections on biological, chemical, and radiation safety precautions.

b. The state of New York has its own recombinant DNA guidelines which must be followed. In general, they parallel the NIH guidelines (51FR 16958-16985, 7 May 1986), but apply to efforts where no federal funds are used. In addition, standards in the March, 1984 CDC/N1H publication "Biosafety in Microbiological and Biomedical Laboratories" are applied to all research, as is National Sanitation Foundation Standard #49.

c. No original cloning of recombinant organisms takes place at this location under BDRP sponsorship. Use and handling of the gene fragments used here falls within guidelines established by the NIH for non-reproducing, non-infectious materials.

d. The State of New York issues the Radiation Materials License. The State has assumed conduct of their own program, which is equivalent to the Federal (NRC) program. There is a full time radiation safety officer on the staff to monitor storage, use, and disposal of radioisotopes.

e. All research involving chemicals is conducted within the guidelines and standards set forth by the New York State Right to Know law, the (Federal) Occupational Safety and Health Administration, the New York State Environmental Conservation Law, and the (Federal) Resource Conservation and Recovery Act, which establishes requirements for managing hazardous waste.

f. There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations either in general or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.8.5 Waste discharges

a. The laboratory wastes are carried by a separate

collection system within the building, and are discharged to the Albany regional wastewater treatment system.

b. Waste disposal: All biological wastes are autoclaved. A separate laboratory sewer system goes through three acid neutralizing tanks for pre-treatment prior to discharge into the city sanitary sewer system. Only salts can be flushed into the laboratory drains. Organic, chemical, radioactive, and biological wastes are collected in separate containers for pickup by Safety Office personnel.

c. Biological safety cabinets are used for cell culture and recombinant DNA work. They are physically separated to prevent cross-contamination of eucaryotic cells and procaryotic cells. Cabinets are certified by the chief safety officer, who has received specific training in this procedure from the manufacturer. Certification is performed on a yearly basis or when moved or when the filters are changed.

d. The laboratory was designed in the late 1960's and built in the 1970's, using many features of the BL-4 containment technology of that time. All lab space is negative in pressure to the hallways. Hallways are negative in pressure to the outside environment. Air flow is one way with input from the courtyard and exhaust at the top of the 42 story tower. Large fans pull the air up through a hollow internal core in the tower complex. All air flow, including both offices and laboratories is "once through," with approximately 15 air changes per hour.

e. There are no labs at Wadsworth now rated higher than BL2. When the facility was built and occupied in 1976, it had BL-3 and BL-4 capabilities. These containment levels were never used. The suite with BL-4 capability was remodeled and converted to normal laboratory space.

f. Disposal of test animals, their wastes and bedding is through autoclaving, followed by incineration in a pathological waste incinerator operated under state permit.

3.8.6 Security Provisions

Restricted access to the laboratory complex is by photo-id badge displayed through two access points, to a central receptionist. Visitors are identified and escorted by research staff. Visitor badges are photo-inactivated within a few hours. After normal working hours, sign-in rosters are used. Rooms are kept locked after hours.

3.8.7 Accidents and Incidents

a. The most serious credible accident in this laboratory would be the accidental injection of vaccine containing live vaccinia constructs which had been inadvertently contaminated with bacteria: a bacterial infection would be the result. This

type of incident is not inherently related to BDRP research. Incidents such as glass breakage with resultant abrasions to the skin of a technician or an animal handler being scratched by a rabbit with concomitant vaccination with the vaccinia virus would not be a hazardous event. Each such event is reported, and medical personnel routinely test for increased titers to vaccinia and for antibodies to foreign genes used in experiments. Personnel who work directly with the vaccinia virus are vaccinated.

Another scenario is the possibility of a lab worker contracting vaccinia through a break in the skin, and passing vaccinia on to an infant in the immediate family. Adult "revaccination" is not normally a serious illness. Accidental infant infection or infection of an immuno-suppressed adult is potentially serious, and could be life-threatening if undiagnosed and untreated. Note that the smallpox vaccine, i.e. the vaccinia virus, was used to immunize hundreds of millions of individuals world-wide in the successful effort to eradicate smallpox.

b. No credible incidents may be envisioned that would result in the spread of any disease or organism to the general public. No animal inside the Wadsworth Laboratory is infected with any organism other than the vaccinia virus containing small non-infectious gene fragments of other viruses. For the BDRP-sponsored research, all animal challenge tests against the target diseases are conducted at USAMRIID, Ft. Detrick, MD, under appropriate biological containment conditions.

3.8.8 Research Benefits

Viral vaccines have been used with great success in the control of diseases such as polio, smallpox, yellow fever, mumps, measles and rubella. Success in this research endeavor offers the promise of developing safe, polyvalent vaccines for use in protection against multiple viral diseases. Such vaccines would be useful not only to the military, which currently immunizes troops against a number of diseases, but also to the public. Effective polyvalent vaccines could eliminate the need for multiple immunizations to achieve protection against individual viruses, as well as the need to formulate vaccines containing individually developed components, for example, the current mumps, measles, rubella vaccine.

3.9. Wright State University, Dayton, OH

Contract Title: Freshwater Cyanobacteria (Blue-Green Algae) Toxins: Isolation and Purification

3.9.1 Descriptive Summary:

Freshwater blue-green algae (Cyanobacteria) are ubiquitous throughout the world, and certain species produce potent toxins that affect humans and other animals. The objectives of this

study are to develop methods to grow blue-green algae in the laboratory, to isolate and characterize chemically the various toxins, to study and understand their mechanisms of action and toxicity, and to develop methods for toxin detection. The toxins studied under BDRP support are microcystin, a liver toxin, and anatoxin, a neurotoxin.

3.9.2 The proportion of all research at this institution which is represented by the BDRP-funded work is:

a. Percentage dollar value: 2.75%
b. Percentage person-hours: < 3%
c. Percentage space allocation: < 3%
d. Work with algal toxins is approximately 70% BDRP-funded.

e. Work with algal toxins at this institution would continue in the absence of BDRP funds, and was a part of the basic research program prior to Army contract funding.

The persons employed under BDRP contract account for about 0.002% of the employment in the county and also generate, directly and indirectly, about 0.003% of the county's personal income and 0.003% of the local business volume.

3.9.3 The setting in which this work is being carried out is a building on a suburban, planned-development university campus. The Life Sciences building is a multiple-use building containing laboratories, offices, and classrooms. All extraction and purification of algal culture materials takes place in research laboratories in this building. In addition, algal culture and growth takes place in laboratory space in a dedicated research building operated by Antioch College in Yellow Springs, OH, approximately 10 miles from the main campus. Growth of 15-liter algal cell cultures takes place in the Yellow Springs laboratory, and unpurified cells are concentrated and dried there.

3.9.4 Environmental, Health, and Safety Compliance

a. The university has an Institutional Biosafety Committee that provides oversight for all recombinant DNA research; however, no cloning or production of recombinant organisms takes place in connection with the BDRP work.

b. Management of general laboratory safety hazards is the responsibility of the Department of Environmental Health and Safety. This department has prepared, and all departments are using, a general safety manual covering normal research laboratory work procedures. Specific coverage of biohazards other than recombinant DNA research is being supplemented at this time.

c. The university also has a Biological/Chemical Occupational Health and Safety Committee, a Radiation Safety Committee, and a Laboratory Animal Use Committee. The State of Ohio is currently developing a Bio-Waste Management Program. All laboratories that use hazardous materials are posted with warning signs that inform employees and visitors of the nature of the hazard and provide a means to determine whether or not special precautions are required.

d. The Department of Environmental Health and Safety is developing a common hazardous waste handling procedure throughout the university covering all areas: chemical, biological, and radiological. The university has prepared a Radiation Safety Manual, which covers the handling of radioisotopes according to NRC and State of Ohio standards. At this time, standards for management of other chemical safety hazards are taken from individual guidance as provided in rules and recommendations prepared by the OSHA, EPA, NFC, and guidelines from the American Conference of Governmental Industrial Hygienists. Biological materials handling guidance is taken from standards published by NIH, NCI, and CDC. The State of Ohio is in the process of developing standards for the handling of biologically hazardous waste, which will be adhered to by the university when published.

e. Lab coats are kept in BL-2 rooms and laundered separately by the research staff. Masks and gloves are worn during toxin handling activities, and are disposed of as hazardous waste. Only trained technicians handle toxins and test animals. Only these individuals bag and carry waste materials, bedding, and dead test animals to the incinerator.

f. There is no organizational history of non-compliance with any environmental, health and safety, or pollution control regulations either in general or as they may relate to materials used in the performance of the Biological Defense Research Program.

3.9.5 Waste discharges

a. The university discharges wastes into the Dayton municipal wastewater treatment system.

b. Spent biological research waste materials (cell residues and extracts) are chemically decontaminated by overnight exposure to a solution of sodium hypochlorite (bleach) and sodium hydroxide. Periodic animal assays are conducted to confirm inactivation.

c. Biological safety cabinets are used for all potentially hazardous work, including final preparation of toxin-containing culture residues and transfer of toxins between containers. *The* Department of Environmental Health and Safety certifies safety cabinets semiannually or when they are moved, or when the filters

are changed. Service representatives change filters and principal investigators are responsible for decontamination when it is required.

d. There are no biological containment areas managed at the BL-3 or BL-4 level related to BDRP-sponsored research, and the nature of the work performed is such that they are not required.

e. The incineration of test animals, their wastes and/or bedding is performed by the animal maintenance department, which provides all animal handling services for the university and associated medical college. No toxic animal residues or infectious organisms are associated with any BDRP-sponsored research at Wright State University.

3.9.6 Security Provisions

a. There are no specific security provisions required under the local safety program for the type of research performed.

b. General institutional security provisions which aid overall laboratory security include locked exterior doors after 10 p.m. and locked laboratory doors after working hours or when the rooms are unoccupied.

3.9.7 Accidents and Incidents

a. The most serious credible accident that may reasonably be envisioned with respect to potential for effects on laboratory personnel and other building workers is that of breaking or dropping a bottle or pan containing dried algal cell residues between the time the cells are lyophilized and the time they are again placed in solution and the toxins are extracted. This operation, at the Yellow Springs laboratory, involves the transfer of a drying tray from the freeze-drier to a biological safety cabinet. The total toxin content of the tray at this stage is approximately one-half a human lethal dose. Inhalation of a small portion of the contents of the tray could, at most, result in absorption of 1 to 2 mg of unpurified cell residues containing toxins. This is at most approximately 5% of a human lethal dose, assuming total transfer to the bloodstream. No acute effects other than mild irritation are postulated. No long-term chronic effects are known to exist, and no bioaccumulation effects have been reported. At all other stages, all operations are with materials in solution and/or conducted totally in biological safety cabinets. No incident of this type has actually taken place.

b. No credible accident may be envisioned which would place at risk the external natural environment and surrounding human population centers. All organisms involved in the research are common in freshwater communities throughout the world. The specific cultures utilized have been grown from single-cell

isolates obtained from the International Culture Foundation maintained at the Institute Pasteur.

3.9.8 Research Benefits

The basic research conducted in this effort will lead to a better understanding of several algal toxins, the factors which regulate their production by the blue-green algae, and the chemistry of the toxins themselves. Because animal and human toxicoses frequently result from ingestion of these toxins, the methods developed for their identification will be of public benefit. Increased understanding of this family of toxins, and development of methods for their identification, support the efforts of the military medical community in the development of approaches to the diagnosis and therapy of toxicoses caused by blue-green algal toxins.

Materials consulted for information on primary sites:

1. "Frederick County Comprehensive Plan. Volume I: Countywide Plan, Volume II: Regional Plans, Board of County Commissioners, Frederick County, Maryland, 31 July 1984.

2. Fort Detrick Environmental Assessment, 20 December 1983.

3. Fort Detrick Natural Resources Management Plan, Directorate of Engineering and Housing.

4. "Construction of and Lease of Land for the USAMRDC's Medical Research Institute of Toxinology -- Environmental Assessment," Fort Detrick, 30 April 1986.

5. "Occupational Safety and Health Act of 1970," 91st U.S. Congress, Public Law 91-596, 1970.

6. "Biosafety in Microbiological and Biomedical Laboratories," J. Richardson and W. Barkley (1984) U.S. Department of Health and Human Services Publication No. (CDC) 84-8395, Washington, D.C.

7. "Department of Health and Human Services, National Institutes of Health, Guidelines For Research Involving Recombinant DNA Molecules, Federal Register (1986) 51, 1695816985.

8. "Lab Safety at the Center for Disease Control" (1974) U.S. Department of Health, Education, and Welfare Publication No. (CDC) 76-8118, Atlanta, Georgia.

9. "National Institutes of Health, Laboratory Safety Monograph: A Supplement to the NIH Guidelines for Recombinant DNA Research," (1978) U.S. Department of Health, Education, and Welfare, Bethesda, Maryland.

10. "The National Institutes of Health Radiation Safety Guide," (1979) U.S. Department of Health, Education, and Welfare Publication No. (NIH) 79-18.

11. "Clinical Laboratory Safety," S. Rose (1984) J.B. Lippincott Co., Philadelphia, Pennsylvania.

12. "Guidelines for Laboratory Safety," Safety Resource Committee, College of American Pathologists, Skokie, Illinois.

13. "Management of Hazardous Occupational Environments," P. Cheremisinoff, (1984) Technomic Publishing Co., Lancaster, Pennsylvania.

14. "Code of Practice for the Prevention of Infection in Clinical Laboratories and Post-mortem Rooms," Department of Health and Social Security, (1979) London.

15. "Safety in the Academic Chemistry Laboratories," Committee on Chemical Safety, American Chemical Society, (1979) Washington, D.C.

16. "Rotor Safety Guide," Spinco Division, Beckman Instruments Inc. (1983) Palo Alto, California.

17. "Demographic and Development Data," Frederick County Department of Planning and Zoning, (1987) Frederick, MD.

18. "1987 Planning Report," Frederick County Planning Commission, (1987) Frederick, Maryland.

19. "Biological Aerosol Test Facility Draft EIS," Department of the Army, Dugway Proving Ground (February 1988).

20. "Dugway Proving Ground Installation Environmental Assessment," Department of the Army, Dugway Proving Ground (Jan 1982).

21. TECOM Regulation 385-2 Safety: "Microbiological Safety."

22. Dugway Proving Ground Regulation 385-1 "U.S. Army Dugway Proving Ground Accident Prevention Program."

23. Dugway Proving Ground Regulation 40-5 "Medical Services Occupational Health Program."

24. Materiel Test Directorate SOP 6 "Safety Guide for Work with Pathogenic Microorganisms and Biological Toxins."

25. Materiel Test Directorate SOP 19 "Emergency Evacuation Plan, Life Sciences Division," (DRAFT).

26. Materiel Test Directorate SOP 15 "The Handling and Assay of Highly Toxic Nonproteinaceous Biological Compounds (trichothecenes)."

27. Materiel Test Directorate SOP 21 "Safety Guide for Working in the High Containment, Biosafety Level 3 (BL 3) Laboratories in Bldg. 2028, Life Sciences Division," (DRAFT).

28. Materiel Test Directorate SOP 55 "Controlled Storage and Access to Freezers Containing Infectious Biologicals/Toxins."

29. Materiel Test Directorate SOP 86 "Audit Trail for Biological Holdings."

30. Materiel Test Directorate SOP 87 "Registration and Control of Infectious Microorganisms or Their Toxins."

31. Materiel Test Directorate SOP 88 "Control of Stored Infectious Biologicals."

32. Department of the Army, Aberdeen Proving Ground "Installation Environmental Impact Assessment - Fourth Edition" (March 1978) Weston Associates.

33. Department of the Army, Chemical Research, Development and Engineering Center "Operational Environmental Assessment" (September 1988).

34. Maryland Department of Transportation "Official Highway Map" (1984).

35. Robinson, D.P., J.W. Hamilton, R.D. Webster and M.J.V. Olson, "Economic Impact Forecast System (EIFS) II: User's Manual, Updated Edition. US Army Construction Engineering Research Laboratory (CERL) Technical Report N-69 (revised). 1980. Available from NTIS: ADA 144-950.

36. State of Maryland, Department of Economic and Employment Information, "Civilian Labor Force, Employment, and Unemployment by Place of Residence" (December 1987).

APPENDIX 6 IDENTIFICATION OF RELEVANT AND SIGNIFICANT ISSUES
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1. INTRODUCTION

CEQ regulations (40CFR 1501.1) require early identification of significant environmental issues deserving study, as well as recommending the Reemphasis of insignificant issues, thus focusing the scope of an EIS. Both CEQ (40CFR 1500-1508) and Army (32CFR 651) regulations instruct proponents to identify and to eliminate insignificant issues from detailed study. The Biological Defense Research Program (BDRP) EIS team applied the scoping process outlined in 40CFR 1501.7 in order to identify the relevant issues and to eliminate issues of no concern. An interdisciplinary approach was used to ensure that relevant or significant issues would not be overlooked and that the EIS would emphasize relevant environmental issues. Because of the highly technical and complex nature of the BDRP, special emphasis was placed on the scoping process to ensure that all relevant areas of environmental concern were identified. These concerns were then compiled into a master list of potential areas impacted by the BDRP. The resources and the process used to identify the relevant or significant issues are described in the following paragraphs.

2. NEPA REQUIREMENTS

The BDRP EIS team reviewed both NEPA and the CEQ regulations to identify the areas of environmental concern that must normally be addressed in an EIS. The regulations require that certain issues, such as endangered species, public health and safety, must always be examined. To assure a comprehensive list for later screening, all of the areas for which consideration is mandated were listed without regard to any a priori opinions as to the significance or insignificance of potential impacts.

3. ISSUE IDENTIFICATION

3.1 SCOPING PROCEDURES

Measures outlined for the scoping process in the CEQ Regulations (40CFR 1501.7) were used to provide an opportunity for potentially concerned Federal, State, and local agencies; public interest groups; and other interested parties to participate in the identification of relevant or significant issues relating to the BDRP (1). Two scoping meetings were held in Tysons Corner, Virginia, on August 12, 1987 (2). Five individuals made presentations at these meetings. In addition, nineteen written statements and letters were submitted. The comments brought forth during the scoping process were reviewed by the EIS team and additional issues identified by the scoping participants were added to the list.

3.2 EICS MODEL

The Environmental Impact Computer System (EICS), (3) is a computer analysis system developed by the U.S. Army Construction

Engineering Research Laboratory (USACERL) to direct the EIS preparer's attention to those elements of the environment considered most likely to be affected by an Army action. The EICS is designed to consider nine functional areas of military activities. The broad functional area "Research, Development, Test and Evaluation" was selected as the area most germane to the BDRP. Environmental considerations for each of the functional areas are subdivided into thirteen technical specialties, from which the eight most pertinent to the BDRP were selected. These eight areas were health and safety, ecology, surface water, ground water, air quality, transportation, sociology, and economics. Output from EICS was then used to identify additional relevant areas of potential impact, which were added to the list.

3.3 OTHER DOCUMENTS

Additional issues or areas of potential environmental impact were identified by reviewing documents such as *Foundation on Economic Trends, et al., v. Caspar W. Weinberger, et al.,* Civil action 86-2436, filed February 12, 1987, in the U.S. District Court of the District of Columbia (4), the first amended complaint in the case of *Foundation on Economic Trends v. Weinberger*, Civil Action No. 86-2436, filed on September 29, 1986 in the U.S. District Court for the District of Columbia, (5), the Interrogatories (6), the "Final Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules" (7), the "Draft Environmental Assessment for Construction of and Lease of Land for the USAMRDC's Medical Research Institute of Toxinology, Fort Detrick, Maryland" (8), the "Draft Environmental Impact Statement, Biological Aerosol Test Facility, Dugway Proving Ground, Utah" (9), the "Working Paper Draft, Operational Environmental Assessment, Chemical Research, Development, and Engineering Center, Aberdeen Proving Ground, Maryland" (10), the "Memorandum Opinion and Order, *Foundation on Economic Trends v. Caspar W. Weinberger, et al.* (11), and the """"Biosaftey in Microbiological and Biomedical Laboratories" (12), etc.

4. IMPACT ANALYSIS MATRIX (JAM)

4.1 DEVELOPMENT OF THE IAM

The BDRP includes a broad set of technical and administrative functions conducted at numerous facilities. To apply the NEPA process efficiently to this extensive program, the EIS team developed a BDRP-specific analytical approach; the Impact Analysis Matrix (IAM).). The IAM forced a systematic, comprehensive examination of all of the potential impacts of the BDRP, evaluated in light of the elements influencing those impacts. The matrix approach produced more than merely a "checklist" because it encouraged a searching, realistic look at every interaction of activity and environment for potential impacts or hazards with reasoned thought and analysis. The

result has been an exhaustive consideration and full disclosure of the potential environmental impacts associated with this program.

4.2 MATRIX DESIGN

The IAM was designed to display graphically program activities, controls exerted upon those activities, areas of the biophysical and socioeconomic environment that might be impacted, relevant areas of concern, and perceived and actual risks associated with the program. Descriptions of these elements as applied within the IAM are given below. At the same time, the application of the IAM to the programmatic areas and to individual sites served as documentation of the EIS team's consideration and analysis of the potential environmental impacts of the total BDRP.

4.2.1 ACTIVITIES

The activities conducted within the BDRP were grouped as laboratory and field (Research, Development, Test and Evaluation) and non-laboratory (Administration and Management) related endeavors. Each of these broad categories was further subdivided into more discrete task areas that could be evaluated individually for potential impacts on the identified areas of environmental concern. These activities and their major components are listed on Attachment I and discussed in section 3.2 of the EIS.*

4.2.2 CONTROLS

The major operational, safety, security, and regulatory controls under which BDRP activities are conducted are identified and defined on Attachment II and discussed in section 3.3.

4.2.3 POTENTIAL AREAS IMPACTED

The BDRP EIS Team developed a comprehensive list, through the method described in the foregoing discussion of issues and concerns, and added others based upon their experience and expertise. This completed list of issues was then grouped into two major elements of the environment, the biophysical and the socioeconomic. Fifteen categories of areas potentially impacted were then formulated and further subdivided to provide greater specificity. These categories and sub-categories were thoroughly reviewed by the EIS team to ensure that all previously identified issues could be addressed within one of the categories. These fifteen categories, listed in Attachment III, define the relevant potential areas impacted by the BDRP.

* All references to "section..." refer to information in the body of the EIS.

4.2.4 RISKS

Many of the issues and concerns raised during the public scoping process dealt with the potential for risks to the environment arising from the many activities conducted within the BDRP. Thus, the IAM was designed to identify perceived and actual risks for each activity conducted, as well as perceived and actual risk to each area of environment.

4.2.5 RELEVANT AREAS OF CONCERN

Identification of the significant and minor relevant areas of concern is the ultimate result of application of the JAM. Note that both the relevant areas of environmental concern as well as the activities that create these concerns are identified. By virtue of this thorough analysis, this process also identifies areas which will not be impacted, or only minimally impacted. This allows appropriate attention to be focused on the potentially significant issues and concerns and eliminates the others from unwarranted detailed coverage.

4.3 MATRIX APPLICATION

Use of the IAM forced a multi-dimensional evaluation of each program activity. A systematic examination of each potential issue or impact, by an interdisciplinary team approach, ensured a more comprehensive scrutiny than any one individual was capable of providing. The different perspectives and areas of expertise were brought to bear in a synergistic fashion, such that the composite view represents a more thorough, "hard look" than can a number of separate individual opinions. Thus, the objective of identifying significant issues related to a proposed action, as expressed in 40CFR 1501.7, was achieved by the exhaustive and pragmatic analytical process of a scientific, interdisciplinary application of the JAM.

In order to provide an understanding of how the IAM was used, a sample "walk thru" is presented below. The application of the IAM involves selection of an activity (e.g. laboratory work, storage, etc.) to be evaluated. Each type of activity involves tasks or elements which have differing potential for impacts. The activity is then reviewed in relation to each of the four categories of controls (operational, safety, security, and regulatory) to determine which controls are applicable. A check mark indicates that a control is applicable. A knowledge of the nature of typical controls, and their respective effectiveness and limitations, is implicit in this application. The activity is then identified as either presenting a perceived or an actual risk, or both. The degree of risk is classified as being high or low.

Based on the above information, an assessment of the relative impact (high or low and adverse or positive) for each of the potential areas impacted is made. A blank indicates that an

activity does not measurably affect a particular area of potential concern. Finally, a determination is made as to whether the effect is of relevant concern. This involves a reasoned judgement by the interdisciplinary evaluators, who used a synoptic consideration of the pertinent aspects from the matrix, along with other data such as quantities involved, past experiences, and any special circumstances which may be present. The activity is then specified as being either a minor or significant relevant area of concern, or neither. The IAM is completed in a similar manner for the remaining activities. Once all the applicable activities have been evaluated in the vertical direction, each potential area impacted (row of the matrix core) is reviewed for cumulative risks across the horizontal axis of the matrix. This provides an evaluation of risk (high, low or none) from BDRP activities to the potential area impacted. Furthermore, an evaluation is made to determine whether the risks should be classified as actual or perceived, or both, and to what degree. Next, a determination is made of the significance of the impacts or concerns for each of the potential areas impacted. This involves a synthesis by the interdisciplinary team of all available information into an informed judgement. An evaluation of the context and intensity, as defined in 40CFR 1508,27, of each impact or concern guides this assessment and judgement. Again, the impacts or concerns are determined to be either minor, significant, or neither. All of the activities and potential areas impacted are analyzed in this fashion to complete the JAM.

The background and basis for developing the IAM is helpful when considering its application. Particular attention must be paid to such factors as the potential hazards involved, and the magnitude, duration, degree, and severity of possible consequences when ascribing a relative level of potential impact, or concern, upon an area impacted. Other considerations such as relative importance, scarcity, uniqueness, etc., of the resources must be analyzed as well. Proper use of the IAM requires sound, professional judgement to achieve meaningful results. It should also be understood that consideration of the "existing" situation or resource base includes consideration of forseeable future changes that might affect the quality of a resource. Thus, a knowledge and understanding of both the areas or resources which could potentially be impacted, and the manner in which the program element or activity could cause impacts, are necessary ingredients for proper application of the JAM.

The completed IAM provides a thorough, systematic, interdisciplinary analysis of the potential effects of the BDRP activities on the human environment. It is used to identify the areas of significant environmental concern that are emphasized in the EIS. It also identifies the issues that are not significant and are thereby eliminated from detailed study. The risk assessment, by activity and potential area impacted, was useful in developing accident or incident scenarios for further evaluation, (Appendix 9). The existence of perceived risks, which are not substantiated by credible scientific evidence,

indicates a need to provide more, or better, information to the public. Identification of activities as either minor or significant concerns also served to focus the analyses presented in the EIS.

5. IAM APPLICATION TO THE BDRP

The site-specific activities of the BDRP group naturally into primary and secondary sites. The functional, or programmatic aspects of the BDRP, are grouped into seven risk and/or issue categories. Detailed descriptions of the primary and secondary sites and programmatic categories are presented in the body of the DEIS (see sections 2.4, 2.5, 3.5, and appendices 3, 4 and 5). The EIS team applied IAM evaluations to each of the sites and to each of the programmatic categories using the described methodology. The results of these evaluations led to an identification of the relevant areas of concern addressed in this DEIS and to the elimination of insignificant issues from further consideration.

The sites and programmatic areas analyzed using the JAM's are listed below, and the results of the IAM evaluations, along with summaries are contained in Attachment IV.

Primary Sites

	FIGURE
1. U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) Frederick, MD	A6-1
2. U.S. Army Chemical Research, Development and Engineering Center (CRDEC) Aberdeen Proving Ground, MD	A6-2
3. U.S. Army Dugway Proving Ground (DPG) Dugway, UT	A6-3

Secondary Sites* (selected)

4. Jefferson Medical College Philadelphia, PA	A6-4
5. SRI International Menlo Park, CA	A6-5
6. Wright State University Dayton, OH	A6-6
7. The Salk Institute, Government Services Division (TSI, GSD), Swiftwater, PA	A6-7
8. Southern Research Institute (SoRI) Birmingham, AL	A6-8

9. Scripps Clinic and Research Foundation A6-9
La Jolla, CA
10. New York State Department of Public Health A6-10
Albany, NY
11. University of Massachusetts A6-11
Amherst, MA
12. Salk Institute A6-12
La Jolla, CA
Programmatic Evaluation
13. High Hazard Organisms A6-13

14. Low Hazard Organisms A6-14

15. Toxins A6-15

16. Genetically Engineered Microorganisms (GEMs) A6-16

17. Rapid Diagnosis and Detection A6-17

18. Vaccine and Drug Therapy Development A6-18

19. Other Program Research and Activities A6-19

* For a listing of all secondary sites, see Appendix 3.

6. EVALUATION OF FUTURE BDRP ACTIVITIES

This FEIS has been prepared as a programmatic environmental analysis in keeping with the guidance provided in 32CFR 651 and 40CFR 1502.4(c), and will serve as a basis for tiering of future analyses and NEPA documents for proposed future activities of the BDRP.

From a programmatic viewpoint, it has been determined that the most significant issues and environmental concerns arise from the procedures associated with high hazard infectious organisms, GEMs, and toxins. Impacts associated with all other program areas are insignificant. Thus, a tiering approach can be utilized to examine proposed changes to the BDRP or future activities. The requirement for separate NEPA documentation of future site-specific activities associated with new construction or modifications to existing facilities will be evaluated in light of the programmatic environmental analyses presented in this EIS and the potential effects of the proposed action. Application of the IAM serves to identify issues, impacts, areas of concern, and activities related to specific facilities or to future programmatic activities.

ATTACHMENT I

ACTIVITIES DEFINITION

{See Section 3 for detailed description. of activities.)

I. RESEARCH, DEVELOPMENT, TEST AND EVALUATION

A. Laboratory Work
1. Supplies in and out
2. Equipment Maintenance
3. Preparation of reagents and solutions

B. Storage of Chemicals, Biologicals, Supplies, and Radioisotopes
1. Supplies - plasticware, glassware
2. Chemicals - heavy metal salts, acids & bases, organics
3. Biologicals - replicating, nonreplicating, hazard levels
4. Radioisotopes

C. Conduct Specific RDT&E Procedures
1. Logistics - remove, perform, decontaminate, dispose
2. Transportation - in, out, special requirements

D. Laboratory Animal Care and Use

E. Prototype Development of RDT&E Materials
1. Protective equipment and detectors
2. Biological materials for research and test

F. Testing
1. Humans
2. Equipment

II. ADMINISTRATIVE AND MANAGEMENT SUPPORT OF RDT&E ACTIVITIES

A. Operation and Maintenance
1. Utilities
2. Operations

B. Waste Stream Management
1. Air
2. Liquid
3. Solid

C. Planning and Design

1. Preparation of test methods for equipment
2. Preparation of test methods for biological and medical research
3. Design methods for medical protection
4. Design methods for physical protection

D. Program Management

1. Primary sites
2. Secondary sites
3. Publication of Accomplishments and Results

CONTROLS

(See Section 3 for detailed descriptions of controls.)

I. OPERATIONAL
- A. Physical Plant
- B. Waste Stream

II. SAFETY
- A. Laws and Regulations
- B. Institutional Approval
- C. Professional Standards
- D. Good Judgement

III. SECURITY
- A. Laws and Regulations
- B. Enforcement
- C. Physical security

IV. REGULATORY
- A. Controlled and Hazardous substances
- L. Congressional
- C. National Policy and Biological Weapons Convention
- D. Army Regulations

ATTACHMENT III

AREAS OF POTENTIAL IMPACT

Biophysical:

1. LAND USE: General pattern of existing land uses surrounding the research facility or the test site.

a) Agricultural- The use of land for farming purposes, including silviculture, aquaculture, animal and plant husbandry.

b) Industrial- Includes manufacturing and processing, distribution centers, storage warehouses, offices, labs, etc.

c) Commercial- Includes retail, shopping centers, supply stores, professional and business offices, etc.

d) Residential- Includes single-family residences as well as multi-family and mixed-use areas (R-1, R-2, R-3 zoning, etc).

e) Recreation- Includes public open space (parks), forest preserves, zoological parks, golf courses; owned or operated by the city, the county, state, or Federal government or other public agency. Privately owned areas used for this purpose are also considered. f) Wetlands- As defined by the National Wetlands Inventory. g) Floodplains Areas within the 100-year floodplain.

h) Unique Geographical Area- Includes proximity to wild and scenic rivers, ecologically critical areas, and areas of unique activity.

i) Policies- Includes land-use plans, subdivision regulations and zoning ordinance requirements. Siting a new facility would generally have a greater effect on these policies.

2. PLANT AND ANIMAL ECOLOGY: Description of the naturally occurring habitat adjacent to the research facility or the test site.

a) Populations- Description of organisms inhabiting a particular habitat and their relationship with the environment.

b) Terrestrial Habitats- Description of the type of habitats existing adjacent to the research facility. This would include cleared areas, meadows, grasses, woodlands, and disturbed environments.

c) Aquatic Habitats- Description of creeks, marsh areas, and streams, etc., that provide habitat for certain mammals, birds, fish, and other aquatic species.

d) Endangered Species- Description of any identified endangered, threatened, or other "special interest" protected species, and designated critical habitat near the research facility.

3. GEOLOGY: Description of land formations in the area adjacent to the research facility.

a) Soils- Identification and description of existing soil types in the area of concern.

b) Topography- The physical or natural features and their structural relationships in the area of concern.

c) Erosion- Existing erosion conditions and erosiveness of soils in the area adjacent to the research site.

4. WATER: General description of the water quality, quantity, and availability of water supply in the area adjacent to the research facility or the test site.

a) Surface- Includes both water quality and quantity.
b) Ground- Includes both water quality and quantity.

5. AIR QUALITY:

a) Ambient Standards- Primary and Secondary Ambient Air Quality Standards adopted under the Clean Air Act (particulate matter, sulfur dioxide, carbon monoxide, hydrocarbons, ozone, lead, arsenic, and radionuclides).

b) Biological- Includes "emission standards" for "hazardous" air pollutants (asbestos, beryllium, mercury, vinyl chloride, benzene). Also includes biological and other parameters for which there are no standards.

6. AGRICULTURE:
a) Crops- Includes all agricultural crops (grain, forage, fiber, fruits, and vegetables, etc).

b) Livestock- Includes all agricultural livestock (swine, cattle, poultry, etc).

7. CULTURAL RESOURCES:

a) Historical- Includes districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, as well as other significant scientific, cultural, or historical resources.

b) Archeological- Includes the material remains of past human life and activities such as relics, artifacts, and monuments.

8. ENERGY RESOURCES:

a) Depletable Supplies- Includes depletable energy resources such as oil, gas, coal, and electrical energy produced from these resources.

b) Non-Depletable- Includes renewable or non-depletable energy resources such as solar, wind and water, and electrical energy produced from these resources.

Socioeconomic:

9. SOCIOLOGICAL ENVIRONMENT:

a) Demographics- Includes characterization of the human population (1980 census data, with its updates and projections, including age, race, density, distribution, etc).

b) Aesthetics- Visual characterization of the area of concern.

c) Noise- The existing noise levels of the area of concern. Existing noise sources include highway traffic, aircraft, routine facility operations, construction, etc.

d} Odors- The existing odor levels of the area of concern. Potential odor sources include decontamination of containment areas, autoclaving, handling of animal wastes, sanitary landfills, etc.

10. ECONOMIC ENVIRONMENT:

a) Labor Force- Characterization of the labor force in the area of concern (employment, income level).

b) Economic Activity- Total business volume in the area of concern.

c) Property Values- Characterization of property values in the area of concern.

11. PUBLIC OPINION:

a) Controversial Issues- Includes laboratory animal rights, biotechnology-related issues (e.g. genetic engineering), conduct of defensive research in accordance with the BWC.

b) Social Concerns- Includes socioeconomic concerns, such as perceived benefits of research, perceptions of the nature of work conducted (e.g. classified vs unclassified), and overall positive and negative views of Army activities.

12. PROGRAM BENEFITS:

a) National Defense Posture- Existing and future defense posture of the United States with respect to defense against biological warfare threats.

b) Scientific Benefit- Potential spin-off benefits include methods of detection, treatment, and prevention of various diseases, as well as increased understanding of basic biological and disease processes.

c) Public Benefit- Includes benefit to the public at large, arising from the development of vaccines and drugs for protection against naturally occurring animal and human diseases.

13. TRANSPORTATION:

a) Road- Existing roadway transportation system in the area.

b) Rail- Existing rail transport system in the area.

c) Air- Existing air transport system in the area.

d) Traffic- Existing traffic conditions on the roads in the area of concern.

14. HUMAN HEALTH:

a) Workforce- Health of laboratory personnel (Research, Development, Test, and Evaluation activities), and non-laboratory personnel (Administration and Management activities), in the research facility.

b) General Population- Health of the general population in the area of concern.

15. SAFETY:

a) Construction- Current and future construction safety record of the research facility.

b) Occupational- Laboratory safety record of the research facility (includes activities covered under OSHA).

c) Accidents- Accident record of the research facility including accidents resulting in an infection and/or contamination.

Refer to Appendix 5 for detailed site-specific information on each site.

MATRIX ANALYSIS SUMMARY

Site: U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Frederick, MD

The mission of USAMRIID is to conduct studies on the pathogenesis, diagnosis, prophylaxis, treatment and epidemiology of infectious diseases and toxins that pose potential biological warfare threats.

Minor potential impacts on surface water quality and biological air quality are possible due to the high hazard nature of the organisms and toxins under study; however, with the mitigating circumstances of the operational and structural (containment) controls of the BL-3 and BL-4 facilities, these materials are perceived to be of no environmental hazard to the air or water resources. There is a low but acceptable inherent risk to the workforce in working with the high hazard organisms and toxins (including receiving immunization with vaccines that are used to protect personnel at risk) that is minimized by safety procedures, equipment, and practices, etc. The labor force consists of approximately 570 people (combined military and civilian). Although this labor force has an identifiable economic impact on the community, it is of minor importance when considered in the overall economic climate of the immediate region.

USAMRIID:

1. Land Use- (NA)*

2. Plant and Animal Ecology- (NA)

3. Geology- There is a potential for low impact to soils, topography, and erosion arising from the contribution USAMRIID makes to the overall solid waste landfill requirements at Fort Detrick.

4. Water- There is a potential for low level impact to surface water due to the use of high hazard infectious organisms and toxins, which is mitigated fully by the existing controls under normal operating conditions. Activities with potential to produce impacts on surface water are laboratory procedures, operation and maintenance of the facility, and waste stream management. The potential low level impact to ground water is related to use of landfill for disposal of solid wastes (see Geology, #3, above).

5. Air Quality- There is a minor impact on the ambient air quality arising from the steam and electrical energy required for the operation and maintenance of this institute. USAMRIID also contributes to air emissions from the Fort Detrick incinerator through the waste stream management activity; however, with the appropriate controls in place, it is not an area of relevant concern. The potential for low level impact to the biological air quality is the same as for surface water discussed above (#4).

6. Agriculture- (NA)

7. Cultural Resources- (NA)

8. Energy Resources- Operation and maintenance and waste stream management at USAMRIID require the use of relatively small amounts of depletable energy resources. These requirements are for electrical energy, steam, and operation of the incinerator.

9. Sociological Environment- Operation and maintenance and waste stream management at this institute may potentially affect the aesthetics of the area due to the visual impact of the buildings and from the short-term localized impact of the waste plume from the incinerator. These activities also create odor

*(NA)- There are no projected impacts on this parameter since research is being conducted at existing facilities, no new construction is proposed, and no existing environments are being adversely affected or altered.

due to the disposition of animal wastes. However, these odors are transient, are mainly confined to the inside of buildings, and are environmentally insignificant.

10. Economic Environment- USAMRIID employs approximately 570 people, which represent approximately 14% of all the persons assigned to or employed at Fort Detrick. This labor force has a significant economic impact on the local community. It is considered a relevant area of minor concern in the overall economic climate of the region. The positive impacts of this institute are distributed among the activities with the largest number of employees. There are also low level positive impacts on the economic activity due to the purchase of laboratory materials and supplies from local vendors, contracting for cleaning services, and local purchase of supplies for operation and maintenance of the facility.

11. Public Opinion- Research involving high hazard infectious organisms, toxins, and use of rDNA molecules in the construction of genetically engineered microorganisms (GEMs) may be controversial in nature. However, this controversy is not related to specific sites, but to the overall BDRP (refer to section 5.2 on the national environment considerations). Social concerns are related to the perceived controversial nature of this research and are discussed in section 5.2 also.

12. Program Benefits- National defense posture, scientific benefit, and public benefit are discussed as part of the considerations of the national environment, since these benefits are derived from the entire program.

13. Transportation- USAMRIID is the destination of approximately 500 light-duty vehicles each work day. The traffic impacts associated with operation and maintenance of this institution are not considered significant, since they represent less than 10% of the Fort Detrick total traffic flow and less than 1% of the daily traffic flow in the vicinity of Fort Detrick.

14. Roman Health- There is a low but acceptable inherent risk to the workforce in working with the high hazard organisms, (including receiving special immunization with vaccines that are used to protect personnel at risk), that is minimized by safety procedures, equipment, and practices. There is a high perceived risk to the workforce among certain segments of the public; however, the actual risk based on past laboratory history is low. Impacts on the health of the workforce have been identified as a minor relevant area of concern. A small potential impact to the general population was identified due to the waste stream management activities. This was based on the perception of high risk among certain segments of the public. The actual effects with appropriate controls and safeguards in place are nonexistent.

15. Safety- Construction was scored as a minor potential effect for operation and maintenance due to the special containment facilities (BL3-4) required for working with high hazard infectious organisms. Research activities are associated with potential impacts in the area of occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures, has no significant impact. Accidents could involve the exposure of an individual to a toxin or an infectious organism. Although there is a potential for accidents in the laboratory (refer to Appendix 9), the probability of their occurrence is very low with the appropriate controls in place (Appendix 12).

IAM (Fig A6-1) Summary

Significant Relevant Areas of Concern:

Public Opinion- Controversial issues

Program Benefits- National Defense Posture (+)
Scientific Benefit (+)

Minor Relevant Areas of Concern:

Water- Surface

Air Quality- Biological

Economic Environment- Labor Force
(+)
Program Benefits- Public Benefit (+)

Human Health- Workforce

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

PRIMARY SITE: U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Frederick, MD

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓	✓	✓	✓	✓	✓		OPERATIONAL
✓	✓	✓	✓	✓	✓	✓	✓			SAFETY
✓	✓	✓	✓	✓	✓	✓	✓			SECURITY
	✓	✓	✓	✓	✓	✓	✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

RISKS	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	S	M
PERCEIVED	L	L	H	L	L	L	L	L/H	—	L				
ACTUAL	L	L	L	L	L	L	L	L	—	—				
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered species														
3. GEOLOGY:														
Soils								L						
Topography								L						
Erosion								L						
4. WATER:			L				L	L			L	L		✓
Surface														
Ground								L						
5. AIR QUALITY:														
Ambient Standards							L	L						
Biological			L				L	L			L	L		✓
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archaeological														
8. ENERGY RESOURCES:														
Depletable Supplies							L	L						
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics							L	L						
Noise														
Jobs							L	L						
10. ECONOMIC ENVIRONMENT:														
Labor Force	L+		L+		L+		L+		L+	L+	L	—		✓
Economic Activity				L+			L+							
Property Values														
11. PUBLIC OPINION:														
Controversial Issues		L	L	H	L	L		L	L	L	L	H	✓	
Social Concerns			L					L						
12. PROGRAM BENEFITS:														
National Defense Posture	L+	L+	H+	L+	H+	L+	L+			H+	H+	L	✓	
Scientific Benefit	L+		H+	L+	H+	H+			L+	H+	H+	L	✓	
Public Benefit			L+		L+	L+								✓
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic							L							
14. HUMAN HEALTH:														
Workforce	L	L	L	L	L	L	L				L	H		✓
General Population								L			—	H		
15. SAFETY:														
Construction							L							
Occupational	L	L	L	L	L		L	L			L	—		
Accidents	L	L	L	L	L		L				L	—		
SIGNIFICANT	—	—	—	—	—	—	—	—	—	✓				
MINOR	—	—	✓	✓	✓	✓	—	✓	—	—				

Figure A6-1

MATRIX ANALYSIS SUMMARY

Site: U.S. Army Chemical Research, Development and Engineering Center (CRDEC), Aberdeen Proving Ground, MD

CRDEC carries out bench-scale investigations in four primary areas. These are a) receptor technology, b) decontamination of materiel, c) development of toxin and pathogen detectors, and d) immunochemistry. No viruses, insects or other pathogens are grown in CRDEC laboratories under the BDRP. No open-air field testing of biological materials is conducted at CRDEC. Thus, the nature of research conducted under the BDRP at CRDEC is lowhazard, non-controversial (i.e. rapid detection), but of significant importance to the national defense posture. This examination of the CRDEC covers only those activities performed as part of the BDRP.

CRDEC:

1. Land Use- (NA)*

2. Plant and Animal Ecology- (NA)

3. Geology- (NA)

4. Water- There is a potential for low impact to surface water due to the BDRP studies conducted with toxins at CRDEC. However, because of the low hazard nature of the work being conducted, and the small quantities of material being used, it is not indicated as a relevant area of concern.

5. Air Quality- There is a minor impact on ambient air quality at the site of generation from the steam and electrical energy required for the operation and maintenance of facilities at CRDEC. To the extent that these facilities are used as part of the BDRP effort, the impact arising from the BDRP is proportionally small. CRDEC also contributes to air emissions from the incinerator through the waste stream management activity; however, with the appropriate controls in place, it is not an area of relevant concern. There is no potential for impact to the biological air quality because high hazard organisms are not used in the BDRP studies performed at CRDEC.

6. Agriculture- (NA)

7. Cultural Resources- (NA)

8. Energy Resources- Operation and maintenance and waste stream management at CRDEC require the use of small amounts of depletable energy resources. These requirements are for electrical energy, steam, and operation of the incinerator.

9. Sociological Environment- (NA)

10. Economic Environment- There are 19 persons employed full or part time at this facility under BDRP funding. This is only 1.3% of the total employees at CRDEC and 0.1% of the 18,000 Aberdeen Proving Ground employees. Thus, the labor force has a small impact on the local community, and is considered as a relevant area of minor concern. The positive impacts of the BDRP employees are distributed among the activities with largest number of employees. There are also low level, positive impacts

*(NA) There are no projected impacts on this parameter since research is being conducted at existing facilities, no new construction is proposed, and no existing environments are being adversely affected or altered.

on the economic activity due to the local purchase of supplies for operation and maintenance of this research facility.

11. Public Opinion- Research involving toxins may be perceived as controversial in nature by certain segments of the public. However, this controversy is not related to specific sites, but to the overall BDRP (refer to section 5.2 on the national environment considerations).

12. Program Benefits- National defense posture and scientific benefit are discussed as part of the considerations of the national environment, since these benefits are derived from the entire program.

13. Transportation- (NA)

14. Human Health- (NA)

15. Safety- BDRP activities conducted at CRDEC include potential impacts in the area of occupational safety. However, conduct of the research and development effort under controlled conditions and in compliance with the standard operating procedures has no impact.

IAM (Fig A6-2) Summary

Significant Relevant Areas of Concern:

Program Benefits- National Defense Posture
(+)

Minor Relevant Areas of Concern:

Economic Environment- Labor Force
(+)

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

PRIMARY SITE: U.S. Army Chemical Research, Development and Engineering Center (CRDEC), Aberdeen Proving Ground, MD

LEGEND
H=HIGH
L=LOW
+=POSITIVE

CONTROLS	ACTIVITIES: RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT			
	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
OPERATIONAL	✓	✓	✓	✓	✓	✓	✓	✓	✓	
SAFETY	✓	✓	✓	✓	✓	✓	✓	✓		
SECURITY	✓	✓	✓	✓	✓	✓	✓	✓		
REGULATORY		✓	✓	✓	✓	✓	✓	✓	✓	✓

RISKS		LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	S	M
	PERCEIVED	L	L	L	—	—	L	—	L	—	L				
	ACTUAL	L	L	—	—	—	—	—	—	—	—				
BIOPHYSICAL	1. LAND USE:														
	Agriculture														
	Industrial														
	Commercial														
	Residential														
	Recreation														
	Wetlands														
	Floodplains														
	Unique Geographical Area														
	Policies														
	2. PLANT AND ANIMAL ECOLOGY:														
	Population														
	Terrestrial Habitats														
	Aquatic Habitats														
	Endangered Species														
	3. GEOLOGY:														
	Soils														
	Topography														
	Erosion														
	4. WATER:			L											
	Surface														
	Ground														
	5. AIR QUALITY:							L	L			—			
	Ambient Standards														
	Biological														
	6. AGRICULTURE:														
	Crops														
	Livestock														
	7. CULTURAL RESOURCES:														
	Historical														
	Archeological														
	8. ENERGY RESOURCES:							L	L						
	Depletable Supplies														
	Non-Depletable														
SOCIOECONOMIC	9. SOCIOLOGICAL ENVIRONMENT:														
	Demographics														
	Aesthetics														
	Noise														
	Odors														
	10. ECONOMIC ENVIRONMENT:	L+		L+								L+	—		L+
	Labor Force														
	Economic Activity							L+							
	Property Values														
	11. PUBLIC OPINION:						L			L	L	—	L		
	Controversial Issues														
	Social Concerns														
	12. PROGRAM BENEFITS:	L+		L+		L+	L+				H+	H+	L		L+
	National Defense Posture														
	Scientific Benefit	L+		L+											
	Public Benefit														
	13. TRANSPORTATION:														
	Road														
	Rail														
	Air														
	Traffic														
	14. HUMAN HEALTH:														
	Workforce														
	General Population														
	15. SAFETY:														
	Construction														
	Occupational	L	L	L				L				L	—		
	Accidents														
	SIGNIFICANT	—	—	—	—	—	—	—	—	—	—				
	MINOR	—	—	L+	—	L+	L	—	—	—	L+				

Figure A6-2

MATRIX ANALYSIS SUMMARY

Site: U.S. Army Dugway Proving
Ground (DPG), Dugway, UT

DPG is the independent testing organization for all biological defense systems developed by the DoD. One of its principal missions is developmental testing (DT) of biological defense materiel and equipment. Testing with biological materials as part of the BDRP constitutes only a very small portion of the overall DPG mission, and this examination addresses only that part of the DPG activities.

The work performed at DPG includes general laboratory work in BL-1 and BL-2 areas and aerosol testing of equipment in laboratory chambers. DPG has the capability to perform open-air field testing with simulant materials. No recombinant DNA studies or work with genetically engineered microorganisms (GEMs) is performed at this site. Open-air testing is a significant area of concern to the locale because of the perceived high hazard associated with it. Thus, DPG's activities are very important to the national defense posture. The impact of the labor force associated with the biological defense effort at this facility is minor, but when considered in light of the very small total Dugway population, it has relative significance. DPG:

1. Land Use- (NA)*

2. Plant and Animal Ecology- (NA)

3. Geology- There is a potential for low impact to soils due to the contribution the BDRP makes to the overall solid waste landfill requirements at DPG.

4. Water- There is a potential for low level impact to surface water due to the work being done with toxins at DPG. Activities with potential to impact surface water are laboratory procedures and testing.

*(NA) There are no impacts projected for this parameter since research is being conducted at existing facilities, no new construction is proposed (see note below), and no existing environments are being adversely affected or altered.;

Note: DPG has published a separate DEIS for the proposed construction of a Biological Aerosol Test Facility (BATF). Issues relevant to the new construction and to the use of high hazard microorganisms at DPG are discussed in that document (9).

5. Air Quality- There is a minor impact on ambient air quality at the site of generation from testing and from the steam and electrical energy required for the operation and maintenance of facilities at DPG. These facilities contribute to air emissions from the incinerator through the waste stream management activity; however, with the appropriate controls in place, ambient air quality is not an area of relevant concern.

6. Agriculture- (NA)

7. Cultural Resources- (NA)

8. Energy Resources- Operation and maintenance and waste stream management associated with the BDRP effort conducted at DPG require the use of small amounts of depletable energy resources. These requirements are for electrical energy, steam, and operation of the incinerator.

9. Sociological Environment- (NA)

10. Economic Environment- Approximately 10 employees at DPG are supported by funding from the BDRP. This represents 0.7% of the total DPG personnel. This labor force does not have a significant economic impact on the local community; however, it is considered a relevant area of minor concern due to the sparse population of the region. The positive impacts are distributed among the activities with the largest number of employees. There are also low level positive impacts on the economic activity due to the local purchase of laboratory supplies for operation and maintenance of Baker laboratories.

11. Public Opinion- Research involving toxins may be perceived controversial in nature. However, this controversy is not related to specific sites, but to the overall BDRP (refer to section 5.2 on the national environment considerations). Social concerns are related to the perceived controversial nature of this research and are also discussed in section 5.2. Additional controversy and social concerns at DPG arise from the open-air testing of biological simulants that takes place at this site. Much of this controversy and concern relate to other activities conducted at DPG that are not related to the BDRP. Public controversy was identified as a relevant area of significant concern due to the high perceived risk.

12. Program Benefits- National defense posture and scientific benefits are discussed as part of the considerations of the national environment since these benefits are derived from the entire program.

13. Transportation- (NA)

14. Human Health- There is a low but acceptable inherent risk to the workforce in working with toxins which is minimized by safety procedures, equipment, and practices. There is a high

perceived risk to the workforce among certain segments of the public; however, the actual risk based on past laboratory history is low. Thus, impacts on the workforce were not identified as relevant area of concern.

15. Safety- Construction was assigned a low rating for the operation and maintenance activity because testing of high hazard organisms may be required in the future. Development testing activities include potential impacts in the area of occupational safety. However, the conduct of BDRP-related activities under controlled conditions and in compliance with the standard operating procedures has no impact. Accidents could involve the exposure of an individual to a toxin. Although there is a potential for accidents in the laboratory, the probability of their occurrence is low with the appropriate controls in place (Appendix 12).

IAM (Fig A6-3) Summary

Significant Relevant Areas of Concern:

Public Opinion- Controversial Issues

Program Benefits- National Defense Posture (+)

Minor Relevant Areas of Concern:

Economic Environment- Labor Force (+)

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

PRIMARY SITE: U.S. Army Dugway Proving Ground (DPG), Dugway, UT

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT*	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓		✓	✓	✓	✓		OPERATIONAL
✓	✓	✓	✓		✓	✓	✓			SAFETY
✓	✓	✓	✓		✓	✓	✓			SECURITY
	✓	✓	✓		✓	✓	✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activity not applicable

RISKS														
PERCEIVED	L	L	H	L		H	H	L	–	H				
ACTUAL	L	L	L	L		L	L	L	–	–				
POTENTIAL AREAS IMPACTED											A	P	S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY:								L						
Soils														
Topography														
Erosion														
4. WATER:			L			L								
Surface														
Ground														
5. AIR QUALITY:						L	L	L			–	L		
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:							L	L						
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:	L+		L+				L+				L+	–		✓+
Labor Force														
Economic Activity						L+	L+							
Property Values														
11. PUBLIC OPINION:		L	L	L		H	L		L	L	L	H	✓	
Controversial Issues			L			L					–	L		
Social Concerns														
12. PROGRAM BENEFITS:	L+	L+	H+	L+		L+	L+		L+	H+	H+	L	✓+	
National Defense Posture			L+	L+		L+					L	–		
Scientific Benefit														
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:	L	L	L	L		L	L				L	L		
Workforce														
General Population														
15. SAFETY:							L							
Construction														
Occupational	L	L	L	L			L	L			L	–		
Accidents	L	L	L	L			L				L	–		
SIGNIFICANT	–	–	–	–		–	–	–	–	✓+				
MINOR	–	–	✓	✓		✓	✓	–	–	–				

Figure A6-3

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MATRIX ANALYSIS SUMMARY

Site: Jefferson Medical College, Philadelphia, PA

The research conducted at this institution deals primarily with protein neurotoxins. The overall goals of this effort are to define the mechanisms of action of several potent neurotoxins and to develop approaches for the prevention and/or therapy of intoxications with these toxins. Small animals and cultured cell lines are used throughout these studies. None of the BDRP studies conducted here involve cloning or generation of recombinant organisms. The use of BL-3 or BL-4 containment areas is not required for this research. The personnel working with botulinum toxin are immunized to provide maximal protection against inadvertent exposure to the toxin; thus the possibility of a minor impact on the workforce is recognized.

Basic research conducted at this facility does not include prototype development, testing, or operation and maintenance activities. Economic environment, public opinion, program benefits, human health, and safety were assigned low level impacts for applicable activities as discussed below.

The positive low level impact on the economic activity is due to the purchase of laboratory animals, supplies, and equipment from the local suppliers. A low impact was assigned to the procedures activity because of the overall controversy surrounding the work with botulinum toxin under the BDRP.

National defense posture and scientific benefits are discussed as part of the considerations of the national environment since these benefits are derived from the entire program (section 5.2). There is a low but acceptable inherent risk to the workforce in working with potent toxins, (including receiving special immunization with vaccines that are used to protect personnel at risk), that is minimized by safety procedures, equipment, and practices. Thus, impacts on the health of the workforce have been identified as a relevant area of minor concern. Basic research activities include potential impacts related to occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures has no impact. Accidents could involve the exposure of an individual to a toxin. Although there is a potential for accidents in the laboratory, the probability of their occurrence is low with the appropriate controls in place (Appendix 12).

IAM (Fig A6-4) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

Human Health- Workforce

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

SECONDARY SITE: Jefferson Medical College, Philadelphia, PA

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE * DEVELOPMENT	TESTING *	OPERATION AND * MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓				✓	✓		OPERATIONAL
✓	✓	✓	✓				✓			SAFETY
✓	✓	✓	✓							SECURITY
	✓	✓	✓				✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS														
PERCEIVED	—	L	L	—				L	—	—				
ACTUAL	—	L	L	—				—	—	—				
POTENTIAL AREAS IMPACTED											A	P	S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface														
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues			L											
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture			L+											
Scientific Benefit			L+							L+				
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce		L	L								L	—		✓
General Population														
15. SAFETY:														
Construction														
Occupational	L	L	L	L										
Accidents			L	L										
SIGNIFICANT	—	—	—	—				—	—	—				
MINOR	—	—	✓	—				—	—	—				

Figure A6-4

MATRIX ANALYSIS SUMMARY

Site: SRI International, Menlo Park, CA

The objective of the toxin research projects supported under the BDRP funds is to develop compounds for the prevention and/or therapy of certain potent toxins. No cloning or generation of recombinant organisms takes place at this site under the auspices of the BDRP. The research conducted at this facility does not require the use of BL-3 or BL-4 containment areas. BDRP-sponsored research is conducted using in vitro systems, and small laboratory animals are used for the production of antibodies and tests of potential protective antigens. Thus, there were no significant or minor relevant areas of concern identified by the JAM.

Basic toxin research conducted at this institution does not involve prototype development, testing, or operation and maintenance activities. Surface water, economic environment, program benefits, human health, and safety were assigned low level impacts for applicable activities as discussed below.

There is a potential for low level impact to surface water related to the work with toxins at SRI International. A low level positive impact on economic activity is due to the purchase of laboratory supplies and equipment from vendors in the local community. National defense posture and scientific benefits are discussed as part of the considerations of the national environment since these benefits are derived from the entire program (section 5.2). There is a low but acceptable inherent risk to the workforce in working with the toxins that is minimized by safety procedures, equipment, and practices. Basic research activities include potential impacts concerning occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures has no impact. Potential accidents could involve accidental inoculation of a toxin. Although there is a potential for accidents in the laboratory, the probability of their occurrence is very low with the appropriate controls in place (Appendix 12).

IAM (Fig A6-5) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

None

IMPACT ANALYSIS MATRIX

SECONDARY SITE: SRI International

Menlo Park, CA

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT *	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓				✓			OPERATIONAL
✓	✓	✓	✓				✓			SAFETY
✓	✓	✓	✓				✓			SECURITY
	✓	✓	✓				✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS														
PERCEIVED	—	—	L	—				L	—	—				
ACTUAL	—	—	L	—				—	—	—				
POTENTIAL AREAS IMPACTED											A	P	S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface			L											
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Jobs														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues														
Social Concerns														
12. PROGRAM BENEFITS:			L+											
National Defense Posture			L+							L+				
Scientific Benefit														
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce			L											
General Population														
15. SAFETY:														
Construction														
Occupational	L	L	L	L										
Accidents				L										
SIGNIFICANT	—	—	—	—				—	—	—				
MINOR	—	—	—	—				—	—	—				

RELEVANT AREAS OF CONCERN

Figure A6-5

MATRIX ANALYSIS SUMMARY

Site: Wright State University, Dayton, OH

The objectives of the BDRP studies conducted at this site are to develop methods to grow blue-green algae in the laboratory, to isolate and characterize chemically the various toxins produced by these organisms, to study and understand their mechanisms of action and toxicity, and to develop methods for toxin detection. There were no significant or minor relevant areas of environmental concern identified by the JAM.

Basic toxin research at this facility does not involve activities concerning prototype development, testing, or operation and maintenance. Economic environment, public opinion, program benefits, human health, and safety were assigned low level impacts for applicable activities as discussed below.

A low level positive impact assigned to the economic activity is attributed to the periodic hiring of laboratory workers and purchase of supplies and equipment from local vendors. A low level of impact was assigned to the procedures activity due to the controversial nature of the work involving research quantities of toxins under the BDRP. National defense posture and scientific benefits are discussed as part of the considerations of the national environment since these benefits are derived from the entire program (section 5.2). There is a low but acceptable risk to the workforce in working with toxins that is minimized by safety procedures, equipment, and practices. Basic research activities include potential impacts concerning occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures has no impact (Appendix 12).

IAM (Fig A6-6) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

None

IMPACT ANALYSIS MATRIX

SECONDARY SITE: Wright State University

Dayton, OH

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT *	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓				✓			OPERATIONAL
✓	✓	✓	✓				✓			SAFETY
✓	✓	✓	✓				✓			SECURITY
	✓	✓	✓				✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS														
PERCEIVED	—	L	L	—				L	—	—				
ACTUAL	—	L	L	—				—	—	—				
POTENTIAL AREAS IMPACTED											A	P	S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial												*		
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface														
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues			L											
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture			L+											
Scientific Benefit			L+							L+				
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce			L											
General Population														
15. SAFETY:														
Construction														
Occupational	L	L	L	L										
Accidents														
SIGNIFICANT	—	—	—	—				—	—	—				
MINOR	—	—	✓	—				—	—	—				

Figure A6-6

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MATRIX ANALYSIS SUMMARY

Site: The Salk Institute, Government Services Division, *(TS I* -GSD), Swiftwater, PA

This facility provides support to the medical portion of the BDRP in the form of pilot production of investigational vaccines, diagnostic materials, and antibodies. Procedures which require the handling of infectious organisms are carried out in BL-3 containment suites. No cloning or generation of recombinant organisms takes place at this site.

Although the potential for impacts on the surface water quality and the biological air quality may be perceived high due to the high hazard nature of the organisms under study, the actual impacts are minor, because of the control measures implemented and the safety features inherent in the structure and operation of the facility. The impact on ambient air quality arising from the incineration of solid wastes represents a minor concern. There is a minor impact on the labor force since more than 90% of the funding for work conducted at TSI-GSD is derived from the BDRP, and the employment generates about 0.3% of the total business volume for this county. The vaccines and diagnostic reagents produced as part of the BDRP are of significant importance to the national defense posture, to the scientific community, and have positive public health implications. The activity of testing was found not to be applicable to this site in evaluating the relevant areas of concern because clinical testing of products is conducted elsewhere.

The Salk Institute, Government Services Division (TSI-GSD):

1. Land Use- (NA)

2. Plant and Animal Ecology- (NA)

3. Geology- (NA)

4. Water- There is a potential for low level impact to surface water due to the programmatic content of high hazard infectious organisms and toxins, which is mitigated fully by the existing controls under normal operating conditions. Activities with potential to impact on surface water are laboratory procedures, operation and maintenance, and waste stream management. The potential impact to surface water has been identified as a relevant area of minor concern due to high perceived risk.

5. Air Quality- There is a minor impact on the ambient air quality at the site of generation from the steam and electrical energy required for the operation and maintenance of this facility. TSI-GSD also contributes to air emissions from the pathological waste incinerator through the waste stream management activity. This is indicated as a relevant area of minor concern due to the high perceived risk. The potential for low level impact to the biological air quality is the same as for surface water discussed above (#4).

6. Agriculture- (NA)

7. Cultural Resources- (NA)

8. Energy Resources- Operation and maintenance and waste stream management at TSI-GSD require the use of small amounts of depletable energy resources. These requirements are for electrical energy, steam, and operation of the pathological waste incinerator.

9. Sociological Environment- Operation and maintenance activities create odors due to the disposition of animal remains and wastes. However, these odors are transient, are mainly confined to the inside of buildings, and are environmentally insignificant.

10. Economic Environment- TSI-GSD employs about 55 people full or part-time under their contract with the BDRP. This labor force has a significant economic impact due to the small size of (NA)- There are no projected impacts on this parameter since research is being conducted at existing facilities, no new construction is proposed, and no existing environments are being adversely affected or altered.

local community; however, it is considered a relevant area of minor concern in the overall economic climate of the region. The positive impacts of this institute are distributed among the activities with the largest number of employees. There are also low level positive impacts on the economic activity due to the purchase of supplies for operation and maintenance of the facility.

11. Public Opinion- Research involving high hazard infectious organisms and toxins may be perceived controversial in nature. However, this controversy is not related to specific sites, but to the overall BDRP (refer to section 5.2 on the national environment considerations).

12. Program Benefits- National defense posture, scientific benefit, and public benefit are discussed as part of the considerations of the national environment since these benefits are derived from the entire program.

13. Transportation- Existing highways are narrow and sparsely located. The traffic impacts associated with operation and maintenance of TSI-GSD are not considered significant since there are only 55 employees. Thus, the contribution of 55 employees by TSI-GSD to the existing vehicular traffic is not considered a relevant area of concern.

14. Human Health- There is a low but acceptable inherent risk to the workforce in working with the high hazard organisms, (including receiving special immunization with vaccines that are used to protect personnel at risk), that is minimized by safety procedures, equipment, and practices. There is a high perceived risk to the workforce among certain segments of the public; however, the actual risk based on past laboratory history is low. Impacts on health of the workforce have been identified as a minor relevant area of concern.

15. safety- Construction was assigned a low impact for operation and maintenance due to the special containment facilities (BL-3) required by TSI-GSD for working with high hazard infectious organisms. Basic research and development activities include potential impacts concerning occupational safety. However, the conduct of studies under controlled conditions and in compliance with the standard operating procedures has no impact. Accidents could involve the exposure of an individual to a toxin or an infectious organism. Although there is a potential for accidents in the laboratory, the probability of their occurrence is very low with the appropriate controls in place (Appendix 12).

IAM (Fig A6-7) Summary

Significant Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)

Minor Relevant Areas of Concern:

Water- Surface
Air Quality- Ambient Standards
Biological
Economic Environment- Labor Force (+)
Program Benefits- Scientific Benefit (+)
Public Benefit (+)
Human Health- Workforce

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

SECONDARY SITE: Salk Institute, Government Services Division, Swiftwater, PA

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING *	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓	✓		✓	✓	✓		OPERATIONAL
✓	✓	✓	✓	✓		✓	✓			SAFETY
✓	✓	✓	✓	✓		✓	✓			SECURITY
	✓	✓	✓	✓		✓	✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activity not applicable

RISKS	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	S	M
PERCEIVED	L	—	H	L	—		—	L	—	—				
ACTUAL	L	L	L	L	L		L	L	—	—				
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface			L				L	L			L	L		✓
Ground														
5. AIR QUALITY:														
Ambient Standards			L				L	L			L	L		✓
Biological			L				L	L			L	L		✓
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies							L	L						
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors							L							
10. ECONOMIC ENVIRONMENT:														
Labor Force	L+		L+		L+		L+		L+	L+				✓+
Economic Activity							L+							
Property Values														
11. PUBLIC OPINION:														
Controversial Issues				L										
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture	L+	L+	H+		L+		H+			L+	H+	L	✓+	
Scientific Benefit	L+	L+	L+		L+					L+	L	L		✓+
Public Benefit		L+	L+		L+									✓+
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic							L							
14. HUMAN HEALTH:														
Workforce	L	L	L	L	L						L	L		✓
General Population											—	L		
15. SAFETY:														
Construction							L							
Occupational	L	L	L	L	L		L	L			L	—		
Accidents	L		L	L	L		L				L	—		
SIGNIFICANT	—	—	—	—	—		—	—	—	—				
MINOR	—	✓+	✓	✓	✓		✓+	—	—	✓				

Figure A6-7

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MATRIX ANALYSIS SUMMARY

Site: Southern Research Institute (SoRI), Birmingham, AL

The research conducted at this institute includes primary testing of compounds for antiviral efficacy in vitro. There were no significant relevant areas of concern identified by the JAM. Due to the high hazard nature of the BL-3 organisms used in antiviral screening, the impacts on surface water quality and biological air quality are indicated as minor relevant areas of concern. This research is of significant importance to the national defense posture and scientific community since the development of broad spectrum antiviral drugs is one of the major areas of emphasis in the BDRP.

The research conducted at this institute does not involve prototype development, testing, or operation and maintenance activities. Potential areas impacted that were assigned a low level of impact for applicable activities are discussed below:

There is a potential for low level impact to the surface water from procedures and waste stream management activities due to the use of high hazard organisms and toxins, which is mitigated fully by the existing controls under normal operations. Thus, the impacts have been identified as a relevant area of minor concern. There is a minor potential impact on ambient air quality from the waste stream management activity. This is due to the incineration of animal wastes; however, with the appropriate controls in place, it is not an area of relevant concern. The potential for low level impact to the biological air quality is the same as for surface water described above. A low level positive impact on the economic activity is due to the purchase of laboratory supplies and equipment from the local suppliers.

National defense posture and scientific benefits are discussed as part of the considerations of the national environment (section 5.2). There is a low but acceptable inherent risk to the workforce in working with high hazard organisms and toxins, (including receiving special immunization with vaccines that are used to protect personnel at risk), that is minimized by the use of special safety procedures, equipment, and practices. Basic research activities include potential impacts in the area of occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures has no impact. Potential accidents could involve the exposure of an individual to a toxin or an infectious organism by injecting himself. Although there is a potential for accidents in the laboratory, the probability of their occurrence is low with the appropriate controls in place (Appendix 12).

IAM (Fig A6-8) Summary

Significant Relevant Areas of Concern:
None
Minor Relevant Areas of Concern:
Water- Surface
Air Quality- Biological
Program Benefits- National Defense Posture (+)
Scientific Benefit (+)

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

SECONDARY SITE: Southern Research Institute (SoRI)

Birmingham, AL

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT *	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓				✓			OPERATIONAL
✓	✓	✓	✓				✓			SAFETY
✓	✓	✓	✓				✓			SECURITY
	✓	✓	✓				✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	S	M
PERCEIVED	L	—	L	—				L	—	—				
ACTUAL	L	L	L	L				L	—	—				
POTENTIAL AREAS IMPACTED														
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface			L					L			L	L		✓
Ground														
5. AIR QUALITY:														
Ambient Standards								L						
Biological			L					L			L	L		✓
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues														
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture	L+		L+							L+				✓+
Scientific Benefit	L+		L+							L+				✓+
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce	L		L								L	L	—	—
General Population														
15. SAFETY:														
Construction														
Occupational	L		L					L						
Accidents	L		L	L							L	L	—	—
SIGNIFICANT	—	—	—	—				—	—	—				
MINOR	—	—	✓	—				—	—	—				

Figure A6-8

MATRIX ANALYSIS SUMMARY

Site: Scripps Clinic and Research Foundation, La Jolla, CA

The laboratory work performed at Scripps Clinic under the BDRP includes the use of cultured cells, biochemical techniques, cloning of low hazard viral proteins at BL-2, and immunization of mice and rabbits. Through the analysis conducted using the JAM, there were no significant or minor relevant areas of concern identified.

Basic research conducted at this site does not include prototype development, testing, or operation and maintenance activities. Potential areas of impact that were assigned low level of impact are economic environment, public opinion, program benefits, and safety. A low level positive impact on the economic activity would result from the purchase of laboratory supplies and equipment from local suppliers. A low impact was assigned to the procedures activity due to the controversy surrounding genetic engineering research and the perception by certain segments of the public that genetic engineering is inherently dangerous.

National defense posture and scientific benefits are discussed as part of the considerations of the national environment since these benefits are derived from the entire program (section 5.2). Basic research activities include potential impacts in the area of occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures has no impact. Accidents could potentially involve improper handling of the LCM virus, so that a cut or a puncture wound may become infected, and in some cases, could result in clinical LCM disease. However, work with LCM virus, with the existing controls in place under normal operating conditions, mitigates the potential for such accidents (Appendix 12).

IAM (Fig A6-9) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

None

IMPACT ANALYSIS MATRIX

SECONDARY SITE: Scripps Clinic and Research Foundation

La Jolla, CA

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT *	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓				✓			OPERATIONAL
✓	✓	✓	✓				✓			SAFETY
✓	✓	✓	✓				✓			SECURITY
	✓	✓	✓				✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
PERCEIVED	—	—	L	—				—	—	—
ACTUAL	—	—	—	—				—	—	—

POTENTIAL AREAS IMPACTED											A	P	S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface														
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues			L											
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture			L+											
Scientific Benefit			L+							L+				
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce														
General Population														
15. SAFETY:														
Construction														
Occupational	L	L	L	L										
Accidents			L											

	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
SIGNIFICANT	—	—	—	—				—	—	—
MINOR	—	—	✓	—				—	—	—

Figure A6-9

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MATRIX ANALYSIS SUMMARY

Site: New York State Department of Public Health, Albany, NY

The objective of the work performed at the Wadsworth Center for Laboratories and Research under the BDRP is to develop the methods and approaches for utilizing vaccinia (smallpox vaccine) virus as a carrier of specific genetic information from other viruses. This allows the recombinant vaccinia virus to be used as a "multiple" vaccine that would provide protection against two or more viral diseases in a single immunization.

No significant relevant areas of concern were found through the JAM. While public perception of the controversial nature of this type of activity and its potential risk to human health and to the environment may be high, the conduct of work with all the necessary controls in place causes no significant effect to the environment. Due to the controversial nature of genetic engineering in general, and importance of the state of the art technology to the national defense posture and overall scientific benefit, these areas were considered as minor relevant areas of concern.

The research conducted at this laboratory does not involve testing or operation and maintenance activities. Since this program involves basic and applied research, it can potentially lead to development of a prototype genetically engineered vaccine. Economic environment, public opinion, program benefits, and safety were assigned a low level of impact for applicable activities. A low level positive impact assigned to economic activity is attributed to the periodic hiring of laboratory workers, and purchasing of laboratory supplies and equipment from the local suppliers. A low level of impact was assigned to the procedures, laboratory animal care, and prototype development activities because of the overall controversy surrounding the use of genetic engineering, particularly as it relates to the BDRP The procedures activity is perceived to be of high risk due to the controversy surrounding the employment of a genetically engineered product in laboratory animals or in a candidate vaccine.

National defense posture, scientific benefit, and public benefit are discussed as part of the considerations of the national environment since these benefits are derived from the entire program (section 5.2). The procedures activity is considered to have a positive low impact on the public because the development of genetically engineered vaccines holds substantial promise for future vaccine development for illness of concern to public health. Basic research activities include potential impacts in the area of occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures has no impact (Appendix 12).

IAN (Fig A6-10) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

Public Opinion- Controversial Issues
Program Benefits- National Defense Posture (+)
Scientific Benefit (+)

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

SECONDARY SITE: New York State Department of Public Health, Albany, NY

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓	✓	✓			✓			OPERATIONAL
✓	✓	✓	✓	✓			✓			SAFETY
✓	✓	✓	✓	✓			✓			SECURITY
	✓	✓	✓	✓			✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
PERCEIVED	—	—	H	L	L			L	—	—
ACTUAL	—	—	L	—	—			—	—	—

	POTENTIAL AREAS IMPACTED	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	S	M
BIOPHYSICAL	1. LAND USE:														
	Agriculture														
	Industrial														
	Commercial														
	Residential												+		
	Recreation														
	Wetlands														
	Floodplains														
	Unique Geographical Area														
	Policies														
	2. PLANT AND ANIMAL ECOLOGY:														
	Population														
	Terrestrial Habitats														
	Aquatic Habitats														
	Endangered species														
	3. GEOLOGY:														
	Soils														
	Topography														
	Erosion														
	4. WATER:														
	Surface														
	Ground														
	5. AIR QUALITY:														
	Ambient Standards														
	Biological														
	6. AGRICULTURE:														
	Crops														
	Livestock														
	7. CULTURAL RESOURCES:														
	Historical														
	Archeological														
	8. ENERGY RESOURCES:														
	Depletable Supplies														
	Non-Depletable														
SOCIOECONOMIC	9. SOCIOLOGICAL ENVIRONMENT:														
	Demographics														
	Aesthetics														
	Noise														
	Odors														
	10. ECONOMIC ENVIRONMENT:														
	Labor Force														
	Economic Activity	L+		L+											
	Property Values														
	11. PUBLIC OPINION:														
	Controversial Issues			L	L	L						—	L		✓
	Social Concerns														
	12. PROGRAM BENEFITS:														
	National Defense Posture			L+		L+						L	—		L+
	Scientific Benefit			L+		L+					L+	L	L		L+
	Public Benefit			L+											
	13. TRANSPORTATION:														
	Road														
	Rail														
	Air														
	Traffic														
	14. HUMAN HEALTH:														
	Workforce														
	General Population														
	15. SAFETY:														
	Construction														
	Occupational	L	L	L	L										
	Accidents														

	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT
SIGNIFICANT	—	—	—	—	—			—	—	—
MINOR	—	—	✓+	—	✓+			—	—	—

Figure A6-10

MATRIX ANALYSIS SUMMARY

Site: University of Massachusetts, Amherst, MA

The objective of this research is to develop an improved vaccine for protection from Bacillus anthracin (anthrax). No cloning or generation of recombinant organisms involving B. anthracis genetic material takes place at this site under the BDRP sponsorship. No test animals are used under the Army research contract. BL-3 or BL-4 containment is not required for this research. Thus, there were no significant relevant areas of concern found through the JAM. National defense posture was identified to be a minor positive relevant area of concern since the benefit would be the availability of a vaccine to provide rapid protection to troops against anthrax, which is still considered a prime concern from the standpoint of defense against potential biological weapons threats.

The research conducted at this institute does not involve activities concerning laboratory animal care and use, prototype development, testing or operation and maintenance. Economic environment, program benefits, human health and safety were assigned low level of impact for applicable activities as discussed below.

A low level positive impact assigned to the economic activity would result due to the purchase of laboratory supplies and equipment from within the local community. National defense posture and scientific benefits are discussed as part of the national environment since these benefits are derived from the entire program (section 5.2). Basic research activities include potential impacts to the workforce and in the area of occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures has no impact. An accident could produce a localized infection (treatable with antibiotics) on the skin of a protected individual; however, the probability of such an occurrence is low with the appropriate controls in place

(Appendix 12)

IAM (Fig A6-11) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant areas of Concern:

Program Benefits- National Defense Posture {+)

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

SECONDARY SITE: University of Massachusetts
Amherst, MA

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE *	PROTOTYPE DEVELOPMENT *	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓					✓			OPERATIONAL
✓	✓	✓					✓			SAFETY
✓	✓	✓					✓			SECURITY
	✓	✓					✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS															
PERCEIVED	—	L	L					L	—	—					
ACTUAL	—	—	L					—	—	—					
POTENTIAL AREAS IMPACTED												A	P	S	M
BIOPHYSICAL															
1. LAND USE:															
Agriculture															
Industrial															
Commercial															
Residential															
Recreation															
Wetlands															
Floodplains															
Unique Geographical Area															
Policies															
2. PLANT AND ANIMAL ECOLOGY:															
Population															
Terrestrial Habitats															
Aquatic Habitats															
Endangered species															
3. GEOLOGY:															
Soils															
Topography															
Erosion															
4. WATER:															
Surface															
Ground															
5. AIR QUALITY:															
Ambient Standards															
Biological															
6. AGRICULTURE:															
Crops															
Livestock															
7. CULTURAL RESOURCES:															
Historical															
Archaeological															
8. ENERGY RESOURCES:															
Depletable Supplies															
Non-Depletable															
SOCIOECONOMIC															
9. SOCIOLOGICAL ENVIRONMENT:															
Demographics															
Aesthetics															
Noise															
Odors															
10. ECONOMIC ENVIRONMENT:															
Labor Force															
Economic Activity	L+		L+												
Property Values															
11. PUBLIC OPINION:															
Controversial Issues															
Social Concerns															
12. PROGRAM BENEFITS:															
National Defense Posture			L+							L+					✓
Scientific Benefit			L+							L+					
Public Benefit															
13. TRANSPORTATION:															
Road															
Rail															
Air															
Traffic															
14. HUMAN HEALTH:															
Workforce			L												
General Population															
15. SAFETY:															
Construction															
Occupational	L	L	L												
Accidents			L												
SIGNIFICANT	—	—	—					—	—	—					
MINOR	—	—	✓					—	—	—					

Figure A6-11

MATRIX ANALYSIS SUMMARY

Site: Salk Institute, La Jolla, CA

The objective of the work performed at this institute is to develop in vitro methods to generate human monoclonal antibodies to selected antigens (toxins or viral proteins). No cloning or growth of recombinant organisms takes place under the BDRP sponsorship. This research is appropriately conducted in BL-1 and BL-2 laboratories. There are no test animals or any infectious organisms used in this research. Thus, the analysis conducted through the IAM showed no significant or minor relevant areas of concern.

The research conducted at this institute does not involve laboratory animal care, prototype development, testing, or operation and maintenance activities. Economic environment, program benefits, human health, and safety were assigned low level of impact for applicable activities. A low positive impact on economic activity is indicated due to the purchase of laboratory supplies and equipment from within the local community. Scientific benefits are discussed as part of the considerations of the national environment (section 5.2). There is a low but acceptable inherent risk to the workforce from working with cultured human cell lines because they may contain adventitious agents. Basic research activities include potential impacts in the area of occupational safety. However, the conduct of research under controlled conditions and in compliance with the standard operating procedures has no impact (Appendix 12).

IAM (Fig A6-12) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

None

IMPACT ANALYSIS MATRIX

SECONDARY SITE: Salk Institute
La Jolla, CA

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY * ANIMAL CARE	PROTOTYPE *DEVELOPMENT	TESTING *	OPERATION AND *MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓	✓	✓					✓			OPERATIONAL
✓	✓	✓					✓			SAFETY
✓	✓	✓					✓			SECURITY
	✓	✓					✓	✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS													RELEVANT AREAS OF CONCERN	
													S	M
PERCEIVED	—	—	—					—	—	—				
ACTUAL	—	—	L					—	—	—				
POTENTIAL AREAS IMPACTED											A	P		
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface														
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues														
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture			L+							L+				
Scientific Benefit														
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce			L											
General Population														
15. SAFETY:														
Construction														
Occupational	L	L	L											
Accidents														
SIGNIFICANT	—	—	—					—	—	—				
MINOR	—	—	—					—	—	—				

Figure A6-12

Refer to Appendix 4 for detailed information on each programmatic risk/issue category.

PROGRAM MATRIX ANALYSIS SUMMARY

Category: High Hazard Organisms

Matrix analysis of this program category concluded that the use of high hazard organisms in the BDRP brings with it concerns in the areas of surface water, biological air quality, economic activity, controversy, social concerns, health risks to the workforce and the general population, as well as special facility requirements for safe conduct of the work. When site-specific activities are considered, regulatory and other controls adequately address these issues and concerns. Thus, the risks of working with these organisms to human health and to the environment become minor.

High hazard infectious organisms are of major concern as potential national defense threats. The public benefits of the program are potentially significant contributions to the scientific community and to the nation's well-being.

The activities of storage, prototype development, testing, operation and maintenance, and waste stream management were not germane to the analysis of this program category. Prototype development and testing are relevant to the drug and vaccine development category, and are discussed separately. Operation and maintenance and waste stream management activities were evaluated in the site-specific analyses of primary and secondary sites.

There is a potential for low level impact to the surface water from high hazard infectious organisms. The potential impacts are mitigated by controls under normal operations. Activities that could produce potential impacts are laboratory work and procedures. Thus, surface water has been identified as a relevant area of significant concern because of the perceived high risk by certain segments of the public. Biological air quality has also been identified as a relevant area of significant concern for the same reason as discussed above for water quality.

The BDRP has a low positive impact on the economic activity, which is due to the purchase of laboratory supplies and equipment from the local community. Due to the nature of research conducted at each site, the impact on economic activity varies depending on the site. Research involving high hazard infectious organisms is perceived to be of high risk and controversial in nature, thus it is indicated to be a relevant area of significant concern. However, studies of high hazard organisms are conducted in BL-3 and BL-4 laboratory containment facilities (Appendix 12), and in compliance with the CDC-NIH guidelines on biosafety (Appendices 5 and 12), therefore providing protection to the

laboratory workers and to the general population. Social concerns are related to the perceived highly controversial nature of this research.

National defense posture, scientific benefit, and public benefit are discussed as part of the considerations of the national environment (section 5.2). There is a low but acceptable inherent risk to the workforce in working with the high hazard infectious organisms, (including receiving special immunization with vaccines that are used to protect personnel at risk), that is minimized by safety procedures, equipment, and practices. Thus, impacts on the workforce have been identified as a relevant area of significant concern. A low level potential impact on the general population was identified from the procedures activity. However, with the appropriate controls and safeguards in place, the actual impacts are identified as a relevant area of minor concern.

Construction was assigned a low impact rating for laboratory work and procedures activities due to the special containment facilities that are required for work with high hazard infectious organisms. Potential accidents could involve exposure of an individual to a high hazard infectious organism. Although there is a potential for accidents in the laboratory, the probability of their occurrence is low with the appropriate controls in place (Appendices 11 and 12).

IAM (Fig A6-13) Summary

Significant Relevant Areas of Concern:

Water- Surface
Air Quality- Biological
Public Opinion- Controversial Issues
Program Benefits- National Defense Posture (+)
Human Health- Workforce

Safety- Construction

Minor Relevant Areas of Concern:

Program Benefits- Scientific
Benefit
Public Benefit
Human Health- General Population

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: High Hazard Infectious Organisms

ACTIVITIES											
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT					
LABORATORY WORK	STORAGE *	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT *	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT *	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓		✓	✓							OPERATIONAL
✓		✓	✓							SAFETY
			✓							SECURITY
✓		✓	✓					✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS	LABORATORY WORK	STORAGE	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE	WASTE STREAM MANAGEMENT	PLANNING AND DESIGN	PROGRAM MANAGEMENT	A	P	S	M
PERCEIVED	H		H	L					—	—				
ACTUAL	L		L	L					—	—				
POTENTIAL AREAS IMPACTED														
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface	L		L								L	H	✓	
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological	L		L								L	H	✓	
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues	L		H	L					H	H			✓	
Social Concerns										L				
12. PROGRAM BENEFITS:														
National Defense Posture	H+		H+	L+					H+	H+	H+	—	✓	
Scientific Benefit	H+		H+						L+		L+	—		✓
Public Benefit	L+		L+											✓
13. TRANSPORTATION:														
Road														
Rail														
Air														
Water														
14. HUMAN HEALTH:														
Workforce	L		L	L							L	L	✓	
General Population			L								L	L		✓
15. SAFETY:														
Construction	L		L										✓	
Occupational														
Accidents	L		L											
SIGNIFICANT	—		✓	—					✓	✓				
MINOR	✓		—	—					—	—				

Figure A6-13

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PROGRAM MATRIX ANALYSIS SUMMARY

Category: Low Hazard Organisms

Simulants and low hazard organisms are integral to the BDRP, not because they are considered to be potential threats but because working with low hazard organisms poses significantly less risk to the workforce. The proportionately greater ease of working under BL1-2 VS BL3-4 conditions enables a much greater productivity in relation to the man-hours and materials expended and laboratory space occupied. Thus, the use of simulants and low hazard organisms, where applicable, is considered to be a positive minor area of concern for the workforce and to the national defense posture.

The activities of storage, prototype development, operation and maintenance, waste stream management, or planning and design do not apply to this program category. Testing was found to be applicable because open-air testing with simulants, while not conducted on a routine basis, remains an integral part of the program. Surface water, ambient air quality, economic environment, public opinion, program benefits, and human health were assigned a low level of impact for applicable activities.

There would be no impact to surface water from the simulants used in open-air testing because simulant organisms occur naturally throughout the environment. However, a low rating was assigned because of the perception of impacts by certain segments of the public. There is a minor impact on ambient air quality from vehicular traffic during open-air testing. The BDRP has a low positive impact on the economic activity due to money brought into the economy from purchasing laboratory equipment and supplies. There is a perception of risk associated with open-air testing among certain segments of the public. Thus, a low impact was assigned to controversial issues. This is not considered a relevant area of concern.

National defense posture and scientific benefits are discussed as part of the considerations of the national environment (section 5.2). There is a low positive benefit to the workforce because low hazard organisms and simulants pose less risk to the health of the workforce than do the high hazard organisms, thereby minimizing the potential for adverse impacts. Thus, impacts on the workforce have been identified as positive relevant area of minor concern.

IAM (Fig A6-14) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)
Human Health- Workforce (+)

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Low Hazard Organisms

CONTROLS	ACTIVITIES: RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT			
	LABORATORY WORK	STORAGE *	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE *DEVELOPMENT	TESTING	OPERATION AND *MAINTENANCE	WASTE STREAM *MANAGEMENT	PLANNING AND DESIGN *	PROGRAM MANAGEMENT
OPERATIONAL	✓		✓	✓		✓				
SAFETY	✓		✓	✓		✓				
SECURITY				✓		✓				
REGULATORY				✓		✓				✓

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS															
PERCEIVED	—		—	—		L				—					
ACTUAL	—		—	—		—				—					
POTENTIAL AREAS IMPACTED											A	P	RELEVANT AREAS OF CONCERN S	RELEVANT AREAS OF CONCERN M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:						L								
Surface														
Ground														
5. AIR QUALITY:						L								
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Renewable Supplies														
Non-Renewable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:						L								
Controversial Issues														
Social Concerns														
12. PROGRAM BENEFITS:	L+		L+			L+				L+				✓+
National Defense Posture										L+				
Scientific Benefit														
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:	L+		L+											✓+
Workforce														
General Population														
15. SAFETY:														
Construction														
Occupational														
Accidents														
SIGNIFICANT	—		—	—		—				—				
MINOR	—		—	—		✓				—				

Figure A6-14

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PROGRAM MATRIX ANALYSIS SUMMARY

Category: Toxins

Studies on toxins are integral to the BDRP contribution to the national defense posture and contribute to the scientific community at large. Inclusion of toxins in the BDRP may be a controversial issue. Regulated disposal methods are necessary to prevent potential adverse impacts on surface water.

The activities involving storage, prototype development, testing, operation and maintenance, and waste stream management do not apply to this program category. Surface water, economic environment, public opinion, program benefits, human health, and safety were identified as impacted by applicable activities as discussed below.

There is a potential for low level impact to surface water from toxins. Although the potential impacts are dependent on the varying degrees of toxicity, they are mitigated by controls under normal operations. Activities with potential for impact are laboratory work and procedures. Surface water has been identified as a relevant area of minor concern because of the perceived risk by certain segments of the public. The BDRP has a low positive impact on the economic activity due to the money brought into the economy from purchase of laboratory supplies and equipment. The public controversy relates to the overall BDRP and whether toxin research should be a legitimate element of the defensive program. Thus, public controversy is considered a relevant area of minor concern.

The development of vaccines and therapeutic drugs for potential biological warfare threat toxins enhances the national defense posture. Additional program benefits are discussed as part of the considerations of the national environment (section 5.2). There is a low but acceptable inherent risk to the workforce in working with the toxins. These risks are minimized by the use of special biosafety facilities, equipment, and procedures for those activities that would otherwise cause a high potential for exposure. Basic research activities with toxins use extremely small quantities at any one time, which also minimizes the potential risk to the health of laboratory workers. Potential accidents could involve exposure of an individual to a toxin; however, the probability of this occurring is very low with the appropriate controls in place (Appendix 12?.

IAN (Fig A6-15) Summary -

Significant Relevant Areas of Concern:

Program Benefits- National Defense Posture (+) Minor Relevant Areas of Concern:

Water- Surface
Public Opinion- Controversial Issues

Program Benefits- Scientific Benefit (+)

All other areas were determined to have insignificant environmental impacts.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Toxins

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE *	PROCEDURES	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT *	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT *	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓		✓	✓							OPERATIONAL
✓		✓	✓							SAFETY
			✓							SECURITY
✓		✓	✓						✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS														
PERCEIVED	L		L	—					—	—				
ACTUAL	L		L	—					—	—				
POTENTIAL AREAS IMPACTED											A	P	S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface	L		L								L			✓
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues			L						L	L				✓
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture	H+		H+	L+					H+	H+			✓	
Scientific Benefit	L+		L+						L+	L+				✓
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce	L		L											
General Population														
15. SAFETY:														
Construction														
Occupational														
Accidents	L		L	L										
SIGNIFICANT	—		✓	—					—	—				
MINOR	✓		—	—					✓	✓				

Figure A6-15

PROGRAM MATRIX ANALYSIS SUMMARY

Category: Genetically Engineered Microorganisms

Genetically engineered microorganisms (GEMs) were included for separate analysis, not because they were perceived to be a significant risk, but because GEMs have been the object of controversy within certain segments of the population. Nevertheless, the controversial issue notwithstanding, genetic engineering is an integral part of any viable biomedical research program. The inclusion of genetic engineering methodology in the BDRP is critical to developing effective defense measures.

The activities of storage, laboratory animal care, prototype development, testing, operation and maintenance, waste stream management, and planning and design do not apply to this category. Economic environment, public opinion, and program benefits, were impacted by applicable activities and are discussed below.

There are low level positive impacts to the economic activity associated with the laboratory work and procedures. Research involving use of rDNA molecules in the construction of genetically engineered microorganisms is perceived to be controversial in nature. However, this controversy is not related to specific sites, but to the overall BDRP (refer to section 5.2 on the national environment considerations). Social concerns are related to the perceived controversial nature of this research. National defense posture, scientific benefit, and public benefit are also discussed as part of the considerations of the national environment.

IAM (Fig A6 - 16) Summary

Significant Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)

Minor Relevant Areas of Concern:

Public Opinion- Controversial Issues

Program Benefits- Scientific Benefit (+)

All other areas were determined to have insignificant environmental concerns.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Genetically Engineered Microorganisms

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE *	PROCEDURES	LABORATORY ANIMAL CARE *	PROTOTYPE DEVELOPMENT *	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT *	PLANNING AND DESIGN *	PROGRAM MANAGEMENT	CONTROLS
✓		✓								OPERATIONAL
✓		✓								SAFETY
										SECURITY
✓		✓							✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS															
PERCEIVED	L		L							L					
ACTUAL	—		—							—					
POTENTIAL AREAS IMPACTED											A	P	RELEVANT AREAS OF CONCERN S	RELEVANT AREAS OF CONCERN M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface														
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archaeological														
8. ENERGY RESOURCES:														
Renewable Supplies														
Non-Renewable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+											
Property Values														
11. PUBLIC OPINION:														
Controversial Issues			H							H				✓
Social Concerns			L											
12. PROGRAM BENEFITS:														
National Defense Posture	L+		H+							H+			✓	
Scientific Benefit			H+							L+				✓
Public Benefit			L+											
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce														
General Population														
15. SAFETY:														
Construction														
Occupational														
Accidents														
SIGNIFICANT	—		✓							—				
MINOR	—		—							✓				

Figure A6-16

PROGRAM MATRIX ANALYSIS SUMMARY

Category: Rapid Diagnosis and Detection

While the rapid diagnosis and detection portion of the BDRP is an important component of the defensive effort, no relevant areas of concern were perceived for this element of the program. Where development of reagents for testing of products and/or equipment would involve higher levels of risk, such as use of infectious organisms or toxins, the analysis of environmental impact for this subject area was considered under those appropriate categories.

The activities of storage, laboratory animal care, testing, operation and maintenance, and waste stream management do not apply to this program category. Economic environment and program benefits were impacted by applicable activities. The development of prototypes of assay systems, detection methodologies based on potential biological materials, and remote sensor detection equipment have a positive low level impact on the local community associated with these activities. The development of rapid identification and diagnosis methodologies for potential biological warfare threat agents enhances the national defense posture with respect to these threats. The BDRP scientists have shared their expertise, methodologies, and reagents with health scientists in other countries where outbreaks of diseases such as Rift Valley fever have occurred, thus contributing to the overall scientific benefit.

IAM (Fig A6-17) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)

All other areas were determined to have insignificant environmental concerns.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Rapid Diagnosis and Detection

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE *	PROCEDURES	LABORATORY ANIMAL CARE *	PROTOTYPE DEVELOPMENT	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT *	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓		✓		✓				✓	✓	OPERATIONAL
										SAFETY
										SECURITY
		✓		✓				✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS → PERCEIVED	—		—		—				—	—				
RISKS → ACTUAL	—		—		—				—	—				
POTENTIAL AREAS IMPACTED											A	P	S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface														
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+		L+									
Property Values														
11. PUBLIC OPINION:														
Controversial Issues														
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture	L+		L+		L+				L+	L+				✓
Scientific Benefit	L+		L+											
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce														
General Population														
15. SAFETY:														
Construction														
Occupational														
Accidents														
SIGNIFICANT	—		—		—				—	—				
MINOR	—		—		—				—	—				

Figure A6-17

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PROGRAM MATRIX ANALYSIS SUMMARY

Category: Vaccine and Drug Therapy Development

The program category of "vaccine and drug therapy development" applies only to the preclinical and clinical testing of these medical items. Other research and developmental aspects of this topic are covered under one or more of the other "risk" categories. For this reason, laboratory work, procedures, operation and maintenance, and waste stream management were considered to be not applicable to this impact analysis. The preclinical animal challenge efficacy studies, which may involve use of infectious organisms or toxins, were also considered under those risk categories and were not considered under this impact analysis. The controversial aspect of vaccine and drug development relates to the use of laboratory animals.

In addition, Phase III clinical testing of drugs, biologics or vaccines is conducted only where and when natural disease occurs. In such cases, tests are conducted under appropriate controlled conditions meeting the human testing standards of the United States and the country in which the study may be conducted. Under test conditions, no introduction of an organism into the environment occurs, and no additional risk to human health and safety occurs beyond that which results from the natural disease.

The development and testing of these drugs and vaccines have proven benefits to public health and to the scientific community, in addition to significantly contributing to the national defense posture as an integral part of the BDRP. Vaccines developed by the BDRP have been used to fight outbreaks of disease such as the Rift Valley Fever outbreak in central Africa and VEE epidemic in south Texas.

As with testing of any new drug or vaccine, there is a small, but identifiable, risk to the medical research volunteer subject (MRVS) who participates in phase I and II clinical trials. Thus, impacts on the general population (MRVS) have been identified as a relevant area of minor concern.

IAM (Fig A6-18) Summary

Significant Relevant Areas of Concern:

Program Benefits- National Defense Posture (+)

Minor Relevant Areas of Concern:

Program Benefits- Scientific Benefit (+)

Public Benefit (+)

Human Health- General Population (MRVS)

All other areas were determined to have insignificant environmental concerns.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Vaccine and Drug Therapy Development

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK *	STORAGE	PROCEDURES *	LABORATORY ANIMAL CARE	PROTOTYPE DEVELOPMENT	TESTING	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT *	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
	✓		✓	✓	✓					OPERATIONAL
	✓		✓	✓	✓					SAFETY
	✓		✓	✓	✓					SECURITY
	✓		✓	✓	✓			✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS														
PERCEIVED		—		—	—	L			—	—				
ACTUAL		—		—	—	L			—	—				
POTENTIAL AREAS IMPACTED											A	P	S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface														
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity														
Property Values														
11. PUBLIC OPINION:														
Controversial Issues				L										
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture		L+		L+	L+	H+			L+	L+			✓	
Scientific Benefit		L+			L+	L+			L+	L+				✓
Public Benefit					L+	L+								✓
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce														
General Population **						L					L	L		✓
15. SAFETY:														
Construction														
Occupational														
Accidents														
SIGNIFICANT		—		—	—	—			—	—				
MINOR		—		—	✓+	✓			—	—				

**Refers To Medical Research Volunteer Subjects (MRVS)

Figure A6-18

PROGRAM MATRIX ANALYSIS SUMMARY

Category: Other Program Research and Activities:

This category includes those subject areas of the program that do not appropriately fit into one or more of the categories defined, that are likely to have imperceptible, if any, impact on the human or natural environment, and were not discrete subject areas warranting separate consideration. Examples of these types of activities are literature studies, purification of immune plasma, and handling of non-hazardous biological laboratory materials. This category does not involve activities concerning storage, laboratory animal care, testing, operation and maintenance, and waste stream management. These activities were evaluated in relation to this program area under site-specific evaluations.

While portions of this category are inherent to the overall contribution of this BDRP to national defense, no detrimental relevant areas of concern were perceived in this element of the program.

IAM (Fig A6-19) Summary

Significant Relevant Areas of Concern:

None

Minor Relevant Areas of Concern:

Program Benefit- National Defense Posture (+)

All other areas were determined to have insignificant environmental concerns.

IMPACT ANALYSIS MATRIX

PROGRAM CATEGORY: Other Program Research and Activities

ACTIVITIES										
RESEARCH DEVELOPMENT TESTING AND EVALUATION						ADMINISTRATION AND MANAGEMENT				
LABORATORY WORK	STORAGE *	PROCEDURES	LABORATORY ANIMAL CARE *	PROTOTYPE DEVELOPMENT	TESTING *	OPERATION AND MAINTENANCE *	WASTE STREAM MANAGEMENT *	PLANNING AND DESIGN	PROGRAM MANAGEMENT	CONTROLS
✓		✓		✓				✓	✓	OPERATIONAL
										SAFETY
										SECURITY
		✓		✓				✓	✓	REGULATORY

LEGEND
H=HIGH
L=LOW
+=POSITIVE

*Activities not applicable

RISKS														
PERCEIVED	—		—		—				—	—				
ACTUAL	—		—		—				—	—				
POTENTIAL AREAS IMPACTED											A	P	RELEVANT AREAS OF CONCERN S	M
BIOPHYSICAL														
1. LAND USE:														
Agriculture														
Industrial														
Commercial														
Residential														
Recreation														
Wetlands														
Floodplains														
Unique Geographical Area														
Policies														
2. PLANT AND ANIMAL ECOLOGY:														
Population														
Terrestrial Habitats														
Aquatic Habitats														
Endangered Species														
3. GEOLOGY:														
Soils														
Topography														
Erosion														
4. WATER:														
Surface														
Ground														
5. AIR QUALITY:														
Ambient Standards														
Biological														
6. AGRICULTURE:														
Crops														
Livestock														
7. CULTURAL RESOURCES:														
Historical														
Archeological														
8. ENERGY RESOURCES:														
Depletable Supplies														
Non-Depletable														
SOCIOECONOMIC														
9. SOCIOLOGICAL ENVIRONMENT:														
Demographics														
Aesthetics														
Noise														
Odors														
10. ECONOMIC ENVIRONMENT:														
Labor Force														
Economic Activity	L+		L+		L+									
Property Values														
11. PUBLIC OPINION:														
Controversial Issues														
Social Concerns														
12. PROGRAM BENEFITS:														
National Defense Posture	L+		L+		L+				L+	L+				L+
Scientific Benefit	L+		L+											
Public Benefit														
13. TRANSPORTATION:														
Road														
Rail														
Air														
Traffic														
14. HUMAN HEALTH:														
Workforce														
General Population														
15. SAFETY:														
Construction														
Occupational														
Accidents														
SIGNIFICANT	—		—		—				—	—				
MINOR	—		—		—				—	—				

Figure A6-19

CITED MATERIALS

1. Department of the Army Notice, "Intent To Prepare Environmental Impact Statement on the Defense Department's Biological Defense Research Program," Federal Register, Vol 52, No 67, April 8, 1987.

2. Department of the Army Notice, "Intent To Prepare an Environmental Impact Statement for the Biological Defense Research Program and Schedule Public Scoping Meeting," Federal Register, Vol 52, No 138, July 20, 1987.

3. U.S. Army Corps of Engineers, Construction Engineering Research Laboratory, "Computer-Aided Environmental Impact Analysis for Industrial, Procurement, and Research, Development, Test and Evaluation Activities - User Manual," Technical Report N-43, May, 1978.

4. *Foundation On Economic Trends, et al., v. Caspar W. Weinberger, et al.,* Civil Action 86-2436, "Offer Of Judgement" and "Order", February 12, 1987.

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8. Department of the Army, "Draft Environmental Assessment for Construction of and Lease of Land for the USAMRDC's Medical Research Institute of Toxinology, Fort Detrick, Maryland," April 1986. (Unpublished)

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10. U.S. Army Materiel Command, "Working Paper Draft, Operational Environmental Assessment, Chemical Research, Development and Engineering Center, Aberdeen Proving Ground, Maryland," December 1987. (Unpublished)

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12. "Biosafety in Microbiological and Biomedical Laboratories," J. Richardson and W. Barkley (1984), U.S. Department of Health and Human Services Publication No. (CDC) 84-8395, Washington, D.C.

APPENDIX 7 Biological Considerations

1. Microorganisms and Toxins
    1.1 Bacteria
    1.2 Rickettsiae
    1.3 Viruses
    1.4 Toxins
    1.5 Simulants

2. Epidemiology
    2.1 General
    2.2 Environmental Influences

3. References Cited

This appendix is intended for those individuals who have not previously studied microorganisms and toxins and who would like to know more about the factual scientific background for some of the discussions and conclusions in this environmental impact statement.

1. MICROORGANISMS AND TOXINS

The term "microorganism" applies to an extraordinarily diverse and ubiquitous group of biological entities ranging in complexity from bacteria, which have cell walls and may exist in the absence of host organisms, to rickettsia and viruses, that require a living organism for life support systems that they do not possess. During their growth, some microorganisms produce toxins that affect man. Man may be infected by microorganisms and affected by the toxins that are produced by these organisms during the infection. Other microorganisms grow and produce toxins in man's foods and when these toxins are ingested with the food they can cause illness or toxicosis. Most of these microorganisms, thousands of species, exist in the environment and have little or no negative interactions with man or his food chain. Some organisms cause human disease, and their survival depends on the successful parasitism of man, contamination of his foods, or successful survival in the environment until the opportunity to infect man occurs. Although the number of microorganisms responsible for crop, animal or human diseases is relatively small, when compared to the number of beneficial microorganism, they occupy more attention and have been the subject of intensive study. Of the approximately 160 known disease-causing species that directly or indirectly affect man, about 30 have been considered as biological weapons in the open literature. The remaining species do not meet the criteria of infectivity, virulence, resistance to adverse environmental conditions, and ability to disseminate in a respirable particle size, required for consideration as a potential biological threat.

Given the inherent hazards of experimentation with these infectious/toxic organisms, the safety of laboratory workers and the surrounding environment assumes paramount importance. To illustrate the rationale for laboratory design, procedures, safety precautions, and containment measures, the following discussion focuses on the unique characteristics of certain infectious organisms and microbial toxins that make them more difficult to contain and control. Also, these organisms and toxins selected as examples have been studied in laboratories participating in the BDRP. For example, the causative agent of Q fever, *Coxiella burnetii,* does not pose a life-threatening hazard; Q fever is an acute but rarely fatal disease of mild to moderate severity. C. *burnetdi* was selected for this analysis because of the difficulties that are encountered in the safe handling and containment of the organism. This organism is highly infectious (one organism when inhaled and retained in the lungs), has a high degree of environmental stability, and is

extraordinarily successful as a parasite. If laboratory design and operations ensure safe handling and effective containment of C. burnetii, then research and testing with other less infective, less robust but more hazardous organisms can be conducted with a high degree of assurance that the facility will be safe. This concept is not new and is derived from the fundamental principles of microbiological sterilization and disinfection. In the following sections, two bacteria, a rickettsia, a virus and three microbial toxins are discussed in terms of their basic biology and the natural cycle of the infection or intoxication in the environment.

1.1 Bacteria

Bacteria are single-cell microorganisms that multiply by binary fission. With few exceptions, the cells are encased within rigid or semirigid cell walls that confer a constancy of form. The three basic forms are cylindrical (bacillus or rodshaped), spherical to ovoid (coccus), and spiral (spirillum). The name bacillus is also used for a genus of rod shaped bacteria that includes the organism causes that disease anthrax. These organisms generally vary in size from 1 micron (u) in width or diameter to 1-4 u in length; a micron, or micrometer, is 1/1000 of a millimeter. One way of differentiating the bacteria, in addition to the shapes described above, is by their ability to be stained with specific dyes or stains. One staining technique that is quite useful in the identification of bacteria is the Gram stain. This method of staining separates bacteria into "gram positive" and "gram negative" groupings based on the staining characteristics of the cell walls. The following discussions of specific bacteria includes a gram positive and a gram negative organism.

1.1.1 Gram Negative Bacteria

This diverse group of bacteria contains numerous medically important organisms. Included are the bacteria that cause typhoid fever, brucellosis, syphilis, meningitis, gonorrhea and, historically, one of the most deadly diseases, plague (caused by *Yersinia pestis). Francisella tularensis,* the causative agent of tularemia, rather than the plague bacillus, has been selected as the model pathogenic organism for the gram negative bacteria because of its very high infectivity (10-50 cells when inhaled) in comparison to Y. *pestis* (3,000 cells when inhaled) and relative stability.

Tularemia is found throughout the United States in a variety of wildlife that make up the reservoir of this disease. Most commonly, the cottontail rabbit is the primary carrier, with approximately 100 other species of mammals and insects implicated in the transmission of this disease to man. Usually, humans are infected by direct contact with infected tissues, blood, skins etc., or from bites or scratches from animals that feed on infected rabbits or rodents, or by ticks, deer flies or body lice

that have fed on infected hosts. *Francisella tularensis* usually enters the body by means of minute abrasions on the skin of the hand (e.g., during the dressing of infected rabbits) (1,2) Granulomas in wild animals have been reported to contain up to 10 organisms per gram of tissue (3). The appearance of lesions between the fingers suggests that the organisms may also penetrate intact skin. *F. tularensis* may infect the eyes when they are touched by contaminated hands. If poorly cooked meat or drinking water contaminated by infected animals is ingested, the organism may penetrate the mucous membranes of the mouth or gastrointestinal tract. Large outbreaks of gastroenteritis traced to water contaminated with *F. tularensis* were described in Eastern Europe during World War II; this contrasts with U. S. experience (1,2). However, other data from human studies indicate that the gastrointestinal tract is resistant to infection, with infection only initiated with inocula of at least 10 8 colony-forming units/ml (4,2).

Man-to-man transmission has been reported only rarely and is considered to be of no importance epidemiologically (2,5). Tularemia has been found to occur throughout the year, with distinct peaks or incidence in July and December (2). Tick associated disease is prevalent in the warm months of May through September, while rabbit-associated disease is most common during the rabbit hunting season of November through February. From 1951 to 1973, a trend toward a greater proportion of summer cases and a smaller proportion of winter cases was identified (2).

Both Saslaw et al. (6) and Wedum et al. (7) concluded, from their independent risk assessments of *F. tularensis*, that working with this organism poses an extreme hazard of infection to the laboratory worker. In a retrospective study by Pike (8), tularemia ranked as the third most frequent laboratory-acquired infection and accounted for 13% of the laboratory-acquired diseases. It should be emphasized that this is a historical laboratory infection rate and is not representative of laboratories employing current high-hazard biosafety control procedures, but reflects the lack of knowledge of the hazards associated with the organism in the past and the state of the of containment facilities available at that time. Tularemia caused numerous infections in laboratory workers at Ft. Detrick prior to the development and use of an effective vaccine (9).

1.1.2 GRAM POSITIVE BACTERIA

The gram positive bacteria are also a heterogeneous group of organisms with members that are of medical significance. This group of bacteria is made up of rod forms (bacilli) and spherical forms (cocci). Diseases caused by this group of organisms include strep throat and rheumatic fever, impetigo, boils, toxic shock syndrome, pneumonia, meningitis, and anthrax. Some of the gram positive bacteria produce potent toxins, and illness results when people ingest these toxins or are infected by the organisms that produce the toxins. Tetanus and botulism are produced by

members of the genus *Clostridium.* Staphylococci can produce toxins that are responsible for food poisoning and some of the symptoms associated with the toxic shock syndrome. Diphtheria is caused by a member of the genus *Cornyebacterium.*

One additional feature of some of the rod shaped gram positive bacteria is their ability to produce endospores, spores within the bacterial cell. The endospore differs significantly from the vegetative cell in being much more resistant to heat and other sterilizing or disinfecting agents. The spore-forming bacilli are divided into two groups based on their oxygen requirement. The genus *Bacillus is* aerobic (grows in the presence oxygen). The genus *Clostridium* forms spores and is anaerobic (grows only in the absence of oxygen). The genus *Bacillus* contains a highly diverse group of species that includes *Bacillus anthracis,* the causative organism of anthrax. *B. anthracis* has been selected as the model organism for discussion of the gram positive bacteria because its ability to infect man and animals and to produce spores gives it significant advantages in the environment. Research has been conducted with anthrax in the BDRP for a number of years, and there is a substantial base of data on the procedures required to work safely with this organism.

1.1.2.1 Anthrax

Anthrax organisms are found throughout the United States and the world (10). As stated in the previous section, the anthrax bacillus produces endospores as a survival mechanism. Although the vegetative cells are very susceptible to chemical and heat disinfection, the spores are more resistant. Anthrax spores are usually destroyed by repeated boiling, dry heat, hydrogen peroxide, or sodium hypochlorite bleach. They can persist for many years in soil and in animal hides. They are stable in aerosol form, and in contrast to most pathogens, will live for several days if direct sunlight is avoided; in the presence of direct sunlight, they will survive only for several hours. It can be assumed that atmospheric gasses will have no appreciable deleterious effects (11). Based on the experiences of the British at Gruinard Island, Scotland, it can be expected that anthrax spores on the ground could survive and persist in the soil for upwards of 40 years (12), although spore numbers, would decrease rather than increase over this time. During the course of infection, or when grown in a culture medium, *B. anthracis* produces three proteins, which when in specific combinations, act as toxins. These toxins are not as potent as tetanus or botulinal toxins, but they are directly responsible for the ability of the anthrax bacteria to resist host defenses and invade host tissues. None of the toxin components are active by themselves. The protein given the designation protective antigen (PA) must bind with either the edema factor (EF), or the lethal factor (LF) to have activity. The combination of LF+EF has no activity. PA+EF produces edema (swelling in the tissues). PA+LF kills certain types of white blood cells. All three components

are sensitive to heat and mild chemicals and are easily degraded and contained in the laboratory.

Anthrax is a disease of wildlife and domestic livestock, primarily cattle and sheep, and is transmitted to humans through activities involving contaminated animal products, such as, ingestion of poorly cooked meat, working with contaminated hides, hair and wool, and by biting flies that have fed on infected hosts. Three routes of infection of humans are recognized: 1) the skin (cutaneous anthrax), 2) the respiratory tract inhalation anthrax), and 3) the alimentary canal (gastrointestinal anthrax). Cutaneous anthrax results when spores gain entry through the broken skin and establish an infection. The cutaneous lesion may be quite large, but usually resolves when treated with appropriate antibiotics. In some cases, the bacteria escape from the skin lesion and invade the blood stream. This is a serious infection and has a high fatality rate. Cutaneous infections account for 95% of all cases of anthrax in this country (13). Respiratory infections are acquired by inhaling large numbers of spores, 8,000 to 20,000, in contaminated work sites. Following respiratory exposure, the spores are carried throughout the body by the lymphatic system with few organisms found in the lungs (11). These infections have an insidious onset and a high mortality rate.

Respiratory anthrax infections have occurred in workers from woolen mills, hide processing plants, goat hair processing facilities, and in laboratories where there were high concentrations of anthrax spores (15, 16) Human-to-human infections have not been reported (13). Gastrointestinal disease results from the ingestion of poorly cooked meat from infected animals (17). Oral-oropharyngeal infections have also been reported from similar sources (18). Wildlife and domestic animals ingest anthrax spores in contaminated food, either commercial products containing bone meal contaminated with spores or in pastures where soil conditions support the growth and survival of B. *anthracis.* When an infected animal dies of anthrax in the wild or in a pasture, it recontaminates the soil with a new crop of spores. Some soils that have become contaminated with anthrax spores remain contaminated for long periods of time. Others will not support the survival of anthrax spores (10). Anthrax is best controlled in animals by vaccination.

1.2 Rickettsiae

The rickettsiae are very similar to bacteria in form and structure. They have typical bacterial cell walls and resemble minute, nonmotile, cocco-bacillary bacteria. What distinguishes them from most bacteria is that the majority are obligate intracellular parasites and can survive only briefly outside of animal cells. Whereas infection without disease is common with many bacteria, rickettsial infection is tantamount to disease.

Rickettsiae have a wide range of natural hosts, which include mammals and arthropods.

Rickettsiae are the causative agents of Rocky Mountain spotted fever, tsutsugamushi disease, typhus, and trench fever. The group also includes the rickettsia-like organism C. *burnetii*, the causative agent of Q fever. The combined biological properties of C. *burnetii* (high infectivity, hardiness, and exceptional success as a parasite) require close scrutiny if an laboratory handling this organism operate safely. Of the organisms discussed to this point, C. *burnetli* has the greatest potential to cause infection among laboratory workers. The main cause of concern with Q fever is not the severity of the disease but, rather, the extent to which numbers of mammals could be infected if the organism were not adequately contained. Because containment and control design rationale are tied to the properties of C. *burnetii*, this organism is discussed in greater detail than the other model organisms.

1.2.1 General Characteristics of C. *burnetii*

C. burnetii is a small (0.2-0.4 x 0.4-1.0 u), nonmotile, coccobacillary organism that is capable of passing through filters that retain bacteria in aqueous suspension. The organisms are propagated, in the laboratory, in the yolk sacs of embryonated chick eggs (as many as 10 11 viable particles can be obtained from a single egg) or tissue culture cells. The organisms actually grow inside the microbiocidal milieu of the digestive vacuoles of cells. There it undergoes a developmental cycle which consists of sporogenic differentiation (19).

Unlike typical rickettsiae, C. *burnetii is* unusually stable in an extracellular environment, more resistant to common antiseptics, and remains viable and virulent for longer periods in tick feces, wool, sterile skim milk, and water. C. *burnetii* is more resistant to physical and chemical agents than the majority of nonsporogenic microorganisms; it is not completely inactivated by exposure to 63° C for 30 minutes or to 85-90° C for a few seconds. Treatment with 0.5% NaOH for 6 hours does not entirely destroy the organism in infected yolk sacs. Similarly, the organism remains viable after 48 hours in 0.5% formaldehyde and after several days in 0.4% phenol. However, 24-hour exposure to 0.5% HC1 or 1% phenol renders it inactive.

1.2.2 Occurrence and Host-Vector Relationship

C. burnetii occurs worldwide; the existence of diverse natural reservoirs and vectors is well documented. In nature, C. *burnetii is* transmitted among animals by ticks that act both as vectors and reservoirs and may feed on more than one host species. Cattle and sheep serve as incidental hosts and frequently are infected by tick bites. Distribution of C. *burnetii is* widespread in areas where sheep or cattle are raised or held for market. The prevalence of C. *burnetii* among cattle,

in some areas of the United States, is as high as 65% (20). Natural infections have been found in 22 species of ticks belonging to eight genera, in human body lice, in a large number of wild and domesticated animals, and in birds. C. *burnetii was* first isolated in the United States in the Great Salt Lake Desert (21) in native rodents and their ticks. Epizootic infections of resident mammals in that area have been documented (22). Infected animals shed the organism in large numbers in milk, excreta, amniotic fluids, and, particularly, placentas, which may contain as many as 10 9 infectious particles per gram of tissue. The infected animal also sheds the organism in nasal and salivary secretions. Although vector transmission is a major route of exposure for animals, the high degree of extracellular stability and small particle size of C. burnetii make the aerosol route of transmission equally important.

Exposure in man occurs most frequently by contact with the airborne microorganisms. Q fever is acquired by inhalation of contaminated dusts and aerosols generated from dried excrete, dried secretions, and bedding. The disease is most prevalent among slaughter house, tannery, and farm workers. Pike (8) reported 186 accounts of laboratory-acquired Q fever that could be traced to improper procedures in the presence or absence of adequate primary and secondary barriers. The profile developed by Wedum et al. (7) for Q fever indicated that:

1) Q fever was the second most frequently acquired laboratory infection

2) The infectious dose by inhalation for 25-50% of volunteers was 1-10 organisms (23)

3) Although C. burnetii is a notorious cause of laboratory infection, it is rarely transmitted from an infected animal to a normal cagemate

4) C. *burnetii* is readily isolated from the urine and feces of infected animals

The overall results of the qualitative risk analysis indicate that the ease of transmission of C. *burnetii* in aerosols and the very low infective respiratory dose for man make this organism especially hazardous for routine laboratory work.

Studies on airborne Q fever suggest that the infectious dose for man by the inhalation route can be as low as one organism (24, 25, 23, 26). Q fever rarely results in mortality, although complications, secondary infection or preexisting heart disease, may result in death. This disease is generally an acute systemic illness that has an incubation period of 14-26 days; this period depends on the route of exposure, age of the infected individual, and dosage (increased dose levels shorten the incubation period). Disease symptoms persist for approximately 1-2 weeks.

Interstitial pneumonitis, resembling primary atypical pneumonia, usually develops by the fifth or sixth day (27). The heart, spleen, and kidneys may become involved in latent or chronic cases of Q fever (27,28,29).

Lasting immunity is believed to result from one infection with C. *burnetii (* 25,27); however, chronic and latent infections have been reported. The disease may persist after its overt clinical features have subsided. A recurrence of the disease may occur if the carrier is appropriately stressed (30,27). Antibody levels usually rise to diagnosable levels approximately 2 weeks after infection and may persist for 2-3 years (31,32,33).

Humans are an incidental host of C. *burnetii*. Human infection has been found to result almost exclusively from contact with infected animals, their products, or their environments. Sources of exposure that have been identified to explain the spread of Q fever include infected livestock, contaminated dust, and the use of raw milk from infected animals (34,35,36). Studies of serum antibodies among seven separate occupational groups in Southern California showed that persons who had contact with livestock consistently showed higher proportions of positive serological reactions (34). The major reservoirs of C. *burnetii* are dairy cows, sheep, and goats, which can shed enormous numbers of rickettsiae in their milk and birth fluids while appearing healthy (27). It has also been hypothesized that contaminated fields and roadways may serve as sources for airborne dissemination of C. *burnetii (* 34,37,35) Numerous case studies have documented human infection resulting from the inhalation of airborne dust originating in environments contaminated with the body secretions or excrete of infected livestock (34,35,37). It was found that contamination of the environment in this manner would not only increase the hazard of infection for persons in casual or close contact with livestock, but would enhance the possibility of infection of persons at some distance from the source (35,37). Many cases of Q fever with no evidence of livestock contact involved persons whose occupations require them to be in an enclosed room or in a relatively static atmosphere; e.g., bartender, barbers, store clerks, mechanics, and telephone operators (35). Contaminated clothing is considered to be the route of dissemination (24,37) Airborne dust containing the rickettsiae is believed to infect janitors and secretaries who work in buildings containing Q fever laboratories (24,38).

The airborne dissemination of C. *burnetii* has been found to be enhanced by windy, dry weather (31,24). During 1959, a Q fever epidemic in California was attributed to windborne dissemination of C. *burnetii (31)* . A case study of airborne dissemination involved an invalid confined to an apartment. After the subject contracted Q fever, it was found that his apartment was located directly downwind from a tanning plant (31,24). The distance between the plant and the apartment building was not specified.

Studies have been conducted on the air of dairy barns and sheep holding pens. Pens housing animals that had received 109 infectious doses of C. *burnetii* contained rickettsiae 9-14 days after the birth of lambs (39). According to the investigators, this study showed conclusively that parturition was responsible for the long-lived source of aerosolized C. *burnetii*. In another study, five groups of guinea pigs developed Q fever and/or serological response from an inoculum of airborne dust particles from a dairy milking barn (40).

Quantitative data on aerosol survival in the environment are sparse. Beebe et al. (41), in a laboratory simulation of outdoor conditions, demonstrated that C. *burnetii* has a relatively high degree of resistance to light. The authors calculated a decay rate of 4% per minute for C. *burnetii* during exposure, at 30% RH, to the full spectrum of light.

1.3 Viruses

Viruses are a unique class of infectious agents that are obligate intracellular parasites. They are distinctively different from the bacteria and rickettsiae in their simple organization, composition, and mechanism of replication. A complete virus may be regarded as a nucleic acid (DNA or RNA) surrounded by a protein coat that protects it from the environment and facilitates transmission from one cell to another. Viruses are smaller than the smallest bacteria, and their obligatory intracellular parasitism accounts for their infective and pathogenic properties. Viruses infect a cell, multiply in characteristic burst sizes (e.g. 100 to 1,000 particles), and invade other cells, causing a spreading infection. Viruses also cause important functional alterations in the cells they invade. All living cells can be parasitized by specific viruses. The viral range of infections is host specific: animal, bacterial, and plant viruses attack only specific hosts or a limited group of host organisms. The virus that causes Venezuelan equine encephalomyelitis (VEE) has been selected as the model viral organism because it is transmitted by a common and widely distributed vector (carrier, specifically a mosquito) and because it can infect both equine species and humans.

1.3.1 General characteristics

The infectious agent VEE is classified in the heterogeneous group called arboviruses (arthropod-borne viruses). VEE virus contains a single positive strand of RNA, and the envelope contains at least 2 glycoproteins and membrane lipids. VEE is heat-sensitive (56° C) and readily inactivated by diethyl ether, sodium desoxycholate, chloroform, and ultraviolet light. It can be preserved in the frozen state or by freeze-drying, and will grow in a variety of tissue cultures of mammalian, avian, and mosquito origin.

1.3.2 Epidemiology

VEE is a mosquito-borne viral disease that cycles in nature between mosquitos and rodents. VEE infects equine species and man as incidental hosts in South and Central America. A less virulent subtype of VEE cycles in limited ecologic foci in Florida. Equines may serve as amplifying hosts during outbreaks; humans are not involved in the transmission cycle. The disease can be transmitted via aerosols, and has a high infectivity rate when inhaled. Laboratory infections associated with inhalation exposure have been reported (8). Infection in man usually results in relatively mild influenza-like disease with little or no central nervous system involvement. An infection confers immunity; however, the duration of immunity is unknown. Immunization for high-risk personnel is available.

Epidemiologic surveys performed by Pike (8) and Wedum et al. (7) listed VEE as the second most frequent cause of laboratory acquired viral infections. The three most frequently identified sources of viral infections were exposure to animals or ectoparasites, direct work with the virus, and laboratory accidents. Immunization with live attenuated VEE vaccine has been proven to be beneficial in protection of laboratory workers at risk of exposure to VEE in natural and artificial conditions. Since 1969, when immunization of all laboratory workers at risk to VEE became routine, only five "breakthrough" laboratory infections have occurred. In all cases, infection was related to accidental aerosol exposure to high concentrations of non-epidemic VEE strains. Because these strains are generally less virulent than the epidemic VEE strains against which the vaccine was prepared, these infections were mild, in three cases documented only by seroconversion. Prior to development and routine use of attenuated VEE vaccine, only a marginally effective, killed VEE vaccine was employed to afford protection. Between 1950 and 1962, an average of 4 laboratory infections occurred each year at Fort Detrick. After 1963, when the attenuated VEE vaccine was being developed and tested for efficacy, incidence declined to less than one infection per year (See Appendix 8). Since the documentation that breakthrough infections occurred only with non-epidemic VEE strains, work high concentrations of these viruses has ceased, and no laboratory infections of immunized personnel have occurred since 1975. Thus, immunization, in combination with strict adherence to appropriate containment and biosafety practices, can reduce the occupational risk of laboratory work with infectious organisms to the vanishing point.

VEE infection in man results in a mild influenza-like disease. The incubation period is considered to be from 2 to 5 days. A complete recovery usually follows within 3-5 days; in more severe cases, recovery may take up to 8 days (42,43). Mortality is less than 0.5%. Subclinical infections in man are considered to be relatively common in endemic areas. Although

there have been no reported cases in Trinidad since 1943, a survey of 160 individuals revealed 6.9% of the sera to contain antibodies against VEE virus, indicating undiagnosed infections (42).

1.3.3 Modes of Transmission

Little quantitative information is available on the survival of aerosolized VEE virus in the environment. The single study that provides relevant data (44) indicated that after 1 hour of exposure to simulated solar radiation, 0.02 and 0.006% of aerosolized VEE virus survived at 30 and 60% RH, respectively. VEE is a mosquito-borne viral disease that occurs in equine species and mammals; however, man is only incidentally involved as a dead-end host in the epizootic cycle. Laboratory studies indicate that mosquitoes are able to transmit the infection among guinea pigs up to 13 days after infection (42). There is no evidence of man-to-man transmission of the respiratory infection, nor of feedback of virus from man to mosquitoes in nature.

1.4 Toxins

Representative toxins of interest in the BDRP include staphylococcal enterotoxins, botulinal toxins, and the mycotoxin known as T-2 toxin. Staphylococcal enterotoxins are a group of toxins of similar structure and identical mechanism of action produced by the genus of bacteria *Staphylococcus.* Outbreaks of food poisoning result from the ingestion of poorly refrigerated foods in which these bacteria have grown and produced enterotoxin. The intoxication that follows results in a significant gastrointestinal upset that lasts a few hours, but resolves without treatment in most cases. Another bacterial toxin, produced by *Clostridium botulinum,* results in the disease syndrome known as botulism. This is a life threatening disease that usually requires hospitalization and is fatal in some cases. The toxin is usually ingested in foods and acts on the nervous system at the nerve muscle junction. Both of these toxins are proteins and are easily degraded by sodium hypochlorite or similar solutions. Botulinal toxins are destroyed by boiling, but the staphylococcal toxins require higher temperatures and longer exposure times for complete inactivation. With these considerations in mind, these toxins can be safely handled in most laboratories using established containment practices. One laboratory accident documents the need for the protection of workers against aerosolized botulinal toxins (45). An accidental exposure to an aerosol of staphylococcal enterotoxin at Ft. Detrick was described by Lamanna (46). Aerosols of toxins have been produced experimentally to test the efficacy of toxoids, inactivated toxins, used to immunize personnel (47). It is assumed that man is as susceptible to aerosolized botulinal toxins as the guinea pig, and thus laboratory safety practices must protect workers

from this hazard. Although the normal route of exposure for man is by ingestion, data from animal studies and the previously mentioned laboratory accidents point to the need to follow established safety and containment procedures.

Mycotoxins are produced by fungi and are distinct from the two bacterial toxins discussed above. While the bacterial toxins are proteins, the mycotoxins are complex cyclic organic molecules that are more resistant to physical and chemical degradation. They are however, significantly less toxic. T-2 toxin can be absorbed through the skin and causes a broad spectrum of reactions which include respiratory distress, suppression of the immune response, skin necrosis, and protein synthesis inhibition which leads to death in laboratory animals. T-2 and related toxins can be inactivated with 3.2% sodium hypochlorite and are safely handled in laboratories with appropriate containment and safety procedures.

1.5 Simulants

Where they are appropriate and where they provide meaningful results, simulants can be used in place of actual pathogens or toxins. Two simulants, *Bacillus subtilis* var. *niger,* and MS-2, are used or proposed for use in outdoor tests conducted at DPG.

Bacillus subtilis var. *niger* (often abbreviated as BG, *B. subtilis* was previously designated *Bacillus globigii) is* used extensively as a simulant for *Bacillus anthracis* in chamber and field testing of protective and decontamination equipment. *Bacillus subtilis* is a gram positive, spore-forming bacterium. It is commonly found in soil samples throughout the world, and it is frequently aerosolized by winds and dust storms (60). *Bacillus subtilis* is identified in the CDC/NIH biosafety guidelines as an non-pathogen (59). Dr. John Jaugstetter of the Centers for Disease Control, Biosafety Office (personal communication) indicated that CDC does not have any case histories or data where *B. subtilis is* identified as an organism responsible for an infection in humans. A review of outdoor testing conducted by the Army with *Bacillus subtilis* var. *niger* (BG) was presented to congress in the 24 February 1977 Department of the Army report on the Biological Warfare Program.

Bacillus subtilis has been isolated from man types of soils. Desert soil samples have yielded 1.0 x 10 spores per gram of surface soil (60). It has been used for forty-one years at Dugway with no discernible environmental impact. Aerosol studies at Dugway have demonstrated that the aerosol concentration of *B. subtilis* at 10 kilometers (6.2 miles) downwind of the dissemination point (i.e., 5.0 x 104 colony forming units/m3 air) is less than the concentration expected from aerosolization of one gram of soil by the wind (62).

MS2 is a picorna (small virus) bacteriophage. A bacteriophage is a virus that grows only in bacteria. MS2 is

is further classified as a coliphage, being a virus that will only grow in certain strains of *Escherichia cold (E.* cold is a bacterium common to the human gut) such as F+ strain (63).

MS2 is found throughout the environment. It has been isolated in untreated sewage and in wastewater treatment facilities (64, 65), where its host bacteria can also be isolated. MS2 has previously been used in outdoor dissemination tests, as a simulant organism for pathogenic viruses, without adverse environmental impact (66, 67).

MS2 and *B. subtilis (BG)* have been handled in laboratories observing Biosafety Level 1 and 2 (depending on the operation performed) containment guidelines and released outdoors at DPG. There have been no ill effects. Controlled outdoor aerosol testing with these materials by trained personnel does not present a hazard to workers or the environment (62). They have been determined to be safe for humans and the environment. They are the only biological simulants currently used at Dugway for outdoor testing.

2. EPIDEMIOLOGY

2.1 General Discussion

Progress in microbiology has advanced our understanding of the infection process and modes of disease transmission, and has led to the development of safety procedures and laboratory design intended to minimize the chance of accidental exposure. Laboratory-acquired infections still occur, but the frequency has continued to decline with the advent of effective vaccines, improved laboratory design, sophisticated safety equipment, and the implementation of strict safety procedures. Although the epidemiology of laboratory-acquired infections is imprecise, there is enough information on well-studied microbiological substances to develop procedures that can prevent or minimize accidental exposures. The most frequent type of laboratory accident involves either manipulations with syringes or contact with infectious materials through spills and splashes accompanied by aerosol formation. In the past, a large percentage of accidents resulted from mouth pipetting errors, but the use of automatic pipetting devices has virtually eliminated this procedure as a source of infection. The strict use of safety equipment and adherence to safety procedures have greatly reduced the impact of laboratory accidents. Almost all laboratory accidents are clearly preventable if the necessary precautions are taken and a conscientious effort is made to avoid accidents.

Aerosol dissemination of infectious material is of concern for the safety of the laboratory staff and of personnel who occupy the same building but are not within the working laboratory. Hence, laboratory design, protocols, and safety measures designed to prevent and contain aerosols for the protection of laboratory personnel also serve to protect

personnel outside the laboratory from this kind of exposure. The accidental creation of aerosols during routine laboratory procedures can be avoided by implementation of laboratory design, equipment and standard operating procedures based on the CDC/NIH (48) guidelines. The biological safety cabinet (see Appendix 11) forms a primary barrier between the worker and the infectious material and provides protection at the source of potential contamination. Vertical laminar airflow biological safety cabinets, combined with high-efficiency air filters, are now standard equipment in most medical and microbiological laboratories. They afford a high degree of protection for both the worker and the product. For highly hazardous organisms such as Lassa virus (7), cabinets maintained under negative pressure and equipped with rubber glove ports provide absolute containment. In addition to the primary barriers, secondary barriers for containing infectious materials include control of airflow, high efficiency air filtration, incineration of exhaust, special clothing, and vaccination (see Appendix 12). The safety afforded by the implementation of primary and secondary barrier systems of protection is exemplified by the outstanding safety record over the past several years of containment laboratories worldwide.

2.2 Environmental Influences

Organisms released into the environment are subject to a variety of stresses that may destroy or modify their ability to survive and subsequently infect man. The subject environmental survivability is a complex one, because different organisms show a wide range of different responses. Thus, the generalities presented here are illustrative rather than comprehensive. The focus of this discussion is mainly on airborne transmission, because this is the dispersion mode of primary concern to the environment.

2.2.1 Relative Humidity (RH)

Low RH (20-30%) as well as high RH (95%) enhance microbial death (49). Hatch and Dimmick (50) studied the effects of abrupt changes in RH on airborne *Serratia marcescens* and *Yersinia pest is.* Their results showed that rapid changes in RH may decrease or increase organism death depending on the shift direction. These data indicate only narrow RH zones in which microbes display sensitivity. Optimal ranges for survival are between 40 and 80% RH (51).

2.2.2 Temperature

In a controlled laboratory experiment, airborne suspensions of *Francisella tularensis* were sampled over a range of temperatures and RH (52). The highest recovery of viable cells was observed between -7 and 3°C (ambient RH), and recovery decreased significantly above and below this range. A progressive increase in atmospheric temperature from 24 to 35° C

at 85% RH resulted in a linear increase in the death rate. The percent recovery of viable organisms 4 minutes postaerosolization ranged from 0.9% at 35° C to 10.1% at 0° C. The results for bacteria are consistent with the conclusions of Harper (53): that aerosolized viruses, including Venezuelan equine encephalomyelitis virus, survive best at low temperatures. A review of the limited data on this subject suggests that as temperature increases, death rates of microbial aerosols increase .

2.2.3 Solar Radiation

Sunlight, as well as artificially produced ultraviolet radiation, can be lethal to microbial aerosols. This knowledge has been exploited as a method of air disinfection in hospitals and laboratories. Goodlow and Leonard (51) observed that (1) large aerosol particles are more resistant to the lethal effects of solar radiation than small particles, (2) dry aerosols are more resistant than wet aerosols, and (3) RH above 70% promotes microbial survival. Beebe et al. (41) found that *F. tularensis* loses viability in proportion to light intensity. According to the data of Babudieri and Moscovici (54), C. *burnetii is* relatively resistant to ultraviolet rays; however, Siegert et al. (55) showed a marked decrease in survival of suspensions of C. *burnetii* within 2 minutes. Beebe et al. (41) compared the stability and resistance of C. *burnetii, F. tularensis, Y. pest is,* and S. *marcescens* to artificial sunlight at different humidities. At 30% RH, C. *burnetii* aerosols were markedly affected by irradiation; less than 2% was recovered after 10 minutes, and 0.5% was recovered after 30 minutes. Increased humidity (60%) enhanced survival; the percentage of cells dying/minute was approximately 0.9%. The death rate for the other organisms was 5-50 times greater than that for C. *burnetii.* The findings of these studies support the concept that sunny days with low RH should provide the most adverse conditions for microbial survival. In contrast, the most favorable conditions for survival of microbial aerosols should be at night, when the RH is usually high, or on overcast and humid days. The validity of this hypothesis is strengthened by the results of open-air experiments conducted by Graham et al. (56). To simulate "captive aerosols" and the unique conditions under which natural aerosols are generated by rain or water drops falling on infected plants, microthreads were loaded with aerosols of *Erwinia carotovora (* var. *atroseptica)* at 90-95% RH. The prepared microthreads were exposed to weather conditions ranging from warm sun to cool, dark conditions in heavy rain. After 30 minutes, viability assessments showed that the bacteria survived poorly under warm, dry conditions (0% survival), better when it was cooler and more humid (15% survival), and best when humidity was high (70% survival). The authors concluded that conditions on a warm, dry day would preclude the danger of long distance dissemination of a viable aerosol.

2.2.4 Atmospheric Gases

An end product of fossil fuel combustion, nitrogen dioxide (NO 2), has a marked virucidal effect on airborne VEE virus, causing a threefold increase in viral death (57). The highly toxic open-air factor (OAF), which probably arises from atmospheric pollution, was first described by Druett and May (1969). May et al. (11) noted that a liter of air containing one part extraneous gas per hundred million parts of air killed 10 bacterial Cells. Since the mass of gas exceeded the cells by about 40 times, the merest trace of the OAF can be extremely toxic. The same authors demonstrated that while the OAF has a profound effect on the survival of E. *cold* and F. *tularensis*, spores of B. *anthracis* and *B. subtilis* (var. niger) do not show any sensitivity to it. It is noteworthy that spores of bacilli are among the most common viable microorganisms in the upper atmosphere (58).

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APPENDIX 8 - HISTORICAL PERSPECTIVE: BIOSAFETY DURING OFFENSIVE AND DEFENSIVE PROGRAMS AT FORT DETRICK, MARYLAND

PART I - BIOSAFETY DURING OFFENSIVE AND DEFENSIVE PROGRAMS AT FORT DETRICK, MARYLAND

1. INTRODUCTION

2. PILOT PLANT STUDIES

3. CONTAINMENT OF INFECTED EXPERIMENTAL ANIMALS

4. CONTAINMENT OF INFECTED MOSQUITOES

5. SHIPMENT OF HAZARDOUS INFECTIOUS ORGANISMS AND TOXINS

6. LABORATORY AND EQUIPMENT DESIGN

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PART 2 - RISK ASSESSMENT

1. INTRODUCTION TO RISK ASSESSMENT

2. STATISTICAL METHODS

3. QUANTITATIVE RISK COMPUTATIONS

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PART 1 BIOSAFETY DURING OFFENSIVE: AND
DEFENSIVE PROGRAMS AT PORT DETRICK MARYLAND

1. INTRODUCTION

A historical perspective of biosafety during both offensive and defensive programs at Ft. Detrick is provided to give the reader an understanding of the evolution of biosafety technology over time and an appreciation for the differences between the offensive and defensive programs. Ft. Detrick was the operational center for offensive and defensive research and development studies on biological warfare (BOO) from 1943 until 25 November 1969, when all offensive studies were terminated and the disestablishment of the U.S. Army Biological Warfare Laboratories was initiated (see Appendix 1). Shortly thereafter, the responsibility for physical defensive studies was transferred to Edgewood Arsenal, while medical defensive programs continued at Ft. Detrick as part of the mission of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

A brief review of selected biological weapons research and development operations conducted at the U.S. Army Biological Warfare Laboratories at Ft. Detrick from 1943 through 1969 provides a realistic perspective on the issue of biological safety. The quantities of biological materials used in the offensive operations dwarf, by many orders of magnitude, the amounts of hazardous infectious organisms and toxins which are used in research institutes and laboratories involved in the current BDRP.

This historical perspective reviews: (a) the development of pilot plant production of an organism adapted from research methodology and quantities; (b) the containment of infected experimental animals; (c) the containment of infected mosquitoes; (d) the shipment of hazardous infectious organisms and toxins; (e) the evolution of containment laboratories, biological safety cabinets, and other biocontainment equipment and methods. Finally, Ft. Detrick's experience with biosafety during both offensive (1941-1969) and defensive (1970-present) programs will be discussed.

2. PILOT PLANT STUDIES

The research and development studies conducted using *Franciscella tularensis,* the bacteria that causes tularemia (rabbit fever), serve to illustrate the differences in hazard levels and biosafety requirements between defensive and offensive programs. Defensive studies of *F. tularensis,* conducted in parallel with weapons research and development studies, focused on the development and production of a tularemia vaccine for use in protecting at-risk laboratory personnel. Weapons research and development studies were directed toward optimizing the organism growth conditions, maximizing the stability of the organism and developing methods of dissemination. The weapons development

effort ultimately involved the production and handling of large quantities of *F. tularensis* in a pilot plant. The volumes of *F. tularensis* and corresponding numbers of organisms required for the defensive program and weapons development program are shown in Table A8-1. It is obvious that defensive and offensive programs are not distinguishable solely on the basis of the quantity of organisms needed to conduct research studies. Both programs involved growth of *F. tularensis* in small quantities, up to about 1 liter per day, so that by the end of one week, perhaps as much as five liters had been obtained. Because *F. tularensis* may grow to a concentration of 1 x 10 9 cells per ml, the maximum number of organisms processed during a research week was approximately 5 x 10 cells (5,000 ml x 1 x 109). One to 10 cells of freshly prepared organisms, delivered by aerosol, is reported to be the infectious respiratory dose for man(l). Thus, even those laboratory research quantities contained a large number of potentially infectious doses.

As weapons research studies transitioned to the development phase, the volume disparity between defensive and offensive programs becomes more obvious (Table A8-1). For the amounts of material required in a defensive program, there is a minimal increase from research quantities to the quantities required for vaccine development. For example, only about 35 liters of the attenuated strain of *F. tularensis* are needed to produce one million doses of tularemia vaccine (2). Volume requirements increase by several orders of magnitude between the research and the development phases of the offensive program (Table A8-1);

TABLE A8-1: VOLUME REQUIREMENTS FOR *F. TULARENSIS BY* STUDY PHASE

Type Program	**Study Phase**	**Weekly *F. tularensis* Volume Requirement**	***Maximum* Number Of Organisms(xl0^{12})***
Defensive	Research	5 Liters	5
Offensive	Research	5 Liters	5
Defensive	Development	10 Liters	10
Offensive	Development	3634 Liters	3,633

specifically, from approximately 5 liters to 3634 liters of F. *tularensis* per week (a greater than 700-fold increase). The number of *F 12 tularensis cells* grown correspondingly increased from 5 x 10 cells to 3.6 x 10 cells* per week. The increase

*1 x 10 ^{12} = 1,000,000,000,000 (trillion)

*8 fermenters, 2x weekly x 60 gal x 3785ml/gal x 10 ^{9} cells = 3.6 x 10 ^{15}

in volume of material, and concomitant increase in numbers of organisms, made the potential for accidental infection of the worker much greater and highlighted the need for even greater containment to prevent risk to pilot plant personnel. Many engineering and containment problems had to be solved as the studies progressed. Examples of technology developments during this period included pump and agitator seals, improved centrifuge containment, and improved sterilization procedures for fermenters and process equipment.

The types of studies conducted in the pilot plant, in contrast to those conducted in the defensive program, had the potential to generate highly-infectious, small particle aerosols of F. *tularensis.* For example, 100 gallons of *F. tularensis* slurry, contained in a tank, is not in and of itself a highly infectious hazard. An energy source is required to disperse the liquid into a particle size (between one and five microns in diameter) that is infectious. The commercial pumps initially used to transfer 100 gallons of slurry, for example, from a holding tank to a centrifuge, were capable of creating infectious aerosols. In addition, early attempts to contain *F. tularensis* during centrifugation were not successful. Lack of adequately tight pump seals and inadequate centrifuge containment are now believed to have been the sources for over 90 percent of the infections during pilot plant development of a liquid *F. tularensis* agent.

The pilot plant personnel faced an entirely new set of safety problems when studies were initiated with dry powders, the next step in the development process. The dried powder, with an inherent particle size of about five microns and containing about 2.3 x 10 1 cells per pound, could produce a hazardous aerosol with a very low energy input. Merely moving an unsealed container of dried powder created a potential hazard.

Most pilot plant studies of *F. tularensis* were conducted in a building constructed in 1950-1952, in full compliance with building codes and engineering equipment design, and safety concepts from the late 1940's. The pilot plant experience provided the foundation from which safety and engineering concepts made substantial gains. However, pilot plant and other development personnel who worked in the biohazardous areas experienced a number of tularemia infections (Figure A8-1). During the research phase of weapons development, there were about six infections per year. However, when development studies were initiated, infections rose to about 15 per year over the next few years. None of the infections occurred outside the biohazard area. Administrative personnel, who were separated from the biohazard area by a single wall, and worked in an environment where air pressure was positive relative to that of the biohazard area, did not experience a single infection (3).

The most important lesson that can be derived from the 26 years of experience in weapons research and development is that

while identified breaches of safety led to some infections within the biohazard laboratories, the safety features inherent in the building design, albeit relatively primitive compared to today's standards, totally prevented the escape of *F. tularensis* to the outside environment. The major components of the overall safety system were: maintenance of the laboratory areas at negative pressure, filtering of all exhaust air, autoclave sterilization of all waste materials and blow-case steam sterilization of all sewage. Because of the efficacy of these safety systems, there were no infections in the general community caused by the organisms used in the pilot plant or any other part of Ft. Detrick. In later years, an improved vaccine provided significant additional protection for at-risk laboratory workers.

3. CONTAINMENT OF INFECTED EXPERIMENTAL ANIMALS

During the most active years of weapons research and development, a large number of experimental animals were used in the biohazard laboratories. In 1968 alone, over 1,000,000 mice, 100,000 guinea pigs, 40,000 hamsters and 4,700 rhesus monkeys were used in experimental protocols. Thus, another potential hazard was the escape of infected experimental animals that could potentially cause infection of other animals or the civilian population. However, because infected animals were housed in containment laboratories and handled in accordance with rigorous safety protocols, there was not a single incident of an infected animal escape from a biohazard laboratory (4).

4. CONTAINMENT OF INFECTED MOSQUITOES

From 1951 to 1969, the Biological Laboratories conducted an entomological program for mass production of mosquitoes and their subsequent infection with selected viruses. Major emphasis was placed on rearing and infecting *Aedes aegypti*. Approximately 1.5 million *Aedes* were reared each month, about one million of which were infected with viruses. Infected mosquitoes were always contained in specially constructed boxes, and never left the boxes alive. At the end of each day, the area around the entomology building was netted for *Aedes aegypti*. The netting was always negative. Virus-infected mosquitoes caused no problems to the general population or to the environment.

5. SHIPMENT OF HAZARDOUS INFECTIOUS ORGANISMS AND TOXINS

During weapons research and development operations, large amounts of various hazardous infectious organisms and toxins were packaged in specially designed containers and transported safely to Dugway Proving Ground, Utah for field tests (3). Ft. Detrick researchers were instrumental in developing the packaging criteria for the safe transport of hazardous infectious organisms and toxins in interstate commerce (8), and today, these containment principles are incorporated into the Department of

Transportation regulations for shipment of hazardous materials (42CFR Part 72, Shipment of Etiologic Agents and see Appendix 2).

6. LABORATORY AND EQUIPMENT DESIGN

The weapons research and development operations described above were conducted in buildings that were largely constructed in the 1952 time frame. Building code and engineering and safety concepts incorporated into the design of these buildings and the type of biosafety cabinets used to contain the most hazardous operations were derived from earlier safety technology. As previously noted, Ft. Detrick pioneered in the principles of containment of high hazard infectious organisms (9). As improved safety measures were developed, they were promptly and successfully incorporated into the offensive program operations. A table from the final environmental impact statement on the NIH Guidelines For Recombinant DNA Research (5) Table A8-2) which summarizes the incidence rate of Ft. Detrick laboratory infections during the weapons research and development program is extracted and presented here. The summarized data suggest a strong correlation between increased biosafety levels

TABLE A8-2: ESTIMATED LABORATORY-ACQUIRED INFECTION RATES AMONG FORT DETRICK LABORATORY PERSONNEL

Period	Group at risk	Approximate bio-containment levels[3]	Laboratory-acquired infections per million man-hours worked[1]
1943-45	All laboratory-admitted personnel[2]	PI	35(6)
1954-58	All laboratory-admitted civilians	P2	9(6)
1960-62	All laboratory-admitted civilians	P3	2(6)
1960-69	All laboratory-admitted personnel in Building 1412B	P4	1(7)

[1] Includes subclinical infections and mild illnesses where hospitalization was not required.

[2] During this time, personnel were predominantly military rather than civilian; after 1946 the reverse was true.

[3] Biocontainment levels P1, P2, P3 and P4 approximate the levels of biosafety currently specified as BL-1, BL-2, BL-3 and BL-4 respectively.

and reduced infection rate for laboratory personnel, and indeed, in a general sense, this is true. There is no doubt that during

weapons development, where large quantities of infectious organisms were handled *in operations unique to the offensive program,* improvements in the design of laboratory facilities and equipment contributed greatly to reducing the risk of laboratory acquired infection. However, it must be recognized that other factors, such as immunization of laboratory personnel with effective vaccines, and development of improved laboratory procedures and protocols, contributed at least equally to the reduction in the laboratory infection rate from 1943 to 1969.

In 1968, construction was started on Building 1425, which currently houses USAMRIID. The architects of building 1425 took into account the engineering and safety design of biosafety containment in older buildings, as well as newer containment technology. For example: high efficiency particulate air (HEPA) filters replaced the older fiberglass filters; air intakes and air exhausts were interlocked so that any disruption to air flow would shut down the system and thus prevent air pressure in the biocontainment suites from becoming positive relative to clean areas; laboratory suites were equipped with individual air intake and exhaust systems; and walls, ceilings and floors were sealed with epoxy resins. Use of Class III stainless steel safety cabinets (Freon gas-tight under positive pressure) was replaced by use of Laboratory Biosafety Level 4 (BL-4) rooms in most cases. Laboratory workers enter the rooms dressed in protective plastic suits with individually filtered air supplies. The suit allows operational flexibility without reduction in protection.

The present USAMRIID facility has been operational since 1970. The safety record of USAMRIID is outstanding, and is all the more notable when compared to that of the old "Biological Laboratories". In the last 7 years, there has not been one laboratory-acquired illness in any worker at USAMRIID. Table depicts the most recent accounting of laboratory accidents associated with laboratory accidents/incidents at USAMRIID. There were 20 accidents, but zero resultant illnesses. Similarly, at the other BDRP primary sites, CRDEC and DPG, there have been no accidents resulting in a laboratory acquired illness.

Improvement in biosafety is attributable to two primary factors: (a) the building is better designed and engineered, and (b) USAMRIID is engaged in medical defensive studies, which do not require large quantities of hazardous infectious organisms or toxins. Improved guidelines, equipment, controls and monitoring also play a significant role in minimizing the risk to employees and the public. When new laboratories, such as the Australian BL4 and CDC facilities, are designed and built for studies with hazardous biological agents, the architects and engineers employ engineering and safety improvements derived from the experience at USAMRIID and Ft. Detrick (9).

7. DISCUSSION

Although during 26 years of operation a variety of hazardous bacteria, viruses, rickettsiae and toxins were studied in approximately 20 buildings located throughout Ft. Detrick, there was not a single incidence of disease in the general Frederick Community caused by these organisms or toxins. Senator Margaret Chase Smith of Maine placed Dr. A. G. Wedum's summary of Ft. Detrick safety into the August 19, 1970 issue of the Senate Congressional Record. The importance of this summary cannot be over emphasized; the following is extracted from the Congressional Record:

SUMMARY OF SAFETY AT FORT DETRICK MAY 1, 1970

"1. No open-air testing of infectious or toxic biological material is, or ever has been done at Fort Detrick.

2. No member of the general public has ever been infected as a result of Fort Detrick's experiments.

3. Transportation: There never has been leakage of infectious or toxic biological material in the BW program during a shipment by Army, Navy or Air Force, by commercial or military transport. The rough handling test standards, for qualification of packaging for shipment, exceed the requirements for packaging of any other dangerous material: the only closely comparable standards are those for radioactive materials.

4. Laboratory Infections:

a. Since December 1965 there have been no hospitalized laboratory-acquired illnesses; during this time there were 9 minor non-disabling infections.

b. During 1943 to date there have been 422 laboratory-acquired infections at Fort Detrick, among these 27% had such mild illness that hospitalization was not required.

c. The 3 deaths (Anthrax 1951, 1958; Bolivian hemorrhagic fever 1964) among the 422 cases represent a mortality rate of 0.71% which compares favorably with the 4.2% deaths among 3,178 cases revealed by a Public Health Service-supported survey (Sulkin-Pike, U. Texas, 1969). Among the 3,178 cases are 389 reported by Fort Detrick.

d. The man with pneumonic plague in September 1959 did not die as stated by a member of Congress in a public broadcast 3 May 1969. The case was reported 6 November 1959 to the State of Maryland, which is the appropriate channel for report to the World Health Organization.

e. As regards Rocky Mountain Spotted fever in Maryland, Governor Marvin Mandel announced 12 August 1969 that the increased incidence was not related to research at Fort Detrick.

f. Examination of National Safety Council figures for rates of disabling (lost-time) injuries per million civilian man-hours worked shows that the Fort Detrick rates from 1960 to the present time are equal to or better than any all-industry average, are 8 to 14 times better than for all civil service employees and are 20 to 50 times better than many industry averages."

A. G. Wedum, M.D.
Director, Industrial Health and Safety

The Ft. Detrick experience of 26 years (1943-69) of conducting research with hazardous organisms and toxins leads to only one conclusion: hazardous organisms and toxins can be studied safely and without impact on the surrounding populace and environment. Although it is alleged that biotechnology has made possible the theoretical risk of an accidental creation of novel infectious organisms, the safeguards to the work force and population at large (animal and man) are no less today than existed earlier, and are greater now because of improved safety practices, equipment and biocontainment technology. A high efficiency particulate filter does not distinguish between genetically engineered and natural microorganisms. Moreover, the multiple sterilization, inactivation and decontamination procedures used in the treatment of laboratory effluents and wastes are thoroughly effective in neutralizing any and all types of organisms and toxins.

Finally, it is inconceivable that present or future studies conducted for medical and other defensive studies against potential biological warfare agents would require more than a fraction of the quantities of an organism required for development leading to weaponization. Defensive studies simply do not pose the same level of safety problems or risks as do offensive studies. This concept, so simple in its description, is not widely appreciated. This historical review of Ft. Detrick operations should facilitate the discrimination between biosafety requirements of defensive and offensive research, and the requirements for operations for defensive and offensive product development.

TABLE A8-3: POTENTIAL ACCIDENTAL EXPOSURES
(1 January 1983 - 31 December 1987)

Accident Number	Accident	Organisms Involved	Action Taken
1	Contaminated needle stick	Yellow Fever virus	Employee had been vac cinated for Yellow Fever and no illness developed.
2	Laboratory spill*	Chikungunya virus	Decontaminated spill. Employee's health was monitored and no illness developed.
3	Laboratory spill	VEE virus	Decontaminated spill. Employee had been vac cinated for VEE and no illness developed.
4	Contaminated needle stick	JE virus	Employee had been vac cinated for JE and no illness developed.
5	Contaminated laceration	*Bacillus anthracis*	Employee given peni cillin and no illness developed.
6	Contaminated laceration	RVF virus	Employee had been vac cinated for RVF and no illness developed.
7	Centrifuge accident	*Coxiella burnetii*	Employees had been vac cinated for Q Fever, were treated with doxy cycline, and no illness developed.
8	Contaminated puncture	*Bacillus anthracis*	Employee given erythro mycin and no illness developed.
9	Contaminated needle stick	Yellow Fever virus	Employee had been vac cinated and no illness developed.

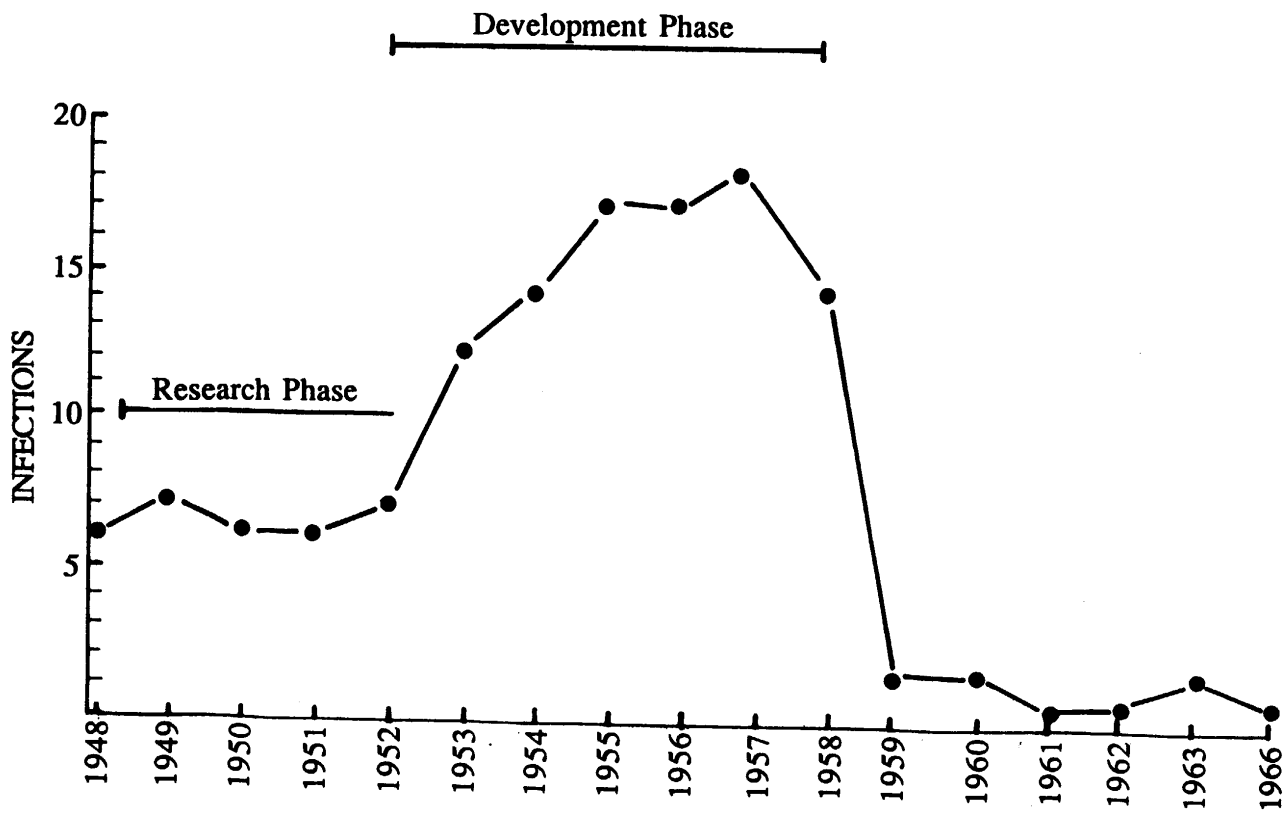
*All spills identified in this Table were completely contained within the laboratory room in which they occurred.

TABLE A8-3] (continued)

10	Contaminated needle stick	Bungarotoxin	Employee had been ex posed to a minute quantity of venom and no illness developed.
11	Contaminated needle stick	Junin virus	Employee had been vaccinated and no illness developed.
12	Laboratory spill	RVF virus	Employee had been vac cinated for RVF and no illness developed.
13	Mucosal	*Bacillus anthracis*	Employee given erythro contamination mycin and no illness developed.
14	Contaminated needle stick	*Bacillus anthracis*	Employee developed no illness.
15	Contaminated needle stick	JE virus	Employee was treated with immune plasma and no illness developed. (Employee not vaccinated with JE vaccine, which is prepared from mouse tissues, because of allergy to mice.)
16	Contaminated needle stick	*Bacillus anthracis*	Employee was treated with antibiotics and no illness developed.
17	Contaminated needle stick	*Bacillus anthracis*	Employee was treated with antibiotics and no illness developed.
18	Contaminated puncture	Brevetoxin (minute amt.)	Employee was monitored and developed no illness.
19	Laboratory spill (minute amt.)	T-2 toxin	Employee was monitored and developed no

			illness.
20	Laboratory spill (minute amt.)	T-2 toxin	Employee was monitored and developed no illness.

Fig. A8-1 NUMBER OF TULAREMIA INFECTIONS AMONG "AT RISK" WORKERS DURING RESEARCH VS. DEVELOPMENT PHASES



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2. Personal communication, Dr. George French, Manager, Government Services Division, the Salk Institute, Swiftwater, PA.

3. Senator Margaret Chase Smith introduced Ft. Detrick's safety record, as summarized by Dr. A. G. Wedum, into the Congressional Senate-Record on August 19, 1970.

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PART 2 - ANALYSIS OF RISK ASSOCIATED WITH HANDLING HAZARDOUS INFECTIOUS ORGANISMS

1. INTRODUCTION TO RISK ASSESSMENT

The incidence of laboratory-acquired infections in workers handling hazardous infectious organisms can be evaluated quantitatively, using appropriate statistical approaches, to arrive at an analysis of the risk that such incidents will occur. Using-available health and injury data from the period of biological weapons development at Ft. Detrick (1941 to late 1969)* and the comparable data from the BDRP as conducted at USAMRIID, the health risks to the current workforce and community have been evaluated. Historical medical records from the "offensive program" show that 419 infections and 3 deaths were associated with exposure to hazardous organisms. Since the inception of the BDRP as it exists today (from 1970-1988), there have been five documented laboratory-acquired infections and no fatalities. During the entire time period that hazardous infectious organisms have been studied at Ft. Detrick, there have been no instances of infection in the surrounding on- and offpost community caused by organisms used in the laboratories. This is consistent with the experience associated with non-BDRP laboratories, such as clinical laboratories and other research organizations. To quote from the CDC-NIH guide, "In contrast to the documented occurrence of laboratory-acquired infections in laboratory personnel, laboratories working with infectious agents have not been shown to represent a threat to the community" (Richardson and Barkley 1984)

Preliminary inspection of the data suggest that the potential risks to the current BDRP workforce are low, and also that risks to the general population associated with the BDRP are quite low. In order to arrive at a less subjective conclusion, however, the frequency of laboratory acquired infections, their distribution in time, and their probability of occurrence have been analyzed mathematically. These statistical analyses support the intuitive conclusion, namely, that the health risks to the BDRP workforce are very low, and the risks to the general population are well below the level at which risks to the health of the populace are generally considered to require regulation.

This introduction to the discussion of quantitative risk assessment includes four topics. First, several terms used in the ensuing discussion are defined. Second, the data available for risk analysis is described. Third, factors potentially affecting the rates of illness are identified. Fourth, a brief discussion of the statistical methods used is presented. Following these discussions, the next major section presents the results of the quantitative analyses.

* The weapons research and development program was initiated in 1941, and established at Fort Detrick in 1943.

1.1 Definitions

a. The term "possible exposure" includes all persons who might have been exposed through an identifiable accident such as a needle puncture, a bite from an infected animal, a spill or other laboratory accident with the potential for transmission of a pathogen.

b. The term "infection" includes 1) all persons not sick enough to be hospitalized or take sick leave at home. (Some persons might not know they were infected; in these cases the infection would only be revealed by changes detected in the blood serum during routine medical examinations); 2) all who were hospitalized or mildly ill at home.

c. The term "illness" includes only those who were sick enough to be hospitalized.

d. A "disabling injury" is one in which a physician has decided that the employee is not able to return to work on the day following the injury. This term is synonymous with "lost-time injury."

e. "Disabling injury rate per million man-hours worked" is a standard of comparison used internationally.

f. "Fatality rate" is the number of deaths per 100 cases.

1.2 Sources and Description of the Health/Injury Data

Health and injury data for the laboratories and pilot plant involved in weapons development (1941-1969), and for USAMRIID personnel, were obtained from several sources. The primary sources for historical data for the weapons research and pilot plant scale-up years (1941-1969) were summaries and tabulations prepared by Dr. Wedum during this period. Most of the data were contained in "memoranda to file" and briefing documents. Additional data and analyses were found in drafts of Dr. Wedum's speeches and in his publications from this period. Occasionally, researchers later recompiled some of these data from the original health records for other purposes. Where ambiguities existed, we attempted to locate and verify final diagnoses and dates of exposure, illness, or injury for specific individuals.

An amended list by Dr. Wedum, "Occupational Illnesses Cases on File in Medical Investigation Division" dated July 1970, reported 422 cases. Of these, 30 cases with incomplete information or an indication, such as "subclinical, were not included in these analyses. However, since recurrences were treated as separate incidents of "illness," the data base used for the risk analysis consisted of 419 records. Additional data for the period 1958 to 1969 were obtained from a memorandum for record dated 8 August 1969. However, the specific day of the month on which the admission for treatment was made is not available in these lists.

Since late 1969, all studies with hazardous infectious organisms have been conducted as part of the defensive program for development of defensive measures against potential biological warfare threats. USAMRIID was identified as the lead laboratory for development of medical defensive measures in 1972. At that time, the safety program and record keeping requirements changed. Data for this transitional era, 1972-1976 are available from hospital admission records and other sources. Since these records are regularly reviewed and used by USAMRIID researchers and health and safety professionals, lists were available.

As discussed subsequently, four hospitalizations, possibly due to occupational exposure, occurred during 1972-1976. These records were examined and four cases of work-related illness were identified. A fifth individual, having an unconfirmed diagnosis, was excluded from the analysis.

By the end of 1976, a comprehensive safety program, which forms the basis for the present program, was formulated and instituted. Thus, for statistical purposes, the period beginning 1 January 1977 represents the "modern" era. During this period, one confirmed diagnosis of a laboratory-acquired infection was made in 1980. Lastly, a list of 20 potential exposures for the period 1 January 1983-31 December 1987 was consulted (see table A8-3).

1.3 Factors Affecting the Rates of Illness 1941-1988

During the period 1941-1988, there were at least seven major changes in the biological and safety programs which would affect the expected rates of potential exposure and illness. The first six are expected to decrease the actual rate, and the last to increase the apparent rate.

First, the program changed in emphasis from biological weapons research and development during 1941-1969, to solely research for defensive purposes thereafter. Accompanying this reorientation was a 10-fold reduction in the potentially exposable workforce, from over 2000 during the height of the offensive effort, to approximately 200 researchers presently engaged in defensive studies with hazardous biological materials. In addition, whereas the staff during the weapons development era included a large workforce of technicians and less technically trained individuals, the present workforce is composed of more highly trained personnel. It also has a much higher ratio of highly educated professionals.

Second, the quantities of materials used and maintained have decreased by 10,000-fold or more. During the weapons development era, batches of hazardous organisms on the order of 10,000 liters were produced about twice each week. The current defensive research program maintains normal research quantities of 10-100 milliliter batches. The organisms studied are not necessarily

unique to the BDRP, but are available to qualified researchers from the American Type Culture Collection and the Centers for Disease Control.

Third, better vaccines have been developed. For example, during the weapons research and development era, 31 cases of anthrax were recorded. The use of an improved vaccine, starting in the mid-1950s, subsequently reduced this number to 0. There has been no confirmed case of anthrax among researchers at Fort Detrick since 1958.

Fourth, the design of containment laboratories and of the equipment used in them improved. Structural changes include the use of air filtering systems, protective clothing, isolation of changing rooms from the research suites, forced exiting from the B W (protective-suit) suites through chemical showers, backup and rigorous routine testing of electrical and mechanical systems, and installation of alarm systems. From the beginning, special isolated drainage systems and special disposal treatments have been used for containment of laboratory research and sanitary wastes. By maintaining the research suites at negative pressure relative to the rest of the facility, the non-laboratory portions of the facility are protected in the event of an accidental spill. Mechanical improvements include the use of specially sealed pumps and motors, and use of seals and barriers around doors. Furthermore, the use of inward-opening doors for the BL3 and BL4 research suites, and the use of special animal cages in the BL4 suites, are substantial mechanical barriers reducing the chance (or consequences to the workforce and surrounding area) of an accidental escape of laboratory rodents.

Fifth, research personnel are immunized regularly with available vaccines and toxoids. On-site hospital facilities and personnel provide immediate treatment of an exposed worker. Isolation of a potentially infected worker protects others in the workforce and the community, and allows for rapid medical intervention in the event that overt disease develops.

Sixth, a vigorous facility and personal safety program has been in effect for over a decade. The occupational biosafety program teaches personnel proper procedures for handling hazardous biologicals, and for responding to an accident or potential exposure.

Seventh, the safety program has improved the quality and comprehensiveness of reporting practices. Follow-up investigations are routinely conducted, and reports are prepared and reviewed by the standing USAMRIID biosafety committee and, as appropriate, concerned others such as maintenance (for structural or mechanical repairs or modifications) or animal care personnel. More accurate monitoring and reporting tends to increase the recorded number of incidents, not the number of incidents *per se*.

The expected statistical consequences of these changes are discussed in the next section.

2. STATISTICAL METHODS

2.1 DESCRIPTION OF THE DATA

The database upon which we begin the examination of current and future risk to the worker and general population is the record of laboratory-acquired illness during the period 19411969. These data are presented as a frequency histogram in Figure A8-2. The histogram shows the illness rates (occurrences/year) to come from a probability distribution which is skewed (long-tailed) to the right. For example, these frequencies might be represented initially by a Poisson distribution. The exact distribution is unimportant at this point in the discussion. What is important for the purposes of risk analysis is the evident decrease in illness frequencies (i.e. the right skewing) during the course of nearly 30 years of weapons research and pilot plant facilities operations.

Examined more closely, the frequency distribution in Figure A8-2 is more complex than a Poisson distribution, which would normally show a single peak and a smooth, right-sided tail. One cycle of increase and decrease in illness is evident between 1941-1949, representing the increase in work during the World War II period, followed by several years of decreasing illness frequencies. A second cycle starts in 1950, as a result of increased activity associated with conflict and the Cold War. A dramatic decrease around 1960 was the result, in large part, of changes in pump seal design, other mechanical improvements in batch handling of organisms and improved safety procedures, vaccination programs, and improved laboratory equipment. These changes are fully consistent with the expectation developed in the preceding section that the frequency rate of illness would decrease dramatically as a result of these changes.

The weapons research and development program ended in 1969, and in 1972 the defensive biological research program at USAMRIID became fully operational. Since 1972, five illnesses (actual hospitalizations) have been reported, the latest in 1980. Again, this dramatic change is in agreement with the a *priori* expectations developed in the preceding section.

Figure A8-2: BAR GRAPH OF REPORTED ILLNESS/RECURRENCE

YEAR	COUNT	PERCENT OF TOTAL NUMBER OF CASES		
Weapons Research and Development Program (1941-1969, N=419)				
41	2	0.48	*	Start-up
42	0	0.00		
43	1	0.24		
44	18	4.30	*********	World War
45	60	14.32	**********	II era
46	6	1.43	***	
47	1	0.24		
48	13	3.10	******	Korea and
49	23	5.49	**********	Cold War
50	16	3.82	********	era
51	34	8.11	**********	
52	26	6.21	**********	
53	17	4.06	********	
54	25	5.97	**********	
55	24	5.73	**********	
56	25	5.97	**********	
57	24	5.73	**********	
58	24	5.73	**********	
59	27	6.44	**********	
60	8	1.91	****	New Pump
61	8	1.91	****	Seals and
62	7	1.67	***	Mechanical
63	4	0.95	**	Changes
64	4	0.95	**	
65	7	1.67	***	
66	3	0.72	*	
67	10	2.39	*****	
68	0	0.00		
69	2	0.48	*	
Defensive Medical Research & Development Program (1970-1988, N=5)				
70	0			
71	0			
72	1			
73	0			
74	0			
75	1			
76	2			
77	0			
78	0			
79	0			
80	1 (focal infection)			
81	0			
82	0			
83	0			
84	0			
85	0			
86	0			
87	0			
88 (March)	0			

Another type of data, the time between incidents (TBI), is available from the lists of illness. An example is presented in Table A8-4 for the 20 reportable incidents, none of which resulted in illness, for the period 1 January 1983 - 31 December 1987 (see Table A8-3). For each reportable incident, the number of days from the start of reporting period to the reportable incident (TTI) and the number of days since the previous incident (TBI) are reported. The frequency distribution for the time to incident *(TTI) is* shown as a normal probability plot in Figure A8-3. Using a Lilliefors test (after standardization), the distribution of TBIs does not differ significantly from a normal distribution. The mean time to incident (MTTI) is 607.5 (+/-462.1, 1 S.D.) days.

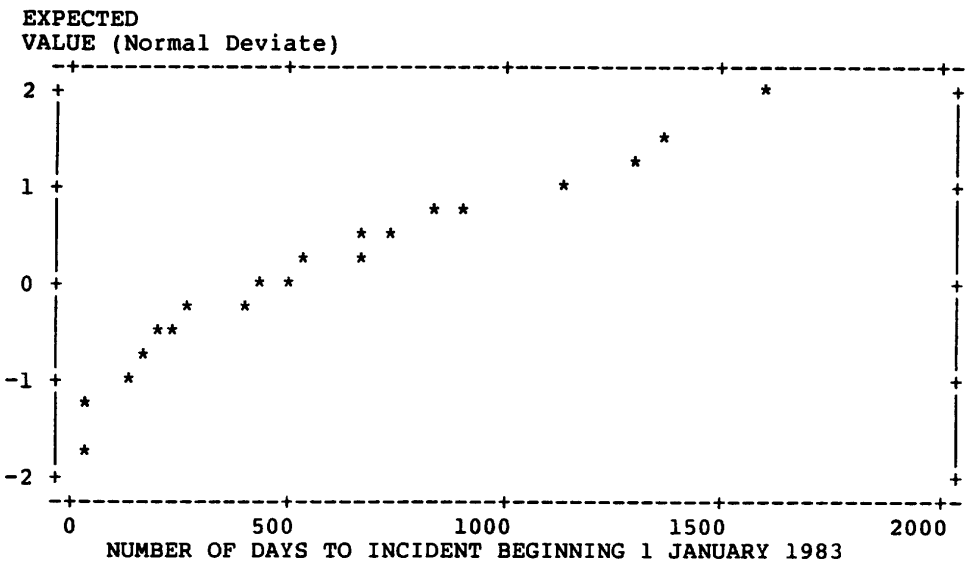
Similarly, a probability distribution for the time between incidents (TBI) is shown in Figure A8-4. From this distribution, the mean TBI (MTBI) is about 89 days (± 71). In interpreting this curve, it is important to recognize that it is based on a small amount of data. As identified above, the duration of this period (1983-1987) is the same as that for one earlier period of interest and is about half the duration of two other periods of interest.

Table A8-4. Reportable Incidents
1 January 1983 - 31 December 1987

Year	Day[1]	TTI[2]	TBI[3]
1983	209	209	209
1984	96	461	252
1984	172	537	76
1984	341	706	169
1985	179	909	203
1985	263	993	84
1985	350	1080	87
1986	70	1165	85
1986	79	1174	4
1986	195	1290	116
1986	236	1331	41
1986	296	1391	60
1986	317	1412	21
1987	90	1550	139
1987	131	1591	41
1987	180	1640	49
1987	182	1642	2
1987	226	1686	44
1987	320	1780	94
1987	343	180-	23

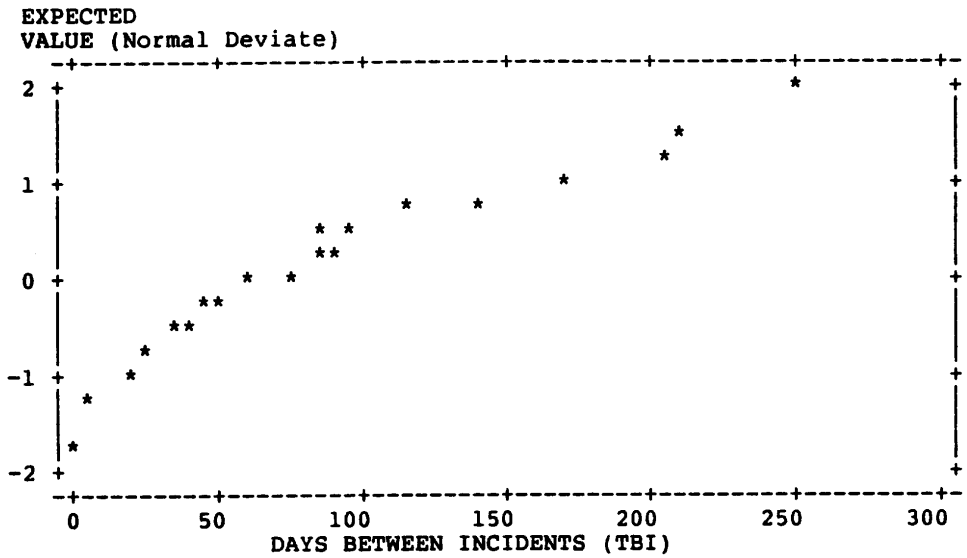
1Julian Day for year specified.
2Number of days from 1 January 1983 to incident.
3Number of days between incidents.

Figure A8-3. Normal Probability Plots for Time to Incident (TTI) for 20 Incidents (1 January 1983-31 December 1987)



(Units of the vertical axis (Y) are standard deviations.)

Figure A8-4. Normal Probability Plots for Time Between Incidents (TBI) for 20 Incidents (1 January 1983-31 December 1987)



(Units of the vertical axis (Y) are standard deviations.)

Having defined and illustrated TTI and TBI using a small data set, we return to an examination of the historical data from the offensive era. For this period, the year and the month, but not the specific day of admission, were available. It was assumed that incidents in a given month were random events. Furthermore, given the small number of accidents in a month and the overall low rate of illnesses (see below), it is reasonable to expect that most incidents involved only one person. Given these assumptions, dates were assigned to each of the 419 cases by adding a uniform random number to each*. For example, say three events occurred in a given month. Under the initial assignment each was treated as having occurred on the first day of that month. Drawing uniform random numbers, an increment of 12 was added to the first event, 3 to the second, and 8 to the third; that is, the events are treated as having occurred on the

*A similar procedure applied to the year and month data in Table A8-4 resulted in estimates of the TTI and TBI for that data which was statistically indistinguishable from those calculated using the actual dates.

12th, 3rd, and 8th of the month. The resulting distribution had mean=26.31, sd=61.1, skew=7.4, kurtosis 70.4. The histogram shown as Figure A8-5 suggests that the underlying distribution could be modeled by a lognormal distribution (if continuous) or as the discrete analog of this distribution, the Poisson. Supporting this, the logarithms of the TBI values had mean=2.35, sd=1.30, skew=0.18, kurtosis=-0.008.

FIGURE A8-5: BAR GRAPH SHOWING LOGNORMAL/POISSON-LIKE DISTRIBUTION OF TBI VALUES[1] (1941-1969)

TBI VALUE	Loge	COUNT	PERCENT	
1	0.000	36	8.59	**********
2	0.693	25	5.97	**********
3	1.099	24	5.73	**********
4	1.386	18	4.30	*********
5	1.609	25	5.97	**********
6	1.792	21	5.01	**********
7	1.946	12	2.86	******
8	2.079	14	3.34	*******
9	2.197	15	3.58	*******
10	2.303	16	3.82	********
11	2.398	12	2.86	******
12	2.485	7	1.67	***
13	2.565	13	3.10	******
14	2.639	9	2.15	****
15	2.708	12	2.86	******
16	2.773	11	2.63	*****
17	2.833	7	1.67	***
18	2.890	10	2.39	*****
19	2.944	4	0.95	**
20	2.996	4	0.95	**
21	3.045	9	2.15	****
22	3.091	8	1.91	****
23	3.135	3	0.72	*
24	3.178	5	1.19	**
25	3.219	3	0.72	*
26	3.258	7	1.67	***
27	3.296	5	1.19	**
29	3.367	5	1.19	**
30	3.401	4	0.95	**
31	3.434	1	0.24	
32	3.466	2	0.48	*
33	3.497	4	0.95	**
34	3.526	1	0.24	
35	3.555	2	0.48	*
36	3.584	1	0.24	
	.	.		
	.	.		
204	5.318	1	0.24	
224	5.412	1	0.24	

248	5.513	1	0.24
287	5.659	1	0.24
378	5.935	1	0.24
656	6.486	1	0.24
726	6.588	1	0.24

1 TBI values have increment drawn from uniform distribution added.

2.2 BAYESIAN RISK ANALYSIS

Closely following Kaplan and Garrick (1979), we treat the approach to Bayesian risk assessment by example. The example relates to the reliability of health protection measures for which safety improvement practices have been implemented. This case history shows how the chance of a serious accident has been reduced with experience, or comparably, how reliability has increased as safety training of personnel, facilities, and equipment have improved. It serves as an example of how one can quantitatively assess, or predict, the reliability (risk) of hazardous infectious organism programs on the usually limited data in hand.

The data is that four individuals were hospitalized for exposure to infectious organisms during 1972-1976. A difficulty with these data is that the sample size is very small - too small to examine the statistical distributions needed in the subsequent analysis. To overcome this, we make the following reasonable assumption. If nothing had changed since the 1941-1969 era, these four incidences would be a subset of the distribution in Figure A8-5. Basically, we are taking as a null hypothesis the statement: the TBI for the 1972-1976 period was equivalent to the TBI in the earlier period. Rejection of this hypothesis means that the time was either shorter during 1972-1976, or it was longer. We treat the problem as this two-sided question, although it is clear from the data that if we reject the null hypothesis we are, in effect, accepting that the time has increased.

There are three pieces of information we have for use in making this prediction. The first is the historical availability of performance (reportable incidences) summarized in Figure A8-5. The second is our knowledge of the safety improvements made at specific dates, and the known and anticipated effects of these improvements. The third, and most important, is the actual number of potential accidental exposures prior to, and after the safety changes. We need a way of quantitatively incorporating this information.

The proper conceptual tool for this purpose is Bayes' theorem. The hypothesis is that the mean accident-free time or availability, A, has increased as a result of better safety practices. To begin, we discretize the availability axis into definite values A , j=1,2,3,...k. Then, letting B stand for the evidence of 1825 days with four illnesses (1972-1976), we write p(Aj/B) = p(Aj)[p(B/AjJ/p(B)],

where p(A /B) is the probability we assign to the proposition that the Future lifetime availability will be Aj after we become aware of the evidence B. The term p(A) is the "prior" probability that we would assign before we become aware of B; (A) therefore represents our state of confidence solely on the basis of the reportable incident history and the safety changes.

To work up to $p(A_j)$, we first plot the probability distribution of TBIs for the period 1941-1969. With this as background and using our knowledge of the safety changes, we then judgmentally assign a prior distribution for accidental exposures for each of the three periods of interest. Prior to 1977, there was no permanent safety officer, so the accidental exposure rates during the period 1972-1976 might be expected to be a little longer in the left tail than the distributions represented in Figures A8-2 and A8-3. Most importantly, we expect that this distribution will have a very long right tail, in contrast to the very long left tail displayed by the historical data in Figure A8-5.

To incorporate the evidence B, we need $p(B/A_j)$, the probability that, we would have experienced four illnesses in 1825 days of operation if the TBIs were truly A_j. For this purpose, we use a Poisson failure model to represent the reliability of the operations. In this model, there is a failure rate λ_j, related to the removal by

$$\lambda_j = \frac{1}{\tau} \left(\frac{A_j}{1-A_j} \right)$$

where tau is the mean time between illnesses. If T is the total length of the period for which the prediction is being made, the probability of having exactly k failures in T days is

$$p(B/A_j) = (\lambda_j T)^k \exp(-\lambda_j T)/k!$$

For k=4 the specific model is:

$$p(B/A_4) = (\lambda_4 T)^4 \exp(-\lambda_4 T)/24$$

From these relations, and noting that

$$p(B) = \sum_j p(A_j) \; p(B/A_j)$$

we have all we need to use Bayes' theorem.

2.3 SURVIVAL ANALYSIS

While Bayesian methods are used to estimate future rates of illness based on past rates and present experience, survival analysis is used in the toxicological and health sciences to determine the statistical equivalence of two or more groups of time-to-event data. The field of survival analysis is extensive and discussion of the statistical aspects of survival analysis is beyond the present scope. Pertinent references are Elandt-

Johnson and Johnson (1980), Lee (1980), Cox and Oaks (1984), Kalbfleisch and Prentice (1980), SAS Institute Inc. (1985). This discussion follows Lee.

We are concerned here with the statistical analysis of survival data derived from clinical studies of humans who have acute diseases. Specifically, we wish to evaluate the results of programmatic and safety changes on worker illnesses between the periods 1941-1969 and 1972-1976. A measurement of patient survival is necessary to evaluate treatment effectiveness. There are two appropriate measures of survival time available: the time from the start of treatment to the response (TTI) and the time between incidents (TBI).

Formally, if T denotes the survival time (here, TTI or TBI), the distribution of T can be characterized by the survivorship function. (This is also called the cumulative survival rate, or the survival function). This function, denoted S(t), is defined as the probability that an individual survives longer than t:

S(t) = P(an individual survives longer than t) = P(T > t).

From the definition of the cumulative distribution function F(t) of T.

S(t) = 1 - P(an individual fails before time t) = 1 - F(t).

In practice, the survivorship function is estimated as the proportion of patients surviving longer than t.

S(t) is a nonincreasing function of time t with the properties: S(t)=1 for t=0 and S(t)=0 for t=infinity. That is, the probability of surviving at least at the time 0 is one, and that of surviving at infinite time is zero. Mathematically equivalent measures of survival are the probability density function (or simply, density function), f(t), and the hazard function, h(t).

We are specifically concerned with comparing two survival distributions: the distribution of TTI or TBI for 1941-1969 with the corresponding distribution for 1972-1976. There are several parametric and nonparametric tests to compare two survival distributions. We used the logrank test. A brief description of this test follows; details can be found in Lee (1980).

Suppose there are n1 and n2 individuals in time periods 1 and 2, respectively. Let $x_l,...,x_{r1}$, be the rl failure observations in group 1. In group 2, let $Y_1,.-.,Y_{r2}$ be the r2 failure observations. Let t(l) < ... < t(k) be the distinct failure times in the two groups together and m(i) the number of failure times equal to t(1);), or the multiplicity of t_i. Peto and Peto's (1972) logrank test is based on a set of scores w_i

assigned to various observations. -The scores are functions of the logarithm of the survival function. An estimate of the log survival function at t_i is:

$-e(t_i) = -$? m_j/r_j

where £ designates summation from $j < t_i$. The scores are $w_i = 1 - e(t_i)$ for an uncensored observation at T. Thus, the larger the uncensored observation, the smaller its score. (Censored observations receive negative scores; there are no censored data.) The w scores sum identically to zero for the two groups together. The logrank test is based on the sum of the w scores in one of the two groups. Specific details can be found in Lee.

3. QUANTITATIVE RISK COMPUTATIONS

3.1 BAYES ANALYSIS

3.1.1. Using 1941-1969 TBI Data to Project Risk During 1972-1976

Example calculations are carried out in Table A8-5. As expected, the results in the last column for P(Aj./B) confirm that (1) the distribution has a long right tail and virtually nonexistent left tail and (2) that the MTBI increased.

We use the data as in Figure A8-5 (incident date treated as coming from a uniform random distribution), taking `=26.3 and T = 1825 days) (5 years). Table A8-5 gives an estimated MTBI of about 410 days (365 to 456 days), in excellent agreement with the true mean. We emphasize that the results shown in Tables A8-5, A8-6 and AB-7 are representative of a large number of trials which used different priors: unreasonable (no change, right skewed), symmetrical, and reasonable (left skew) distributions. All reasonable distributions, regardless of the exact prior, gave similar estimates to those used here.

Table A8-5. Example Bayes Calculations: Estimated MTBI During 1972-1976 Using Evidence from 1941-1969 (Data in Figure A8-5 (A=26.3)

j	Aj	P(Aj)	λ	P(AjB)
1	0.1000E-01	0.00005	0.000384	0.001901
2	0.l000E+00	0.00195	0.004225	0.980640
3	0.2000E+00	0.02000	0.009506	0.0168121
4	0.2500E+00	0.07800	0.012674	0.000638 [1,2]
5	0.3000E+00	0.30000	0.016295	0.000009
6	0.3500E+00	0.50000	0.020474	0.000000
7	0.4500E+00	0.10000	0.031110	0.000000

[1]MTBI = 0.20*1825 = 365 days, 0.25*1825 = 456 days.
[2]The estimated P(B) for these data is 0.000131.

Table A8-6. Bayes Calculations: Estimated MTBI During 1976-1987
Using Evidence from 1972-1976

Aj	P(Aj)	λ	P(AjB)
1 0.1000E-01	0.00005	0.000025	0.000103
2 0.l000E+00	0.00195	0.000277	0.016112
3 0.2000E+00	0.02000	0.000623	0.092616
4 0.2500E+00	0.07800	0.000831	0.209173
5 0.3000E+00	0.30000	0.001068	0.398799
6 0.3500E+00	0.50000	0.001342	0.278055
7 0.4500E+00	0.10000	0.002039	0.005142 [1,2]

[1]MTBI = 0.45*4015 = 1807 days
[2]The estimated P(B) for these data is 0.044037.

3.1.2 Using the 1972-1976 TBI Data to Project Risk During 1977-1987

Having demonstrated the first set of predictions matched experience during 1972 to 1976, we can use the same approach to confirm or deny that another substantial increase in the MTBI has occurred since 1977. To do this, we use the information that 1 illness has occurred in 11 years. The prior for this analysis is tau=401.5 days. As Table A8-6 shows, the 1 illness in 11 years provides evidence that the mean of the distribution increased about four-fold (to about 1807 days, about 5 years) since 1976.

3.1.3 Using the 1941-1969 Deaths to Project Worker Deaths Since 1971

During the period 1941-1969 there were three deaths, two due to anthrax (1951, 1958) and one to Bolivian hemorrhagic fever (1964). No deaths have occurred since 1964. The question is: "Do these data provide evidence that the death rate has decreased?" We examine this question using the data in the three ways identified in Table A8-7. The results show that, regardless of which prior we use, the time between deaths has increased by 110% - 150%. Equivalently, the annual death rate has decreased substantially since the last death.

Table A8-7: Projected Death Rates Using Different Priors

Prior: 1941-1971 (30 yrs)
Actual Rate: 1 per 10 years (0.10/year)
Projected Rate 1971-1987: 1 per 0.65*17 = 11 years (0.09/year).

j	Aj	P(Aj)	λ	P(AjB)
1	0.2000E+00	0.00005	0.025000	0.000159
2	0.2500E+00	0.00195	0.033333	0.005385
3	0.3000E+00	0.02000	0.042857	0.046976
4	0.3500E+00	0.07800	0.053846	0.151988
5	0.4000E+00	0.30000	0.066667	0.470091
6	0.5500E+00	0.50000	0.122222	0.304694
7	0.6500E+00	0.10000	0.185714	0.020708

1The estimated P(B) for these data is 0.205466.

Prior: 1941-1964 (24 yrs)
Actual Rate: 1 per 8 years (0.125/year)
Projected Rate: 1965-1987 1 per 0.55*24 = 13.2 years (0.076/year)

j	Aj	P(Aj)	λ	P(AjB)
1	0.2000E+00	0.00005	0.031250	0.000313
2	0.2500E+00	0.00195	0.041667	0.009497
3	0.3000E+00	0.02000	0.053571	0.073194
4	0.3500E+00	0.07800	0.067308	0.205290
5	0.4000E+00	0.30000	0.083333	0.537476
6	0.5500E+00	0.50000	0.152778	0.169193
7	0.6500E+00	0.10000	0.232143	0.005037

1The estimated P(B) for these data is 0.075539.

Prior: 1951-1964 (14 yrs)
Actual Rate: 1 per 4.67 years (0.214/year)
Projected Rate:1965-1987 1 per 0.65*24=15.6 years (0.064/year).

j	Aj	P(Aj)	λ	P(AjB)
1	0.2000E+00	0.00005	0.053533	0.000761
2	0.2500E+00	0.00195	0.071378	0.019347
3	0.3000E+00	0.02000	0.091771	0.121633
4	0.3500E+00	0.07800	0.115302	0.269682
5	0.4000E+00	0.30000	0.142755	0.536704
6	0.5500E+00	0.50000	0.261718	0.051479
7	0.6500E+00	0.10000	0.397675	0.000394

The estimated P(B) for these data is 0.018174.

3.2 Putting These Rates and Projections in Perspective

3.2.1 Rates of Infections

Table A8-8 (W5) gives estimated frequency rates for laboratory infections for laboratory personnel only. It dramatically illustrates the exceptionally good record of controlled laboratory safety at Fort Detrick over 20 years. Even the highest rate at Fort Detrick of 35 per million man-hours worked during 1943-1945, is appreciably smaller than the 15 year average at a large European laboratory of SO per million manhours worked. Thereafter, although the weapons research and development program was producing large quantities of pathogens on a regular schedule, the infection rate dropped dramatically. As shown in Table A8-9, by 1960, the infection rate was comparable to the rate at the National Institutes of Health laboratories for the same time frame. Dr. Wedum noted that all of the bacteria and rickettsia that caused laboratory-acquired diseases at Fort Detrick occur naturally in the United States.

Table A8-8 (w5): Estimated Frequency Rates for Laboratory Infections Among Laboratory Personnel Only1

Laboratory Type and Location	Time Period	Rate per 10 6 man-hours worked
Fort Detrick:		
All laboratory personnel	1943-1945[2]	35.00
All laboratory-admitted civilians	1954-1958	9.10
All laboratory-admitted civilians	1960-1962	2.01
A Large European Laboratory,	1944-1950	50.00
Tuberculosis Laboratory Technicians, Canada,	1947-19544	19.00
Research Institutes,	1930-1950	4.10
National Institutes of Health,	1954-19603	3.41
Public Health Laboratories,	1930-19504	0.35

1 Data were taken from Phillips (1965) and Wedum (1964).

2 During this time, personnel were predominantly military rather than civilian; after 1946 the reverse was true.

3 Includes unconfirmed cases.

4 Primarily diagnostic, not research, laboratories.

3.2.2 Rates of Death

Table A8-9 places the three laboratory infection-related deaths during the 26 year history of the Ft. Detrick weapons research and development program in perspective. There have been no deaths since 1964, and the estimated death rate is very low (see Table A8-10). As noted by Senator Margaret Chase Smith in the 19 August 1970 Congressional Record - The Senate (pp. S13737137-40):

"There have been two deaths from pulmonary anthrax and one from Bolivian hemorrhagic fever, which was being studied at the request of the U.S. Public Health Service. The mortality rate of 0.71% is less than the rates of 1.60% and 7.47% compiled by other investigators from surveys of laboratory infections elsewhere."

Table A8-9: Fatality Rates for Laboratory-Acquired Infections

Infections	Deaths	Geographical Area	Fatality Rate, %	Reference
442	33	Foreign countries	7.47	Lit. survey
1156	57	U.S. and foreign	4.93	Lit. survey
2348	107	U.S.	4.56	Sulkin (1961)
426	17	U.S. and foreign	4.00	Wedum
26	1	Texas	3.85	Cook (1961)
1342	39	U.S.	3.00	Sulkin 6 Pike (1951)
504	8	U.S. hospital personnel	1.60	Bureau of Labor Statistics (1958)
419	3	Fort Detrick	0.72	1943-1967
	Estimated combined fatality rate		4.0	

1 American Committee on Arthropod-borne Viruses. (1970; an update was published in 1980); Sulkin et al. (1962); Pike et al. (1965); Kulagin et al. (1962); Sulkin and Pike (1949); Cook (1961); Bureau of Labor Statistics (1958).

3.3 SURVIVAL ANALYSIS

An analysis was carried out to compare the survival functions represented by the TBI data for the 1941-1969 and 19721976 periods. To provide a conservative analysis, the 260 TBI values > 6 for the 1941-1969 period were used. This analysis is conservative because it raises the mean for this period and thereby decreases any difference between the groups.

The survival functions for the two groups differed significantly ($X = 16.1$, $p < 0.005$). This supports the previous Bayes analyses, which found that the elapsed times between incidents were significantly shorter in the 1941-1969 period.

3.4 RISK TO THE COMMUNITY

Quantifying the risk to the nearby community is difficult, because in over 40 years of laboratory studies of hazardous infectious organisms at Ft. Detrick, no member of the general public has ever been infected with a laboratory organism (ChaseSmith, 1970). Furthermore, the opportunity for community exposure is limited for several reasons which are enumerated below.

(1) No open-air testing of infectious or toxic agents has ever been done, and such testing at Fort Detrick is specifically prohibited by Ft. Detrick regulation FOR 385-1 "Safety Regulations: Microbiological, Chemical and Industrial Safety, 9 May 1969", Part A, Subpart IX, paragraph 4a.

(2) All exhaust air, sewage, and waste, from laboratories, is sterilized using experimentally verified methods.

(3) The risk to the population from exposure to an infected animal is negligible (<<10-). Based on experience and research, we can assign upper limits on Bayesian priors for each of the major events that would have to occur for an infected animal to infect an animal or human outside of the facility.

a. Researchers at these facilities are conducting research for devising and testing treatments (drugs, vaccines) for infections caused by hazardous organisms.

b. In many protocols, about 90 percent of the animals are uninfected controls or are treated experimental animals. Only the 10 percent which are untreated experimental animals potentially pose risk to the public. Hence, although large numbers of animals are used, there is an initial 90 percent reduction in potential risk.

c. The possibility of escape from the BL3 and BL4 suites, where virulent organisms are used is very low, as discussed in Appendix 9. No such escape has ever occurred. To escape from the suite, an animal has to get past at least 6 barriers including

the cage, multiple inward-opening doors in the suite, elevated barriers and a pit (around the autoclave). In a deliberate release study of 10 uninfected mice, 8 were found around the cages. Two, which had sought water in the autoclave pit (the only source), could not get out of the pit. This is a general phenomenon: these animals have only known cages, handlers, supplied food and water, and on escape from the cage either remain outside of it or move to the nearest source of water and food.

Escape from the suite is not equal to escape from the building. Getting outdoors requires the animal to negotiate corridors and get through doors, find food and water along the way, and elude deliberate searches and accidental discovery. If an animal has a 1-in-10 chance at each of these k>6'points, its chances of actually getting out of the building are $0.l^K << 10^{-6}$.

d. The chance that an escaped laboratory animal will survive outside the laboratory (<10-) is negligible when its difficulty in finding appropriate shelter, food and water, the long durations of relatively hostile weather, and predation are considered.

e. Transmission of a disease caused by a laboratory organism also presupposes that an infected animal can find a suitable insect or vector, animal or human host before it succumbs to the environment or the infection. The chances of this are much less than 0.01.

Since successful transmission requires all of these independent events to happen, the probability is given by the product of the separate probabilities:

$$P_{max} = 0.1 \times 10^{-6} \times 10^{-6} \times 0.01 = 10^{-15}.$$

We can approach the problem another way. No infections of the general public have occurred in over 40 years. Thus the upper limit on the rate of such infections is 1 infection in 40 years, or 0.025 infections per year. Treating this average as the parameter lambda (x) from a Poisson distribution, the probability of at least 1 infection per year, P(X>O|X=0.025), is obtained from a table of the cumulative Poisson distribution (Daniel 1978, p. 461) as: P(X>01 A=0 . 025) = 0.025.

Carrying this further, we can ask, what is the probability of having had at least one infection in the general population in 40 years as a result of activities at Fort Detrick, if the probability of infection were as high as 0.025/year. The answer is obtained using the binomial distribution with p=l/40=0.025 and q=l-p=0.975. We estimate this probability as:

$$P(X>O) = 1 - q^{40} = 1 - 0\ 975^{40} = 0\ 64$$

Since there has been O infections in over 40 years, we infer that the actual rate must be less than the theoretical, postulated rate of 0.025 infections/year.

Bayes analysis can be used to revise the estimate of the true infection rate. Taking the prior mean infection rate as A = 0.025/year, and using the supplemental information that 0 infections have occurred in 40 years, the maximum infection rate is < 0.005/year. Substituting this value in the binomial gives f(x>O) = 0.18. Although this probability is much more reasonable than 0.64, it is still much too high since 1) we obtained the prior by assuming that 1 infection had occurred when it had not, and 2) there is a 47 year rather than 40 year history of safety. Thus we conclude that the true potential infection rate is <<0.005/year, and the probability of at least one infection in 40 years is c<0.l8.

4. RESULTS IN PERSPECTIVE; SUMMARY AND FINAL COMMENTS

This section restates the foregoing technical discussion in simple language. It addresses several questions, to wit:

(1) How have the rates of worker illness from laboratory exposures changed over the years?

(2) Is there any evidence that work conducted by USAMRIID since 1972, as part of the defensive RDT&E program is, less risky than the previous weapons development conducted at Fort Detrick?

(3) Do these results mean that there is no risk to current workers or to the public?

(4) If there is a risk to workers or the public, is this risk high enough to be of concern?

The analyses presented here lead to the following conclusions:

(1) How have the rates of worker illness from laboratory exposures changed over the years?

There are several ways of computing rates of worker illness. Three ways were identified here: time to infection (TTI), time between infections (TBI) and infections per million man-hours worked. The formal statistical analyses in this report used TBI, whereas Dr. Wedum's data from 1970 (Table A8-8) used infections per million man-hours worked. Time to infection was not used in our formal analysis because necessary information, especially the initial employment and termination dates of each infected individual, were not available for the 1941-1969 period. Dr. Wedum presented convincing evidence that infection rates decreased significantly during this period, and were eventually comparable to rates in well-managed chemical and biological research laboratories of that period which used pathogenic organisms.

The formal analysis used the data in a "Bayesian context." All this means is that we combined the actual data with our best technical judgment to develop a "prior," that is, an expected rate, and a model of how that rate changed with implementation of safety programs and other improvements such as mechanical modifications. The quantitative data used in developing the priors were the actual mean TBI for the periods 1940-1969 and 1972-1976. The judgmental part (our estimates of how the underlying statistical distribution would be changed by an improving safety program) was expressed as the *a priori* probabilities. The analysis was not very sensitive to this choice. If the initial probabilities were poorly chosen, the results were meaningless; different *a priori* probabilities were chosen and the analysis was rerun. We anticipated, for reasons enumerated previously, that the overwhelming effect would be to increase the mean TBI and substantially decrease the number of incidents occurring at short intervals. We expressed this by postulating that the statistical distribution of TBI values would shift from one having a long tail to the right (high TBI values being rare) to one with a long tail to the left (low TBI values rare). The results of many analyses unequivocally bore this out.

The mean time between worker illnesses in 1972-1976 was increased dramatically from rates in the 1941-1969 period. There has been another significant increase since 1977. In other words, laboratory workers become ill far less frequently today than they did prior to 1977.

(2) Is there any evidence that work conducted by USAMRIID since 1972 as part of the defensive RDT&E program is less risky than the previous weapons development conducted at Fort Detrick?

This question has been answered, in part, in question 1. Corresponding to the increase in the MTBI is the significant reduction in absolute numbers of infections since 1941. There has been 1 laboratory-acquired infection since the current biosafety program was established in 1977.

(3) Do these results mean that there is no risk to current workers or to the public?

No. There is some very small risk to workers since they handle virulent organisms. Worker exposure generally occurs through the bite of an infected animal, or by puncturing, cutting or tearing the skin. Direct contact of the skin with a culture, or inhalation, are less likely since protective clothing is worn and protective laboratory equipment (see Appendix 11, 12) is used.

(4) If there is a risk to workers or the public, is this risk high enough to be of concern?

In a 1981 decision vacating an agency rule concerning worker exposure to benzene, the Supreme Court required that an agency had to make a finding that a risk was "significant" before it could consider regulating it, and the finding had to be part of the record. The *"de minimus"* concept from common law holds that the court does not concern itself with trivia. Thus, a finding of *de minimus* risk would be sufficient to conclude that an exposure was not a significant risk and not of concern. The converse is not necessarily true. A risk that is not *de mimimus* still may not be significant. In this context, a 10 6 risk level is often used by federal, state and local regulatory agencies as the *de minimus* reference point for the management and regulation of, for example, carcinogenic chemicals that are widely dispersed in the environment (Milvy 1986; Byrd and Lave 1988).

The risk that a member of the public will become infected as a result of BDRP activities is many orders of magnitude smaller than the risk to a worker who regularly handles infectious organisms and infected animals. Even our most liberal estimates of this risk are much smaller than the *de minimus* risk of 1 per 1,000,000 person-years used by the federal government for regulatory decision making (NAS 1983). The risk to a member of the surrounding community of becoming infected as a result of BDRP studies conducted at USAMRIID is placed in perspective in Table A8-10, which lists rates for risks, including diseases commonly encountered in daily life.

The bottom line is that the defensive biological research program at USAMRIID poses a negligible risk to the worker, and an even smaller, more negligible risk to the general public.

Table A8-10: Best-Value Analytical Estimates for Selected Risks

Risk	Rate per 1,000,000 person-years
All disease	7,277
Heart disease	3,170
All cancer	1,850
Motor vehicle accidents	245
Breast cancer	164
Suicide	117
Accidental falls	59
Drowning	34
Fire and flames	27
Firearm accident	10
Tuberculosis	8
Electrocution	5
Motor vehicle-train collision	4
Excess cold	3
Flood	0.6
Lightning	0.5
Nonvenomous animal	0.4
Venomous bite or sting	0.2
Fireworks	0.02
Poisoning by vitamins	0.001
Public infection from USAMRIID	<0.001[2]
Fort Detrick Laboratory Worker Risk of Death:	
Offensive era, 1954-1958	298[3]
Offensive era, 1960-1964	144[4]
Defensive era, 1970-present 0.0005	

Adapted from Morgan et al. (1983) and Lichtenstein et al. (1978).

2 Our risk estimate, 10-15, was the probability that an infection happened at all. To get units comparable to this table, assume that all 105 individuals in the area around Fort Detrick might be expose}5 The risk that at least one individual would be exposed is 10-15 x 105 = 10-10.

3 Wedum gave the illness rate for the 122 illnesses during the period 1954-1958 as 9.10 per million man-hours (500 man-years). Using this rate and an average work year during that period of 2000 hours, the estimated rate for the two deaths between 1951 and 1958 is: (2 deaths/122 ill) (l06 years/500/yr)(9.10) = 298. This is about the current rate for motor vehicle accident deaths.

4 Wedum gave the illness rate for the 28 illnesses during the period 1960-1962 as 2.01 per million man-hours (500-man years). Assuming this rate of illness for 1964, and an average work year during that period of 2000 hours, the estimated rate for the one death in 1964 is: (1 death/28 ill)(10 6 years/500/yr)(2.01) = 144. This is about the current rate for death by suicide.

5 This value was calculated as follows: The denominator was calculated as 220 workers x 17 years = 3,740 person years. The numerator is 0, since no deaths occurred during this period. The data lack sufficient power for application of a Poisson failure analysis.

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APPENDIX 9 - MAXIMUM CREDIBLE EVENTS

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1. INTRODUCTION

The BDRP has been examined on a programmatic and selected site-specific basis for normal operating conditions (See Appendix 6). It is apparent that at least part of the controversy and concern over the BDRP arises from apprehension and misunderstanding about what could happen if accidents or unforeseen incidents occurred. Because of the complexity of the BDRP and controversy related to the program, it is appropriate to consider the range of potential consequences that would be associated with an accident or incident.

Because the perceived impacts of the BDRP are much greater than the actual observed impacts, it might appear that there is scientific uncertainty or incomplete information regarding potential adverse environmental impacts that could result from accidents or incidents. Under the provisions of the CEQ regulations (40 CFR1502.22) such information could, in principle, be essential to a reasoned choice among alternatives. This appendix has been prepared in order to provide a clearer understanding of the BDRP activities and the extent of the potential impacts that could arise from these activities under unusual circumstances. The term "Maximum Credible Event" (MCE), as used herein, is analogous to a worst case analysis. The best available credible information is applied to calculation of the results of various MCEs using assumptions that yield the potential for more severe consequences, as opposed to assumptions that operational and safety controls will always perform as designed. However, the rule of reason is applied to confine the discussion to realistic or believable occurrence. Discussion of extremes that were not based on realities would not serve the decision maker or the public. A number of scenarios have been selected for analysis and display. These represent the potentially most severe circumstances. Many more variations could be theorized but they would have equivalent or less adverse environmental impacts than those considered here.

It has been determined that releases of aerosols of biological materials from facilities performing BDRP studies under appropriate containment conditions are not reasonably foreseeable. Catastrophic events, such as an airplane crash directly on a facility, have been perceived as a potential cause of aerosol release; however, it has been determined that the probabilities of such events are too small to be considered reasonably foreseeable and/or the quantity of organisms on hand are too low to be of any risk from such an event (this is also true for most secondary sites). For the purpose of perspective and information, this appendix also presents estimates of the extent of potential impacts, under various conditions, resulting from accidental releases of biological aerosols from the primary BDRP facilities. The findings are presented even though the event or series of events are not considered to be reasonably foreseeable. These estimates support the determination that such events would be noncatastrophic. Since the estimates show impact

would occur only within primary site boundaries, (i.e. Dugway Proving Ground), or within a few meters for other sites, they are not of catastrophic dimensions. The estimates also respond to the reasonable public interest in what might happen if the unforeseeable does occur and in whether the public would be at risk. The conclusion reached is that they are not.

It should be understood that the following examples and accompanying discussions are brief simplifications of a complex topic and are intended only to inform readers about the general principles and assumptions underlying the estimates of extent of impact. Because of the nature of the studies performed as part of the BDRP, the small quantities of toxins or hazardous organisms used in these studies, and the operational and safety controls used during normal operations (See section 3.3.), no significant impacts to the health and safety of the work force or to the environment were identified. A variety of potential hazards were postulated and examined for any potential impacts before reaching this conclusion. The history of the program also supports this finding (see Appendix 8).

1.1 Ventilation System

When considering an MCE, it is appropriate to consider the redundancy of safety systems engineered into the facilities, depending on containment level required (See Appendices 11,12), to make them as fail-safe as practical. The USAMRIID facility, with its BL-3 and BL-4 containment laboratories, serves as a practical example. These laboratory suites are maintained under constant negative pressure to retain any released material within the laboratory. All biological safety cabinets are exhausted through one HEPA filter and then an additional baggy filter (BL-3) or baggy filter plus second HEPA filter (BL-4) to remove aerosol dispersions or particulates from the air before discharge into the effluent air stream flowing through the exhaust stacks. The air is pulled through these filters by a blower that is supplemented by an identical reserve blower that automatically operates should the primary blower fail. Should the normal facility electrical system fail, a diesel generator starts automatically and provides energy to the air supply and exhaust system. In the event of the failure of the first generator, a second back-up generator provides the required power. Failure of any individual system is recorded and transmitted by the automated building monitoring system through alarms which will signal the Building Engineer of this condition. Safety technicians will notify laboratory personnel to terminate operations and not to initiate new experimental procedures. Because of these protective systems and standard operating procedures, the ventilation system, which provides the primary means of containment, will not fail in such a way as to cause a compromise of physical containment. Thus the MCE in this facility is limited to considerations of the safety and containment systems.

1.2 Individualized Considerations

The particular circumstances associated with the use of hazardous organisms and toxins varies from site to site and even within an individual site; e.g. within USAMRIID, they vary from containment suite to containment suite. Depending upon the type of toxin or infectious organism, objectives of study, experimental approach, etc., the MCE for each of the research rooms would have some variations related to the research purposes and particular characteristics for each room. Also, because each toxin and hazardous organism has a unique set of physical and biological properties, the effects of a release after an MCE would vary as a function of the type of material being considered.

The MCE for each room could be estimated, but to calculate the actual release associated with such an event, many features about the room in which it occurred must also be known. While the actual dimensions of each room vary, for convenience an average size room can be used for calculation of the potential maximum or worst case aerosol material concentration that could be released in the event of an MCE.

Aerosols represent the primary pathway for infection. Therefore during an MCE, the amount of toxin or hazardous organism released into the atmosphere via aerosolization must be considered. Because each containment laboratory is maintained under a negative pressure, all aerosolized material would be contained within the room or biological safety cabinet and exhausted through the cabinet and/or filter elements associated with each suite. The amount of any organism or toxin that would aerosolize will depend upon the nature of the agent and the process producing the aerosol.

1.3 Toxins and Infectious Organisms

The MCE for containment laboratories must be considered in terms of physical containment for both toxins and biological organisms. Therefore, both toxin and biological maximum credible events will be considered.

The toxins, chemical substances of biological origin, are lethal or incapacitating over a wide range of concentrations, depending on the toxin, from less than 1 nanogram (botulinum toxin) per kilogram body weight to several milligrams (mycotoxin) per kilogram body weight (i.e., one part in a quadrillion to one part in a million, or, for the average adult rat that weighs about 450 grams, this range would be from 8.5 picograms to 8.5 milligrams. Research quantities of these compounds (milligrams for most toxic compounds, up to a few grams for less toxic compounds) may be prepared, synthesized, and stored to support the experimental protocols.

The studies of infectious disease organisms such as pathogenic bacteria, rickettsia, and viruses require, in accordance with established regulations and procedures, physical containment of these organisms in biocontainment laboratories for the protection of the workforce within the facility and the general population external to the facility.

2. Accidents within the laboratory

Microbiology laboratories are unique work environments that may pose special risks to personnel working within that environment. Laboratory accidents have and can be expected to occur in which from one, to a few, individuals are affected. Historically, a majority of these accidents were related to mouth pipetting, use of needle and syringe, and accidental aerosol generation from centrifuging, etc. Evolving biosafety practices and improved biocontainment equipment and facilities have greatly reduced risks to the workforce but the individual accident or incident (where, for example, an individual would, by one means or another, puncture through safety gloves and break the skin with an instrument that would allow the introduction of an organism or toxin into the body) is still an ever present risk. The outstanding safety record (no illness resulting from laboratory exposure to agents or toxins in last 10 years) at USAMRIID (see Appendix 8) and DPG (see references 1 and 31) is indicative of how safely research with hazardous infectious organisms can be conducted.

2.1 MCE: Q FEVER

Coxiella burnetii, the rickettsial organism that causes Q fever (see Appendix 7), was used as the model for an MCE with an infectious organism. The postulated accident takes place in a BL-3 laboratory at USAMRIID. It must be emphasized that the series of events described here have <u>never</u> occurred within the BDRP, but have been thought through in an effort to envision the consequences of such an MCE. For convenience, the scenario is divided into these sections: 1) description of the organism; 2) description of the laboratory; 3) description of the accident, which involves the operation of a centrifuge; 4) description of the infectious aerosol and its fate; 5) impact of the accident on the general population and surrounding environment; 6) impact of the accident on laboratory workers.

2.1.1 Description of the Organism

The organism selected for this scenario is *Coxiella burnetii* (see Appendix 7), the rickettsia causing Q fever, a disease of varying degrees of incapacitation (2,3,4). *Coxiella burnetii* grows to high concentrations in chick embryos [2×10^{10} guinea

pig (GP) intraperitoneal (IP) infectious doses].* It is a hardy organism which withstands laboratory manipulation with little or no loss in viability. It is highly stable in aerosol and undergoes a biological decay rate of about one per cent per minute over a wide range of humidities (30 to 85% relative humidity) and temperatures (0° to 30°C). *Coxiella burnetii* is extremely infectious in a small particle aerosol (5). One to 10 $GPIPID_{50}$ doses is equivalent to one respiratory ID_{50} dose causing infection 50% of the time for man(6). These properties (high concentration of rickettsial agent, low rate of biological decay, low infective dose for man) make *Coxiella burnetii* an ideal organisim to use in a hypothetical, maximum credible laboratory accident. If the accident were not adequately contained or neutralized within the building, a number of organisms sufficient to cause infections could be released as an aerosol to the outside and in the surrounding community.

2.1.2. Description of the Laboratory

A typical BL-3 laboratory suite at USAMRIID is depicted in Figure A9-1. The suite layout is described on the left margin, the safety features on the right. Only major components of the suite will be described.

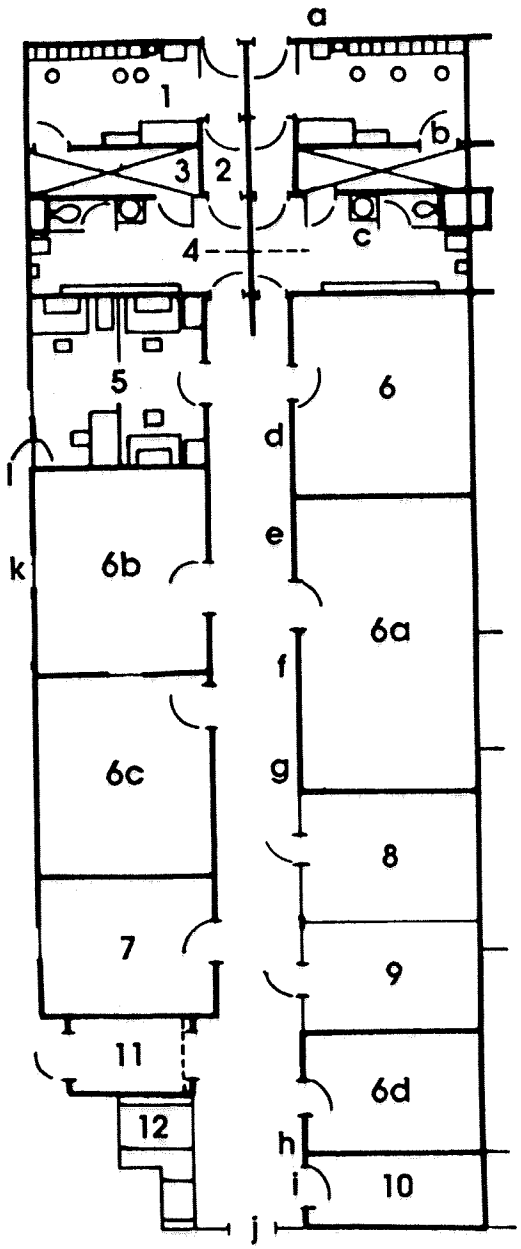
The entire containment suite is at negative air pressure to non-laboratory, or BL-1 or BL-2 laboratory areas of the Institute. This means that the air pressure inside the suite is lower that the air pressure outside. Thus, there is a net inward flow of air to the suite from external areas. The air flow in individual rooms of the laboratory and animal areas are negative to the suite corridor. An alarm sounds if the negative air pressure falls to 0.1 inch of water pressure. An interlock system shuts off air supplied to the suite if negative pressure is lost and therefore prevents the suite from becoming positive to the clean areas. Intake air is supplied to the suite through a dust filter. Exhaust air is removed from the suite through a duct which leads to a Baggy Filter in the attic. The filter is 95 percent efficient in removing 1.2-micron or larger particles. The filtered air leaves the building to the outside environment through a 50-foot high exhaust stack. There are about 12 air changes per hour in the containment suite. Laboratory drains lead into the specially designed Fort Detrick isolated laboratory-contaminated wastewater system and all effluent is sterilized in large holding tanks (see section 5.2.2 and Appendix 5).

Should the suite experience an electrical outage, it holds a slightly negative pressure for several hours before coming to equilibrium with the adjacent clean areas. This is because

*A guinea pig IP infectious dose is the amount of organisms needed to cause infection in 50% of the animals injected with that dose.

Suite Layout

1. Cold Change Rooms
2. Air Locks (Entrance)
3. Showers (Exit)
4. Hot Change Rooms
5. Office
6. Laboratory Rooms
7. Animal Rooms
8. Incubator Room
9. Cold Room
10. Utility Room
11. Air Lock
12. Autoclaves



Safety Features

a. Equipment Alarm Panel
b. UV Light Barrier
c. UV Laundry Bag
d. Mask Boxes
e. Emergency Lights,Portable
f. Emergency Shower
g. Emergency Assistance Alarm
h. Fire Alarm
i. Pressure Differential Alarm
j. Emergency Crash Door
k. Window-Speaking Diaphragm
l. UV Passbox
m. 0.2 negative water pressure maintained in Hot Area to Outside
n. 12 Air Changes per Hour

Fig. A9-1 Typical Hot Suite Plan for BL 3 Laboratory

special construction techniques were used to produce a very tight enclosure, with all walls, crevices, and joints sealed with epoxy resin.

The suite is entered through the clean dressing room where street clothes and shoes are removed and laboratory clothing and shoes are donned. The practices and clothes are similar to a hospital operating room up to this point. Exit from the suite is through the "contaminated" dressing room, where laboratory clothing and shoes are removed. Clothing is deposited in a special bag which is autoclaved before removal from the suite. A soap and water shower is required before leaving the "contaminated" area, entering the clean change room, and again donning civilian clothes.

2.1.3. Description of the Hypothetical Accident

An immunized laboratory worker is processing one liter of *Coxiella burnetii* slurry which will be used to prepare an experimental vaccine. After harvest of the infected chick yolk sacs, the first step is to clarify the slurry of gross impurities, i.e., particulate matter that contains few, if any of the *C. burnetii* rickettsiae. Centrifugation is conducted in a Sorvall PR-5 centrifuge at 10,000 rpm for 30 minutes. The centrifuge is free-standing in Room 6 (Figure A9-1). The centrifuge rotor holds six 250-ml polyproplene centrifuge tubes fitted with O-rings to obtain a tight seal; each bottle contains 165 ml of slurry. The potential number of respiratory infectious doses for man is represented by: 1×10^{10} $GPIPID_{50}$ per ml x 6 bottles x 165 ml per bottle. This represents a total of 990×10^{10} human infectious doses if one $GPIPID_{50}$ causes infection, or 99×10^{10} human infectious doses if ten $GPIPID_{50}$ are used for the calculations. For purposes of this scenario, one $GPIPID_{50}$ is used because it represents the greater hazard (6).

In this scenario, the laboratory worker failed to use rubber O-rings to seal the centrifuge tubes, and all six bottles leaked, allowing some of the slurry into the rotor. Because the worker also failed to tighten properly the safety centrifuge caps designed to prevent just such a leak, some of the slurry also escaped into the centrifuge compartment that houses the rotor. This compartment is not sealed against the release of organisms in a small partical aerosol. The leakage of one bottle during centrifugation is an uncommon event, but it does occur. The leakage of six bottles is highly improbable, but could potentially occur as a result of operator error as described above. However, most of the solution would remain in the centrifuge tubes. Of that which leaked, most would be contained within the covered rotor and not aerosolized (99%). Of that which escaped into the centrifuge cabinet, only a fraction would be aerosolized, and of that which was aerosolized, approximately 90% would settle as liquid droplets on the inside of the chamber.

A few minutes after the rotor stopped, the worker opened the centrifuge door and reached in to remove the rotor. He now noticed that there had been a leak of the slurry within the centrifuge. Two co-workers provided assistance in managing the spill. Four other co-workers entered the lab shortly after the incident and thus also accidentally exposed themselves to the uncontained infectious organisms.

The worker has compromised several key safety regulations and standard operating procedures. He failed to use O-ring seals on the centrifuge tubes. Safety centrifuge cups, with gasketed screwcaps, designed to prevent aerosols from being released, even if a bottle within breaks (7) are normally used to contain the 250-ml bottles. However, he failed to tighten these caps and thus allowed leakage into the centrifuge cabinet to occur. When the centrifuge lid was opened, and the spill observed, the lid should have been closed and a specially designed vacuum apparatus should have been used to clean up the spill. Certainly the worker should not have left the centrifuge lid open. This permitted maximum escape of the organism. At the time of the accident, the worker should have notified everyone in the suite that bottles of slurry had leaked during centrifugation, and the room should have been secured to prevent others in the laboratory from being exposed. As a result of this inappropriate behavior, all of the workers in that laboratory may have been exposed to a dose of organisms sufficient to cause infection in the unimmunized individual.

The MCE described here is based on an unlikely cascade of sequential events: the failure to seal properly both the centrifuge tubes and the safety centrifuge cups, the leakage of not one, but six, centrifuge bottles containing *Coxiella burnetii*; and the inappropriate behavior of the laboratory worker. The possibility of an accident of this degree, which is based on the sequential or simultaneous failure of multiple operational and procedural controls, is remote. Nevertheless, these circumstances will be used in calculating the associated release of infectious aerosol and its potential impact on the laboratory workers, and on the general population and surrounding community.

2.1.4. Description of the Aerosol and its Fate

Percent aerosol recovery (aerosol efficiency) is defined as the number of infectious doses of *Coxiella burnetii* rendered airborne in a one- to five-micron particle size. This range represents the maximum infectivity for man, and is based in part on size of the bronchial structure of human respiratory tract and influenced by a multiplicity of other factors. Percent aerosol recovery must be derived empirically, based on observed data and informed experience. This professional judgement suggests the most reasonable aerosol recovery to be about 0.01 percent, with a range from 0.001 to 0.1 percent. The logic for the selection of these parameters is as follows. Embryonated-chicken-embryo

slurry is thixotropic (much like raw egg white), and unlike a Newtonian liquid such as water, absorbs a considerable amount of energy before it undergoes a change in physical properties. Thixotropic liquids are difficult to disseminate as small particle aerosols, and require a high-level, efficient energy source to achieve such aerosolization.

Based on previous research conducted by former organizations at Fort Detrick, a high efficiency, two-fluid nozzle disseminator could produce no more than a one to two percent aerosol recovery from a substance similar to the relatively crude *Coxiella burnetii* slurry; that is, a slurry containing about 20 percent total dry solids and a viscosity of 20 to 25 centipoises. The Fort Detrick experience also showed that, as the slurry was purified, contained less solids and exhibited a lower viscosity, aerosol recoveries with a two-fluid nozzle increased to a maximum level of about ten percent. The slurry used in this scenario is crude, representing the first step in a purification procedure, and a spinning centrifuge rotor is not an efficient aerosol generator. From the standpoint of aerosol generation, centrifugation constitutes one of the most potentially hazardous operations conducted in the laboratory (8). However, when centrifugation is compared to the two-fluid nozzle disseminator as a means of creating infectious aerosols, it is much less efficient by several orders of magnitude. Thus, aerosolization efficiency would likely be less than 0.01% but we will assume in this scenario that 0.1% is aerosolized.

A calculation is also necessary to determine the volume of air of the centrifuge room and those adjacent areas into which the aerosol might infiltrate. Room volume will be expressed in liters, because medical literature defines man's breathing rate in liters of air breathed per minute. Infectious aerosol studies also report organism concentrations in infectious doses per liter.

The size of the centrifuge room (Room 6, Figure A9-1) is 10 x 12 x 9 or 1080 cubic feet. This is converted to liters; 1080 cubic feet x 28 liters per cubic foot = 30,240 liters. Since the suite air is continuous with the intake portion of the building filter system because of the negative pressure differential, the duct, which leads from the centrifuge room to the filter, must be considered. The duct is 2.6 feet x 2.6 feet x 90 feet and contains an additional 17,024 liters of air. The total volume of air, centrifuge room plus its air duct, is 47,264 liters.

2.1.5 Maximum Number of Infectious Doses Presented to the Building Filter System

Potentially, the most serious consequence of the laboratory accident would be the release of enough infectious doses to override the building filter system, would allow the subsequent release of a concentrated aerosol into the surrounding community. It is therefore necessary to calculate the maximum

number of aerosol infectious doses presented to the filter. The total initial human infectious doses was assumed to be 990 x 10^{10}. Ten percent leaked from the tubes, of which 99% remained in the rotor cups. Of that which escaped out of the cups, 0.1% was aerosolized by the rotor and of that aerosolized, 90% settled as liquid droplets on the inside of the chamber. Thus, 10% (leaked from tubes) x 1% (escaped from rotor cups) x .1% (aerosolized) x 10% (did not settle out) equals 0.000001% aerosol escape into the room. Thus, 0.000001% x 990 x 10^{10} HID_{50} equals 9.9 x 10^5 HID_{50} aerosolized.

The building exhaust filter is 95% efficient, thus approximately 5 x 10^4 HID_{50} would have escaped from the building exhaust stack.* Since laboratory work is normally performed during the day, ultraviolet rays from the sun would also destroy a large number of these rickettsiae.

2.1.6. Impact of the Accident on the General Population and Surrounding Environment

This quantity of human infectious doses, by simple Gaussian plume dispersion models, is expected to be dissipated to less than 1 HID_{50}/Liter of air in less than two meters from the stack, and less than 0.1 HID_{50}/Liter at 16 meters, and less than 0.01 HID_{50}/Liter at 38 meters (see section 3.3, this appendix). Thus this level of "escape" of *Coxiella burnetii* from the containment laboratory, even under worst case meterological conditions, does not represent a credible risk to the community population.

Fort Detrick, when operated as the research and development center for biological warfare from 1943 to 1969, undoubtedly experienced accidents when handling large quantities of hazardous organisms during pilot plant operations and developmental laboratory studies. Yet, during these 26 years of offensive operations (1943-1969), Fort Detrick did not cause a single infection in the surrounding Frederick community (see Appendix 8). The support for this statement is published in the Senate Congressional Record of August 19, 1970 (9). Senator Margaret Chase Smith introduced a summary of the Fort Detrick safety record prepared by Dr. A. G. Wedum. The importance of this safety record and its direct bearing on the MCE described here cannot be overemphasized.

Another perspective on the release of 5 x 10^4 infectious doses of *Coxiella burnetii* from this contrived laboratory accident is provided by consideration of the release of infectious material as a result of natural causes. For example, a pregnant ewe that aborts a fetus because of an enzootic Q fever (*C. burnettii*) infection is significantly more hazardous to

*No filtration is actually required by the CDC/NIH guidelines (7). All USAMRIID BL-3 suites use two filters in series, but 95% is used to show maximum potential consequences.

people and the environment. The bursting amniotic sac releases about one liter of fluid. This fluid contains about $1x10^9$ infectious doses per ml. Thus a total of $1x10^{12}$ infectious doses are released (10). This number of rickettsiae would pose a health problem to any attending personnel, as well as to other sheep who are up to about fifty yards downwind of the aborting ewe. An even more striking example of infectious agent entering into the environment by natural means is the abortion of a pregnant ewe due to Rift Valley fever. In this infection, the virus grows to a concentration of $1x10^{10}$ infectious doses per ml of amniotic fluid (11), a ten-fold increase in concentration over that of Q fever. In either case, the abortions of sheep, precipitated by natural infections, pose far greater health concerns to humans and to the environment than the maximum credible accident which could occur in a well-designed BL-3 biomedical research laboratory.

2.1.7. Impact of the Accident on Laboratory Workers

In the example above, the centrifuge operator is at the greatest risk of becoming ill with Q fever. In opening the centrifuge, the infectious aerosol would be released initially and momentarily into a very confined area. It is estimated that the $9.9x10^9$ infectious doses immediately rendered airborne were contained in an area above and around the centrifuge compartment of 3x3x3 feet, or 756 liters. The number of airborne infectious doses per liter, seconds after the lid was opened, was calculated as $1.3x10^3$/Liter of air.

It is further estimated that the centrifuge operator was: a) excited by the accident; b) was breathing 15 liters of air per minute; and c) was in the confined aerosol (756 liters) for no more than 5 minutes. The centrifuge operator therefore could have inhaled approximately 100,000 infectious doses. The two co-workers who came to his assistance were exposed to only slightly less quantity.

Benenson (12) reported that previously vaccinated men, when exposed to defined aerosols of 150 or 150,000 infectious doses of virulent *Coxiella burnetii*, AD Strain, did not consistently become ill. Since the centrifuge operator received about the same dose reported in the reference, it is problematical whether the centrifuge operator would have become sick, since he was, by required procedures, immunized. Benenson further indicates that if a non-immunized person is exposed to 150 or 150,000 infectious doses, the disease can be aborted by giving one ml of vaccine within 24 hours after exposure and by instituting antibiotic therapy, 20 grams over six days. In this case, the three individuals who received the greatest exposure were treated with doxycycline.

The other four laboratory workers were exposed for less than one minute to the aerosol after it was dispersed in the room and are unlikely to have been exposed to more than 100 to 300

(HID_{50}). The aerosol not only has undergone considerable dilution in the room volume of air, but there has been a partial exchange of room air. The other four laboratory workers, since they also have been vaccinated, should not develop Q Fever. As a precautionary measure, the Chief, Medical Division, USAMRIID, institutes prophylactic antibiotic therapy (doxycycline) and prevents the potential development of disease in all four laboratory workers. During the three months of intensive follow up, there were no signs of disease or of infection with Q-fever.

To conclude this description of the MCE with *C. burnetii*, the team leader and one assistant put on face masks, caps, gowns, and gloves and enter Room 6 to initiate decontamination procedures (see Appendix 13). One gallon of two percent Lysol® solution is poured into the contaminated drain. The centrifuge bottles are carefully removed from the centrifuge rotor and placed in a container of two percent Lysol® solution, which is later sterilized in the autoclave. The centrifuge rotor and all available surfaces are washed thoroughly with two per cent Lysol® solution. While the surfaces are still wet with Lysol®, the centrifuge is moved into the airlock. The airlock is sealed with tape and personnel from Safety Division employ paraformaldehyde to sterilize the centrifuge (see Appendix 13).

2.2. MCE: BOTULINUM TOXIN

Botulinum toxin is an exotoxin of *Clostridium botulinum*, a common soil pathogen, and is most familiar to the public as a causative agent in food poisoning, notably canned seafoods or low acid vegetables (see Appendix 7). Botulinum A toxin is the most potent toxin known in the world today. This toxin is currently studied at USAMRIID as part of the BDRP, and data are available to calculate the risks associated with a laboratory accident. Botulinum toxin, a non-volatile protein, is 3.2×10^5 times as toxic intraperitoneally (IP) in mice as the highly volatile chemical nerve agent, soman, an organophosphate. A credible worst-case scenario for the use of this toxin in a high-containment research suite would again be the generation of an aerosol from the breakage of spinning centrifuge bottle containing toxin in various stages of purification. The scenario is similar to the MCE for Q fever (paragraph 2.1 preceding) but there are also some notable differences as well. The initial stages of purification do not require centrifugation, thus when the processing stage of this MCE is reached, the volume of toxin being purified would be less than the volume for Q fever, thus leakage of only one centrifuge tube is postulated. Because of the lethality of Botulinum toxin, this centrifugation step is performed in a Class II safety cabinet. Also because a toxin MCE is being included for comparative purposes, the minutiae have been omitted, however all pertinent steps have been included.

2.2.1 In this analysis, we use an example of the rupture of a 250-ml centrifuge tube containing 240 ml of toxin at a concentration of 2×10^9 mouse IP LD_{50} ($MIPLD_{50}$ per ml of 50%

pure type A botulinum toxin). One $MIPLD_{50}$ is the amount of toxin required to cause death in 50% of the mice injected IP. The toxic dosages of botulinum toxin are very different when comparing toxin aerosol exposures (human respiratory) with toxin solution challenges (mouse IP). It has been estimated that, where a given concentration of toxin in an aerosolized solution yields one human respiratory LD_{50} ($HRLD_{50}$), the same concentration injected IP into mice is approximately 2.38×10^3 $MIPLD_{50}$, i.e. the human dose is about 2400 times the mouse dose.

If a centrifuge bottle breaks during centrifugation, an aerosol of the toxin-containing solution would be generated within the rotor of the centrifuge. Most of the solution would remain unaerosolized and be contained within the covered rotor. Of that which was generated into an aerosol within the centrifuge cabinet, approximately 90% would settle as liquid droplets on the inside of the chamber. Both of these areas (the inside of the rotor and the centrifuge cabinet) can be decontaminated efficiently by trained research personnel who have taken the appropriate personal protection measures and employ the appropriate decontamination procedures to handle the spill.

Therefore, only an equivalent of 0.1 ml of the total 240 ml of toxin-containing solution would be aerosolized into 1 to 5 micron particles, median mass diameter. This is an efficiency of 0.04%, in comparison with the lesser efficiency of 0.001% for the Q fever slurry. This quantity is approximately 8.4×10^4 $HRLD_{50}$ ($0.1 \times 2 \times 10^9 \div 2.38 \times 10^3$). With an inward face air velocity of at least 75 feet per minute at the work opening of the Class II cabinet, (see Appendix 11) essentially all of the areosol generated passes through the cabinet Hepa filters (99.97% efficiency) before entering the containment suite duct system where it now passes through a Baggy Filter (95% efficiency). Thus, only 25.2 $HRLD_{50}$ enters the duct system of the suite and a maximum of 1.3 $HRLD_{50}$ could be discharged out of the exhaust stock. Within inches of the exhaust stack, this amount of toxin would undergo infinite dilution in the atmosphere and the toxin itself would rapidly undergo physical degradation. Thus, this concentration of toxin, released through the exhaust stack, would be negligible and would pose no threat to the human or animal populations. Immunized at-risk workers exposed to what little, if any, toxin that escaped out the opening of the Class II cabinet would not suffer any adverse effects. Animal experiments have shown that immunization with botulium toxoid provides good protection from aerosolized botulium toxin.

2.3 MCE: VIRUS

Again, an aerosol-generated hazard from an accident involving a spinning centrifuge is considered to be a worst case event. Other types of laboratory accidents would most likely involve only an individual laboratory worker or at most one or two others and, except for direct injection (contaminated accidental needle sticks etc), infection by aerosol poses the

greatest general risk. Since this scenario is similar to that for the MCE for Q fever or for botulinum toxin, details which are repetitive have been omitted.

2.3.1 Rift Valley fever virus (RVFV) was selected for this postulated MCE because epidemiology studies have shown RVFV to be one of the most infectious viruses in aerosol exposures. Because of the nature of the studies and the greater purity of the starting material, i.e. RVF in cell cultures versus Q fever in whole chick embryo egg slurry, most studies would use relatively small quantities of virus. But for this MCE, let us assume a need would exist for a larger volume. Hence, four 250 ml centifuge tubes are filled with 240 ml each of a viral culture containing 1 $x10^9$ plaque forming units (PFU) of viral particles per ml, or 960 x 10^9 PFU total. One PFU is the number of viral particles required to cause successful infection of target cells. For mice, one ID_{50} (C57B16 inbred or ICR outbred strains) is equivalent to one PFU.

The centrifugation is conducted in a Class II cabinet within a BL-3 containment suite. If a centrifuge tube breaks during centrifugation, a viral aerosol would be generated within the rotor of the centrifuge. Most of the solution would be contained within the covered rotor (99%). Of that which escaped into the centrifuge cabinet, less than 1% would be aerosolized with this inefficient aerosol generator. Of that which was aerosolized within the centrifuge cabinet, approximately 90% would settle as liquid droplets on the inside of the chamber. Both of these areas (the inside of the rotor and the centrifuge cabinet) can be decontaminated efficiently by trained research personnel who have taken the appropriate personal protection measures and employ the appropriate decontamination procedures to handle the spill. If appropriate safety procedures are practiced by all personnel, no viral releases would occur because even the air in the centrifuge chamber would be evacuated through a liquid disinfectant trap during and following the breakage. Since the centrifuge is manually operated and subject to human error, we must assume several irresponsible actions for an MCE. We also will assume that all four bottles will rupture, a very unlikely event which has never taken place.

Therefore, only an equivalent of approximately 0.096 ml of the total 960 ml (0.01% aerosolization efficiency) of viral culture solution would be aerosolized into 1 to 5 micron particles, median mass diameter. This quantity is approximately 9.6 x 10^7 PFU (0.096 x 1 x 10^9 PFU). The human respiratory infective dose has never been determined or estimated; however, for a credible worst case analysis, we will assume that humans and mice are equally sensitive, and that 1 mouse ID_{50} (IPFU) is the equivalent of a human respiratory infective $dose_{50}$ ($HRID_{50}$). Essentially allof this accident induced aerosol would be contained within the Class II safety cabinet and exhausted through its HEPA filters (99.97% efficient at 0.3 micron), thereby reducing the aerosol to 2.8 x 10^4 $HRID_{50}$. After passing

through the Class cabinet filter, the aerosol is subsequently exhausted through the duct system of the containment suite, thereby passing through another filter (Baggy 95% efficient or HEPA 99.97%). Thus only 1440 $HRID_{50}$ could be vented out of the exhaust stack. Within one meter from the stack, there would be less than one $HRID_{50}$/liter air and would not constitute a risk to the community, animals or man.

2.4 DISCUSSION

The MCEs postulated in this section assumed basic building containment was still operable but that one or more accidents, mechanical and human, resulted in the creation of a potential risk, principally to the work force, but perhaps also to the external environment. To generate these MCEs some things were assumed most likely would not or could not occur. The volumes assumed for Q and RVFV are much greater than used in most, if not all, such experiments. The efficiency of aerosolization with these low-speed centrifuges are most likely far less than those efficiencies postulated. If one were to hypothesize a higher-speed centrifugation, by necessity of the capacity of the rotors, while the efficiency of aerosolization may increase slightly over those postulated, the volumes handled would be much much smaller. The three MCEs theorized in this section indicate no risk to the environment, and only an insignificant risk to the immunized work force.

3. Aerosol release from facility

A review of aerosol concentrations of organisms studied during offensive and defensive operations at Fort Detrick from 1943 to 1969 indicated that the number of organisms aerosolized in any given study rarely exceeded $1x10^5$ infectious doses per liter. This concentration, or less, is typical for studying a variety of subjects represented by, but not limited to: aerosol recovery, biological decay, definition of respiratory dose for experimental laboratory animals, gas mask and clothing penetration-refractive relationships, biological alarm systems, and biodetection systems. The exception to absence of aerosol concentrations exceeding $1x10^5$ infectious doses per liter occurred during agent-munition development. Here, the concentration of infectious doses increased by several orders of magnitude (100 to 1000 times). Since defensive studies of potential biological warfare agents are far removed from the needs of agent-munition development and agent weaponization studies, it is reasonable to assume concentrations of biological materials in the range of $1x10^3$ to $1x10^5$ infectious doses per liter are those typically found for the purpose of considering MCEs within the BDRP.

The difficulty in getting a significant quantity of an infectious or toxin-containing aerosol past the multiple and redundant safety constraints incorporated into a correctly designed BL-3/BL-4 laboratory has been described above. Even in

these contrived "maximum credible events," any aerosol released within the laboratory environment poses no threat to the community.

The succeeding paragraphs 3.1 and 3.2 present the results of modeling efforts in which infectious aerosols of varying concentration were considered to be released directly into the environment, without the application or consideration of building design and operational safety procedures. The potential impact of these aerosols, on the population and environment, will be described by application of mathematical models that predict the level of biohazard of the aerosol as it travels downwind.

3.1 Aerosol Release, Dugway Proving Grounds*

This MCE was included for comparative purposes. A separate DEIS (See ref 1, App X) for a facility designed for the conduct of indoor aerosol test studies was made available to the public in February, 1988. This example was taken from that source with minor editing to fit the MCE into this document, but none of the data or analysis was changed.

3.1.1 Method

The following analysis focuses mainly on infectious organisms because much of the testing conducted indoors is done in biological-containment laboratories with infectious organisms. The specific model used, *Coxiella burnetii*, was selected because it can infect at the exposure level of a single organism, and it is also exceptionally robust in comparison with most other potential biological test materials; i.e., it can survive greater extremes of temperature, humidity, ultraviolet rays, moisture, etc.

Aerosol generation, release, and downwind transport of an infectious organism to a susceptible animal, human or environmental reservoir has been chosen as the mode of impact for analysis because: 1) aerosol testing is the BATF's chief purpose; 2) the aerosol state, during generation or holding for observation, is generally the physical state most apt to escape control; 3) the human respiratory system is the most vulnerable and most important "environment" at risk; and 4) the airborne route is generally the swiftest and most certain, with briefest exposure to environmental influences.

3.1.2 Aerosol Generation

The generation of biologically relevant aerosols from aqueous suspensions requires considerable energy, efficiently applied, to break the fluid up into sufficiently small

* Adapted from Appendix X, DEIS Biological Aerosol Test Facility (1)

droplets. The only way in which energy can be thus applied in the BATF is in the planned generation of aerosols for test procedures. There are two types of test procedures: 1) those in which aerosols are generated over a period of time, passed over or through the item under test (e.g., detector device to measure response; field radio to test decontamination effects), and then trapped/destroyed by filters/incinerator; and 2) those in which the aerosol is held, typically for 24 hours, in a slowly rotating drum, to observe the effects of aging on viability, infectivity, or virulence, and then discharged through the filter/incinerator system.

The continuous generation process offers the greater potential for aerosol release because the atomizer is driven by air pressure and the aerosol is released into an airstream; i.e., there is a propulsive force. The maximum amount atomized in a test will be 30 ml (about 1 fluid ounce) of aqueous suspension, at 1 ml/min; the maximum concentration for *Coxiella burnetii* will be 1×10^9 organisms/ml; i.e., a total of 3×10^{10} organisms aerosolized.*

The aerosol-holding test involves a volume of 250 liters of aerosol at a maximum concentration (for *Coxiella burnetii*) of 1×10^8 organisms/liter; i.e., a total of 2.5×10^{10} organisms. Once filled, the drum is at or slightly below laboratory air pressure; i.e., there is no propulsive force to favor leakage. (Note that only one test will be done at a time, so the quantities in the two kinds of test are not additive.) Note also that aerosol generation will take place only in daylight hours and that members of the technical staff will be present at all times during aerosol aging tests. The concentration of live, infective organisms in the aerosols held in the drum will decrease continually through two mechanisms: loss of viability (ability to multiply) or of infectivity, and physical loss by deposition onto the interior of the drum. Typically, the maximum infective concentration after 24 hours is no more than 10-20% of the original, and it may be very much lower, approaching zero. Therefore, the maximum amount of infectious aerosol in the drum when night falls is expected to be substantially less than the initial maximum of 2.5×10^{10} organisms, probably generated several hours earlier.

3.1.3 Possible Causes of Aerosol Release and Amounts Involved

The possible causes of total release of the entire test aerosol (from either continuous generation or aerosol holding) are all of very low probability, since they involve either coincidental total failure of sequential hazard controls (e.g., two HEPA filters and an air incinerator in series) or major

*(sic) Note that this calculation assumes 100% efficiency of aerosolization, an efficiency impossible to achieve.

damage to the laboratory from impact (projectile off trajectory, aircraft crash) or explosion; in either case, damage would release the aerosol only if it coincidentally destroyed both external containment (laboratory structure) and internal containment (both aerosol apparatus and its enclosing safety cabinet). Further, accompanying fire, as is common with aircraft crashes and explosions, would certainly destroy much or all of the aerosol.

There is also the possibility of partial release of the generated/held aerosol through deterioration of multiple engineering controls or a procedural error. There is no data base to support a quantitative estimate of the likelihood or extent of such a partial release, since failures of hazard control in modern facilities are far too infrequent for analysis and there is a lack of quantitative data. The only basis on which to hypothesize the upper limit of such a partial release (to permit a tentative estimate of its downwind extent of impact) is expert consensus (Harper, 1986; Housewright, 1986; McKinney, 1986), which suggests that 1% of the maximum (i.e., 3×10^8 units of *Coxiella burnetii*) is certainly not an underestimate. This estimate takes into account considerations such as the likelihood that abnormal air flow/pressure caused by omission of an air filter or failure of air incinerator would immediately alert an operator to suspend aerosol generation.

The other possible cause of aerosol release is a similar impact or explosion acting on unaerosolized suspension; e.g., prepared for a test but not yet used. Such applications of energy are very inefficient in aerosol formation; even an explosive munition designed for the purpose may have an efficiency of only a few percent in terms of creation of a respirable aerosol. The hypothesized 1% of maximum will amply cover this mode of dispersal as well as laboratory accidents such as spills or breakage of a container during centrifugation.

3.1.4 Receptor

The most sensitive environmental target for defining the hazard zone from *Coxiella burnetii* emissions is the human respiratory system; it is known to be highly susceptible, with an ID_{50} (dose infecting 50%) in the 1-10 organism range (evidence from volunteer exposure supported by occupational epidemiology, public health epidemiology, and extrapolation from various animal species). For the purpose of assessing the infective impact of *Coxiella burnetii* exposure, a typical person at risk is assumed to be an adult who is walking or driving a car and can be considered to have an air "sampling" rate (respiratory volume per minute) of 15 L/min.

3.1.5 Viable Decay Rate

The decay (loss of infective power) of biological aerosols is highly dependent on environmental conditions. The

calculations in this appendix use meteorological conditions that are typical of those favorable to extended downwind impact. Two general circumstances are covered: daylight conditions, relevant to periods of test aerosol generation, and night conditions, relevant to part of the period in which a test aerosol may be held in the BATF. The decay rate assumed for night conditions is 0.9% per minute, based on various laboratory experiments with *C. burnetii* in the dark. Diffuse daylight (overcast sky) increases the decay of most biological aerosols markedly, and full sunlight is extremely destructive to most pathogens. However, there are no field data for *C. burnetii* to support an estimate of its decay rate in daylight hours; one expert has stated that "there is no information available for even a wild guess at the viable decay in daylight" (Harper, 1986). Therefore, the calculations in this appendix, which use the "night" decay rate for daylight conditions, may overestimate the extent of the hazard considerably, especially for conditions of full sunlight that predominate at DPG. To illustrate the kind of effect that daylight might have, this appendix also includes figures based on a decay rate of 4.0% per minute, which was measured in laboratory exposure to simulated sunlight (Beebe et al., 1962), although it is recognized that simulated and actual environmental effects can differ widely.

3.1.6 Extent of Downwind Hazard

The only solid data base for estimating the likelihood and amount of accidental aerosol release from the BATF is the record of similar laboratory operations. As indicated above, there has been no reported evidence, in about a half-century of operations worldwide, of aerosol release affecting persons outside laboratories of BL4/BL3 or similar containment standards (U.S. Army Dugway Proving Ground, 1986; Wilson, 1986). However, for reasons presented above, this appendix attempts estimation of the extent to which an accidental aerosol release might create an environmental hazard (without implying that such an event is to be expected).

The discussion above has arrived at reasonable estimates of the parameters related to amount of release, human sensitivity, and viable decay rate. The values used are believed to favor overestimation of the downwind extent of impact. The least reliable of the three factors is the decay rate, since there is no useful quantitative information from field observations of the decay rate of *C. burnetii* in daytime conditions. The same lack of data applies generally to infectious materials, for which nighttime release has long been the usual assumption in biological defense doctrine. Meteorological conditions other than solar radiation also affect the decay rate; they are temperature, humidity, and atmospheric gases; all are generally less significant than full-spectrum sunlight.

Meteorological conditions, to a large extent, control downwind travel and dispersion; these parameters can be modeled

with confidence because there is a sound theoretical basis and an extensive data base of field observations. In other words, it is possible in the present analysis to make well-supported estimates of total downwind concentrations from a given release in stated conditions, but it is not possible to predict, with nearly the same degree of confidence, what proportion of the downwind aerosol would have remained infective (especially in full daylight). The estimates in this appendix are therefore not firm predictions; they are no better than very rough estimates, provided to give a general idea of the possible scale of environmental impact. Use of the nighttime decay rate ensures that they are overestimates for daylight, probably by a large margin.

3.1.7 Method of Calculating Downwind Extent of Impact

For a ground-level source, axial concentration at ground level downwind is given by:

$$\chi\ (x,o,o;o) = \frac{Q}{\pi\sigma_y\sigma_z u}$$

where x = concentration in units m^{-3} (PFU or, more loosely, organisms)

χ = distance downwind

Q = rate of emission, units min^{-1}

π = 3.142

σ_y, σ_z = lateral and vertical dispersion coefficents, m

u = wind speed, m min^{-1}

The application here of the simple Gaussian-plume model is not taken beyond about 7 km and therefore conforms with Pasquill and Smith's warning against extrapolation to greater distances (Pasquill and Smith, 1983).

For a total release of $Q\tau$ units, the exposure (or "dosage," not to be confused with "dose") at χ m downwind is:

$$D\tau = \frac{Q\tau}{\pi\sigma_y\sigma_z u}$$

where $D\tau$ = exposure, units min m^{-3}

$Q\tau$ = total release, units

If the released aerosol is subject to exponential decay, the model becomes:

$$D\tau = \frac{Q\tau}{\pi\sigma_y\sigma_z u} \exp(-kt)$$

where k = decay constant, min^{-1}

t = time of travel, min (given by x/u)

Total respiratory intake from total exposure Dt is given by:

$$I\tau = D\tau R$$

where $I\tau$ = total intake, units

R = respiratory minute volume, $m^3\ min^{-1}$

It should be noted that intake is greater than the dose available to infect, as some particles will escape retention and be exhaled and others will be retained in the upper respiratory tract where they are much less infective.

For nighttime release, a very stable atmosphere is assumed; in technical terms, Pasquill category F. For daytime release, neutral stability is assumed (Pasquill category D); this represents the conditions most favorable to downwind extent of effects that are likely to occur on most occasions of morning release and during downwind travel over periods of a few hours. The affected environmental target is the human respiratory system, breathing at 15 L/min (Green and Lane, 1957). Distances downwind are calculated for total intake of 10 and 1 organisms; this range brackets the retention of 1 organism (lung retention of respirable particles is one-half or less of total intake), and therefore the two distances indicate the zone where downwind impact (i.e., infection) is in transition from likely to unlikely or negligible.

3.1.8 Results

Table A9-1 gives estimates of the extent of downwind hazard for an accidental release of 3×10^8 plaque-forming units ("organisms") of *Coxiella burnetii*. Windspeeds of 2.25, 4.5, and 6.75 miles per hour (1, 2, and 3 meters per second) are assumed. It will be seen that the greatest distance in the table is less than 5 miles at night and is 2 miles by day.

Table A9-1. Estimates of Extent of Downwind Hazard Following Accidental Aerosol Release of 3×10^8 PFU* of *Coxiella burnetii*

Estimated respiratory intake, PFU*		Wind speed, miles/hr		
		2.25	4.5	6.75
Decay rate 0.9% per minute		Distance, miles		
Night:	10	1.4	1.1	0.8
	1	4.5	4.0	3.5
Day:	10	0.6	0.4	0.3
	1	2.0	1.7	1.3
Decay rate 4.0% per minute				
Day:	10	0.5	0.4	0.3
	1	1.2	0.9	0.8

*Plaque-forming units

3.1.9 Extent of Impact at DPG

Figure A9-2 shows data from Table A9-1 in relation to DPG. The calculated zone of potential effect is well within the controlled area of DPG and far from any public highway or residence.

It is pertinent to note that the greatest distance from a known source of *C. burnetii* at which human infection with Q fever, attributable to aerosol release, has occurred is about 10 miles (Wellock, 1960). The probable source of this outbreak was from continuous operation of an animal product processing plant where diseased sheep were handled; i.e., it can be surmised that the cumulative source over a considerable period was much larger than the small source and brief exposure assumed in Table A9-1.

3.1.10 References

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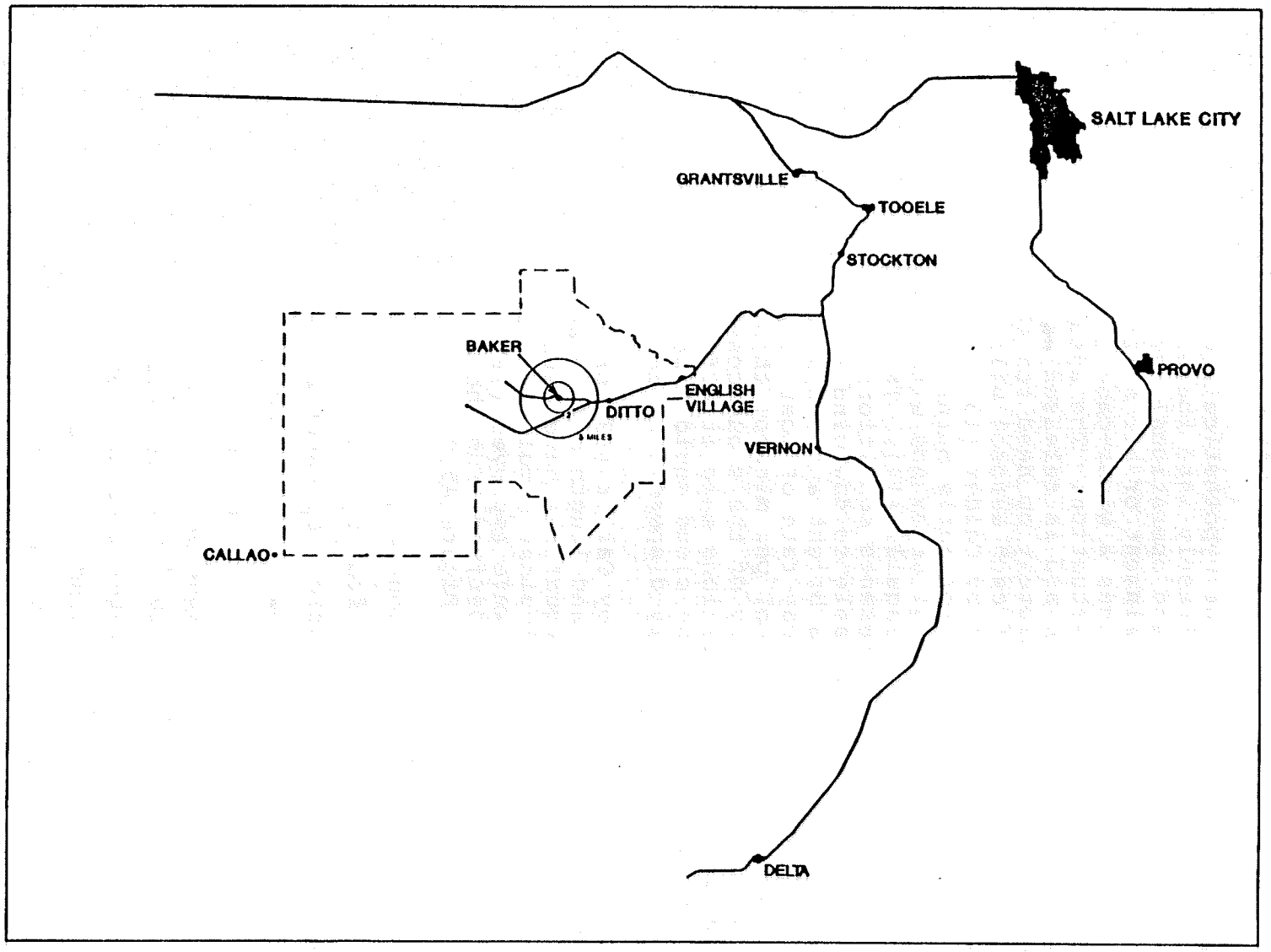


Fig. A9-2 Estimates of Extent of Downwind Hazard Following Accidental Aerosol Releases of Coxiella burnetii in Relation to DPG and Local Population Centers.

3.2. AEROSOL ESCAPE FROM A BL-4 LABORATORY

This section describes the hypothetical release of varying concentrations of aerosols directly into the environment without regard to laboratory design and operational safety procedures. It will be assumed that no containment or air filtration whatsoever exist. This clearly establishes a worst-case scenario, and is far worse than the MCE for this situation. The assumption is that the aerosol intentionally created and is released as a point source at ground level. There is absolutely no need for this ever to be done in the BDRP. Downwind hazard of each aerosol will be estimated using mathematical models developed by Calder (13). The postulated release of the aerosol is calculated for early morning meterological conditions with zero biological decay and with an atmosphere stability category D as described by Pasquill (14). This catagory assumes a "neutral stability" and represents conditions common during early morning hours and most favorable to downwind travel. If, for example, an aerosol were released on a bright and sunny day at noon or in the afternoon, the biological decay rate of most biological agents could rise to greater than 20 percent per minute; this would shorten the effective downwind infectivity of the cloud considerably. Moreover, daylight meteorological conditions make it difficult for an aerosol to remain at ground level and the cloud could rise quickly into the atmosphere (15) and be rapidly dispersed to an inocuous condition.

The equations generated by Calder (13) project an aerosol in the dimensions of height, width, and length as the aerosol travels downwind. These particular equations have been verified many times by field tests in which the biological simulants *Bacillus subtilis* var. niger and *Serratia marcesens* were employed (16). The data presented in Tables A9-2 and A9-3 were derived from the isopleths on page 54 of the referenced document (13), Figure A9-3.

In Table A9-2, doses to source strength ratios (dosages) are plotted in distances downwind from the source in meters. The $\frac{d}{Q}$ (dosages), given in the table, represent a fraction of the source strength that an individual downwind exposed to the cloud would inhale and retain. From Table A9-2, it is noted, for example, at 135 meters downwind, a $\frac{d}{Q}$ of $5x10^{-7}$ is expected. This means that an unprotected individual should retain a $5x10^{-7}$ fraction (.0000005) of the source strength released. At the center line axis of the downwind travel of the aerosol at 135-meter downwind point, an exposed individual could be expected to retain five organisms if the source strength is 10^7 organisms. This figure is calculated from:
$d = Q \times \frac{d}{Q} = 10^7 \times 5 \times 10^{-7} = 5$. Further examination of Table A9-2 reveals that the number of organisms retained by a host will vary

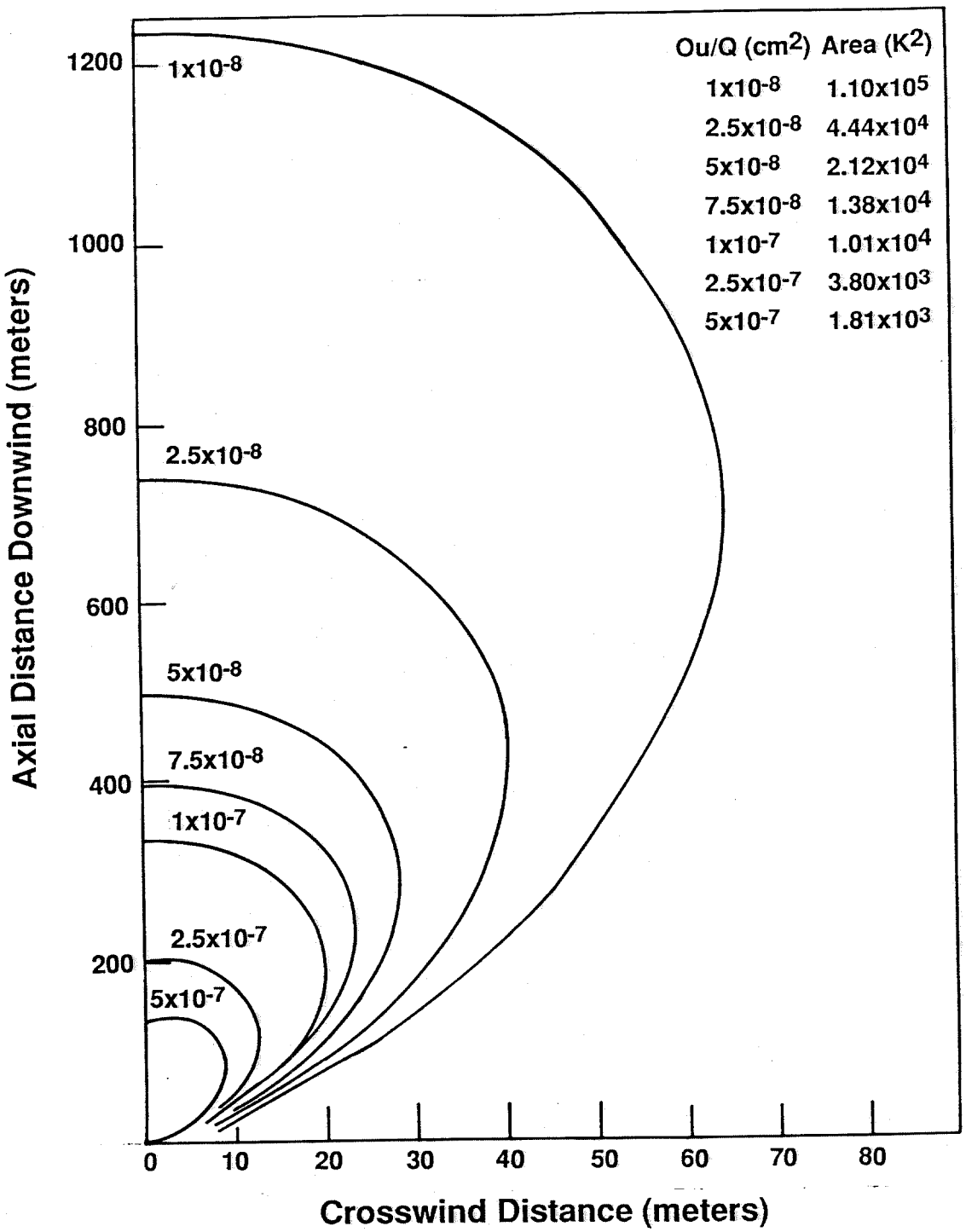


Fig. A9-3 Page 54 of BWL Technical Study No. 3

Table A9-2. Downwind Hazard of Aerosol, In Meters, After Point Source Release, and Assuming No Biological Decay

Axis of cloud[b]

Meters Downwind	$\frac{d}{Q}$	Dose d in organisms retained when Q[a] is: $Q=10^8$	$Q=10^7$	$Q=10^6$	$Q=10^5$	$Q=10^4$	$Q=10^3$	$Q=10^2$
1	2.7×10^{-3}	270,000	27,000	2,700	270	27	2.7	.27
1.7	1×10^{-3}	100,000	10,000	1,000	100	10	1	.1
2.7	5×10^{-4}	50,000	5,000	500	50	5	.5	--
7	1×10^{-4}	10,000	1,000	100	10	1	.1	--
11	5×10^{-5}	5,000	500	50	5	.5	--	--
16	2.5×10^{-5}	2,500	250	25	2.5	0.25	--	--
26	1×10^{-5}	1,000	100	10	1	.1	--	--
38	5×10^{-6}	500	50	5	0.5	0.25	--	--
57	2.5×10^{-6}	250	25	2.5	0.25	--	--	--
92	1×10^{-6}	100	10	1	0.1	--	--	--
135	5×10^{-7}	50	5	0.5	0.25	--	--	--
200	2.5×10^{-7}	25	2.5	0.25	--	--	--	--
335	1×10^{-7}	10	1	0.1	--	--	--	--
390	7.5×10^{-8}	7.5	0.75	--	--	--	--	--
495	5×10^{-8}	5.0	0.5	--	--	--	--	--
735	2.5×10^{-8}	2.5	0.25	--	--	--	--	--
1230	1×10^{-8}	1.0	0.1	--	--	--	--	--

a. Total source strength in organisms.

b. Data from Page 54 of referenced document; for example, if $\frac{d}{Q}=5\times10^{-7}$: then d for $Q=10^{10}$ is $d/10^{10}=5\times10^{-7}$; $d=5\times10^{-7}\times10^{10}=5\times10^{3}$ or 5000 at wind speed of about 1 meter per second(2 miles per hour)

Table A9-3. Downwind Hazard of Aerosol, In Meters, When Source Strength is Changed* and Assuming No Biological Decay

Median Dose (ID_{50}) (Organisms)	Morbidity 1%	Morbidity 10%
	Source Strength=10^3 organisms	
1	7.5	4
10	0.2	0.1
	Source Strength=10^4 organisms	
1	13	7
10	7.5	4
100	0.2	0.1
	Source Strength=10^5 organisms	
1	80	46
10	13	7
100	7.5	4
1,000	0.2	0.1
	Source Strength=10^6 organisms	
10	80	46
100	13	7
1,000	7.5	4
10,000	0.2	0.1
	Source Strength=10^7 organisms	
10	400	205
100	80	46
1,000	13	7
10,000	7.5	4
	Source Strength=10^8 organisms	
10	1500	760
100	400	205
1,000	80	46
10,000	13	7
	Source Strength=10^9 organisms	
10	5600	2800
100	1500	760
1,000	400	205
10,000	80	46

* % Morbidity x Source Strength x Median Dose.

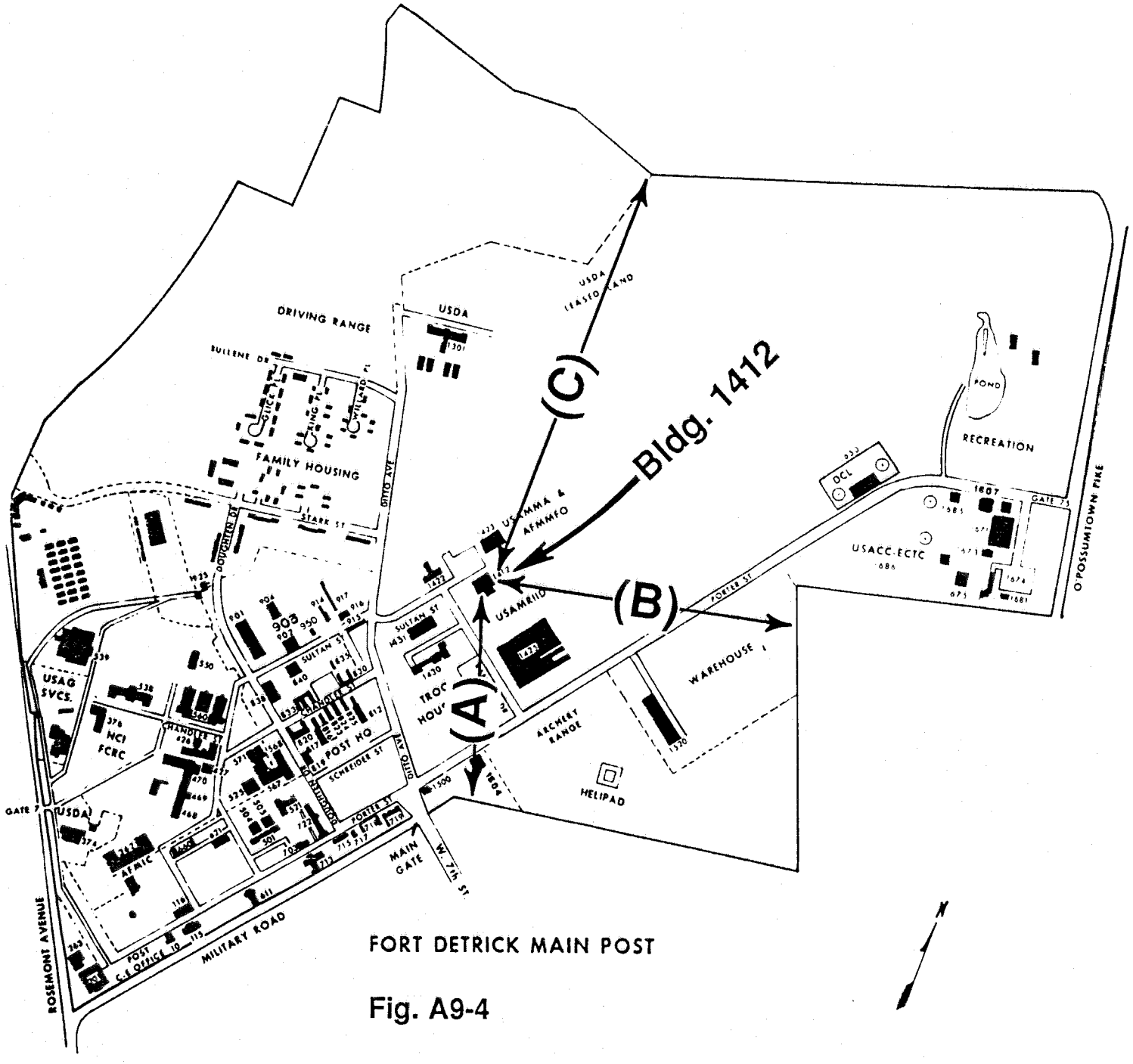
directly with one log change in source strength giving a one log change in organisms retained.

The important conclusion to be drawn from these data is that it requires the release of more than 10^7 infectious doses under ideal conditions to cause significant infections more than 100 meters downwind.

Downwind travel of a hazardous aerosol is presented somewhat differently in Table A9-3. Downwind distance, in meters, is provided for seven levels of source strengths, two levels of percent infections, and varying levels of ID_{50}s. Thus, knowing the number of organisms that constitute an ID_{50}, and the source strength, one can read the estimated downwind distance in meters at which a morbidity of 1% or 10% can be expected. Once again, the range of source strengths in which USAMRIID conducts any aerosol studies (and those only indoors) falls well within the 10^3 to 10^5 organism range. Actually, a source strength of 10^5 organisms constitutes an upper range of organism concentration and one that is rarely achieved during normal operations.

A map of Fort Detrick is given in Figure A9-4. Building 1412 is where USAMRIID conducts indoor aerosol tests. The shortest line between Building 1412 and the fence that delineates Fort Detrick from the surrounding civilian community is 481 meters (line A). In order for an infectious aerosol to reach this distance greater than $Q = 10^7$ organisms would have to be released accidently and under optimal meterological conditions for organism survival and idspersion. Since the prevailing wind is west by northwest during fall and winter months, line B should/would probably predict aerosol travel more reasonably. If line B is used, the distance from Building 1412 to the fence is 722 meters. In spring and summer, the prevailing wind is from the south, and the distance from Building 1412 to the fence is 1000 meters (line C). In any case, the use of $Q = 10^7$ organisms is two logs (1000 times) greater than the $Q = 10^5$ organisms employed as an upper limit in aerosol studies conducted at USAMRIID.

There are several conclusions to be drawn from this scenario. First, defensive medical research studies of infectious aerosols within the BDRP are routinely conducted in the range of $Q = 10^3$ to $Q = 10^5$ infectious doses and during normal working hours. At these levels, even with escape of an aerosol under optimal meterological conditions for survival and dispersion, and with zero biological decay, an aerosol would be potentially infectious only a few meters downwind from the point of release. Infectious aerosols that have an initial range of $Q = 10^5$ and $Q = 10^6$ are still quite limited in downwind travel, 26 and 92 meters downwind, respectively, to achieve one infective dose. A strength of $Q = 10^7$ would result in one infective dose retained at 335 meters, still well within the Fort Detrick perimeter. A strength of $Q = 10^8$ could cause some infections past the main gate of Fort Detrick, since one infective dose is theoretically present at 1230 meters. Nevertheless, the important message is that defensive biomedical aerosol studies use concentrations of organisms at least two and usually four logs (one hundred- to ten thousand-fold) below the $Q = 10^8$ threshold. This provides a great safety margin for the accidental release of pathogens as small particle aerosols. In practice, several levels of safety precautions would reduce such a release by several orders of magnitude even before release to the atmosphere. Also, aerosol studies require a team effort and operating hours are during the day. Since there is no imperative for nighttime studies, all studies have been and will continue to be conducted during normal daytime hours, when ultraviolet radiation from the sun can be expected to kill large percentages of the organisms commonly used in these studies, thereby providing yet another barrier against consequential results.



FORT DETRICK MAIN POST

Fig. A9-4

3.3 Prediction of Downwind Hazards for Aerosol Dispersions

The transport and dispersion of aerosol particles subject to forces exerted by the prevailing winds can be described by meteorologic mathematical models developed for weather and air pollution predictions. These models have a sound physical and theoretical basis and have been tested with an extensive database of field observations to show that downwind concentrations of dispersions can be predicted accurately and with confidence (13,14,17-26). The dispersion of particulates or aerosol droplets in the atmosphere is predicted with a basic Gaussian diffusion model. Factors affecting dispersion include release characteristics, meteorological conditions, and terrain geography.

Potential aerosol emissions from BDRP activities could include releases from exhaust stacks as a result of failures in air filtration systems, and explosive releases resulting from external catastrophic events (aircraft collision, earthquake, or tornado) at facilities performing research operations with high-hazard infectious organisms.

For vertical emissions through a stack into the open atmosphere, the quantity of the aerosol emitted is a function of volume, physical characteristics, moisture content, exit velocity, and temperature. The aerosol release is also affected by stack height and location. Computer models have been developed (24,25) to predict downwind dispersions of toxic or flammable materials from stack emissions or ground level spills.

For any aerosol emission, meteorological and terrain effects govern dispersion. Wind direction determines which terrain features participate in the dispersion of the aerosol cloud. Wind speed determines the dilution rate of the aerosol and the effects on its biological viability. Increases in relative humidity enhance the settling of particulates. Rainfall removes particulates, gases, and droplets from the aerosol cloud. Atmospheric stability affects the dispersion of the aerosol by resisting or enhancing vertical motion and turbulence of the cloud. Pasquill (17) has separated atmospheric stability into six classes. These are summarized in Table A9-4.

The Pasquill categories classify the turbulence intensity within the atmospheric surface mixing layer. At one extreme, the Pasquill A stability category represents the very unstable thermal stratification and highly turbulent conditions typically found on a clear summer day with light winds. At the other extreme, the Pasquill F stability category represents the very stable thermal stratifications and minimal atmospheric turbulence typically found on clear nights with light winds. Intermediate between the two extremes is the Pasquill D stability category, which is associated with neutral stratifications and moderate turbulence typically found under overcast skies or with moderate to strong winds. The D category is the most stable one which can occur during the day. The top of the surface mixing layer serves

Table A9-4: Pasquill Stability Codes[a]

Insolation[b]/Cloud Cover		Surface Wind Speed (meters per second) <2	2 to <3	3 to <5	5 to <6	=>6
Day	Strong Insolation	A	A-B	B	C	C
	Moderate Insolation	A-B	B	B-C	C-D	D
	Slight Insolation	B	C	C	D	D
Day or Night Overcast		D	D	D	D	D
Night	>= 0.5 Cloud Cover	-[c]	E	D	D	D
	<= 0.4 Cloud Cover	-	F	E	D	D

[a] "Air pollution," H. C. Perkins (1974) McGraw-Hill, p. 223.

[b] Strong insolation corresponds to a solar elevation angle of 60° or more above the horizon. Slight insolation corresponds to a solar elevation angle of 15°-35°.

[c] Emissions under clear nighttime skies with winds less than two meters per second are subject to unsteady meandering. Downwind predictions are unreliable.

as a barrier to upward mixing. Therefore, materials emitted into the atmosphere within the surface mixing layer tend to become uniformly mixed between the surface and the top of the mixing layer at long distances from the source of emission. The mixing layer depth varies from 100 meters to 1000 meters for stable and unstable conditions respectively.

The models used for predicting downwind hazards give diffusion coefficients and measurement parameters for each of these stability classes or a similar type of conditional descriptor. The smoothness of the terrain affects the rate of dissipation of an aerosol cloud. Some models account for this in parameters developed for urban settings versus open level country. The maximum downwind migration of aerosol droplets occurs in open country, while minimum migrations occur in urban settings and in dense forests. Therefore, for the calculation of maximum credible events in the BDRP we selected the open, level terrain feature for our calculations. While the topography of Dugway Proving Ground fits this open condition, most of the other sites of BDRP activities are suburban to urban in character.

For our purposes, an algorithm was developed from the Gaussian model described by Calder (12). The maximum downwind dosage can be predicted from equation A9-1,

$$\ln\left[\frac{Q}{\pi\,\sigma_y(100m)\,\sigma_z(100m)\,D\,u\,(x/100)^{\alpha+\beta}}\right] = \frac{kx}{u} \qquad \text{A9-1}$$

where,
- Q = source strength
- D = dosage
- u = wind speed
- x = downwind distance
- k = decay constant
- π = the constant 3.14159
- ln = base e logarithm function

and the following are diffusion parameters that vary according to stability classes and nature of terrain (Table A9-5),

- $\sigma_y(100m)$ = standard deviation of the crosswind distribution in meters
- $\sigma_z(100m)$ = standard deviation of the vertical distribution in meters
- α = slope of σ_y versus x curve at 100m
- β = slope of σ_z versus x curve at 100m

Table A9-5 : Diffusion Parameters from Representative Models

Pasquill Class[a]	σ_y(100m)	α	σ_z(100m)	β
A	25.2	.9	18.	1.63
B	20.2	.9	11.3	1.191
C	13.9	.9	8.9	.852
D	9.02	.9	6.5	.682
E	6.43	.9	4.	.664
F	4.8	.9	2.6	.633
Porton Urban[b]				
Poor	41.19	.5	25.17	1.344
Average	30.99	.5	5.45	1.091
Good	31.18	.5	5.57	.755
Porton Open Country[c]				
Poor	3.41	1.87	25.	1.87
Average	3.41	.88	5.8	.88
Good	3.41	.66	3.8	.66

[a]"Personal computer program for chemical hazard prediction (D2PC)," C. G. Whitacre, J. H. Greiner III, M. M. Myirski and D. W. Sloop (1987) U.S. Army Chemical Research, Development, and Engineering Center Report CRDEC-TR-87021, p. 80

[b]"Mathematical models for dosage and casualty coverage resulting from single point and line source releases of aerosol near ground level," K. L. Calder (1957) U.S. BW Laboratories Technical Study No. 3, DTIC AD-310361, p. 25.

[c]Ibid., p 26.

For the worst-case example of an aerosol release of organisms that do not undergo biological decay ($k = 0\ min^{-1}$), Q in total organisms released, D in organisms-min/liter, u in miles/hour, the equation can be simplified and rearranged to allow the calculation of the downwind distance, x, from equation A9-2,

$$x = 100 \left[\exp \left[\ln \left[\frac{Q}{F\ \pi\ \sigma_y(100m)\ \sigma_z(100m)\ D\ u} \right] \Big/ \left[\alpha+\beta\right] \right] \right] \qquad \text{A9-2}$$

where, exp = denotes base e exponentiation
F = 26822.4 composite conversion factor for miles per hour to meters per minute, cubic centimeters to liters, and meters to centimeters.

A similar Gaussian treatment allows the calculation of the crosswind distance, y, from equation A9-3 for the worst-case example of an aerosol release of organisms that do not undergo biological decay,

$$y = sqt(2)\ \sigma_y(100m)\ (x/100)^{\alpha}\ sqt(W) \qquad \text{A9-3}$$

where, sqt = denotes square root function
W = argument of the square root function defined as

$$W = \ln \left[\frac{Q}{F\ \pi\ \sigma_y(100m)\ \sigma_z(100m)\ D\ u\ (x/100)^{\alpha+\beta}} \right]$$

where, f = 26.8224 conversion factor for miles per hour to meters per minute.

Using this algorithm, downwind distances were calculated by the diffusion parameters from a variety of atmospheric stability models. The sources of these parameters were the Pasquill stability classes (17), the worst-case scenario from the DPG BATF DEIS (1), the Porton model (13), the Hansen model (24), and the D2PC model (24). Effect summaries were prepared for varying point-source releases (Table A9-6), for varying Pasquill stability conditions (Table A9-7), for different wind speeds (Table A9-8), for various biological decay rates (Table A9-9), and for the conditions of stability reported in Table X-1 of the DPG BATF DEIS (Table A9-1). The Pasquill stability class F was chosen for night-time conditions.

Table A9-6 : Downwind Hazard of Aerosol for Variable Point Source Releases[a]

DwD	Du/Q x 10^8	Organisms released $Q=10^8$	$Q=10^7$	$Q=10^6$	$Q=10^5$	$Q=10^4$	$Q=10^3$
(meters)	(cm^{-2})	Dosage (organism-minutes/liter)					
0.20	1000000.0	82844.55	8284.46	828.45	82.84	8.28	0.83
0.24	750000.0	62133.41	6213.34	621.33	62.13	6.21	0.62
0.31	500000.0	41422.28	4142.23	414.22	41.42	4.14	0.41
0.48	250000.0	20711.14	2071.11	207.11	20.71	2.07	0.21
0.86	100000.0	8284.46	828.45	82.84	8.28	0.83	0.083
1.0	75000.0	6213.34	621.33	62.13	6.21	0.62	0.062
1.3	50000.0	4142.23	414.22	41.42	4.14	0.41	0.041
2.1	25000.0	2071.11	207.11	20.71	2.07	0.21	0.021
3.7	10000.0	828.45	82.84	8.28	0.83	0.083	0.008
4.4	7500.0	621.33	62.13	6.21	0.62	0.062	0.006
5.7	5000.0	414.22	41.42	4.14	0.41	0.041	0.004
8.9	2500.0	207.11	20.71	2.07	0.21	0.021	0.002
15.9	1000.0	82.84	8.28	0.83	0.083	0.008	0.001
19.0	750.0	62.13	6.21	0.62	0.062	0.006	0.001
24.6	500.0	41.42	4.14	0.41	0.041	0.004	0.000
38.1	250.0	20.71	2.07	0.21	0.021	0.002	0.000
68.0	100.0	8.28	0.83	0.083	0.008	0.001	0.000
81.5	75.0	6.21	0.62	0.062	0.006	0.001	0.000
105.3	50.0	4.14	0.41	0.041	0.004	0.000	0.000
163.3	25.0	2.07	0.21	0.021	0.002	0.000	0.000
291.4	10.0	0.83	0.083	0.008	0.001	0.000	0.000
349.5	7.5	0.62	0.062	0.006	0.001	0.000	0.000
451.6	5.0	0.41	0.041	0.004	0.000	0.000	0.000
699.8	2.5	0.21	0.021	0.002	0.000	0.000	0.000
1248.9	1.0	0.083	0.008	0.001	0.000	0.000	0.000
1498.0	0.75	0.062	0.006	0.001	0.000	0.000	0.000
1935.6	0.50	0.041	0.004	0.000	0.000	0.000	0.000
2999.9	0.25	0.021	0.002	0.000	0.000	0.000	0.000
5353.7	0.10	0.008	0.001	0.000	0.000	0.000	0.000

[a]Determined for a wind speed of 4.5 mph, Pasquill stability class D, where

$\sigma_y(100m) = 9.02$ m
$\sigma_z(100m) = 6.5$ m
$\alpha = .9$
$\beta = .682$

Table A9-7: Variable Downwind Hazard of Aerosol by Pasquill Stability Class[a]

Dosage (org-min/liter)	Pasquill Stability Class A	B	C	D	E	F
	Maximum Downwind Distance (meters)					
828.49	0.92	0.48	0.24	0.20	0.32	0.45
621.37	1.0	0.55	0.28	0.24	0.38	0.55
414.25	1.2	0.66	0.36	0.31	0.49	0.71
207.12	1.6	0.92	0.53	0.48	0.77	1.1
82.85	2.3	1.4	0.89	0.86	1.4	2.0
62.14	2.6	1.6	1.1	1.0	1.7	2.5
41.42	3.0	2.0	1.3	1.3	2.2	3.2
20.71	3.9	2.8	2.0	2.1	3.4	5.0
8.28	5.7	4.3	3.3	3.7	6.0	9.1
6.21	6.4	4.9	3.9	4.4	7.2	11.0
4.14	7.5	6.0	4.9	5.7	9.4	14.4
2.07	9.8	8.4	7.3	8.9	14.6	22.6
0.83	14.1	13.0	12.4	15.9	26.3	41.0
0.62	15.8	14.9	14.6	19.0	31.6	49.5
0.41	18.5	18.1	18.4	24.6	41.0	64.5
0.21	24.4	25.1	27.3	38.1	63.8	101.3
0.083	35.0	39.0	46.1	68.0	114.6	184.2
0.062	39.2	44.7	54.3	81.5	137.7	222.2
0.041	46.0	54.3	68.4	105.3	178.5	289.5
0.021	60.5	75.6	101.7	163.3	278.1	455.0
0.008	86.9	117.2	171.5	291.4	499.6	827.1
0.006	97.4	134.5	202.1	349.5	600.4	997.9
0.004	114.3	163.3	254.7	451.6	778.1	1300.0
0.002	150.4	227.5	378.4	699.8	1212.1	2043.2
σ_y(100m) meters	25.2	20.2	13.9	9.02	6.43	4.8
σ_z(100m) meters	18.0	11.3	8.9	6.5	4.0	2.6
α	.9	.9	.9	.9	.9	.9
β	1.63	1.191	.852	.682	.664	.633

[a]determined for a wind speed of 4.5 mph and a point source release of 10^6 organisms.

Table A9-8 : Downwind Hazard of Aerosol for Different Wind Speeds[a]

DwD (meters)	Du/Q x 10^6 (cm^{-2})	Wind Speed (miles per hour) 2.25	4.50	6.75	9.00	13.00	17.00
		Dosage (organism-minutes/liter)					
0.20	1000000	1656.89	828.45	552.30	414 22	286.77	219.29
0.24	750000	1242.67	621.33	414.22	310.67	215.08	164.47
0.31	500000	828.45	414.22	276.15	207.11	143.38	109.65
0.48	250000	414.22	207.11	138.07	103.56	71.69	54.82
0.86	100000	165.69	82.84	55.23	41.42	28.68	21.93
1.0	75000	124.27	62.13	41.42	31.07	21.51	16.45
1.3	50000	82.84	41.42	27.61	20.71	14.34	10.96
2.1	25000	41.42	20.71	13.81	10.36	7.17	5.48
3.7	10000	16.57	8.28	5.52	4.14	2.87	2.19
4.4	7500	12.43	6.21	4.14	3.11	2.15	1.64
5.7	5000	8.28	4.14	2.76	2.07	1.43	1.10
8.9	2500	4.14	2.07	1.38	1.04	0.72	0.55
15.9	1000	1.66	0.83	0.55	0.41	0.29	0.22
19.0	750	1.24	0.62	0.41	0.31	0.22	0.16
24.6	500	0.83	0.41	0.28	0.21	0.14	0.11
38.1	250	0.41	0.21	0.14	0.10	0.072	0.055
68.0	100	0.17	0.083	0.055	0.041	0.029	0.022
81.5	75	0.12	0.062	0.041	0.031	0.022	0.016
105.3	50	0.083	0.041	0.028	0.021	0.014	0.011
163.3	25	0.041	0.021	0.014	0.010	0.007	0.006
291.4	10	0.017	0.008	0.006	0.004	0.003	0.002
349.5	7.5	0.012	0.006	0.004	0.003	0.002	0.002
451.6	5.0	0.008	0.004	0.003	0.002	0.001	0.001
699.8	2.5	0.004	0.002	0.001	0.001	0.001	0.001
1248.9	1.0	0.002	0.001	0.001	0.000	0.000	0.000
1498.0	0.8	0.001	0.001	0.000	0.000	0.000	0.000

[a]Determined for a point source release of 10^6 organisms and Pasquill stability class D, where

$\sigma_y(100m) = 9.02$ m
$\sigma_z(100m) = 6.5$ m
$\alpha = .9$
$\beta = .682$

Table A9-9 : Downwind Hazard of Aerosol for Different Biological Decay Rates[a]

DwD	Du/Q x 10^6	Decay Rate (min^{-1}) k=0.000	k=0.009	k=0.025	k=0.050	k=0.100	k=0.200
(meters)	(cm^{-2})	Dosage (organism-minutes/liter)					
0.48	250000.0	207.12	207.12	207.10	207.08	207.04	206.96
0.86	100000.0	82.85	82.84	82.83	82.82	82.79	82.73
1.0	75000.0	62.14	62.13	62.12	62.11	62.08	62.03
1.3	50000.0	41.42	41.42	41.41	41.40	41.38	41.33
2.1	25000.0	20.71	20.71	20.70	20.69	20.68	20.64
3.7	10000.0	8.28	8.28	8.28	8.27	8.26	8.23
4.4	7500.0	6.21	6.21	6.21	6.20	6.19	6.17
5.7	5000.0	4.14	4.14	4.14	4.13	4.12	4.10
8.9	2500.0	2.07	2.07	2.07	2.06	2.06	2.04
15.9	1000.0	0.83	0.83	0.83	0.82	0.82	0.81
19.0	750.0	0.62	0.62	0.62	0.62	0.61	0.60
24.6	500.0	0.41	0.41	0.41	0.41	0.41	0.40
38.1	250.0	0.21	0.21	0.21	0.20	0.20	0.19
68.0	100.0	0.083	0.083	0.082	0.080	0.078	0.074
81.5	75.0	0.062	0.062	0.061	0.060	0.058	0.054
105.3	50.0	0.041	0.041	0.040	0.040	0.038	0.035
163.3	25.0	0.021	0.021	0.020	0.019	0.018	0.016
291.4	10.0	0.008	0.008	0.008	0.007	0.006	0 005
349.5	7.5	0.006	0.006	0.006	0.005	0.005	0 004
451.6	5.0	0.004	0.004	0.004	0.003	0.003	0 002
699.8	2.5	0.002	0.002	0.002	0.002	0.001	0.001
1248.9	1.0	0.001	0.001	0.001	0.000	0.000	0.000

[a]Determined for a point source release of 10^6 organisms, a wind speed of 4.5 miles per hour and Pasquill stability class D, where

$\sigma_y(100m) = 9.02$ m
$\sigma_z(100m) = 6.5$ m
$\alpha = .9$
$\beta = .682$

Table A9-10 : Comparison of Predicted Downwind Distances From DOWNWIND.BAS Program[a] With the BATF DEIS Table X-1

		Wind Speed (miles per hour)		
		2.25	4.5	6.75
	pfu[b]	Distance (miles)		
Night:				
Pasquill F	10	1.46 (1.4)[c]	0.98 (1.1)	0.78 (0.8)
$\sigma_y(100m)=4.0$ m[d]				
$\sigma_z(100m)=2.3$ m	1	5.39 (4.5)	3.66 (4.0)	2.89 (3.5)
$\alpha=.88$				
$\beta=.88$				
Day:				
Pasquill D	10	0.63 (0.6)	0.43 (0.4)	0.34 (0.3)
$\sigma_y(100m)=8.2$ m				
$\sigma_z(100m)=4.9$ m	1	2.33 (2.0)	1.57 (1.7)	1.25 (1.3)
$\alpha=.88$				
$\beta=.88$				

[a]Algorithm developed assuming zero decay for equation 57 in "Mathematical Models for Dosage and Casualty Coverage from Single Point and Line Source Releases of Aerosol near Ground Level" K.L. Calder (1957) BWL Technical Study No. 3, BW Laboratories, Fort Detrick, DTIC Technical Report AD-310361 (12).

[b]Respiratory intake in plaque-forming units.

[c]Parenthetical values are those reported in the DPG BATF DEIS (1).

[d]The diffusion parameters, $\sigma_y(100m)$ and $\sigma_z(100m)$, were supplied by Dr. Harrison Cramer, preparer of Table X-1 from DPG BATF DEIS. The number of organisms released in an instantaneous ground level event was proposed to be 3×10^8 pfu. The α and β diffusion parameters were taken from the Porton model (12).

with wind speeds <3 meters per second and the Pasquill stability class D was chosen for daylight conditions to represent times of low incoming solar radiation (early morning or overcast) and low to moderate wind speeds. While class D conditions are not frequent, they could occur during the normal work day and were used to consider risk of the maximum credible events.

The effects of biological decay, which is a function of solar energy, drying, and particular characteristics of an organism, are shown for comparative purposes. Daytime biological decay of 5% to 20% per minute or greater is common for most organisms, even on slightly overcast days. High wind conditions and low to moderate humidity contribute greatly to biological decay. Thus, summertime, with high solar input, more unstable meterological conditions, and consequently higher biological decay rates would tend to greatly diminish any downwind hazard. Similarily, while the wintertime with lower solar input and a more frequent occurrence of neutral stability class D conditions might favor more distant downwind hazard, this effect would be greatly diminished by much lower humidity and higher wind speeds that would result in a higher rate of biological decay.

Table A9-6 summarizes the effect of decreasing point source releases on the dosage levels predicted at various downwind distances. The conditions chosen for this comparison are the Pasquill D stability as a worst case daytime atmospheric condition, a 4.5 mile per hour wind speed, and a maximum organism release of 10^8 organisms. Dosage predicted is directly proportional to the decrease in release. The downwind distances predicted for a dosage of 1 organism-minute per liter at these release levels range from less than 291 meters for a 10^8-organism release to less than 20 centimeters for a 10^3-organism release. The maximum credible event for an aerosol escape from a BL-3 laboratory, described in Section 3.2 of this Appendix, postulates a release in the range of 10^5 to 10^6 organisms.

Table A9-7 summarizes the effect of different atmospheric stability classes on the downwind diffusion of an aerosol cloud. The conditions chosen for this comparison are a wind speed of 4.5 miles per hour and a maximum release of 10^6 organisms. The downwind distances predicted for a dosage level of 1 organism-minute per liter range from less than 15 meters for the A class to less than 41 meters for the F class.

Table A9-8 summarizes the effect of varying wind speeds on the downwind diffusion of an aerosol cloud. The conditions chosen for this comparison are the Pasquill D stability class and a release of 10^6 organisms. The downwind distances predicted for a dosage level of less than 1 organism-minute per liter range from less than 25 meters for a 2.25 mile per hour wind to less than 9 meters for a 17 mile per hour wind.

Table A9-9 summarizes the effect of biological decay rate on the hazard distances predicted for a release of 10^6 organisms in

a 4.5 mile per hour wind under atmospheric conditions described by the Pasquill D stability class. The downwind distances predicted for a dosage level of less than 1 organism-minute per liter range from less than 16 meters at all biological decay rates examined.

Table A9-10 summarizes the distances downwind predicted for the scenario described in Appendix X of the DPG BATF DEIS using DPG diffusion parameters. The distances which were predicted for conditions of no biological decay are essentially the same as thise reported in Table X-1 of the DPG BATF DEIS. DPG distances reflect the higher levels of organisms used in testing the efficacy of biological detectors and protective equipment at the Baker Laboratory of DPG. Significantly lower levels of organisms and consequently lower levels of potential releases would be expected for maximum credible events developed for the research laboratories participating in the BDRP at the other primary sites and all of the secondary sites.

3.4 DISCUSSION

It may be concluded that getting an infectious aerosol past the multiple and redundant safety constraints incorporated into a well designed BL-3/BL-4 laboratory is most difficult. Even the release of an aerosol directly into a nighttime environment while ignoring the presence of existing safety provisions, would produce only limited downwind hazard. This is because the concentrations of infectious material used in defensive aerosol studies are low. For example, biomedical studies employ aerosols that routinely contain between 10^3 and 10^5 (1,000 to 10,000) infectious doses. Rarely does the aerosol concentration reach the upper limit of 10^5 infectious doses. Even under the combination of the worst accident conditions and optimum meteorological conditions for transport, such aerosol concentrations of organisms are simply not hazardous beyond a few meters (25 to 30). An aerosol containing 10^8 infectious doses would create a greater concern, since under idealized conditions a released cloud would remain infectious after 1,000 meters of downwind travel. This concentration, however, is 1000 to 10,000 times greater than those concentrations used in defensive biomedical studies. It is therefore safe to assume that the BDRP studies are conducted with a safety margin of at least 1000-fold. Moreover, in the scenario just discussed (aerosol escape from a BL-4 laboratory) the assumption was of a release of preformed aerosols into the environment, which deliberately ignores the presence of all building safeguards; i.e, negative pressure, biosafety cabinet filters, and laboratory exhaust filters.

The Dugway Proving Ground DEIS (1) for a Biological Aerosol Test Facility describes, in relation to future use of th4 proposed BATF facility, the "worst-case scenario" release of *Coxiella burnetii*. However, in that scenario, there is an implied assumption of 100% aerosolization efficiency, and a stated assumption of 1% (a very generous estimate) escape of the

aerosol as a result of one or more mechanical failures of the facility or equipment. As was indicated in the BATF DEIS (1), the occurrence of the scenario as presented would be nearly impossible. Moreover, the aerosol more likely would be released to the outside, not as a single burst but probably over five minutes or more, reflecting 12 changes of laboratory air per hour. If air flow to the laboratory has been stopped, then the aerosol would escape even more slowly to the outside through diffusion, perhaps over 24 hours. Thus, the use of $3x10^8$ units of *Coxiella burnetii* for an estimation of infectious aerosol release greatly exaggerates the postulated MCE, and as was stated in that document (1), it was not a "reasonably forseeable event."

The information presented here does not imply that infectious aerosols are not dangerous. Indeed they are. This is dramatically illustrated by the outbreak of Legionnaires disease in Philadelphia, PA, in July 1976 (28). The causative organism, a bacterium normally found in soil, was uprooted from its environment by digging equipment located about 50 yards from the air intake of the Bellevue Stratford Hotel air conditioning system. Subsequent investigation demonstrated that the organism was present in water in the evaporative condenser of a malfunctioning air-conditioning system. Of the several thousand people who were known to have been inside the hotel during an American Legion convention, 182 became ill, and 29 died. Hotels are designed to accommodate people with the amenities of life and do not assume hazards are present; BL-3 and BL-4 laboratories are specifically designed to contain biohazardous agents and their aerosols. The Legionnaires organism, unlike organisms studied within BDRP, has peculiar nutritional adaptations, i.e., the ability to metabolize the limited organic and inorganic nutrients found in the water evaporation condenser of an air conditioning system and replicate. Under similar conditions, organisms used in the BDRP, to the contrary, do not replicate, but rather undergo rapid biological decay.

In conclusion, the BL-3/BL-4 laboratory is well designed to contain laboratory accidents, including the release of infectious aerosols. Personnel who work directly with these agents will continue to be in an "at-risk" category; however, other laboratory employees such as administrative and support personnel are not "at-risk." Neither is the general population nor the environment.

4. Other Possible Modes of Release of Organisms From Facilities

Establishment of a new enzootic disease in wildlife would require a susceptible population large enough to sustain a transmission chain, to establish persistent-nonlethal infections in appropriate host animals, and/or to establish infections in the presence of competent vectors. For animals to serve as a environmentally significant reservoir of disease it is necessary for transmission of infection to either their offspring or to other members of their species, other species, and/or vectors.

4.1 Infected Rodent

The design and construction of a BL-3/BL-4 laboratory makes it virtually impossible for an infected laboratory animal to escape into the environment. The occurrence of this remote event would require the simultaneous breakdown of multiple controls and barriers. The infected animal would first have to escape from its cage. Special cages designed to withstand daily handling, washing, and decontamination while maintaining their shape are used to house animals. Daily inventories are performed by both animal care and professional personnel. These checks reduce the possibility that a missing animal would be undetected. If an animal overcame the insurmountable odds, got out of its cage, and was loose in the laboratory, it would have difficulty in leaving the animal room and gaining access to the suite corridor, even if it should attempt to do so. Animal room doors are specially fitted to block escape. Moreover, the doors open toward the inside of the room, which minimizes the chances of an animal escaping when the door is opened. If the animal should gain access to the suite corridor, several additional barriers prevent its escape. The autoclave and the emergency exit are both sealed, and the airlock doors are also specially fitted. The corridor of a containment suite (Figure A9-1) is approximately 90-feet long. All doors along the corridor close automatically in order to maintain proper air balance relationships. If an infected animal gained access to the suite corridor, it would have no place to go. The door to the "dirty" change room would have to be negotiated. If this obstacle were overcome, then it would have to pass through the shower stall (which has high ledges on either side) and negotiate the door to the clean dressing room, and the door to the clean hallway. These doors, like the animal room door, are specially fitted to prevent rodent escape. Gaining access to the clean hallway of the facility does not guarantee that the animal will reach the outside. It would have to travel anywhere from about 50 to 250 feet down a hallway to reach an outside door. Most outside doors are either locked or manned by security personnel. If the integrity of even a single control barrier prevails, the animal would not be able to leave the facility. All loose, unidentified, and uncaged animals are contained immediately upon siting.

If an infected animal managed to overcome the barriers described above and escape to the outside, it would face another series of insurmountable hazards. Most small experimental animals (mice, rats, hamsters, and guinea pigs) used in biomedical research have been specially bred in order to provide uniform experimental data. Selectively bred animals give more uniform responses to experimental manipulations but only at considerable expense of survivability in a hostile environment. Since the animal has always been maintained in an ideal environment of temperature and humidity, and has always been provided water and proper nutrition, it simply does not have the experience or genetic hardiness to fend for itself outside the laboratory. In practice, loose animals stay near their cages where they can find food.

Outside the building, the natural environment is extremely hostile to a laboratory-bred animal, and survivability may be measured in hours to days. Outbred animals, while more hearty and healthy than their inbred counterparts, have also led a pampered life. Their sudden escape to the outside would also create severe problems of survival. Thus, the probability of an escaped laboratory animal reaching a populated animal reservoir and making intimate contact with a susceptible host is quite low. A "successful" escape also assumes that the infected animal would be both healthy enough to overcome all of these obstacles, and yet sick enough to be infective. Animals that do not die as a result of an infection often become incapacitated to varying degrees, which would further limit their ability to venture forth from a laboratory.

Even if an animal did escape a laboratory, the inhospitable environment and the low susceptible indigenous animal population would probably not be adequate to establish epizootics of disease. Transmission of disease from an infected animal to other animals by carnivores and birds is remotely possible, although predators and scavengers are generally resistant to the diseases of their prey.

The complete sequence of failures required for an infected animal to escape its cage, the animal room, the suite corridor, the "dirty" and clean change rooms, the shower and finally, the hallway of the building to the outside, is quite remote. The event becomes even more remote because the integrity of only one functioning control barrier would negate the escape. The discussion presented here is supported by the actual operational experience of the Biological Warfare Laboratories, Fort Detrick, from 1943 to 1969; that is, during 26 years of research and development in which tens of thousand of laboratory animals were infected, there was not <u>one</u> instance of an infected animal escaping from the laboratory and causing an adverse impact on the environment (see Appendix 8). If the chance for an animal to cross each of these barriers is assumed to be 1 in 100, and this is much better than the actual chance for some barriers, then the chances of a mouse to get completely outside is about 1×10^{-14}, or 0.00000000000001.

4.2 POTENTIAL FOR THE ESCAPE OF ARTHROPODS

Arthropod-borne diseases remain one of the principal causes of human morbidity and mortality in the world. In order to develop therapies or preventive measures for these diseases, it is necessary to have a better understanding of how they are transmitted in nature. Thus, arthropods from various locations throughout the world are studied to learn more about how they are involved in the disease transmission cycle. The presence of exotic and potentially infected arthropods in the laboratory raises concern for the possibility of their escape from the laboratory and introduction into the local ecosystem.

There are several possible scenarios in which potential infected vectors could potentially escape from the laboratory into the local ecosystem. These include escape of uninfected mosquitoes from the "cold" insectary (breeding area where no mosquitoes are infected), escape of uninfected mosquitoes during transport through the building from the cold insectary to the BL-3 suite, or escape of an infected arthropod from the BL-3 suite. Each of these will be considered separately using the insectary and arthropod studies conducted at USAMRIID as an example.

4.2.1 Escape of mosquitoes from the cold insectary:

All mosquitoes are maintained in screen cages specifically designed to prevent escape. However, individual mosquitoes do occasionally escape during routine handling procedures. Because of this, a mosquito trap that attracts and kills mosquitoes is operated continuously in the insectary. In order for an "escaped" mosquito to get outside of the insectary room, it must first avoid this trap and then get through each of the two sets of double doors between the insectary and the hallway. Because mosquitoes require a high relative humidity for survival, and the low relative humidity and rapid air movement in USAMRIID general work areas greatly reduce their survival, it is unlikely that any mosquitoes would survive for very long in general hallway areas. However, if one mosquito managed to escape into the hallways, it would still have to negotiate a minimum of three additional doors (including at least one where it had to go against the airflow due to the pressure system in use at USAMRIID) before it reached the outside. Thus, it is extremely unlikely that any mosquito could survive long enough to escape from USAMRIID or any other similarly designed facility.

Even if one managed to do so, unless it escaped during a season that was conducive to mosquito survival, it would not live long enough to be able to reproduce. In addition, it is extremely unlikely that a single escaped mosquito, or for that matter several mosquitoes, would be able to establish themselves in Frederick County, as daily mortality is high and the mosquitoes would have to be able to find a suitable site for egg deposition. In addition, these eggs would have to be fertilized (note, like animals, mosquitoes must mate with their own species in order to produce viable offspring.) After hatching, the larvae must survive, and the resulting adults would have to find each other if there were to be a next generation. As a final consideration, none of the mosquitoes maintained in the (cold) insectary are known to be infected with any virus that can infect a vertebrate animal or human, and nearly all of the species maintained there are currently found in the United States. The few exotic mosquitoes maintained in the insectary are not known to be able to transmit any disease that cannot already be transmitted by local, indigenous mosquitoes.

4.2.2 Escape of mosquitoes during transport to the BL-3 Suite:

While the potential for mosquitoes to escape from the insectary and establish themselves in the natural environment is very low, the transport of mosquitoes (usually 200-300 per cage) from the insectary to the BL-3 Suite bypasses several of the barriers mentioned earlier. To reduce the possibility of accidental escape, the mosquito cages are carried inside a sealed plastic bag. Although it is not likely to occur, one possible scenario for mosquito escape would require that a person transporting mosquitoes fell in such a way that they crushed, and thereby ruptured the plastic bag holding the mosquito cages at the same time that they crushed the cage itself. While most of the mosquitoes would still be trapped in the cage or the remnants of the plastic bag, some of the mosquitos could potentially escape into the hallway. However, as described above, it is extremely unlikely that any of these uninfected mosquitoes would survive long enough to escape from USAMRIID, or if any of them did manage to make it outside, that they would be able to establish themselves in the outdoor environment. Such an accident and consequent break of bag and cage have never occurred at USAMRIID.

4.2.3 Escape of potentially infected arthropods from the BL-3 Suite:

Because escape of a virus-infected arthropod not only poses the threat of an alteration of the ecological balance due to the introduction of a new species, but also may serve as the means of introducing an exotic disease into the environment, special precautions are taken to prevent the escape of potentially infected arthropods. As in the insectary, it is always possible for an arthropod to escape from its cage during routine manipulations. However, it is Standard Operating Procedure to suspend work and to find and capture or kill any unaccounted for arthropod if it is potentially infected. If a mosquito were to escape unobserved, it would have to negotiate a minimum of six doors or barriers (nearly all of which would also require the mosquito to fly against the airflow due to the pressurization pattern in the suite) before that mosquito would escape to the hallway. The low relative humidity and rapid airflow in the suite would greatly reduce mosquito survival, and there are two mosquito traps operating at all times to further reduce the likelihood of mosquito escape. Thus, it is extremely unlikely that even a single potentially infected mosquito could survive and escape from the containment suite to the hallway.

In addition to mosquitoes, ticks (including exotic species) are studied in BDRP activities conducted at USAMRIID. While ticks can't fly, they are much less susceptible to adverse environmental conditions than are mosquitoes, and they have the potential to survive for more extended periods of time.

To prevent a tick from escaping from a containment laboratory, all studies with ticks are conducted in a special laboratory. This room has a raised door threshold and the entire doorway is ringed with a substance known to entrap ticks. As a further precaution, ticks are only handled on a special table designed to prevent tick escape. The table has a built in "moat" around the edge containing the tick-trapping substance. No ticks have ever been observed in the suite outside of the tick laboratory room, and it is extremely unlikely that a tick (which cannot fly) would be able to escape from the suite under its own power. The three most likely ways in which ticks could potentially escape from a laboratory, include: 1) a tick escapes unnoticed from its sealed cage and crawls out of the suite, 2) a tick attaches unnoticed to the clothing of one of the laboratory workers and is carried out of the suite, or 3) a tick escapes unnoticed into the bedding of one of the animal cages and is discarded from the suite.

All personnel working with ticks are trained to conduct routine examination of themselves and their fellow workers for ticks. In any case, all clothing worn in the containment laboratory is autoclaved before it is removed from the suite. Also, personnel check themselves in the shower for any attached ticks. None has ever been found.

During experiments where ticks are allowed to feed on an infected animal, it is theoretically possible for a small number of ticks to drop from the animal and to hide in the bedding of the cage. If this material were inadvertently removed from the suite, there would be potential for the ticks to escape. However, after each such experiment, the animals are removed and each cage is sealed in a plastic bag and frozen at -70°C to kill any ticks that might have escaped into the bedding. The cages and bedding are then autoclaved in accordance with the routine procedures for removal of such materials from the containment laboratory. This is believed to be totally effective in killing any tick (or organism).

Procedures for operating both the insectary and for maintaining arthropods in the BL-3 containment suite have been approved by the Animal and Plant Health Inspection Service of the United States Department of Agriculture. Thus, because of the handling procedures used, multiple barriers, and autoclaving of all material out of the suite, it is extremely unlikely that any potentially infected arthropod could escape to the hallway, much less manage to escape outside of USAMRIID.

4.3 Terrorist Scenario

In consideration of a terrorist (saboteur) act on a facility associated with the BDRP, several facts and assumptions need to be stated: seed cultures of high hazard infectious organisms are stored in secure facilities to which access is closly controlled, and terrorist acquisition of them is an improbable event. The

act of a disgruntled employee would require the collusion of one or more specific co-employees. Only milliliter (ml) quantities of seed stocks of highly infectious organisms exist. Quantities of working cultures are small (10-100 ml) and vary with the requirements of a given study. Working stocks are secure within BL-3 and BL-4 containment suites, which require special access privileges, the record of which is traceable. A disgruntled employee with access to a particular suite could potentially accomplish surreptitous removal of a culture. However, without immediate refrigeration, special incubators, or frozen storage, biological decay would rapidly degrade the infectivity of the organisms, and physical decay could impair the physical properties required to disseminate the organisms. The quantities of toxins on hand are small and toxins do not reproduce themselves. One might also logically assume that an act of sabotage would be covert, because detection or discovery of the sabotage act would activate corrective measures and defeat the motives of the terrorist.

4.3.1 Types of Potential Sabotage Actions:

4.3.1.1 Damage to one or more containment features:

For a deliberate removal of a filter in Class II or III biosafety cabinetry and/or tampering with BL-4 laboratory access in an attempt to decrease the level of safety or containment, at least two filters, (usually three filters) would need to be rendered ineffective. Such an act would also require specific knowledge of both biosafety containment and facility design in order to know what to do, and would require specific knowledge of the particular system and facility targeted. In most facilities, built in sensors and security systems would detect alterations of filter effectiveness (through monitoring of air pressure balances) and quickly render the action ineffective. Ultimately, this action really would not cause a major risk to the outside environment, because a) the quantities of agents in use are low, b) the quantity that might become airborne is a small fraction of the total and c) the organisms would not be spread more than a few meters, from air exhaust stack (see MCE discussions). In the case of a biosafety cabinet, damage to the filter might result in added risk to employees working in the suite.

4.3.1.2 Damage to containment suite autoclaves:

To accomplish this action, the saboteur would need to tamper with or adjust recorders and indicators to indicate "successful autoclaving" at the same time that the autoclave was rendered ineffective. It would require very precise knowledge of the autoclaving system and the electronics/sensors of the monitoring system. Special non-electronic indicators (inspected with every autoclave load) would still indicate failure of autoclaving unless the indicator devices were also tampered with. In this case, the person loading or inspecting the autoclave load would have to be working in collusion with the saboteur (e.g. an inside

job) as well. Many different people use any one autoclave. Therefore it is highly likely that even an "inside job" would be detected quickly. Most items leaving a containment laboratory e.g. cultures, glassware etc., are also partially or completely chemically decontaminated before autoclaving; thus, even if the sabotage were successful, it would have minimal consequences for these items. If despite all precautions, the terrorist (sabatoge) act on the autoclave were successful and undetected, the primary risk would be to glassware and cagewash personnel, and that risk would be minimal. Contaminated dead animals and animal waste, in this circumstance, potentially would pose the greatest risk, and these are incinerated after autoclaving. Thus, even if autoclaving were bypassed and failed to kill or inactivate hazardous organisms, the dead animals and animal wastes would be incinerated and ultimately not constitute any significant environmental hazard.

4.3.1.3 Deliberate release of infected animal or deliberate self-infection with intent to create spread within environment:

This scenario would not apply to toxins because they do not replicate. The release of animals (or a person) infected with a BDRP-related bacteria would not constitute a major environmental risk because animal to animal, man to man transmission would be minimal, if it occurred at all, and the disease would not be self-pepetuating (See paragraph 6 below and Appendix 7). Therefore, such a deliberate release would not be a successful means of dissemination. The release of animals (or man) infected with rickettsia, without further action, (e.g. deliberate replication and an alternative means of dissemination) would again be self-limiting and not of great concern. Dissemination to the environment of a disease carried by a rodent infected with viruses transmitted by insect vectors would require the right vector for the particular virus. This would also need to be the proper vector that naturally feeds on the animal or man. The virus would also have to produce a sufficient viremia in the infected subject for infection of an insect vector to occur. Such viremia would either occur for a short period before death, or the virus would need to be such that a high viremia without death would develop in the animal. Somewhere in this cycle, the virus would need to get from the rodent to man via an insect vector or other hosts, and this transition also would require the right set of vectors at the right time.

It would require an extremely knowledgeable person to select an infected rodent at right stage of the right infection, and to release it where the appropriate vectors exist. Still, it is highly improbable that one laboratory animal (or a few) could initiate an epizootic. All in all, this constitutes a most improbable sequence of events. Unless a "terrorist" would infect himself, and then station himself in the right location, thereby being a "feeding station" for the right insect vectors, and do so without being too ill to continue, this scenario too is rather

improbable. Normally, individuals who become infected would seek medical attention and the disease would be self-limiting. Also, the viral diseases of concern to the BDRP are not the urban, communicable, man-to-man transmitted diseases but the "field," endemic diseases that are transmitted to humans by animal and/or insect vectors.

Animals (or man) infected with a virus whose primary means of transmission is by aerosols from dried body secretions represent another consideration. In this scenario, man is an unlikely participant in the transmission of such a disease. There are no known epidemics of viruses studied in the BDRP that occur through this mode of transmission. Laboratory-reared rodents do not survive well in non-laboratory settings; the chance of survival would become even smaller if the animal were infected. The released rodent would need to travel immediately to an area frequented by wild rodents. The rodent's secretion/excretions (saliva, urine, feces) would need to be concentrated in a very small area to develop a critical mass of virus capable of becoming aerosolized. Also, a variety of environmental conditions, such as soil type, temperature, and humidity would have to be suitable for survival of the virus. Again, this represents a very unlikely sequence of events.

4.3.1.4 Steal vial of organisms for release to outside environment:

Suppose a terrorist removed a sealed vial of virus and was not caught. The quantities in sealed vials are small, on the order of one (common) to ten ml (rare) (one thirtieth to one third of an ounce). If the terrorist intended to grow the organism in vitro, there are other commercial sources of seed stock, and yet one could still incriminate the BDRP as the source. Therefore, the assumption is that a terrorist is unlikely to steal seed stocks of organisms and attempt to grow them outside of the laboratory. While such stolen quantities could be adequate to infect a few individuals by conventional means e.g. foodstuffs/foodchains, this would not constitute a catastrophic public health event. The natural course of diseases produced by organisms of concern to the BDRP tend to be self-limiting in man, because they require complex transmission cycles in order to be self-perpetuating. However, a terrorist act with toxins could create secondary psychological problems which could lead to severe economic distress. For example, there is the history of the contamination of tylenol with cyanide in U.S., oranges spiked with mercury from Israel shipped to Europe, etc. Such events arouse public fear, and such fears associated with only one or two poisoning events could become significant. However, this type of risk is independent of any relationship to the BDRP. The organisms of interest require special growth media and do not multiply outside warm-blooded animals (including man) If the terrorist created a small particle aerosol, and was technologically competent, potentially more people could be infected initially, but still this would not be a runaway

epidemic because of the lack of success in man to man transmission of the disease-causing microorganisms studied in the BDRP (see Section 4.4 of this Appendix).

4.4 Disgruntled Employee Scenario

Discussion of this scenario and its attendant calculations is not intended to minimize or trivialize the serious nature of such a potential incident. Rather, it is intended to illustrate the multiple factors that would require consideration in order to arrive at a realistic estimate of both the probability and of the impact of such an act, and to place in perspective the nature of the potential risks associated with infectious organisms.

In this scenario, an employee who works in a research program for medical defense against biological warfare threats becomes disgruntled and steals an ampoule of virus. He surreptitiously sprays the virus into the air system of a commercial movie theatre. The theatre contains an audience of 75 people. Two basic questions are: does this event result in infections among the audience, and if so, how many? In other words, does the event produce an "at-risk" situation for the general population in the theatre? These two questions will be addressed by following the fate of the virus through the critical pathway of events below.

The disgruntled employee steals a frozen ampoule of Venezuelan equine encephalomyelitis (VEE) virus. The ampoule contains one ml of virus at a concentration of $1x10^9$ mouse intracerebral lethal doses ($\log_{10}9$), fifty percent ($MICLD_{50}$) per ml (see glossary for definition of dosages). (Virus concentrations are often expressed in terms of logarithm to the base 10.) On thawing the ampoule, virus concentration undergoes a 0.3 log drop in titer. The number of $MICLD_{50}$ doses is now $\log_{10}$ 8.70. Several hours elapse between thawing and spraying, and infective virus concentration undergoes another 0.3 log reduction. The number of $MICLD_{50}$ doses available now is $\log_{10}$ 8.4. The respiratory infectious dose of VEE for man is assumed to be approximately 50 $MICLD_{50}$. The number of available human infectious respiratory doses becomes $\log_{10}$ 6.7 (Log_{10} 8.4 mouse doses divided by 50). Since the employee cannot effectively spray one ml of virus solution (about one thirtieth of an ounce), the virus is diluted with tap water to obtain 10 ml (about one third of an ounce). The municipal water is non isotonic, contains chlorine, and causes a 1.1 log loss in concentration, leaving $\log_{10}$ 5.6 potential human doses. The employee purchases a hand-held (cylinder) insecticide sprayer from a local hardware store, gains access to the ventilation system of the theater, and sprays the viral suspension into the system. The spray device, although readily available, is not an efficient energy source for breaking the viral suspension into a small particle aerosol (one to five microns for maximum human infectivity), and only one percent of the total virus becomes airborne in the optimum particle size. This reduces the number

of human respiratory doses to $\log_{10}$ 3.60. In actuality, the spray can only expel 80 percent of the 10 ml originally put in, leaving $\log_{10}$ 3.50 human doses released into the theater air circulation system.

The theater is located in a suburban shopping center and is rather small, measuring 100 feet long, by fifty feet wide by 40 feet high. The theatre contains 200,000 cubic feet or 5,600,000 liters. The number of human respiratory doses per liter of theatre air is obtained by dividing the number of human respiratory doses available ($\log_{10}$ 3.50 = 3.2×10^3 doses) by liters of theatre air (5,600,000). Thus, 0.0056 doses per liter are present at the time of initial release of virus. The theatre, by law, must undergo spell changes of air per hour, or one air change per 15 minutes (many have more). Assuming a breathing rate of eight liters per minute for the average person at rest, complete homogeneity, and no decay of the aerosol during the first 15 minutes after spray release, the maximum human dose of exposure for each member of the audience would be: 8 liters x 15 minutes x 0.00056 doses per liter or 0.067 doses. A dose of 0.067 over 15 minutes exposure does not appear to represent a credible infective dose.

The first impression on hearing that VEE seed virus has been used to attack a small theatre in a suburban shopping center is that it may represent a credible hazardous event, with potential for a disaster. However, as the concentration of virus is reduced through the critical pathway of steps, the reality of the situation becomes apparent. It is highly unlikely that any member of the audience would become infected with VEE virus. The casual population of the shopping center where the theater is located is also not at any risk.

Many variations on this scenario could be postulated: the particular strain of virus stolen, the amount of virus stolen, the size of the theater or target, etc. These possibilities notwithstanding, the disgruntled employee must still meet five criteria in order make this sort of scenario even remotely possible. First, the individual must have specific laboratory training or knowledge in order to identify the "starting material" (virus). Second, the person must have access to the biocontainment laboratory in which the virus is stored. Third, and most critically, this person must have a motive. Assuming that this individual has sufficient knowledge, access and motive, he must further have knowledge of the theater ventilation system as well as access to that system and a method of aerosol delivery. Thus, the calculation of the actual human infectious doses delivered to each person in the theater must be multiplied by the infinitessimally small probability that the "terrorist" will fulfill all five criteria (knowledge-access-motive-knowledge-access) in order to arrive at a realistic estimate (probability) of an event of this nature ever occurring. On this basis, the possibility of a scenario of this type occurring or resulting in significant harm are very remote. Many other

scenarios for a deranged individual to attack segments of the population could be postulated with or without access to BDRP organisms.

5. Unexpected external event

The accidental means by which biological test materials might be released from a facility of the BDRP include laboratory-associated mechanical failures, and human errors; accidents external to the facilities (aircraft hazards and terrorist bomb, etc.), and natural disruptive phenomena (i.e., meteorite impact, windstorms, tornadoes, and earthquakes). Human error or multiple mechanical failure theoretically could lead to accidental release of biological test material. The redundancy of safety equipment and procedures, operational safeguards, and monitoring systems associated with biocontainment laboratories, and the overall excellent safety record of medical microbiology laboratories suggest that accidental release of infectious materials from laboratories to the environment as a result of such unexpected events is not a realistic risk (see this Appendix Section 6). The possibility of any of these external events happening is highly unlikely. No plausible combination of human error or mechanical failures can be conceived that would result in materials being released because of the design and redundancy of control systems, safety procedures, and mitigating and monitoring steps. For the biological material to be released, some type of catastrophic accident would have to occur, such as an airplane crash, or meteorite impact, or a terrorist bomb. The probabilities of manmade and natural disasters of sufficient magnitude to destroy a facility and release the biological materials have not been estimated, but are likely to be a very remote possiblity.

However, no matter how likely or unlikely such an event would be, the primary question is "what might occur should such an event happen." For an event that only made a hole in the exterior walls of a containment laboratory, the primary exhaust of the laboratory would still be through the filter system and all work with hazardous organisms would be halted immediately. A larger rupture resulting in breakage of vials, flasks etc would still not necessarily result in the creation of a significant aerosol release even when the activity in progress was an aerosol experiment. In this latter event, results are most unlikely to be catastrophic (See this appendix section 3). In the former, much of the liquid would spill and/or be absorbed by debris etc. and aerosolization would most likely be of an efficiency of .01% to 001% or less. Again, only the immediate surroundings would be at risk and self-perpetuation of an infectious disease to second- and third- generation cases of illness is most unlikely.

A catastrophic event might also result in fire and explosion. Small fires that are brought under control would not be of a concern with regard to the release of the test materials, even if a test were underway at the time of the fire. The test

would be immediately terminated at the discovery of the fire, and appropriate safety measures taken to assure zero release of the infectious or toxin material while the fire was being contained. If the fire became so large that structural damage occurred, with concomitant damage to the biosafety cabinetry and laboratory chambers, then the heat would destroy any pathogen or toxin, thereby precluding its spread and release from the facility. Thus, fire is not a credible hazard with regard to the potential release of infectious biological materials or toxins.

6. DISCUSSION

Under the normal operating conditions of BDRP-associated facilities, no scenario, however likely or unlikely, presents a significant threat of accidentally releasing test materials to the environment outside the facility. Historically, defensive studies have not addressed the organisms responsible for communicable diseases because these organisms were not considered to be potential biological warfare threat agents. Toxins may be produced by living organisms but they are not living themselves, and do not multiply like organisms. The MCE's described in this appendix focused on the accidental release of organisms or toxins in the form of aerosols because this pathway or mode of transmission represents the greatest theoretical risk to the environment. Most of the organisms and toxins of concern to the BDRP are considered to be potential biological warfare threats because of their potential for acute effects when delivered by a small-particle aerosol (for a more comprehensive discussion on characteristics of biological warfare threat agents, see reference 29).

The MCE scenarios for aerosol transmission assumed F(stable) or D(neutral)(30) meteorological conditions, because unstable atmospheric conditions rapidly fragment and disperse an aerosol cloud, diluting it and rendering it harmless. Air turbulence also greatly hastens the killing of live organisms by drying, air pollutants, etc. It is important to note that atmospheric conditions D & F are not the common day-time meteorological conditions, when most if not all of the activities associated with the theoretical MCEs are performed. Rather, D and F conditions are more likely to be present at night or very early dawn.

The accidental release of organisms into "contaminated liquid effluent" was not considered a substantive MCE. Aside from the operational controls on liquid effluent, including steam sterilization of contaminated wastes where BL3/4 agents are under investigation, most if not all organisms of concern to the BDRP do not pose a serious risk through movement into the surface water as they do from aerosol releases. These organisms do not multiply in water. They require insects, warm-blooded animals (including man), living tissue, or special supplemental media (some bacterial organisms) to survive and replicate. Most are very labile in the natural environment. In the event of the

release of an organism to the liquid waste stream, the initial concentration would be diluted immediately by sewage wastes to levels below their threshold of infectivity. For most of the organisms studied in the BDRP, the infective dose for man or animals by ingestion, if it exists at all, is much greater than the aerosol infective dose. These factors notwithstanding, great effort is devoted to safety controls to assure the public and the environment that no infective waste will reach the effluent stream.

If one were to discharge a vial or flask of hazardous organisms or toxins on the ground, pavement etc., except for whatever miniscule quantity might initially disseminate in the immediate area (measured in feet), no lasting threat to the health of animals or man would ensue because the organisms or toxins would quickly be killed or inactivated by unfavorable environmental conditions. One exception would be anthrax spores, which could survive possibly for years in soil, but these could be readily decontaminated in limited areas. Even with no special efforts to decontaminate, the spores would be most unlikely to spread, would not multiply, and based on the experience of the British with Gruinard Island, likely to decrease in number.

6.1 BIOLOGICAL PATHWAYS

The infectious microorganisms studied in the BDRP multiply in warm-blooded animals and normally are transmitted to man only by secondary means. These organisms have biological pathways that are important in determining the success of transmission and perpetuation of disease spread.

Essential to an understanding of these pathways is a consideration of certain characteristics of the infectious, disease-causing organisms and of their corresponding clinical infections, which determine the possible channels of transmission. The more important of these are:

1) The route by which the infective organism enters the body.

2) The route by which the infective organism leaves the body.

3) The resistance of the organism to the deleterious effects of the outside environment.

4) The presence or absence of an intermediate host or vector.

On the basis of such fundamental information, infectious diseases can be categorized on the basis of the normal epidemiological pathway of the disease as follows:

1) Diseases of non-primates transmissible directly from animal to man:

a) By direct contact; tularemia is an example and is studied in the BDRP.

b) By aerosol, infective, dried excreta/secreta, or body fluids. Arenaviruses, hantaviruses, and anthrax are examples and are studied in the BDRP.

2) Diseases of animals or man transmitted by insect vectors in which:

a) The insect serves as mechanical vector; typhoid fever is an example - but the causative organism is not studied in the BDRP, nor are any other organisms which are transmitted by this pathway.

b) Organism multiplies in the insect vector.

Man-vector-man; dengue fever is an example, but is not studied in the BDRP, nor are any other organisms which are transmitted by this pathway.

Animal-vector-man or animal; Venezuelan equine encephalomyelitis is an example and is studied in the BDRP.

c) Organisms transmitted from one insect generation to next by egg-infection; Rocky Mountain spotted fever is an example, but it is not studied in the BDRP.

d) Organism undergoes a portion of its life cycle in the insect; malaria is an example but it is not studied in the BDRP, nor are any other organisms which are transmitted by this pathway.

3) Diseases of animals or man transmitted indirectly by food, water, fomites; typhoid fever and cholera are examples, but they are not studied in the BDRP, nor are any other organisms which are transmitted by this pathway.

4) Diseases of man transmitted directly man-to-man; respiratory and venereal diseases are examples, but they are not studied in the BDRP, nor are any other organisms which are transmitted by this pathway.

The above discussion illustrates the pathways of disease transmission in naturally occurring epidemics. All of the infectious agents studied in the BDRP can be transmitted to man by the creation and spread of a small particle aerosol. Such conditions are an inherent risk to laboratory workers, and considerations of this risk were instrumental in the development of the principles of biological laboratory safety and containment (7). The perpetuation of disease-causing organisms studied in the BDRP through a man-to-man cycle by aerosol transmission (or

any other man-to-man route) to produce an epidemic has not occurred in modern history. Man-to-man transmission theoretically can occur and has occurred (for example, nosocomial transmission of Ebola fever), but such episodes have been rare and self-limiting.

6.2 Purposeful release

An act of sabotage that would cause purposeful release of material from a BDRP facility is always a possibility, albeit remote. However, even the purposeful release of material outside of a containment laboratory area is unlikely to result in human or environmental exposures beyond a small and finite area, and then for only a short period of time. The worst-case situation would clearly be the deliberate release of material to the outside environment. Even then, few secondary cases would be anticipated, although there is frequently a relatively high rate of nosocomial transmission in emergency care situations. Direct man-to-man transmission is not common for the disease-causing organisms currently studied in the program.

Generally speaking, any BDRP disease that reached humans or animals would be acute, as opposed to persistent, and would not be transmitted or become established in the environment. Even in the face of all postulated variations on the themes of escape of an organism and transmission, the inherent controls (see 3.3, and Appendices 11, 12), facilities design, and operational practices employed in the studies of infections organisms, make the escape of an infected rodent or vector a most unlikely event. The limited survivability and reproducability of these hosts and/or vectors in external environment further adds to the improbability of adverse impacts on the environment arising from the BDRP. The release or "escape" of any potentially hazardous biological materials from a BDRP laboratory would require the sequential failure or circumvention of multiple safety devices or procedures. For any given facility or situation, the probability of such a concatenated series of failures is infinitesimally small, certainly less than $1x10^{-6}$ (one in a million) and probably $<1x10^{-12}$ (one in a trillion).

6.3 Evacuation plan consideration

There are no mass evacuation plans formulated specifically with reference to the BDRP. Moreover, there is no identified need for special evacuation plans tailored to the existence of BDRP sites, because the quantities of infectious organisms or toxins on hand, their environmental lability and the limited scope of impact of even the largest potential "escapes" or "releases" do not warrant the development and implementation of such public policies. For any plan that would be developed or implemented specifically for the BDRP, there is far greater likelihood of casualities or impacts as a consequence of carrying out the evacuation plan itself than there is from any accident, incident, or release of biological materials from a BDRP

facility. In addition, such a plan potentially could cause public concerns that would be grossly out of proportion to the actual risks at hand.

In contrast to the potential effects of radiation released from a nuclear power plant, or of toxic chemicals released from a factory or storage tank, the potential effect of exposure to most of the organisms and toxins studied in the BDRP is debilitating illness, rather than death. In addition, the quantities of potentially hazardous biological materials stored or handled in any given BDRP facility are minute in comparison to the quantities of radioactive materials at a power plant, or chemicals at an industrial site. Another significant difference between the effects caused by infectious organisms and those caused by massive exposure to radiation or chemicals, is that the infectious diseases studied in the BDRP do not affect the human germ line, and do not perpetuate themselves from generation to generation. Unfortunately, some of the most noticeable effects of inappropriate radiation or chemical exposure are believed to be on the offspring of the exposed individual.

7. CONCLUSION

The BDRP, and the biological materials used in the program, do not pose a significant threat to the general population. Only small quantities of materials are used in defensive studies. There are multiple, rigorous, and adequate controls implemented at BDRP facilities where hazardous biological materials are used. Whenever possible, the workforce is immunized or vaccinated for protection from the organisms or toxins studied. The transmission of diseases of the type studied in the BDRP from person-to-person is a rare occurrence; the diseases studied are not communicable. Even in the extremely unlikely event that an infectious organism or toxin were "released" to the environment from a BDRP facility, the effects of such a release would be localized in time and place, and would in no way cause pervasive, catastrophic consequences to the human environment.

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APPENDIX 10: GENETIC ENGINEERING AND PUBLIC CONTROVERSY

1. Introduction

2. Accidental Cloning Experiments that Yield a Hazardous GEM

3. Public Controversy

4. Cited Materials

Appendix 10: GENETIC ENGINEERING AND PUBLIC CONTROVERSY

1. Introduction

Deoxyribonucleic acid (DNA) is the molecule, located in every cell of an organism, which carries the information for the synthesis of structural, regulatory, and biosynthetic proteins. Enzymes are proteins that catalyze reactions, involved in the pathways of biosynthesis and metabolism, which are required for the maintenance and reproduction of life. The identification of regions on the DNA molecule which contain specific nucleotide sequences (genes) that code for particular proteins is performed readily in the research laboratory. These regions can be physically isolated and excised from the parent DNA molecule with special enzymes. This DNA can be reattached to DNA (vector) from another organism (host). This resultant, new DNA molecule is recombinant DNA (rDNA). The host-vector (HV) system is selected for its capability of reproducing while carrying the foreign DNA and expressing both its own proteins and potentially the foreign protein. The host organism containing the rDNA is usually a microorganism (bacteria or virus) and is referred to as a genetically engineered microorganism (GEM). The development of genetic engineering technology quickly followed the first successful transfer of DNA from one organism to another in 1973 (1)

Genetic engineering approaches have been applied as modern research tools for understanding the molecular biology, genetics, pathogenesis, biochemistry, and immunology associated with disease processes. This new biotechnology has applications in vaccine development, drug discovery, and diagnostic reagent development in the BDRP, as it does throughout the medical/pharmaceutical industry (2-4). For the study of several protein toxins and of potentially protective proteins or glycoproteins from many of the hazardous bacteria, rickettsia, and viruses, genetic engineering techniques are employed in the BDRP to identify, isolate, and clone the appropriate gene which codes for the protein of interest. Genetic engineering affords new opportunities for the study of structure, function, and mode of action of these proteins. The use of this biotechnology in the BDRP is no different than its use in most universities, medical centers, and research institutes devoted to biological and biomedical research and development.

In the BDRP, all research protocols involving GEMs must be forwarded to the appropriate Institutional Biosafety Committee (IBC) for review. Each primary and secondary site performing GEM-related research must have a properly constituted IBC. Notices of IBC approval from the secondary sites are submitted to the contract management offices of the primary sites prior to contract award. Review by the IBC may identify proposed experiments for which the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (5)

require submission to the NIH Recombinant DNA Advisory Committee (RAC) for further comment or approval. The NIH RAC is the public advisory committee on rDNA activities, and is chartered to advise the Secretary of the U.S. Department of Health and Human Services (HHS), the Assistant Secretary for Health, and the Director of the NIH. The NIH RAC is responsible for carrying out the functions specified in the NIH Guidelines. It is composed of 25 members appointed by the Secretary, HHS. At least fourteen of the members are selected from authorities knowledgeable in the fields of molecular biology or r DNA research, and at least six are knowledgeable in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields. Proposed research protocols must receive favorable IBC or NIH RAC review before they are allowed to be initiated, and then only under the specific physical containment (see Appendix 12 in this EIS) and biological containment conditions recommended by the IBC or NIH RAC.

Biological containment, as opposed to physical containment, refers to the selection or construction of a host-vector combination such that the survival of the vector in a host outside the laboratory, and the transmission of the vector from a host to non-laboratory hosts, have an extremely low probability of occurrence. A biological host is the bacterial species chosen for propagation of rDNA molecules. In GEM experiments, the biological vector is either a small, circular, extrachromosomal DNA molecule (plasmid) or a virus particle (bacteriophage) which infects the host microorganism. The plasmid DNA or the bacteriophage DNA contains the cloned fragment of foreign DNA. As the host bacteria divide, the r DNA from the vector is propagated simultaneously.

There are potential hazards in using vectors for molecular cloning of DNA fragments from one organism or species into another organism or species to form a GEM. Potential hazards, such as novel genetic combinations or constructions that have never before existed, may result in a certain degree of unpredictability for the system. The environmental fate of the GEMs in accidental releases would be governed by several factors. A GEM's multiplication rate, capability of survival, or change in pathogenicity and ecological potential could conceivably result in unpredictable effects on the biosphere. Biological containment provides the means for controlling these potential hazards. The relative probabilities for occurrence of these potential hazards are considered to be very small, and employment of biological containment reduces these already small probabilities to insignificant levels (6-13).

Two biological containment levels (HV1 and HV2) are specified in Appendix I of the current NIH Guidelines. HV1 provides for a moderate level of containment HV2. provides a high level of containment. The safety of the recommended HV2 systems have been demonstrated in laboratory tests which confirm

that escape of GEMs by either survival of the GEM or transmission of its r DNA to other organisms occurs at a rate of less than one in 10 organisms (i.e., less than one in 100 million) released to the non-laboratory environment (14-16).

2. Accidental Cloning Experiments that Yield a Hazardous GEM

Other than deliberate violations of the NIH Guidelines and institutional policies, which would be detected by scientific peers and IBC review, the only credible possibility of creating a hazardous GEM would come from an inadvertent cloning of DNA for a potentially hazardous gene from a hazardous organism. For the "inadvertent cloning scenario," a cloning experiment is proposed which results in the creation of a GEM that expresses a toxin with an LD50 of less than 100 nanograms per kilogram. This scenario assumes that the NIH RAC had approved of a cloning experiment under specific containment conditions, and that an error in the conduct of the specific laboratory procedures of this approved cloning experiment result in the creation of a potentially hazardous GEM. In this scenario, the use of a hypothetical organism that expresses a toxin is proposed, and this organism is one that requires BL4 level containment according to the Centers for Disease Control hazard classification of etiologic agents (17,18).

The expected result of the approved cloning experiment would have been the creation of a GEM, under specified physical and biological containment conditions, which expresses a nonhazardous, but biologically important, gene fragment. The actual result of the error committed in this scenario would be the isolation of only a potentially hazardous GEM. Such a cloning experiment should involve DNA isolation, cloning, propagation, and screening under high physical and biological containment conditions, movement of the non-hazardous clone from high to low physical containment, and subsequent studies on the non-hazardous clone under low physical and high biological containment conditions. If there were an error in one of the experimental procedures, then the result would be the hypothetical isolation and cloning of the wrong DNA fragments into an approved host vector system to create a potentially hazardous GEM. A problem would only arise in the movement of this GEM from the highest level of physical containment (BL4) to the lowest level of physical containment (BL1) for subsequent studies. Although screening for toxic properties is routine and mandated by the NIH Guidelines, the possibility does exist for an accidental exposure of the laboratory workforce to the potentially hazardous gene product that was cloned accidentally, or accidental release of the GEM to the environment. However, the potential result of this scenario is the creation of a hazardous organism no more dangerous than the parent organism. AS such, the consequences are no different than those developed in the scenarios of Appendix 9.

The current NIH Guidelines are designed to prevent the deliberate creation and environmental release of hazardous GEMs which may express harmful polynucleotides (infectious organism) or harmful polypeptides (protein toxins or pharmacologically active peptides). The Guidelines include specific prohibitions on the deliberate cloning of genes for protein toxins or genes for the biosynthesis of toxic molecules which are lethal to vertebrates at an LD50 of less than 100 nanograms per kilogram body weight without public notification in the Federal Register, formal consideration by the NIH RAC and its Ad Hoc Working Group on Toxins, and final approval by both the Director of the NIH and the local IBC. Cloning of genes for those proteins lethal to vertebrates in the LD50 range of 100 nanograms to 100 micrograms per kilogram body weight, under the specified physical and biological containment conditions, are approved as described in Appendix F of the NIH Guidelines. The RAC Working Group on Toxins provides additional information (l9) to serve as a guide for investigators in planning rDNA experiments and for IBC's in reviewing r DNA proposals. All BDRP activities involving the use of GEMs are conducted in accordance with the NIH Guidelines as required by DoD directive (20,21). At a minimum, review and approval by the local IBC is required for all projects using rDNA molecules.

For this "inadvertent cloning scenario" the actual procedures required to accomplish the hypothetical cloning experiment include methodologies too complex and involved to present in this appendix. Detailed discussions of these cloning methodologies can be found in laboratory manuals and textbooks on molecular genetics (22-32). Here a less technical, abridged discussion of this hypothetical experiment is presented in order to explain where, in the multi-step process of cloning r DNA and isolating a GEM, inadvertent errors could possibly occur.

The following steps are involved in a hypothetical toxin cloning experiment (each are performed at levels of physical containment required for work with the hazardous organism):

a. Preparation of DNA for Cloning Experiment

1) growth and propagation of the approved cloning vector and the hazardous organism

2) isolation and purification of DNA from the cloning vector and the hazardous organism

3) enzymatic cleavage of cloning vector DNA at a unique cloning site

4). enzymatic cleavage of DNA from the hazardous organism for insertion into the vector cloning site (a critical step)

5). isolation, purification, and screening of DNA products from the cleavage reactions (a critical step)

6). enzymatic treatment of the ends of the DNA molecules used in the ligation step to facilitate successful cloning (dephosphorylation and DNA single-strand end hydrolysis)

7) ligation of DNA from the cloning vector with the appropriate DNA fragment from the hazardous organism

b. Molecular Cloning of the GEM

1). transformation of competent E. cold K-12 cells (cell walls made permeable to the ligated circular plasmid r DNA by chemical treatment)

2). spreading of the transformed cells on nutrient agar and growth at controlled temperatures

3). selection of positive transformants (clones)

4). preparation of plasmid r DNA or bacteriophage r DNA from small scale cultures of the clones

c. Characterization of the GEM

1). screening of the cloned rDNA with a battery of restriction endonucleases and/or DNA hybridization probes to test for cloning success

2). screening of any expressed product from the GEM with a library of toxin antibodies to test for cloning success (a critical check point)

3). bioassay of GEM culture supernatants and viable cells as a test for toxicity (a critical check point)

4). identification of the physical location of the gene, coding for the toxin, in the genome of the hazardous organism.

In this experimental protocol, the two critical steps at which an inadvertent cloning becomes possible are a) the enzymatic cleavage of the non-hazardous portions of a hazardous gene from the hazardous organism, and b) the isolation and purification of DNA products from that cleavage reaction.

The cleavage step requires the choice of a special enzyme, a restriction endonuclease, which hydolyzes the DNA from the hazardous organism at the unique recognition site chosen for

ligation into the cloning vector. The selection of the appropriate non-hazardous gene region of DNA from the hazardous organism requires a prior knowledge of the gene size. This information can be obtained from biophysical studies on purified samples of the hazardous protein of interest.

If total genomic DNA from the hazardous organism is used for "shotgun cloning" experiments, a restriction endonuclease is chosen which has a recognition site that occurs frequently in a sequence of DNA. Usually an endonuclease with a 4 base pair recognition site is chosen. A complete digest of a random DNA sequence would theoretically produce the required sequence every 256 bases. This would result in the generation of approximately 9 fragments for a gene consisting of 2300 base pairs and coding for a protein of 85,000 daltons. If a limited, or partial digestion of the total genomic DNA is performed, then a family of DNA fragments is created over a range of sizes. Electrophoresis of these DNA fragments on an agarose gel allows the separation and identification of the DNA in a range of sizes. The researcher then chooses the appropriate region of the agarose gel that contains the size range of DNA fragments which precludes cloning a full length gene from the hazardous organism. This gel region is physically cut from the agarose slab with a razor blade. DNA is eluted from the gel slices and purified for the cloning experiment.

The cloning error could arise if the researcher unknowingly skips the fragment sizing and purification steps and clones larger DNA fragments in the cloning vector. Though possible, this error is not likely because a written protocol describing each step of the total experimental procedure is followed. The cloning error could also arise if the wrong size range of DNA is sliced from the gel and eluted. This would occur if the wrong DNA size standard were used during electrophoresis and the sizes of the excised DNA fragments were misinterpreted to be smaller than they actually were. Though possible, this is also unlikely because the experienced molecular geneticist knows the expected banding patterns for the DNA sizing standards normally used. These check points also represent steps where inadvertent errors could be detected readily in the screening process.

The GEM characterization steps of the protocol represent the last stages, the critical check points, at which an inadvertent cloning could be discovered prior to transfer of the inadvertent biohazardous clone from a BL4 laboratory to a BL1 laboratory for subsequent preparation of stock cultures and further study. The size of the cloning vector portion of the recombinant clone is known from prior characterization. Therefore, an evaluation of the sizes of the recombinant DNA plasmids would quickly reveal clones of a size sufficient to include the entire gene of a hazardous bioactive product. Bioassays would reveal clones expressing a viable toxin.

The hypothetical scenario describes the cloning of genomic DNA fragments into the cloning vector. DNA can actually be isolated from an organism in two different ways, by direct extraction from cells of the organism and, indirectly, by first isolating the messenger RNA (mRNA) pool from the organism and then synthesizing DNA (cDNA) from these mRNA molecules. If all of the cDNA prepared from the total mRNA pool of the organism is used for cloning experiments ("shotgun cloning"), every expressed gene of the organism should be selectable from the library of clones. The ends of the cDNA used in "shotgun cloning" experiments are treated so that they can be linked enzymatically into the vector of choice, which may be a bacterial plasmid or a bacterial virus (bacteriophage).

For the experimental protocol using cDNA, the cDNA for an entire gene coding for the hazardous protein would be cloned into a cloning vector. Because the insertion of a complete gene is expected, in this scenario the experiment would be conducted at the highest biosafety level, BL4. Plasmid or bacteriophage DNA purified from the cloning vector would be prepared at that containment level. The purified DNA would then be hydrolyzed with appropriate restriction endonucleases and evaluated in a BL4 laboratory to assure the preparation of DNA of a size which does not code for a complete, hazardous protein. After this point in the experimental procedure, the subsequent steps are similar to those for the genomic DNA cloning protocol.

The hypothetical scenario describes the inadvertent cloning of a toxin gene into the cloning vector. The cloning of other hazardous characteristics, such as infectivity or virulence factors, can be postulated. The experimental details and consequences of inadvertently creating GEMs with those characteristics are the same as those described for the toxin scenario.

Any protocol involving r DNA requires many labor-intensive steps involving complex technical procedures, and biochemical reactions catalyzed by a number of enzymes. Skill in isolating and purifying DNA that has not been damaged by the procedures is developed only with continued attention to detail and by following, explicitly, established experimental procedures. Consequently, not every individual procedure in a cloning experiment proceeds efficiently to the desired conclusion. The actual degree of efficiency is difficult to estimate. Certainly, the more accomplished and skilled researchers can be expected to have higher success rates in their laboratories, and, by implication, less likelihood of the occurrence of an inadvertent cloning.

Even if the screening steps were skipped, and the GEM were moved to the BL1 laboratory, one must realize that this potentially biohazardous GEM was prepared from an enfeebled hostvector system, and would not be competitive for survival even if accidentally released into the natural environment. At the NIH,

in early studies designed to demonstrate the measure of safety afforded by biological containment, a tumor virus was cloned into the E. *cold* K-12 strain plasmid and tested for tumor formation in laboratory animals. Injection of the GEM into these animals produced no tumors (33). Later, at the medical schools of the University of Maryland and the University of Washington, studies were performed to demonstrate the inability of enfeebled E. *cold* K-12 strains to mobilize cloned foreign traits to the normal bacterial flora in the human intestine (7). Human volunteers were fed the GEMs, and stool samples were analyzed for the transfer of recombinant plasmids from the GEMs to the normal flora. No transfer was found. Examination of the results of many other experiments has demonstrated the efficacy of biological containment in protecting the laboratory worker, the general population, and the natural environment (8-13).

3. Public Controversy

While the majority of the scientific community (34) and policy leaders (35) in the United States are comfortable with the controls established by the NIH concerning research employing the genetic engineering techniques, there are groups of nonscientists, and some scientists, who oppose any research using these modern biotechnologies. There also are a number of scientists who oppose the use of genetic engineering in any defense-related research. The DoD encourages use of all modern techniques in biotechnology, microbiology, and biochemistry in the development of effective defensive systems of prophylaxis, early detection, and therapy to provide full protection of our armed forces, as well as those of our allies, from the employment of biological weapons systems by our adversaries. The use of what has become a routine biochemical and microbiological research technique should not be withheld from scientists and physicians simply because they are performing defense-related biomedical research and development.

Offensive biological warfare, and, therefore, the use of GEMs for offensive biological warfare purposes, is clearly prohibited by the terms of the Biological Weapons Convention (BWC). Statements from prominent government officials, confirming this policy, were made early in the development of rDNA biotechnology and are summarized below.

Dr. David Baltimore, a distinguished biological scientist from the Massachusetts Institute of Technology and a principal force in the early effort for responsible scientific control of the developing r DNA biotechnology (36-37), requested an opinion on whether or not the BWC prohibited production of rDNA molecules for the purpose of constructing biological weapons. On 3 July 1975, James L. Malone, General Counsel of the United States Arms Control and Disarmament Agency (ACDA) replied: "In our opinion the answer is in the affirmative. The use of recombinant DNA

molecules for such purposes clearly falls within the scope of the Convention's provisions."

Furthermore, on 17 August 1976, Ambassador Joseph Martin, Jr. made the following statement to the Conference of the Committee of Disarmament, a group of representatives from 26 nations established, in 1969, to offer plans to the General Assembly of the United Nations for general and complete disarmament:

> When advances in science and technology are made, it is natural to ask about their possible uses for hostile purposes and whether or not such uses are prohibited or restricted by existing international agreements. In the case of potential use of recombinant DNA molecules for weapons purposes, it is our view that such use clearly falls within the scope of the Convention's prohibition.
>
> This interpretation is based upon the negotiating history as well as the explicit language of the Convention, and we believe that it is shared by the other signatories. I do not believe it is possible to read the Biological Weapons Convention and come to any other conclusion. According to the Preamble, the States Parties are "deter mined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons." The intent of Article I, which begins, "Each State Party to this Convention undertakes never in any circumstances . . . ," is equally forceful and clear. To take a more restricted view would rob the Convention of much of its value and could even lead to States to call into question its scope and continued viability. These were the views of the United States when the Convention was negotiated and ratified. They are still its views today. This is a matter of great importance to my Government and one on which doubt cannot be permitted to exist.

Later, during the 28 June 1982 NIH RAC discussions of a proposal (38) for the NIH RAC to add to the NIH Guidelines a prohibition of the use of r DNA technology in biological weapons development, a representative of ACDA said that organization does not distinguish between offensive and defensive biological

weapons. Both are biological weapons and, thus, are prohibited by the BWC. A representative of the DoD confirmed that the DoD is not involved in research on biological weapons. The NIH RAC did not adopt the proposal to amend the Guidelines but did formulate a resolution to the NIH Director which read:

> The Recombinant DNA Advisory Committee advises the Director, NIH, that the existing treaty of 1972 [Convention on the Prohibition of Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction] includes the prohibition on the use of recombinant DNA methodology for development of microbial or other biological agents, or toxins, of types or in quantities that have no justification for prophylactic, protective or peaceful purposes.

During the 3 May 1985 NIH RAC discussions (39) of a proposal (40) for the NIH RAC to establish a working group to examine potential uses of rDNA technology for biological weapons systems, NIH RAC members noted that the Secretary of Defense, in November of 1984, had stated that the U.S. remains committed to the BWC. They also noted that the Director of the Office of Environmental and Life Sciences of the Undersecretary of Defense, in April 1985, viewed the proposal as unnecessary since DoD adheres fully to the national policy concerning the BWC and all DoD programs using rDNA are unclassified and have followed a consistent policy from the initial DoD statement involving r DNA in 1981. The Director had further written that any r DNA activities funded by DoD, whether in-house or by contract or grant, are conducted in full compliance with NIH Guidelines and that a complete file of all research projects is maintained at USAMRDC, with complete lists of these projects having been available to any requester since 1981. The NIH RAC members agreed that they have no reason NIH Guidelines and that they have no specific authority to investigate biological warfare issues.

The environmental considerations of r DNA research activities have been documented in the 1976 NIH Environmental Impact Statement on the NIH Guidelines (41-42) (NIH EIS) and in the 1978 Environmental Assessments (43-44) of the NIH Guideline revision. The NIH concluded that, although the possible hazards from this area of research were purely speculative, the NIH Guidelines provided mechanisms for the protection of the laboratory worker, the general public, and the environment. The NIH Guidelines recognize the potential dangers and call for measures aimed at reducing human and environmental exposure to materials containing rDNA molecules. It is NIH's view that the level of risk is acceptably small for research performed in

conformance to the Guidelines. The initial NIH Guidelines (45) were published in the Federal Register on 7 July 1976. These Guidelines have been revised several times (46) since then to take into account rDNA research experience throughout the world and the impact of those observations in reassessing the potential risk associated with these types of experiments. The current NIH Guidelines were published in the Federal Register on 7 May 1986.

The risks associated with research activities using rDNA molecules have been discussed (47) by the NIH RAC. It is the consensus of the NIH RAC that, for research conducted under the provisions of the NIH Guidelines, there exists no great risk for the establishment of a harmful population of recombinant organisms in the environment as a result of accidental releases. In a recent publication on risk analysis (48), the statement was made that ". . . a few years ago, the people involved in recombinant DNA research rather innocently set out to do what scientists always tend to do: get together and talk about perplexing possibilities in their work. The moment they started, they brought down a storm of public wrath on their heads, much to their amazement. They had created a problem, simply by creating the perception of a problem where none had existed before. One can't say they shouldn't have done this but it's in the nature of the world that a certain amount of chaos and tension accompany any such awakening."

There has been much discussion (6,9,13,49,50) recently concerning the risk associated with intentional releases of recombinant organisms for industrial and agricultural purposes. While quantitative risk assessment measures in this area are in the early stages of development in the biotechnology industry, qualitative measures exist and have been used extensively in the past to evaluate intentional releases of naturally occurring organisms. Environmental releases of naturally-mutated microorganisms have been used in agriculture throughout the world since early in this century with no adverse environmental effect. There are no plans for intentional releases into the environment of any organism, natural or recombinant, during biological research operations in the BDRP, other than the possible immunization of humans with a live, recombinant vaccine after licensing with FDA.

The topic of rDNA research has been thoroughly debated in scientific and public forums, the legislatures, the media, and the courts. Obviously, differences of opinion continue to exist (51-52) about the appropriateness of r DNA research and the adequacy of the NIH Guidelines. For example, a recent issue of The Washington Post Magazine (53) quotes "Biotech Gadfly" Jeremy Rifkin, who says that "genetic engineering is a terrible error, a mistake of massive proportions that it is one of two technologies (nuclear energy being the other) so powerful and so inherently wrongheaded that 'in the mere act of using it, we have the potential to do irreparable psychological, environmental, moral and social harm to ourselves and our world.'" The article

further states "to Rifkin, genetic engineering is the quintessence of the wrong science." The type and intensity of concern/opposition expressed by Mr. Rifkin is such that a change in views may not be possible. On the other hand, exhaustive scientific and environmental inquiry indicates that genetic engineering can be conducted in a safe, reliable manner. Furthermore, in contrast to Mr. Rifkin's claims, it is viewed as providing the key to improved human health and quality of life. There are always risks associated with any action, and genetic engineering brings with it a unique area of speculative scenarios. Genetic engineering is widely practiced in government research laboratories, public and private universities and medical centers, and industry. Meanwhile, the debate continues as to whether responsible scientific applications of this modern research tool, for the greater understanding of biological processes and hopefully the betterment of mankind, is worth the inherent perceived risks and associated threats. It is not likely that the controversy will end in the foreseeable future.

As DoD research laboratories and those of its contractors began to use this new biotechnology in the conduct of research, the Secretary of Defense directed (20,21) that r DNA research activities performed at all facilities supported by the DoD funds be executed under all provisions of the NIH Guidelines. Because all BDRP-funded rDNA research is regulated by the current NIH Guidelines, and because, following litigation (54), the NIH assessment of the environmental impacts of the original NIH Guidelines, as presented in the NIH EIS, was deemed adequate, the use of r DNA biotechnology in the construction of GEMs for research investigations and vaccine development in the BDRP is consistent with prudent and acceptable scientific practice.

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APPENDIX 11

Biological Safety Cabinets

Microbiology laboratories are special, often unique, work environments that may pose special infectious disease risks to persons in or near them. Laboratory-acquired infections have been documented throughout the history of microbiology. Surveys in 1949 (1), in 1951 (2), in 1965 (3), and in 1976 (4) showed that fewer than 20% of laboratory infections were associated with a known accident, and a majority of these were related to mouth pipetting or the use of a needle and syringe. Exposure to infectious aerosols was considered a plausible mechanism of infection for many of the remaining 80% of the reported cases in which the infected person had worked with the agent.

While the possibility of laboratory-acquired infections is a known risk to the laboratory work force, no documentable evidence exists to indicate that these infections become a community health risk as evidenced by the following summary* "In contrast to the documented occurrence of laboratory-acquired infections in laboratory personnel, laboratories working with infectious agents have not been shown to represent a threat to the community. For example, although 109 laboratory-associated infections were recorded at the Centers for Disease Control in 1947-1973, no secondary cases were reported in family members or community contacts. The National Animal Disease Center has reported a similar experience, with no secondary cases occurring in laboratory and nonlaboratory contacts of 18 laboratory-associated cases occurring in 1960-1975. A secondary case of Machupo disease in the wife of a primary case was presumed to have been transmitted sexually two months after his dismissal from the hospital. Three secondary cases of smallpox were reported in two laboratory-associated outbreaks in England in 1973 and 1978. There were earlier reports of six cases of Q fever in employees of a commercial laundry which handled linens and uniforms from a laboratory where work with the agent was conducted, one case of Q fever in a visitor to a laboratory, and two cases of Q fever in household contacts of a rickettsiologist. These cases are representative of the sporadic nature and infrequent association of community infections with laboratories working with infectious agents."

Among the many controls incorporated to protect biological laboratory personnel, biological safety cabinets represent one of the primary echelons of protection. The following description, extracted from Biosafety In Microbiological and Biomedical Laboratories (5), provides an overview of the characteristics of biologic safety cabinets and their protective qualities.

*Extracted from Biosafety in Microbiological and Biomedical Laboratories CDC/NIH 1984 (4).

Biological Safety Cabinets (BSC) are among the most effective, as well as the most commonly used, primary containment devices in laboratories working with infectious agents. Each of the three types - Class I, II, and III - has performance characteristics which are described in this appendix.

Class I and II biological safety cabinets, when used in conjunction with good microbiological techniques, provide an effective partial containment system for safe manipulation of moderate and high-risk microorganisms (i.e., Biosafety Level 2 and 3 agents). Both Class I and II biological safety cabinets have comparable inward face air velocities (75 linear feet per minute) and provide comparable levels of protection to the laboratory worker and the immediate laboratory environment from infectious aerosols generated within the cabinet.

It is imperative that Class I and II biological safety cabinets are tested and certified in situ at the time of installation within the laboratory, at any time the BSC is moved, and at least annually thereafter. Certification at locations other than the final site may attest to the performance capability of the individual cabinet or model but does not supercede the critical certification prior to use in the laboratory.

As with any other piece of laboratory equipment, personnel must be trained in the proper use of the biological safety cabinets. Activities which may disrupt the inward directional airflow through the work opening of Class I and II cabinets must be minimized. Strict adherence to recommended practices for the use of biological safety cabinets is as important in attaining the maximum containment capability of the equipment as is the mechanical performance of the equipment itself.

The Class I biological safety cabinet is an open-fronted, negative-pressure, ventilated cabinet with a minimum inward face air velocity at the work opening of at least 75 feet per minute. The exhaust air from the cabinet is filtered by a high efficiency particulate air (HEPA) filter. This cabinet may be used in three operational modes: with a full-width open front, with an installed front closure panel not equipped with gloves, and with an installed front closure panel equipped with arm-length rubber gloves.

The Class II vertical laminar-flow biological cabinet is an open-fronted, ventilated cabinet with an average inward face air velocity at the work opening of at least 75 feet per minute. This cabinet provides a HEPA-filtered, recirculated mass airflow within the work space. The exhaust air from the cabinet **is also** filtered by HEPA filters. Design, construction, and performance standards for Class II cabinets have been developed by and are available from the National Sanitation Foundation, Ann Arbor, Michigan. (Ref 6, NSF std 49).

The Class III cabinet is a totally enclosed ventilated cabinet of gas-tight construction. Operations within the Class III cabinet are conducted through attached rubber gloves. When in use, the Class III cabinet is maintained under negative air pressure of at least 0.5 inches water gauge. Supply air is drawn into the cabinet through HEPA filters. The cabinet exhaust air is filtered by two HEPA filters, installed in series, before discharge. The exhaust fan for the Class III cabinet is generally separate from the exhaust fans of the facility's ventilation system.

Personnel protection provided by Class I and Class II cabinets is dependent on the inward airflow. Since the face velocities are similar, they generally provide an equivalent level of personnel protection. The use of these cabinets alone, however, is not appropriate for containment of highest-risk infectious agents because aerosols may accidentally escape through the open front.

The use of a Class II cabinet in the microbiological laboratory offers the additional capability and advantage of protecting material contained within it from extraneous airborne contaminants. This capability is provided by the HEPA-filtered, recirculated mass airflow within the work space.

The Class III cabinet provides the highest level of personnel and product protection. This protection is provided by the physical isolation of the space in which the organism is maintained. When these cabinets are required, all procedures involving infectious agents are contained within them. Several Class III cabinets are therefore typically set up as an interconnected system. All equipment required by the laboratory activity, such as incubators, refrigerators, and centrifuges, must be an integral part of the cabinet system. Double-doored autoclaves and chemical decontamination tanks are also attached to the cabinet system to allow supplies and equipment to be safely introduced and removed.

Personnel protection equivalent to that provided by Class III cabinets can be also be obtained with a self-contained personnel protective suit and Class I or Class II cabinets. The laboratory worker is protected from a potentially contaminated environment by a one-piece positive pressure suit ventilated by a life-support system. This "suit" area is entered through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surfaces of the suit as the worker leaves the area. The exhaust air from the suit area is filtered by two HEPA filter units installed in series.

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Fig. A11-1 Class I Cabinet

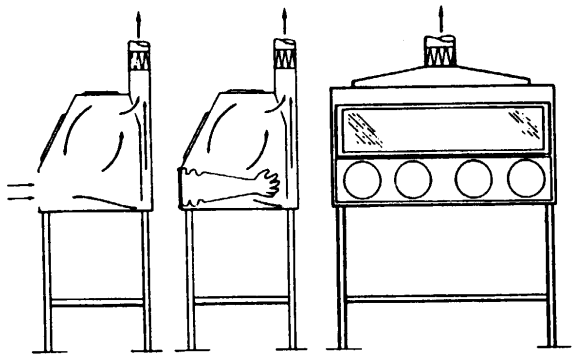
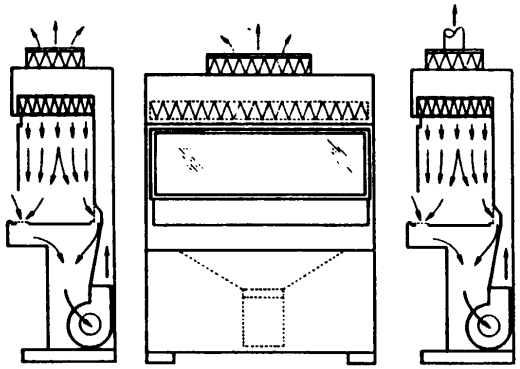
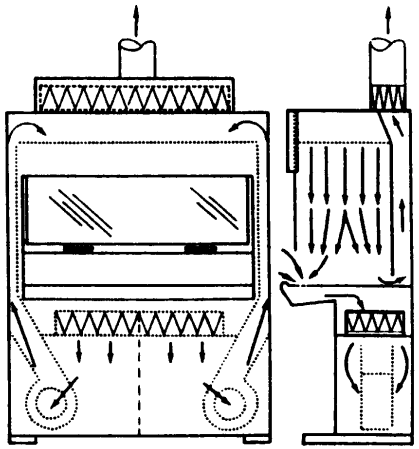


Fig. A11-2 Class II Cabinets

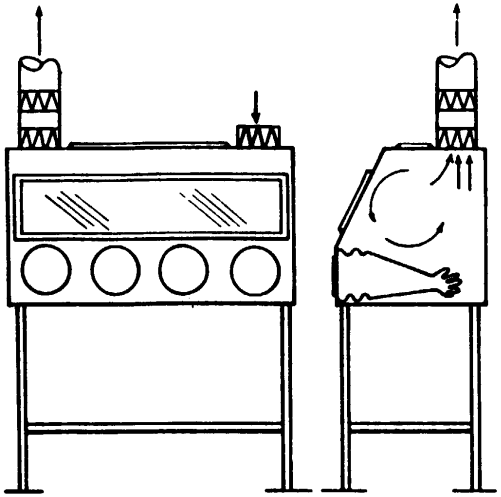


Type A



Type B

Fig. A11-3 Class III Cabinet



APPENDIX 12 - LABORATORY BIOSAFETY LEVELS

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APPENDIX 12

Laboratory Biosafety levels. Excerpted from Biosafety in Microbiological and Biomedical Laboratories (CDC-NIH, 1984)

Selection of an appropriate Biosafety level for work with a particular agent or animal study depends upon a number of factors. Some of the most important are: the virulence, pathogenicity, biological stability, route of spread, and communicability of the agent; the nature or function of the laboratory; the procedures and manipulations involving the agent; the quantity and concentration of the agent; the endemicity of the agent; and the availability of effective vaccines or therapeutic measures.

1. Principles of Biosafety

The term "containment" is used in describing safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained. Primary containment, the protection of personnel and the immediate laboratory environment from exposure to infectious agents, is provided by good microbiological technique and the use of appropriate safety equipment. The use of vaccines may provide an increased level of personal protection. Secondary containment, the protection of the environment external to the laboratory from exposure to infectious materials, is provided by a combination of facility design and operational practices. The purpose of containment is to reduce exposure of laboratory workers and other persons to, and to prevent escape into the outside environment of potentially hazardous agents. The three elements of containment include laboratory practice and technique, safety equipment, and facility design.

1.1 Laboratory Practice and Technique. The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or infected materials must be aware of potential hazards and must be trained and proficient in the practices and techniques required for safely handling such material. The director or person in charge of the laboratory is responsible for providing or arranging for appropriate training of personnel. When standard laboratory practices are not sufficient to control the hazard associated with a particular agent or laboratory procedure, additional measures may be needed.

Each laboratory should develop or adopt a Biosafety or operations manual which identifies the hazards that will or may be encountered and which specifies practices and procedures designed to minimize or eliminate risks. Personnel should be advised of special hazards and should be required to read and to follow the required practices and procedures. A scientist trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling

infectious agents must direct laboratory activities. Laboratory personnel, safety practices, and techniques must be supplemented by appropriate facility design and engineering features, safety equipment, and management practices.

1.2 Safety Equipment (Primary Barriers). Safety equipment includes biological safety cabinets and a variety of enclosed containers e.g., centrifuge cups, which are designed to prevent aerosols from being released during centrifugation. The biological safety cabinet is the principal device used to provide containment of infectious aerosols generated by many microbiological procedures. Open-fronted Class I and Class II biological safety cabinets are partial containment cabinets which offer significant levels of protection to laboratory personnel and to the environment when used with good microbiological techniques. The gas-tight Class III biological safety cabinet provides the highest attainable level of protection to personnel and the environment.

Safety equipment also includes items for personal protection such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, and safety glasses. These personal protective devices are often used in combination with biological safety cabinets and other devices which contain the agents, animals, or material being worked with. In some situations in which it is impractical to work in biological safety cabinets, personal protective devices may form the primary barrier between personnel and the infectious materials.

1.3 Facility Design (Secondary Barriers). The design of the facility is important in providing a barrier to protect, not only persons working in the facility, but those outside the laboratory and in the community from infectious agents which may be accidentally released from the laboratory. Laboratory management is responsible for providing facilities commensurate with the laboratory's function. Three facility designs are described below, in ascending order by level of containment.

1.3.1 The Basic Laboratory. This laboratory provides general space in which work is done with viable agents which are not associated with disease in healthy adults. This laboratory is also appropriate for work with infectious agents or potentially infectious materials when the hazard levels are low and laboratory personnel can be adequately protected by standard laboratory practice. Basic laboratories include those facilities described in the following pages as Biosafety Levels 1 and 2 facilities. While work is commonly conducted on the open bench, certain operations are confined to biological safety cabinets. Conventional laboratory designs are adequate.

1.3.2 The Containment laboratory. This laboratory has special engineering features which make it possible for laboratory workers to handle hazardous materials without endangering themselves, the community, or the environment. The

containment laboratory is described in the following pages as a Biosafety Level 3 facility. The unique features which distinguish this laboratory from the basic laboratory are the provisions for access control and a specialized ventilation system. The containment laboratory may be an entire building or a single module or complex of modules within a building. In all cases, the laboratory is separated by a controlled access zone from areas open to the public.

1.3.3 The Maximum Containment laboratory. This laboratory has special engineering and containment features that allow activities involving infectious agents that are extremely hazardous to the laboratory worker or that may cause serious epidemic disease to be conducted safety. The maximum containment laboratory is described on the following pages as a Biosafety Level 4 facility. Although the maximum containment laboratory is generally a separate building, it can be constructed as an isolated area within a building. The laboratory's distinguishing characteristic is that it has secondary barriers to prevent hazardous materials from escaping into the environment. Such barriers include sealed openings into the laboratory, airlocks or liquid disinfectant barriers, a clothing-change and shower room contiguous to the laboratory, a double door autoclave, a biowaste treatment system, a separate ventilation system, and a treatment system to decontaminate exhaust air.

2. Biosafety Levels. Four biosafety levels are described which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and the hazard posed by the infectious agents and for the laboratory function or activity.

2.1 Biosafety Level 1 practices, safety equipment, and facilities are appropriate for undergraduate and secondary educational training and teaching laboratories and for other facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, and in immunodeficient or immunosuppressed individuals. Vaccine strains which have undergone multiple in viva passages should not be considered avirulent simply because they are vaccine strains.

2.2 Biosafety Level 2 practices, equipment, and facilities are applicable to clinical, diagnostic, teaching, and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing aerosols is low. Primary hazards to personnel working with these agents may include accidental autoinoculation, ingestion, and skin or mucous membrane exposure to infectious

materials. Procedures with high aerosol potential that may increase the risk of exposure of personnel must be conducted in primary containment equipment or devices.

2.3 Biosafety Level 3 practices, safety equipment, and facilities are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents where the potential for infection by aerosols is real and the disease may have serious lethal consequences. Autoinoculation and ingestion also represent primary hazards to personnel working with these agents.

2.4 Biosafety Level 4 practices, safety equipment, and facilities are applicable to work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. All manipulations of potentially infectious diagnostic materials, isolates, and naturally or experimentally infected animals pose a high risk of exposure and infection to laboratory personnel.

The laboratory director is directly and primarily responsible for the safe operation of the laboratory. His/her knowledge and judgment are critical in assessing risks and appropriately applying these recommendations. The recommended biosafety level represents those conditions under which the agent can ordinarily be safely handled. Special characteristics of the agents used, the training and experience of personnel, and the nature or function of the laboratory may further influence the director in applying these recommendations.

Work with known agents should be conducted at the biosafety level recommended unless specific information is available to suggest that virulence, pathogenicity, antibiotic resistance patterns, and other factors are significantly altered to require more stringent or allow less stringent practices to be used.

3. Importation and Interstate Shipment of Certain Biomedical Materials. The importation of etiologic agents and vectors of human diseases is subject to the requirements of the Public Health Service Foreign Quarantine regulations. Companion regulations of the Public Health Service and the Department of Transportation specify packaging, labeling, and shipping requirements for etiologic agents and diagnostic specimens shipped in interstate commerce. The U.S. Department of Agriculture regulates the importation and interstate shipment of animal pathogens and controls the importation, possession, or use of certain exotic animal disease agents which pose a serious disease threat to domestic livestock and poultry (see Appendix 2).

TABLE A12.1 Summary of recommended biosafety levels for infectious agents.

Biosafety Level	Practices & Techniques	Safety Equipment	Facilities
1	Standard microbiological	None: Primary containment provided by adherence to standard lab practices during open bench operations.	Basic
2	Level 1 practices plus: Lab coats; decontamination of all infectious wastes; limited access; protective gloves and biohazard signs as indicated.	Partial containment equipment (i.e., Class I or II Biological Safety Cabinets) used to conduct mechanical & manipulative procedures that have high aerosol potential that may increase the risk of exposure to personnel.	Basic
3	Level 2 practices plus: special lab clothing; controlled access.	Partial containment equipment used for all manipulations of infectious materials.	Containment
4	Level 3 practices plus: entrance through change room where street clothing is removed and laboratory clothing is put on; shower on exit; all wastes are decontaminated on exit from the facility.	Maximum containment equipment (i.e., Class III biological safety cabinet or partial containment equipment in combination with full-body, air-supplied, positive-pressure personnel suit) used for all procedures and activities.	Maximum Containment

4. Laboratory Biosafety Level Criteria

The essential elements of the four biosafety levels for activities involving infectious microorganisms are summarized in Tables A12.1. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community.

4.1 Biosafety Level 1 is suitable for work involving agents of no known or of minimal potential hazard to laboratory personnel and the environment. The laboratory is not separated from the general traffic patterns in the building. Work is generally conducted on open bench tops. Special containment equipment is not required or generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science. Standard microbiological practices are employed. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leakproof container which is closed before being removed from the laboratory. Special containment equipment is generally not required.

4.2 Biosafety Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that 1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists, 2) access to the laboratory is limited when work is being conducted, and 3) certain procedures in which infectious aerosols are created are conducted in biological safety cabinets or other physical containment equipment. Standard microbiological practices are employed. Biological safety cabinets (Class I or II) or other appropriate personal protective or physical containment devices are used whenever procedures with a high potential for creating infectious aerosols are conducted or when high concentrations or large volumes of infectious agents are used.

4.3 Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal diseases as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices or by personnel wearing appropriate personal protective clothing and devices. The laboratory has special engineering and design features. Standard microbiological practices apply.

The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for

program or support purposes. All activities involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module.

Laboratory clothing that protects street clothing (e.g., solid front or wrap-around gowns, scrub suits, coveralls) is worn **in** the laboratory. Laboratory clothing is not worn outside the laboratory, and it is decontaminated before being laundered. Special care is taken to avoid skin contamination with infectious material; gloves should be worn when handling infected animals and when skin contact with infectious materials is unavoidable.

Molded surgical masks or respirators are worn in rooms containing infected animals. All wastes from laboratories and animal rooms are appropriately decontaminated before disposal. Vacuum lines are protected with high-efficiency particulate air (HEPA) filters and liquid disinfectant traps. A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read instructions on practices and procedures and to follow them.

Biological safety cabinets (Class I, II or III) {see Appendix 11) or other appropriate combinations of personal protective or physical containment devices (e.g., special protective clothing, masks, gloves, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals) are used for all activities with infectious materials which pose a threat of aerosol exposure.

The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. Physical separation of the high containment laboratory from access corridors or other laboratories or activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility which requires passage through two sets of doors before entering the laboratory. Windows in the laboratory are closed and sealed. Access doors to the laboratory or containment module are self-closing. An autoclave for decontaminating laboratory wastes is available, preferably within the laboratory. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry area. The exhaust air is not recalculated to any other area of the building, is discharged to the outside, and is dispersed away from occupied areas and air intakes. The exhaust air from the laboratory room can be discharged to the outside without being filtered or otherwise treated. The HEPA-filtered **exhaust** air from Class I or Class II biological safety cabinets is discharged directly to the outside or through the building exhaust system. Exhaust air from class I or II biological safety cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every twelve months. If the

HEPA-filtered exhaust air from Class I or II biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner that avoids any interference with the air balance of the cabinets or building exhaust system.

4.4 Biosafety Level 4 is required for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents, and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics. They are supervised by competent scientists who are trained and experienced in working with these agents. Access to the laboratory is strictly controlled by the laboratory director. The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. A specific facility operations manual is prepared or adopted.

Within work area of the facility, all activities are confined to Class III biological safety cabinets or Class I or Class II biological safety cabinets used along with one-piece positive pressure personnel suits ventilated by a life support system. The maximum containment laboratory has special engineering and design features to prevent microorganisms from being disseminated into the environment. Standard microbiological practices apply. Biological materials to be removed from the Class III cabinet or from the maximum containment laboratory in a viable or intact state are transferred to a nonbreakable, sealed primary container and then enclosed in a nonbreakable, sealed secondary container which is removed from the facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose.

No materials, except for biological materials that are to remain in a viable or intact state, are removed from the maximum containment laboratory unless they have been autoclaved or decontaminated before they leave the facility. Equipment or materials which might be damaged by high temperatures or steam are decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

Only persons whose presence in the facility or individual laboratory rooms is required for program or support purposes are authorized to enter. Access to the facility is limited by means of secure, locked doors; accessibility is managed by the laboratory director, biohazards control officer, or other person responsible for the physical security of the facility. Before entering, persons are advised of the potential biohazards and instructed as to appropriate safeguards for insuring their safety. Authorized persons comply with the instructions and all other applicable entry and exit procedures. Personnel enter and

leave the facility only through the clothing change and shower rooms. Personnel shower each time they leave the facility. Personnel use the airlocks to enter or leave the laboratory only in an emergency. Street clothing is removed in the outer clothing change room and kept there. Complete laboratory clothing is provided and used by all personnel entering the facility. When leaving the laboratory and before proceeding into the shower area, personnel remove their laboratory clothing in the inner change room.

Materials (e.g., plants, animals, and clothing) not related to the experiment being conducted are not permitted in the facility. Hypodermic needles and syringes are used only for parenteral infection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral part of unit) are used for the injection or aspiration of infectious fluids. Needles should not be bent, sheared, replaced in the needle guard, or removed from the syringe following use. The needle and syringe should be placed in a puncture-resistant container and decontaminated, preferably by autoclaving before discard or reuse. Whenever possible, cannulas are used instead of sharp needles (e.g., for garage).

A system is set up for reporting laboratory accidents and exposures and employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses. Written records are prepared and maintained.

All procedures with agents assigned to Biosafety Level 4 are conducted in the Class III biological safety cabinet or in Class I or II biological safety cabinets used in conjunction with one piece positive-pressure personnel suits ventilated by a life support system. Activities with viral agents (e.g., Rift Valley fever virus) that require Biosafety Level 4 secondary containment capabilities and for which highly effective vaccines are available and used can be conducted within Class I or Class II biological safety cabinets within the facility without the one piece positive-pressure personnel **suit** being used if 1) the facility has been decontaminated, 2) no work is being conducted in the facility with other agents assigned to Biosafety Level 4, and 3) all other standard and special practices are followed.

The maximum containment facility consists of either a separate building or a clearly demarcated and isolated zone within a building. Outer and inner change rooms separated by a shower are provided for personnel entering and leaving the facility. A double-doored autoclave, fumigation chamber, or ventilated airlock is provided for passage of those materials, supplies, or equipment which are not brought into the facility through the change room.

If there is a central vacuum system, it does not serve areas outside the facility. In-line HEPA filters are placed as near as

practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement. Other liquid and gas services to the facility are protected by devices that prevent backflow. Access doors to the laboratory are self-closing and lockable. Any windows are sealed and breakage resistant. A double-doored autoclave is provided for decontaminating materials passing out of the facility. The autoclave door which opens to the area external to the facility is sealed to the outer wall and automatically controlled so that the outside door can only be opened after the autoclave "sterilization" cycle has been completed. A pass-through dunk tank, fumigation chamber, or an equivalent decontamination method is provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the facility. Liquid effluents from laboratory sinks, biological safety cabinets, floors, and autoclave chambers are decontaminated by heat treatment before being released from the maximum containment facility. Liquid wastes from shower rooms and toilets may be decontaminated with chemical disinfectants or by heat in the liquid waste decontamination system. The procedure used for heat decontamination of liquid wastes is evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes from the shower rooms are decontaminated with chemical disinfectants, the chemical used is of demonstrated efficacy against the target or indicated microorganisms.

An individual supply and exhaust air ventilation system is provided. The system maintains pressure differentials and directional airflow as required to assure flows inward from areas outside of the facility toward area of highest potential risk within the facility. Manometers are used to sense pressure differentials between adjacent areas maintained at different pressure levels. If a system malfunctions, the manometers sound an alarm. The supply and exhaust airflow is interlocked to assure inward (or zero) airflow at all times.

The exhaust air from the facility is filtered through HEPA filters and discharged to the outside so that it is dispersed away from occupied buildings and air intakes. Within the facility, the filters are located as near the laboratories as practicable in order to reduce the length of potentially contaminated air ducts. The filter chambers are designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are replaced. Coarse filters and HEPA filters are provided to treat air supplied to the facility in order to increase the lifetime of the exhaust HEPA filters and to protect the supply air system should air pressures become unbalanced in the laboratory.

The treated exhaust air from Class I and II biological safety cabinets can be discharged into the laboratory room environment or to the outside through the facility air exhaust system. If

exhaust air from Class I or II biological safety cabinets is discharged into the laboratory the cabinets are tested and certified at 6-month intervals. The treated exhaust air from Class III biological safety cabinets is discharged, without recirculation through two sets of HEPA filters in series, via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or the facility exhaust air system.

A specially designed suit area may be provided in the facility. Personnel who enter this area wear a one-piece positive-pressure suit that is ventilated by a life support system. The life support system includes alarms and emergency backup breathing air tanks. Entry to this area is through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surface of the *suit* before the worker leaves the area. The exhaust air from the suit area is filtered by two sets of HEPA filters installed in series. A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source are provided. The air pressure within the suit area is lower than that Of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the internal shell of the suit area are sealed. A double-doored autoclave is provided for decontaminating waste materials to be removed from the suit area.

5. The BDRP is conducted under containment that meets or exceeds the recommended guidelines as indicated by the following features and practices of USAMRIID biocontainment facilities which exceed recommendations promulgated by CDC/NIH.

5.1 Biosafety Level 2 Laboratories

1. An individual laboratory supply and exhaust air ventilation system is provided.

2. Laboratories and animal rooms have directional air flow.

3 Exhaust air is discharged to the outside without being recirculated to other areas.

4. Laminar flow animal cage rack enclosures and filter-top cages are frequently used.

5.2 Biosafety Level 3 Laboratories

1 A complete change of clothing into total laboratory clothing, including shoes, is required for entry into BL3 containment areas. All laboratory clothing must be removed before exiting.

2. An exit shower with germicidal soap is required.

3. An individual laboratory supply and exhaust air ventilation system is provided. Supply and exhaust airflow are interlocked to assure inward (or zero) airflow at all times.

4. Manometers are provided to sense pressure differentials between adjacent areas that are maintained at different pressure levels. Pressure-sensing devices sound an alarm when a system malfunctions.

5. A duplicate exhaust filtration unit and fan are provided.

6. A self-activating-starting emergency power source is provided.

7. Emergency lighting and communications systems are provided.

8. Room exhaust air is filtered before being discharged to the outside. 95% to 97% of 1.2 um particles are removed. Exhaust air from Class II biological safety cabinets is filtered through a HEPA filter and then through 95% or 97% filters before being discharged. Some cabinets have two sets of HEPA exhaust filters.

9. Foot-operated water fountains are provided.

10. A fumigation airlock is provided so that materials and equipment that cannot be decontaminated in an autoclave can be safely removed from the facility.

11. Supplies and materials taken into the facility enter by way of an airlock.

12. Access into the containment areas is through secure, locked, double--entry doors.

13. All service penetrations into the laboratory facility are sealed.

14. A double-doored autoclave is provided for decontaminating waste materials that leave the laboratory. The autoclave door which opens to the area external to the laboratory is automatically controlled so that it can only be opened after the autoclave sterilization cycle is complete.

15. Liquid effluents from laboratory sinks, floors, toilets and autoclave chambers are decontaminated by heat treatment before being discharged. The procedure used for heat treatment of liquid wastes is evaluated mechanically and biologically.

16. Laminar flow animal cage enclosures and filter top cages are frequently used.

5.3 Biosafety Level 4 Laboratories

1. Waste materials that leave the BL4 containment areas are autoclaved two times before leaving the area.

2. Access to BL4 containment areas is by means of two sets of secure, separately locked doors.

3. In areas where one-piece, positive-pressure suits are required, laminar flow animal cage racks or Class II biological safety cabinets are used.

4. In areas where one-piece, positive-pressure suits are required, exhaust air from Class II cabinets is filtered through one additional filter (three filters versus two).

5. Exhaust air from Class III cabinets is filtered through an additional set of HEPA filters (three filters versus two).

APPENDIX 13 DECONTAMINATION TECHNOLOGIES

1. Introduction
2. Mechanisms of Decontamination
3. Kinetics of Decontamination
4. Decontamination of Waste Streams and Surfaces
5. Safety of Decontamination Procedures
6. Cited References

1. INTRODUCTION

Within the DoD, the term decontamination carries two meanings, one in a military context, and a different meaning in the context of RDT&E The military definition of the term describes the process of physically removing hazardous materials from individual soldiers and combat support materiel on the battlefield and in other military operational areas. This use of the term implies the removal, dilution, or inactivation of chemical warfare agents and biological warfare agents which are contaminating equipment and personnel. On a battlefield contaminated with chemical or biological warfare agents, a critical task that a unit commander must perform, before his unit can resume tactical operations, is the reduction of the contamination of his troops and troop equipment to non-hazardous levels. In addition to his own unit capabilities, the commander has access to the decontamination resources of the U.S. Army Chemical Corps field units for assistance in his decontamination task. These aspects of military decontamination are not described any further in this appendix.

The research definition of decontamination describes those laboratory and waste stream operations designed to completely inactivate or kill hazardous organisms, GEMs, and their bioproducts, after completion of the research experiment and before air, liquid, and solid waste streams are released to the natural environment. Synonyms for this process would be sterilization and disinfection. The chemical and physical materials used in these processes are called decontaminants, sterilants, disinfectants, or biocides. The selection of a decontaminant is dictated by its effectiveness in killing a specific organism or inactivating a specific bioproduct, its suitability for use at the site of contamination (air, waste liquids, or surfaces), its own detoxification requirements, the hazards associated with its use, and its cost.

The control of hazardous microorganisms, GEMs, or toxins and other bioactive molecules, in normal waste stream releases to air, water, and landfills, and in accidental spills on laboratory equipment, benches, and other surfaces, requires the application of appropriate physical and chemical decontamination techniques. These techniques are well documented in the disinfection and sterilization literature (1-20).

2. MECHANISMS OF DECONTAMINATION

The efficacy of decontamination depends upon the concentration of the disinfectant and the contact time on the target organism. The chemical or physical action of the decontaminant results in the inactivation of the organism and its bioactive cell product. This process occurs either through the irreversible loss of the microorganism's ability to grow under optimal conditions on an appropriate culture medium or in its

natural environment (cell death), through the irreversible loss of a spore's ability to germinate, or through the irreversible loss of the biological activity of a virus or cell product upon exposure to a physical or chemical disinfectant. The measurement of irreversible losses of bioactivity is critical, because some microorganisms can resuscitate and grow again (21-22), or cell products such as enzymes, nucleic acids, or toxins may still remain biologically active, after treatment with low concentrations of a disinfectant or inadequate exposures to physical inactivation agents (23). For decontamination purposes, biological activity is related to the self-replication capability of genetic elements, infectivity of viral particles, toxicity of bioproducts, and catalytic efficiency of cellular enzymes.

Mechanisms of inactivation involve the permanent loss of activity or structural integrity of membrane proteins and lipids, essential metabolic enzymes, and nucleic acid molecules. Biocides include physical methods such as heat (steam and dry), ionizing radiation, and high energy ultraviolet irradiation, and chemical methods such as ethylene oxide gas permeation, paraformaldehyde vaporization, and inactivation with chlorine (household bleach, also known as sodium hypochlorite).

In the BDRP steam sterilization is the most common form of physical decontamination used for hazardous organisms. Inactivation occurs irreversibly through denaturation and oxidation of structural and catalytic proteins which causes the loss of membrane integrity and the biosynthetic capability of the cell, and the subsequent leaking of cell components. Here, complete sterilization is defined as the reduction of the probability of the survival of a single organism to 1 in a million (12). Laboratory equipment and media reach this level of decontamination by treatment in an autoclave with superheated steam at 120°C and 15 psig for 20 minutes.

Another form of physical inactivation is irradiation from ionizing and non-ionizing sources. High energy ionizing radiation from beta particles and gamma photons causes both reversible and irreversible damage to nucleic acid molecules through single strand and double strand cleavages. It also causes the ejection of electrons from intracellular molecules. These -electrons ionize intracellular water, forming highly reactive free radicals and protons that induce nucleic acid base alterations. Non-ionizing ultraviolet irradiation induces the formation of pyrimidine dimers in nucleic acid chains, destroying the replication and transcription functions of the molecule through cross-linking of the strands.

Ethylene oxide, a water-soluble gas, is frequently used to chemically decontaminate materials that are sensitive to heat treatment prior to removal from containment suites. Its mechanism of action is alkylation of amino, hydroxyl, carboxyl, and sulfhydryl functional groups in cellular molecules (24-26). Therefore, nucleic acids, proteins, lipids and bioactive cell

products become chemically modified. Formaldehyde also alkylates, and forms cross-links between these same molecules (a, 27-29).

Aqueous solutions of chlorine are commonly used for decontamination of liquid wastes containing microorganisms. Its use in drinking water and wastewater treatment plants has a long history. Chlorine is used as a gas, liquid, or aqueous solution of sodium hypochlorite. It is a strong oxidizing agent that inactivates both proteins and nucleic acids through covalent cross-linking of these long-chain organic polymers. General oxidative actions have been demonstrated on spores, cells, and viruses (30-31). After its use as a biocide, aqueous hypochlorite solutions are diluted with water before discharge into the wastewater stream.

The assessment of efficacy of decontamination requires the demonstration of lack of growth on standard media, or the loss of some other indicator of the presence of a viable microorganism or a bioactive molecule. Because different organisms and their bioactive products exhibit varying degrees of susceptibility to the different decontamination methods, an appropriate verification of cell death or bioproduct nactivation is required. DNA probe technology (32-34) h as been used to identify specific microorganisms by hybridization of DNA probe sequences to unique, complementary DNA sequences isolated from the organisms. For those chemical decontaminants that can be completely removed from the test system, and for materials decontaminated by physical means, bioassays and antibody screening techniques can be used to test for the presence of specific bioproducts.

3. KINETICS OF DECONTAMINATION

Inactivation of a microorganism or its bioproducts, in the presence of a biocide, is a time dependent process. The course of cell death is a function of many factors. Some of these are species and strain of the microorganism, type and concentration of decontaminant, and the physical environment, for example, pH and temperature. The selection of a suitable decontaminant is determined by its effectiveness in killing a specific organism or inactivating a specific bioproduct. The effectiveness of a biocide can be measured by comparing kill curves of the target organism. These curves are plots of concentration of biocide versus the contact time required to achieve a standard percentage of inactivation. For example, if E. coli, growing in a pH 7 medium, is exposed to chlorine at a concentration of 0.05 parts per million, the time required to reach 99% inactivation is approximately 2 minutes (17). The mathematical relationship (35) between the concentration of biocide and the time required to reach a standard level of inactivation is expressed by the following equation:

$$c^n t = k$$

where, C = concentration of biocide
n = coefficient of dilution
t = exposure time to reach a standard activation level
k = empirical parameter that varies with the specific microorganism and biocide, and extent of inactivation for a given environmental condition.

Plots of the logarithm of the exposure time versus the logarithm of the biocide concentration allow the graphical estimation of the coefficient of dilution from the slope, and of the empirical parameter, k, from the intercept. Preparation of log-log plots for groups of biocide/microorganism combinations allows quick comparisons of decontamination efficacies. This relationship has been used to compare the efficacies of various decontaminants on the same organism, the variation in susceptibilities of different organisms to the same biocide, and the effects of temperature and pH on biocidal activity (17). Figure A13-1 is an example of the use of this technique to compare the efficacy of chlorine in the inactivation of several microorganisms (36). The logarithm of the time in minutes for inactivation is plotted versus the logarithm of the free available chlorine concentration in parts per million. Lines for the most sensitive organisms are located near the intersection of the axes (origin) and those lines for the least sensitive organisms are furthest from the origin.

The effect of temperature on inactivation kinetics parallels its effect on chemical reactions. Generally, there is a 2 to 3 fold rise in inactivation rate with a 10°C rise in temperature (5). However, there are differences in this relationship between different biocide/microorganism combinations. These differences have been examined by calculating and comparing Q_{10} values for the different combinations (17,37). A Q_{10} value is the ratio of times required to achieve the same level of inactivation with a 10 degree rise in temperature at a given concentration of biocide. Table A13-1 summarizes the effects of temperature on the efficacy of a variety of biocide/microorganism combinations (17).

The stability and chemical form of the biocides is affected by the pH of the treatment solution. The availability of free chlorine for biocidal activity depends on the pH of the decontaminant solution. Hypochlorous acid is a stronger biocide than hypochlorite ion. Therefore, these chlorine decontaminant solutions are more efficacious at low pH than at high pH. In addition to affecting the ionic nature of the disinfectant solution, the pH also affects the stability of different biocides and the susceptibility of different microorganisms to biocidal activity.

The concentration of biocide required for inactivation of a microorganism also depends on the presence of other organic material in the waste stream. Because many of the decontaminants

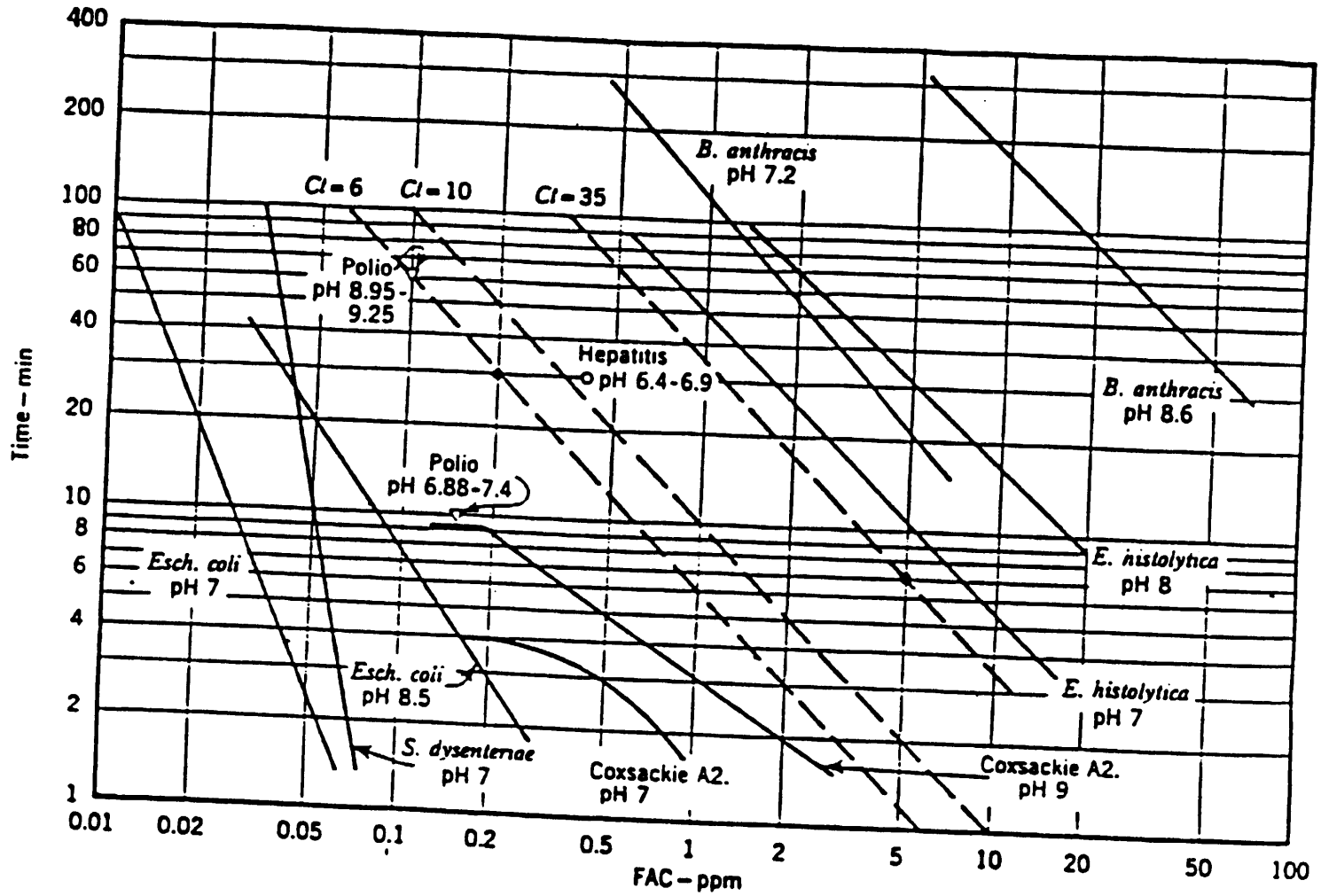

Figure A13-1: Inactivation of Bacteria and Viruses (36)

Table A13-1: Effects of 10°C Changes in Temperature (Q_{10}) On Microorganism Inactivation Rates (17)

Disinfectant	Organisms	Temp (°C)	pH	Q_{10}	Reference
Free Chlorine	E. Coli	5-25	7.0	1.65	(38)
			8.5	1.42	
			9.8	2.13	
			10.7	2.50	
	E. histolytica cysts			2.10	(38)
Chloramines	E. coli	5-25	7.0	2.09	(38)
			8.5	2.28	
			9.5	3.35	
	Poliovirus 1 99% inactive	5-15	9.0	1.50	(39)
		15-25	9.0	4.00	
	Poliovirus 1 90% inactive	5-15	9.0	2.00	(39)
		15-25	9.0	1.90	
	Poliovirus 1 90% inactive	5-15	4.5	2.50	(39)
Chlorine dioxide	Poliovirus 1 monodispersed	5-15	7.0	2.26	(39)
		15-25	7.0	1.99	
	Poliovirus 1	5-15	7.0	4.12	(40)
		15-25	7.0	1.34	
Ozone	Poliovirus 1	10-20		1.50	(41)
	N. gruberi	5-15	7.0	2.07	(42)
		15-25	7.0	1.58	
	G. muris	5-15	7.0	5.17	(42)
		15-25	7.0	1.39	

are oxidative chemicals, the presence of excessive organics competes for the biocidal activity of the decontaminant. Therefore, care must be taken to assure that adequate concentrations of the active forms of the chemical decontaminants are available to fully oxidize all organics as well as the microorganism in the waste stream.

4. DECONTAMINATION OF WASTE STREAMS AND SURFACES

The treatment of contaminated wastewaters has been described in Section 5.3.1.2.9 of the body of the DEIS. Typically, first line decontamination of culture wastes occurs at the bench level in the research laboratory, by either chlorine bleach treatment or by steam sterilization. Chlorine's biocidal activity is the irreparable damage to essential cell components (43-45). Other decontaminants, that have been used for wastewater treatment within the public health, industrial, and academic communities, are chloramchloramines (18,46,47), chlorine dioxide (48-50), ozone (51,52), bromine/bromine chloride (48,53), iodine (48,54), hydrogen peroxide (55,56), potassium permanganate (57), ionizing radiation (58-60), and ultraviolet irradiation (21,22,61-63).

Sterilization of waste air streams, from containment laboratories and biosafety cabinets, is usually accomplished by physical methods. HEPA filtration of laboratory air effluent (64), the most common method used in the BDRP, has been described in Appendices 11 and 12. Containment suite airlocks are irradiated with high intensity ultraviolet light to decontaminate the air and the surfaces of materials in the chamber. Although not commonly used in the laboratories of the BDRP, another method of decontaminating air streams, exhausting from biological safety cabinets and containment laboratories, is by incineration.

The inactivation of microorganisms that might contaminate surfaces in the laboratory is usually performed with chemical washes or ultraviolet irradiation (13). The nature of the surface is considered in the choice of disinfectant. No disinfectant is equally effective under all conditions. Chlorine bleach (31,45), glutaraldehyde (10,15,65), formaldehyde (66,67), ethylene oxide (24,68) and ethanol (66,69) have been used for surface decontamination. Ultraviolet lamps (61-63) are used in airlocks and pass boxes in containment suites to decontaminate surfaces.

5. SAFETY OF DECONTAMINATION PROCEDURES

Large laboratory areas, air handling systems, laboratory equipment, and electrical instruments in the high containment laboratories of the BDRP are usually decontaminated with formaldehyde gas (27). For this process, paraformaldehyde powder is depolymerized to release formaldehyde gas by heating at 450°F. This procedure results in a concentration of 300 milligrams per cubic foot, or 10,000 parts per million by volume in air. This concentration of formaldehyde vapor is 10-fold lower than that at which formaldehyde vapor is potentially explosive.

Laboratory areas or airlocks used for equipment decontamination are sealed off from adjacent areas during the heating of the paraformaldehyde and during the 10-12 hour subsequent contact time. Areas into which the formaldehyde gas may diffuse, during large area decontaminations or air handling

system decontaminations, and be detectable, are posted with warning signs or closed to personnel as appropriate. Any employees who have a documented history of hypersensitivity to formaldehyde are notified before any decontamination procedure using formaldehyde is begun.

After allowing adequate contact time for formaldehyde gas penetration, it is sometimes necessary to enter areas before the ventilation system is turned on. The purpose of such entry is to retrieve spore patches, which are used to verify the adequacy of decontamination, and the formaldehyde concentration during such retrieval is very high, probably about 1000 parts per million. Only qualified and trained safety personnel participate in this procedure. Tyvek suits, surgical gloves and a self-contained breathing apparatus are always worn during this operation. Respirators are worn by safety personnel when weighing and handling the paraformaldehyde. These respirators are fitted with acid gas filters.

Several studies have been conducted during the past six years to determine whether an unhealthful condition is created for employees during the conduct of these formaldehyde decontamination procedures in buildings 1425 and 1412 of USAMRIID.

Airlock decontamination of equipment is done only on weekends except in cases of emergency. The paraformaldehyde is heated at midnight on Friday and the airlock opened on Saturday morning, a time when only a few persons are in the building. The airlock is allowed to ventilate into the surrounding corridor until Monday morning during which time posted signs warn of the possible presence of irritating vapors.

Whenever possible, a large decontamination box is used for freezers or other equipment. The box is pushed into the airlock and the equipment placed within, after which it is taken to the utility penthouse where the decontamination takes place by heating paraformaldehyde inside the box. Following the standard contact time, the box is opened nearby one of the outside doors to the roof and the gas is released directly to the outside atmosphere. Occasionally, the formaldehyde gas generated is neutralized with ammonium carbonate before release into the atmosphere.

The first study was conducted by the Environmental Health Division, Preventive Medicine Activity, Walter Reed Army Medical Center, on 23 December 1981. The conclusion was that the techniques used to contain the formaldehyde vapor during airlock decontaminations of laboratory equipment were adequate. No formaldehyde was detected prior to opening the airlock. The levels detected once the airlock was opened varied from zero to one parts per million. It was recommended that the laboratory equipment not be removed from the airlock for at least two hours after opening the door, a practice which was already in effect.

A two-part study was conducted by personnel from the US Army Environmental Hygiene Agency, Fitzsimons Army Medical Center, during July/August 1984 and December 1984. Formaldehyde levels were determined inside of a laboratory suite during an airlock decontamination, from the time of the initial start-up on a Friday evening, until personnel returned to the suite on a Monday morning. The only detectable formaldehyde levels occurred 30 minutes after start-up and these levels persisted for 3 hours. Levels ranged from 0-17.5 parts per million. No formaldehyde was detected during the remainder of the sampling period. No personnel were exposed to detectable levels of formaldehyde vapors during the survey. It was concluded that the health threat of formaldehyde vapors generated by the decontamination procedures was minimal, and no recommendations were made for modification of the existing ventilation system or operating procedures.

During the period 18-22 December 1987, another analysis of formaldehyde concentrations was conducted by personnel from the U.S. Army Environmental Hygiene Agency, Aberdeen Proving Ground, during the decontamination of an entire laboratory suite, from the preparation of the paraformaldehyde to the clean-up of the suite, using area samplers and personal breathing zone monitors. Results showed a formaldehyde concentration of up to 10 parts per million to be present during the weighing of the paraformaldehyde, but the recommended practice of wearing a respirator fitted with organic filters during this operation was in effect at the time. During the actual decontamination, the maximum detectable level of 0.67 parts per million was in the utility penthouse, but was still below permissible levels. Levels in other areas adjacent to the suite ranged from 0.01-0.09 parts per million. Samples taken inside the suite following postdecontamination ventilation showed a residual concentration of 0.07-0.08 parts per million. During clean-up, an operation performed by personnel wearing appropriate respirators, the concentration never exceeded 0.07 parts per million, well below the regulatory limit (70).

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APPENDIX 14

Public Comments on the
Draft Programmatic Environmental Impact Statement

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Table A14-1: Subject Categories of Comments
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Table A14-2: Identification of Specific Comments
A14-5
and Response Subject Areas

1. FILING AND DISTRIBUTION OF DEIS

The Draft Programmatic Environmental Impact Statement (DEIS) for the Biological Defense Research Program (BDRP) was filed with the Environmental Protection Agency on May 12, 1988, and distribution was made to the agencies and others known to have an interest in the proposed action. The notice of filing, public meeting notice, and notice of public availability appeared in the *Federal Register* of May 17, 1988.

The DEIS was distributed to agencies and officials of Federal, State and local governments, citizen groups and associations, the media, public libraries and other interested parties. Over 650 copies of the DEIS were distributed. The initial DEIS distribution list is in Section 10 of this document.

2. PUBLIC REVIEW PERIOD AND PUBLIC MEETINGS

The public comment period was initially announced to end August 12, 1988, with two sessions of a public meeting scheduled for July 25, 1988, in Arlington, Virginia. The meeting was held as scheduled, with six individuals making presentations. Subsequent to this public meeting, on the basis of requests from public and private sectors in Utah, an additional public meeting was held at Tooele Army Depot, Utah, on September 19, 1988. Twenty comments were presented at this meeting. The public comment period was extended to October 4, 1988, to allow additional opportunity to submit written comments on the DEIS. Including both oral and written input, there were a total of 59 responses to the DEIS.

3. ORGANIZATION OF RESPONSES TO COMMENTS

Appendix 14 consists of the reproductions of public comments received, including the transcripts of those presented verbally at the public meetings. Many commentors raised a number of individual issues in their submissions. Careful review of these submissions yielded over 400 discrete comments. Of the over four hundred questions or comments, many people addressed the same or very similar issues. Several individuals submitted both oral and written comments. Where both submissions were similar or identical, the written text was taken as the more authoritative. If, however, the meeting transcript contained a distinct thought or question not appearing in the text version, then this oral remark was taken as an additional comment. In order to facilitate comprehensive responses to these comments, they have been grouped into five major subject areas with 25 subcategories for purposes of preparing responses (Table A14-1). These categories were developed so that the issues and concerns raised could be addressed more directly and comprehensively.

TABLE A14-1
SUBJECT CATEGORIES OF COMMENTS

1. ALTERNATIVES

    A. Eliminate aerosol testing
    B. Use only simulants
    C. Transfer the medical program to a civilian agency
    D. Eliminate recombinant DNA work
    E. Preferred alternative

2. SAFETY

    A. General
    B. External oversight
    C. DOD/DA oversight
    D. Contingency plans
    E. Disease transmission
    F. Recombinant DNA work
    G. Transportation of etiologic agents

3. VALIDITY OF THE EIS PROCESS

    A. All inclusiveness
    B. Quantification of risk
    C. CEQ considerations
    D. Effluent controls/issues

4. NOT SPECIFIC TO THE BDRP DEIS

    A. Questions raised about non-BDRP issues
    B. Issues not specific to NEPA
    C. Biological Weapons Convention issues
    D. Questions unique to the BATF
    E. Offensive research/trust
    F. Questions about classified research
    G. Scientific validity

5. MISCELLANEOUS

    A. Errors in document
    B. Agreement with the comment

Broadly speaking, commentors raised questions about the possibility of considering different alternatives to the present BDRP, the safety of the program, whether or not the EIS process had been followed adequately, and pointed out a small number of specific errors in the DEIS. In addition, some individuals expressed agreement with the conclusions reached in the DEIS, while others commented on the Biological Aerosol Test Facility (BATF) proposed for construction at Dugway Proving Ground, UT. The BATF proposal is not specifically covered within the BDRP EIS, and these comments would more logically apply to a separate

DEIS that was published for that project. A thorough analysis of these comments, however, did reveal several questions and issues which could be interpreted as applying to the BDRP in general. All such questions were incorporated as comments to this EIS.

Within Appendix 14, more than 400 separate questions and comments were identified as meriting an individual response. On each letter (or transcript), the section where a specific comment has been identified is marked in the left margin with a bracket. Some comments are more than a page in length, others occupy only a part of one line. In the left margin, each bracketed comment has been assigned a number, for example 1-1 or 1-2. The first numeral is that assigned to the entire comment submitted, for example, comment 1 is from the U.S. Department of Agriculture, Forest Service. Two comments were identified in this letter, and they were numbered 1-1 and 1-2. Some complex questions were identified as containing sub-parts, and they were assigned a letter suffix, e.g. 7-2F. Table A14-2 presents a complete listing of the comments submitted, the number of comments identified within each submission, and the response category to which it was assigned which indicates where, in Appendix 15, the response is presented. An abbreviation code next to the commentor's name indicates that the comment is taken from the transcript of the July 25, 1988 public meeting held in the Washington, D.C. area (D.C.) or from the transcript of the September 19, 1988 public meeting held at the Tooele Army Depot, Tooele, Utah (TAD).

TABLE A14-2
IDENTIFICATION OF SPECIFIC COMMENTS AND
RESPONSE SUBJECT AREAS

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
Federal Agencies			
1	David E. Ketcham Director of Environmental Coordination Forest Service, U.S. Dept. Agriculture 12th & Independence SW P.O. Box 96090 Washington, DC 20090-6090	1 2	5 B 1 E
2	Edward W. Christoffers Assistant Branch Chief Management Div Habitat Conservation Branch Oxford Laboratory U.S. Dept of Commerce National Oceanic and Atmospheric Administration Oxford, MD 21654	1	5 B
3	Eugene L. Lehr Environmental Division Office of the Secretary of Transportation U.S. Dept Transportation 400 Seventh St. S.W. Washington, DC 20590	1	5 B
4	Margaret A. Krengel Regional Environmental Officer U.S. Dept Housing and Urban Development Philadelphia Regional Office, Region III Liberty Square Building 105 South Seventh Street Philadelphia, PA 19106-3392	1	5 B
5	Vernon Houk Assistant Surgeon General Director Center for Environmental Health and Injury Control Department of Health and Human Services Centers for Disease Control Atlanta, GA 30333	1 2 3 4	5 B 2 C 3 C 5 B

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
6	Richard E. Sanderson Office of Federal Activities External Affairs (A-100AE) U.S. Environmental Protection Agency Washington, DC 20460	1 2 A 2 B 3	5 B 2 A 2 A 5 B
7	Wayne Owens Congressman, UT	1 2 A 2 B 2 C 2 D 2 E 2 F 2 G 3 A 3 B 3 C	2 A 2 A 2 A 2 A 2 A 2 A 2 A 3 C 1 C 1 C 4 C
8	Francis T. Holt State Conservationist Soil Conservation Service U.S. Department of Agriculture P.O. Box 11350 Salt Lake City, UT 84147	1	3 C
9	James M. Parker State Director Bureau of Land Management U.S. Department of the Interior Utah State Office 324 South State, Suite 301 Salt Lake City, UT 84111-2303	1 2 3 4	1 E 1 E 3 B 5 A
State Agencies			
10	Director Maryland State Clearinghouse for Intergovernmental Assistance 301 West Preston Street Baltimore, MD 21201-2365	1	2 G
11	John K. Van de Kamp Attorney General Department of Justice State of California 3580 Wilshire Boulevard, Room 800 Los Angeles, CA 90010	1	2 G

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
12	Randy G. Moon State Science Advisor Office of Planning and Budget State Advisory Council on Science and Technology 116 State Capitol Building Salt Lake City, UT 84114	1 2 3 4	4 B 1 E 3 C 1 E
13	Martin W. Walsh Secretary Department of the Environment State of Maryland 201 West Preston Street Baltimore, MD 21201	1	5 B
14	Dr. Suzanne Dandoy Executive Director Department of Health Office of the Executive Director 288 North 1460 West P.O. Box 16700 Salt Lake City, UT 84116-0700	1 A 1 B 2 3 4 A 4 B 4 C 5 A 5 B 6 7 8 9 A 9 B 9 C 10 11 12 13 14 15 16 17 18	2 D 2 D 4 E 1 E 1 B 1 B 1 B 2 E 2 E 4 E 1 E 4 B 2 B 2 B 2 B 4 F 3 D 3 D 2 A 2 G 2 E 3 A 2 A 2 B
15	Randy Moon (TAD) See also comment #12.	1	5 B

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
58	A. Kent Powell Deputy State Historic Preservation Officer Division of State History Dept of Community and Economic Development 300 Rio Grange Salt Lake City, UT 84101	1	3 C
16	Royd Smith (D.C.) Maryland delegate, House of Representatives	1	4 B
17	Dr. Goobler (TAD) Chairman, Tooele County Commissioners	1	5 B
59	Palmer DePaulis Mayor Salt Lake City Corporation 324 South State Street Fifth Floor, Suite 500 Salt Lake City, Utah 84111	1	3 C
Individuals and Non-Government Organizations			
18	Mary Ann Putman 5101 Ballenger Creek Pike Frederick, MD 21701	1	4 A
19	John C. Dempsey 7813 Rocky Springs Rd. Frederick, MD 21701	1 2 3 4 5	3 C 3 D 3 B 1 E 3 D
20	David Keppel 22 North Main Street Essex, Connecticut 06426	1 2 3 4	2 F 4 E 4 C 4 E
21	Philip Rosenberg, Ph.D. Professor of Pharmacology and Editor of TOXICON School of Pharmacy The University of Connecticut U-Box 92 372 Fairfield Road Storrs, Connecticut 06268	1	5 B

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
22	Rebecca Goldburg, Ph.D. Environmental Defense Fund 257 Park Avenue South New York, NY 10010	1 A	1 C
		1 B	1 C
		1 C	1 C
		1 D	1 C
		2 A	2 C
		2 B	2 A
		2 C	2 A
		2 D	2 A
		2 E	2 A
		2 F	2 A
		2 G	2 A
		3 A	3 A
		3 B	3 A
		3 C	2 E
		4 A	4 C
		4 B	4 C
		4 C	4 C
		4 D	4 C
		4 E	4 C
		4 F	4 C
		5	3 C
		6 A	4 A
		6 B	4 A
		7 A	2 A
		7 B	2 B
		7 C	2 F
		7 D	2 A
		7 E	2 C
		8	2 A
		9	2 F
23	William C. Patrick* 5659 Etzler Road Frederick, MD 21701	1	5 B

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
24	Barbara Hatch Rosenberg* Memorial Sloan-Kettering Cancer Center Walker Laboratory Rye, NY 10580	1 A	4 C
		1 B	4 C
		2 A	4 E
		2 B	4 E
		2 C	4 E
		2 D	4 E
		3 A	1 E
		3 B	1 E
		3 C	1 E
		4 A	1 D
		4 B	1 D
		4 C	1 D
		5 A	1 A
		5 B	1 A
		5 C	1 A
		5 D	1 A
		6 A	1 E
		6 B	4 B
		7 A	1 B
		7 B	1 B
		7 C	1 B
		7 D	1 B
		8	1 C
		9 A	4 F
		9 B	4 F
		9 C	4 F
		9 D	4 F
		10 A	4 E
		10 B	2 F
		10 C	4 E
		11	2 F
		12	3 B
		13 A	2 E
		13 B	2 E
		14	2 E
		15	4 A
		16 A	2 A
		16 B	1 E
		17	1 C
		18 A	4 E
		18 B	4 E
		18 C	4 E
		18 D	4 E
		19	4 B
25	John C. Dempsey 7813 Rocky Springs Road Frederick, MD 21701	1 A	3 D
		1 B	3 D
		2	3 D

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
26	Francis A. Boyle Professor of Law and Program in Arms Control, Disarmament and International Security Counsel, Committee for Responsible Genetics College of Law University of Illinois at Urbana-Champaign 209 Law Building 504 East Pennsylvania Avenue Champaign, IL 61820	1	4 C
		2	4 B
		3	4 E
		4	5 A
		5	2 F
		6	4 C
		7	4 C
		8	1 C
		9 A	1 A
		9 B	1 D
		9 C	1 C
		9 D	1 E
		10	4 C
		11	4 C
		12	4 A
		13	4 E
		14	1 B
		15 A	4 C
		15 B	4 C

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
27	Jeremy Rifkin The Foundation on Economic Trends 1130 17th St. N.W. Suite 630 Washington, D.C. 20036	1	3 C
		2	1 E
		3	3 C
		4	4 A
		5 A	1 E
		5 B	2 E
		6 A	4 A
		6 B	4 A
		6 C	2 F
		7	4 A
		8	4 A
		9 A	2 E
		9 B	2 A
		9 C	2 A
		9 D	3 D
		9 E	1 E
		9 F	1 E
		9 G	3 D
		9 H	1 E
		9 I	2 G
		10	3 A
		11	2 A
		12	2 A
		13 A	2 A
		13 B	2 A
		14	2 E
		15	1 E
		16	1 E
		17	2 A
		18 A	1 A
		18 B	1 D
		18 C	1 C
		18 D	1 B
		19	1 E
		20	1 C
		21	1 B
		22	1 E
		23	1 C
		24	2 B
		25	2 B
		26	3 A
		27	3 A
		28	1 B
		29	4 B
		30	4 B
		31 A	1 E
		31 B	1 E

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
28	A. J. Martinez 2500 East 2900 South Salt Lake City, UT 84109	1 2	2 A 5 A
29	Dr. Susan Wright and Nachama Wilker* Co-chair, Subcommittee on Military Use of Biological Research Committee for Responsible Genetics 186A South Street Boston, MA 02111	1 A 1 B 1 C 2 A 2 B 3 4 A 4 B 4 C 4 D 5 A 5 B 5 C 5 D 5 E 5 F 6 A 6 B 6 C 6 D 7 A 7 B 8 9 10 A 10 B 11 12	1 E 1 E 4 B 1 E 1 E 4 C 1 E 4 E 4 E 4 E 1 E 4 A 4 A 4 A 4 C 1 E 2 F 2 F 2 F 2 F 4 A 4 A 4 D 1 E 1 B 1 B 1 C 4 C
30	Craig L. Booth, M.D. President Utah Medical Assocociation Environmental Health Committee 540 East Fifth South Street Salt Lake City, UT 84102	1 2 3 4 5 6 7 8 A 8 B 9 A 9 B 10 A 10 B	1 E 4 B 1 B 2 A 2 D 4 B 1 B 1 B 1 B 2 D 2 B 4 B 4 C

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
31	Downwinders 966 East Wilson Avenue Salt Lake City, UT 84105	1	3 C
		2	4 B
		3	1 E
		4 A	1 E
		4 B	1 E
		4 C	4 E
		4 D	3 C
		5	4 B
		6	1 E
		7	4 B
		8	1 A
		9	4 B
		10	2 D
		11	1 E
32	Univ. Utah Petition Department of Biology University of Utah Salt Lake City, UT 84112	1 A	4 C
		1 B	1 E
		1 C	1 E
		1 D	1 B
		1 E	4 B
		2	4 E
		3	1 D
33	Brian Moss U.S. Senate Candidate 833 East 400 South, Suite 103 Salt Lake City, UT 84102	1 A	4 A
		1 B	4 A
		2	4 A
		3	1 B
		4	4 E
		5	4 B
34	Naomi Franklin resident, Utah	1	1 C
		2	4 E
		3	1 C
35	Edwin B. Firmage* resident, Utah	1	4 E
36	Petition Utah	1 A	4 E
		1 B	4 E
		2	1 B
37	Robert W. Sidwell,Ph.D.* Professor of Virology and Director, Antiviral Program Department of Animal, Dairy and Veterinary Sciences College of Agriculture Utah State University Logan, UT 84322-5600	1	5 B
		2	5 B
		3	5 B
		4	5 B
		5	5 B

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
38	Phyllis D. Coley, Ph.D.* Biology Department The University of Utah 201 Biology Building Salt Lake City, UT 84112	1 A	4 E
		1 B	4 E
		1 C	4 E
		1 D	4 G
		2	1 B
		3 A	1 E
		3 B	4 A
		4	2 E
		5	4 F
		6	4 B
		7	2 E
39	David S. Thaler, Ph.D.* Biology Department The University of Utah Salt Lake City, UT 84112	1 A	4 C
		1 B	4 C
		1 C	4 C
		1 D	4 C
		1 E	4 C
		1 F	4 C
		1 G	4 C
		2	2 A
		3	1 B
		4	1 E
		5 A	4 G
		5 B	4 C
		5 C	4 C
		6	4 C
		7	4 B
		8	4 C
		9	4 B
		10	4 B
		11	4 B
		12	4 C
		13	4 B
40	Paige Wilder* Utah Peace Test P.O. Box 11416 Salt Lake City, UT 84147	1	4 D
		2	2 E
		3	4 G
41	Rolf Karlstrom 87 Q Street, #2 Salt Lake City, UT 84103	1 A	4 E
		1 B	4 B
		1 C	4 G
		1 D	4 C
		2	2 E
42	Brian Moss (TAD) (See also comment # 33)	1	4 A
		2	4 B
		3	4 E
		4 A	2 F
		4 B	1 E
		5	4 D

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
43	Andrew Kimbrell (D.C.) Foundation on Economic Trends 1130 17th St. N.W. Suite 60 Washington, D.C. 20036	1	3 A
		2	1 E
		3 A	1 E
		3 B	1 C
		3 C	1 C
		3 D	2 B
		3 E	1 E
		4 A	1 E
		4 B	1 D
		4 C	4 E
		4 D	4 E
		5 A	1 E
		5 B	4 A
		5 C	2 A
		6	3 A
		7	2 F
		8 A	4 C
		8 B	4 C
44	Peter Stickel (D.C.) Resident, Frederick County, MD	1	5 B
45	Steve Erickson (TAD) Downwinders (see comment #31)	1 A	4 A
		1 B	4 A
		1 C	4 A
		2	4 B
		3	4 B
		4	4 B
		5	4 E
		6 A	4 A
		6 B	4 A
		7	1 B
46	Preston Truman (TAD) Downwinders	1	4 D
47	Phyllis Coley (TAD) University of Utah	1 A	2 F
		1 B	2 E
		2	4 G
		3	4 D
48	William Sayres (TAD) Physicians for Social Responsibility Utah	1	2 A
		2	2 E
		3	4 D
		4	4 E
		5	4 C
49	Fred Gottleib (TAD) resident, Utah	1	4 D

IDENTIFICATION NUMBER	SUBMITTER	COMMENT NUMBER	SUBJECT AREA
50	Clifton Spendlove (TAD) resident, Utah	1	4 D
51	Matthew Hahn (TAD) resident, Utah	1	4 A
52	Heidi Wallentine (TAD) resident, Utah	1	4 A
53	Diana Hirschi (TAD) resident, Utah	1	4 B
54	Mary Alice Koebler (TAD) resident, Utah	1	4 A
55	Robert McBride (TAD) resident, Utah	1 2 3 4 5 6 A 6 B 7 8 9	4 A 4 B 4 G 4 D 4 A 2 G 1 E 2 D 4 D 1 B
56	Suzanne Kirkham Utah Public Health Association P.O. Box 16650-CHS 20 Salt Lake City, UT 84116-0650	1	4 D
57	Tim Scherer 1765 Willowbrook Drive Provo, UT 84604	1 A 1 B 1 C 1 D	4 C 4 C 4 C 4 C

* Written and oral presentations identical.

United States Department of Agriculture
Forest Service
Washington Office
12th & Independence SW
P.O. Box 96090
Washington, D.C. 20090-6090

Reply To: 1950-4

Date: July 18, 1988

Mr. Charles Dasey
U.S. Army Medical Research & Development Command
Attn: SGRD-PA
Fort Detrick,
Frederick, MD 21701-5012

Dear Mr. Dasey:

As you requested, we have reviewed your environmental impact statement, "Biological Defense Research Program".

We do not expect adverse impacts from either of the alternatives to National Forest System lands, Forest Service employees, or the environment in general.

We were somewhat surprised that the DEIS considered only the two extreme alternatives in detail, having eliminated intermediate alternatives as being unreasonable.

Thank. you for the opportunity to review this draft environmental impact statement.

DAVID E. KETCHAM
Director of Environmental Coordination

Caring for the Land and Serving People

UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
NATIONAL MARINE FISHERIES SERVICE

Management Division
Habitat Conservation Branch
Oxford Laboratory
Oxford, Maryland 21654

July 22, 1988

U.S. Army Medical Research & Development Command
ATTN: SGRD-PA
Fort Detrick,
Frederick, MD 21701-5112

Gentlemen:

We have reviewed the Draft Programmatic Environmental Impact Statement on the biological Defense Research Program, dated May 1988, and consider it adequate. While we would prefer a more detailed treatment of specific issues, we understand the facility of the broad programmatic approach to this type of action. We will be pleased to assist you further as you implement your "tiered approach" to future actions, and will comment on site specific proposals as they arise.

Edward W. Christoffers
Asst. Branch Chief

U.S. Department of Transportation
400 Seventh St., S.W.
Washington, D.C. 20590

Mr. Charles Dasey
U. S. Army Medical Research and Development Command
Attn: SGRD-PA
Fort Detrick
Frederick, Maryland 21701-5012

Dear Mr. Dasey:

The Environmental Division has reviewed the draft programmatic environmental impact statement for continuation of the Biological Defense Research Program. We have no comments.

Sincerely,

Eugene L. Lehr, Chief
Environmental Division

U.S. Department of Housing and Urban Development
Philadelphia Regional Office
Liberty Square Building
105 South Seventh Street
Philadelphia, Pennsylvania 19106-3392

Major General Philip K. Russell
Commander
U.S. Army Medical Research and Development Command
ATTN: SGRD-PA
Fort Detrick
Frederick, MD 2170l-5012

Dear Major General Russell:

Thank you for providing the opportunity to review the Draft Programmatic Environmental Impact Statement on the Department of Defense Biological Defense Research Program. We do not intend to comment on the document.

Very sincerely yours,

Margaret A. Krengal
Regional Environmental Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control
Atlanta GA 30333

August 11, 1988

Mr. Charles Dasey
USAMRDC
ATTN: SGRD-PA
Ft. Detrick, Frederick, Maryland 21701-5012

Dear Mr. Dasey:

We have reviewed the Draft Environmental Impact Statement (DEIS) for the Department of the Army Biological Defense Research Program (BDRP), and we are responding on behalf of the U.S. Public Health Service. We believe in general, precautions specified for working with infectious agents, toxins, and genetically engineered microorganisms are in compliance with the most stringent practices.

From our review of the document, it appears that the classification of infectious organisms and the specific laboratory precautions are adequate for defined biosafety levels. Potential public and laboratory hazards, waste disposal, and physical security have also been adequately considered. The Final EIS should, however, contain more detail on supervision of work practices of off-site contractors. The Army needs assurance that the institutional authorities at non-Army laboratories are, in fact, assuring safety.

On page 1-4, which begins "The programmatic EIS....," The Department of the Army should describe exactly how future BDRP actions will be examined; that is, (1) what criteria are used for identifying "new" versus continuing BDRP actions, (2) who will be clearly responsible for identifying "new" BDRP actions for review, (3) what organization will actually conduct the review of identified actions, and (4) will there be an ongoing formal program review element that helps to identify new actions? We feel that this identification in the Final EIS of a formal structure would better demonstrate the intent of the Department of the Army.

On page 1-16. the paragraph that begins "For item 2)...." seems to say the BDRP has an excellent track record for safety, particularly in recent year. Is the continuing BDRP using the same research techniques, quantities and types of organisms, safeguards, etc., as have been used in the past when this good track record was established or is the BDRP venturing into new areas of research involving new biohazards and new techniques? The implication throughout the DEIS is that the program is a continuation of activities of similar risk to those conducted in the past. In our review we could not find an explicit statement of how the work described in this DEIS is similar to or different from past BDRP activities. For the Final EIS, it would be reassuring to know that nothing really new is being proposed here, if indeed that is the case.

The Impact Analysis Matrix (Appendix 6) was especially effective in presenting the assessment of risks considered by the EIS team. Based upon the information provided in the DEIS, we feel that the potential for adverse human health effects will be minimized.

Thank you for sending this document for our review. Please ensure that we are included on your mailing list for the Final Environmental Impact Statement for this project as well as further documents which are developed by your agency.

Sincerely yours,

Vernon W. Houk, M.D.
Assistant Surgeon General
Director
Center for Environmental Health and Injury Control

United States Environmental Protection Agency
External Affairs
Washington DC 20460

Major General Phillip K. Russell
Commander
U.S. Army Medical Research and Development Command
Fort Detrick, Frederick, MD 21701-5012

Attn: SGRD-PA

Dear General Russell:

In accordance with Section 309 of the Clean Air Act, the U.S. Environmental protection Agency (EPA) has reviewed the Army's Draft Programmatic Environmental Impact Statement for the Biological Defense Research Program. On August 28, 1987, I transmitted EPA's comments on the scope of this Draft EIS, and we are pleased that many of EPA's concerns are addressed in the Draft EIS.

In 1987, EPA expressed concerns about the possible exposure of workers and the general public to infectious diseases. The Draft EIS does a thorough job of discussing these risks and the Army's efforts to mitigate them at Army and other DOD facilities. In particular, appropriate measures, such as vaccinations and disinfection, have been instituted to guard against accidental exposures.

We also requested that the Draft EIS present the administrative mechanisms by which environmental protection is assured at non-Army facilities. This issue is not discussed sufficiently in either Section 2.5 or Section 5.4. Section 2.5 explains how the Army seeks and funds participation of non-DOD organizations in the program, but with no explanation of environmental requirements being part of this process. Section 5.4 provides the environmental procedures and settings at representative non-DOD sites. However, the Draft EIS does not present the steps the Army will follow to make certain that outside facilities are environmentally satisfactory before initiating Army funded research. We recommend that the Army present a discussion of the mechanisms in the Final EIS.

EPA also commented that all uses of pesticides within the scope of the program must be in accordance with the EPA-approved product labels. Disinfectants are considered to be pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and use of disinfectants and other pesticides are governed by that Act. The Draft EIS indicates that formaldehyde gas generated from heating paraformaldehyde powder will be used as a disinfectant at a concentration of 10,000 parts per million (by volume in air) for a contact time of 10-12 hours. The FIFRA Registration Standard for paraformaldehyde and formaldehyde (copy attached)

lists this as a registered use and provides useful health and safety information. All use of registered pesticides must be in accordance with EPA-approved label directions. While general references are made in the EIS to the use of other antimicrobial pesticides for the decontamination of waste waters and laboratory surfaces, no specific details were provided. Here again, label directions must be followed.

Although, as described in the Draft EIS, the proposed program would be conducted in a safe manner and has no planned releases of biological materials, we do have the concerns discussed above. According to EPA's procedures we have rated this Draft EIS EC-2. This means that we have environmental concerns regarding the program and additional information is requested for the final EIS. I have asked Dr. W. Alexander Williams (202-382-5909) of my staff to follow up on our comments with your staff.

Sincerely,

Richard E. Sanderson
Director
Office of Federal Activities

cc: Mr. Lewis D. Walker, OASA (I&L)

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United States Department of Agriculture
Soil Conservation Service
P.O. Box 11350
Salt Lake City, UT 84147

August 9, 1988

Commander
U.S. Army Medical Research and Development Command
Attn: SGRD-PA
Fort Detrick, Frederick, MD 21601-5012

Dear Sir:

I have reviewed the Draft Programmatic Environmental Impact Statement for the Biological Defense Research Program (BDRP). I have the following comment:

No information has been provided on the impact to prime farmland or potential impacts to the soil in general. The Soil Conservation Service (SCS) has soil information available. Further information can be obtained from Dr. Ferris P. Allgood, State Soil Scientist, at the above address, or by calling (801) 524-5064.

A copy of this letter is being sent to the Grantsville and Shambip Soil Conservation Districts (SCD). In the event that they are not on your mailing list, the Chairman of the Grantsville SCD Board is Glenn Elkington, 450 South 1st West, Tooele, Utah 84074; and the Chairman of the Shambip is Gerald Sagers, Box 312, Rush Valley, Utah 84069.

I appreciate the opportunity to review and comment.

Sincerely,

FRANCES T. HOLT
State Conservationist

cc: Glenn Elkington, Chairman, Grantsville SCD Board
Gerald Sagers, Chairman, Shambip SCD Board
James B. Newman, Dir., ECS, SCS, Washington, D.C.
Stanley N. Hobson, Dir., WNIC, SCS, Portland, OR
James D. Maxwell, DC, SCS, Midvale, UT
G. Arthur Shoemaker, SCE, SCS, SLC, UT
Ferris P. Allgood, SSS, SCS, SLC, UT
R. Deane Harrison, SRC, SCS, SLC, UT
Gary R. Gross, ASTC, SCS, SLC, UT
Robert F. Sennett, W/L Bio., SCS, SLC, UT

The Soil Conservation Service
is an agency of the
United Stated Department of Agriculture

United States Department of the Interior
BUREAU OF LAND MANAGEMENT
UTAH STATE OFFICE
124 SOUTH STATE, SUITE 101
SALT LAKE CITY, UTAH 84111-2303

Commander, U.S. Army
Medical Research and Development Command
Attn: SGRD-PA
Fort Detrick
Frederick, Maryland 21701-5012

Dear Sir:

Thank you for the opportunity to review and comment on the Draft Programmatic Environmental Impact Statement for the Biological Defense Research Program The Bureau of Land Management (BLM), USDI, through the Pony Express Resource Area of the Salt Lake District Office, administers public lands surrounding the U.S. Army Dugway Proving Ground (DPG) in Tooele County.

The mission of the BLM is to manage public lands for multiple use. Consequently, the Resource Area is host to a variety of both consumptive and non-consumptive uses, including but not limited to livestock grazing, recreation, wildlife, and mining. Many of these activities occur on public land adjoining DPG. The BLM does not intend to address activities conducted on DPG except as they might impact surrounding public lands and public land users. The safety and well being of public land users are paramount in the administration of these public lands.

General Comment: The Document is unusually vague as to the type of activities and where these activities will occur on the Dugway Proving Ground facility. Based on the general statements and descriptions in the Draft EIS, the BLM is unable to determine the extent to which there may be a likelihood that neither biological agents (pathogens, viruses, toxins, GEMs, etc.) nor simulants will be deposited on adjacent public lands or come in contact with the flora, fauna, and human users of public lands. Since the possibility of such exposure exists, we must conclude that the proposal is not consistent with proper management of the public lands under BLM management.

Specific Comments:

(1) Page 2-7, section 2.4.3, Paragraph three, states: "Outdoor field tests with simulants (non-pathogenic and/or non-toxic materials) are performed on an "as-required basis after preparation of appropriate NEPA documentation."

COMMENT: The document is not site specific as to the locations of the proposed tests; therefore, it can be assumed that these tests could occur where wind drift might impact public lands and public land users. The BLM Salt Lake District requests that copies of NEPA documents relating to these tests be forwarded for review by the District.

(2) Page 2-7, section 2.4.3, paragraph four, states: "Biological stocks including sera, antigens, toxins, cultured cell lines and microorganisms are maintained at the Baker Laboratory area by Life Sciences Division personnel," Page A9-21 (section 3.1,6 Extent of Downwind Hazard) first paragraph states. "The estimates in this appendix are therefore not firm predictions; they are no better than very rough estimates.

COMMENT: While the risk of accidental exposure to the general public from these biological stocks may be low, it is believed that this risk should De analyzed further in the EIS with regard to the potential for exposure by users of the surrounding public lands.

(3) Page 5-20, section 5.3.3, paragraph one, states "The installation includes more than 800,000 acres in Tooele and Juab Counties..."

COMMENT: To the best of our knowledge, DPG does not extend into Juab County.

The opportunity to comment on this draft is appreciated.

Sincerely,

James M. Parker
State Director

Director
Maryland State Clearinghouse
for Intergovernmental Assistance
301 W. Preston Street

SUBJECT: REVIEW COMMENT AND RECOMMENDATIONS
State Application Identifier: MD880512-0367
Applicant: Department of the Army
Description: Draft Programmatic EIS - Biological Defense Research Program

Responses must be returned to the State Clearinghouse on or before June 12, 188. Based on a review of the notification information provided, we have determined that:

Check One:

___ 1) It is consistent with our plans, programs, and objectives. For those agencies which are responsible for making determinations under the following federal consistency requirements, please check the appropriate response:

___ It has been determined that the subject has "no effect" on any known archeological or historic resources and that the requirements of Section 106 or the National Historic Preservation Act and 36 CFR 800 have been met for the subject.

___ It has been determined that the requirements of Maryland Coastal Zone Management Program have been met for the subject in accordance with 16 USC 1436, Section 307(c)(1) and (2).

_X_ 2) It is generally consistent with our plans, programs, and objectives, but the qualifying comment below is submitted for consideration.

___ 3) It raises problems concerning compatibility with our plans, programs, or objectives, or it may duplicate existing program activities, as indicated by the comment below. If a meeting with the applicant is requested, please check here ___.

___ 4) Additional information is required to complete the review. The information needed is identified below. If an extension of the review period is requested, please check here ___.

___ 5) It does not require our comments.

COMMENTS: The Department of Health and Mental Hygiene recognizes that there are significant dangers involved in the research of biological agents which takes place at Fort Detrick. The safety of the citizens of Frederick and Maryland must be assured. Messenger service,

with deadly potential to those who come in contact with their packages, must be fail-safe; the immediate locale must be assured that any possible leakage into the community has fail-safe protection.

Although the Department is expressing no philosophical viewpoint to the Federal government's experimentation, we do reserve the right to express this concern for the safety of our citizens, and as such respectfully request the United States Army to address these issues prior to their continuation of the program.

A14-24b

JOHN K. VAN DE KAMP
Attorney General
State of California
DEPARTMENT OF JUSTICE

3350 WILSHIRE BOULEVARD
LOS ANGELES 90010
(213) 736-2304

August 3, 1988

U.S. Army Medical Research and Development Command
Attn: SGRD-PA
Fort Detrick
Frederick, MD 21701-5012

To Whom It May Concern:

Re: Draft Programmatic EIS, Biological Defense Research Program

John K. Van de Kamp, Attorney General of the State of California, has previously set forth his concerns regarding the transportation of biological agents through the Postal Service's registered mail. (See attached comments on the Draft EIS for the proposed Biological Aerosol Testing Facility at Dugway Proving Grounds.) The Draft Programmatic EIS, Biological Defense Research Program, which was not cross-referenced in the "Transport of Viable Materials" discussion in the Dugway DEIS, came to our attention after we submitted our comments.

We wish to reiterate our concern that alternative means of transportation be considered, such as the use of specially trained couriers or Army personnel. We believe consideration of such alternatives is necessary to ensure adequate protection to the people and environment of California should such materials be shipped through our state.

Thank you.

Very truly yours,

JOHN K. VAN DE KAMP
Attorney General

SUSAN L. GOODKIN
Deputy Attorney General

May 13, 1988

U.S. Army Dugway Proving Ground
Attention: STEDP-PA
Dugway, Utah 84022-5012

To Whom It May Concern:

Re: Draft EIS on Biological Aerosol Test Facility

These comments on the Draft EIS regarding the Biological Aerosol Testing Facility ("BATF") proposed to be constructed at the Dugway Proving Grounds are submitted on behalf of John K. Van de Kamp, Attorney General of the State of California, acting pursuant to his powers under the California Constitution and the California Government Code to protect the environment of California and the health and welfare of its citizens. These comments are not offered on behalf of any other State agency or official. The comments are filed pursuant to the notice of April 19, 1988, 53 Fed. Reg. 12803, extending the comment period on the DEIR.

We will confine our comments to one topic discussed In the Draft EIS: the shipment of biological agents through the open mails, using the Postal Service's registered mall (DEIS, page D-27). In this context, we wish to request additional information from the Army. Specifically, we would like to know whether any of the biological agents to be sent to the BATF will be intentionally shipped from or through the State of California. The DEIS is totally silent on this point, giving no information as the origin or route of shipment of any of the materials that will be sent to Dugway in connection with this proposed project. We are very concerned about the possibility that these shipments may be routed through California, and will, If necessary, follow these comments with a request pursuant to the Freedom of Information Act that the Army provide this routing information to us. Could you please advise us as to whether a FOIA request will be necessary, or whether the Army will release the information to us without one?

We will now address the topic of shipping biological agents through the Postal Service in the manner described in the DEIS. Briefly put, we are concerned about the possibility of a release of harmful bacteria or viruses during the shipping process, a possibility that is neither considered nor discussed In the DEIR. We are aware that the DEIS takes the position that no release is possible at the BATE itself, and therefore does not analyze or disclose the possible environmental effects of such a release. Since the Dugway Proving Grounds are not within our jurisdiction,

we express no opinion on this position. However, it seems plain to us that the types of controls, equipment, training and procedures that the Army cites to support this position do not exist In the shipping process.

The DEIS states that no release Is possible at the BATF because of the elaborate containment facilities to be used In the BATF, the training and inoculation of BATF personnel, the comprehensive containment procedures that will be used (DEIS, sections G.3 and G.4), and because of the hot, dry climate at Dugway (which is antithetical to the survival of many of the organisms involved DEIS, App. VII, sections 3.1.1 to 3.1.5) and its isolation (DEIS, section D.6.2). Even if it is assumed that these factors would prevent a release of biological agents at the BATF, the Army cannot be sure that any of these factors would be present during shipping, and it can be quite sure that most of them would be absent. For example, Postal Service facilities and vehicles do not have the elaborate containment equipment of a BATF, and Postal Service employees will not be trained to deal with a release of these agents. Indeed, because the warning labors will be placed on the hermetically sealed can, inside the shipping box, where the warnings can only be seen if the package has been partially opened, Postal Service employees will not even know that they ought to be taking any extra precautions. Certainly, they will not have the training or equipment to deal with a release of toxins that may cause anaphylactic shock, or a release of VEE virus or other viruses or bacteria. Further, the temperature, time of day, and humidity prevailing at the time of any accidental release in shipping may be those that favor survival of the agents released, allowing them to live and possibly infect people exposed to them.

We believe that the accidental release of biological agents during shipments is a reasonably foreseeable event, and that therefore the EIS should analyze the possible environmental effects of such a release and reveal them to the public. Certainly, such a possibility is within the "rule of reason" cited In 40 CFR 1502.22. An automobile accident involving a Postal Service vehicle, a fire at a Postal Service facility, carelessness on the part of mail handlers, misdirection of mail and other mishaps are a part of everyday life, and are not only reasonably but easily foreseeable. We therefore believe that the National Environmental Policy Act requires the Army to address these possibilities, and to discuss fully the possible effects of a release during shipping, where containment, specialized personnel training, and other safeguards are absent.

The DEIS states that federal regulations governing shipment of biological agents will be complied with and necessary permits obtained. While we commend the Army for following the applicable rules and regulations, nevertheless, this is not a substitute for

compliance with NEPA. Case law clearly and repeatedly has held that compliance with the regulations of other federal agencies does not substitute for or excuse compliance with the NEPA full disclosure requirements. See The Steamboaters v. FERC, 759 F.2d 1382 (9th Cir. 1985); Oregon Environmental Council v. Kunzman, 714 F.2d 901 (9th Cir. 1983). Similarly, in this case, even though the Army has complied with appropriate regulations and obtained required permits, it must still analyze and reveal the possible environmental consequences of utilizing a shipping method that may result in accidental releases.

In addition, the EIS must address the alternatives to use of the Postal Service to ship these materials. No discussion of alternatives to this facet of the project occurs in the DEIS, even though this may well be the one area of the project most likely to cause an unintentional release of biological agents. The consideration of alternatives is the heart of the EIS process, and certainly here the Army is legally required to consider alternatives to this nonsecure method of shipping. See 42 USC 4332(E);Environmental Defense Fund, Inc. v. Corps of Engineers, 492 F.2d 1123 (5th Cir. 1974); Natural Resources Defense Council v. Calloway, 524 F.2d 79 (2d Cir. 1975). For example, the use of Army personnel, appropriately trained, using military transport that is appropriately equipped, could be considered. Special courier services who are aware of what they are carrying and are prepared to deal with an accident might also be considered. We are confident that the Army can devise and evaluate alternative shipping methods. We believe they are required to do so.

We are aware that the possibility of a release that actually infects people or animals is probably a small one. Nevertheless, the danger posed if such a release does occur is a substantial one. The DEIS states that some of the biological agents to be shipped to and tested at Dugway are infectious at very low rates of exposure (DEIS, App. VII, sections 2.2.2, 2.2.3), and could have serious consequences if released (ace discussion of VEE virus at App. VII, section 3.5.1). We are naturally very concerned about any possible danger of release in California or at its borders, and are concerned about the utter lack of information and notice California will have about these dangers. When the risk of release of biological agents is presented by every Postal Service truck or plane, and when warnings are on labels that are unlikely to be easily discovered by firefighting or other emergency personnel responding to an accident, the State has little means of protecting its citizens. We need the fullest possible information on this danger, and we look to the Army to provide it, as required, through the NEPA process. We therefore urge the Army to include this analysis in the final EIS.

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We thank you for your courtesy and attention to these comments. We also request that you send us a copy of the Final EIS when it is issued.

Very Truly Yours,

JOHN K. VAN DE KAMP
Attorney General

SUSAN L. DURBIN
Deputy Attorney General

OFFICE OF PLANNING AND BUDGET
STATE ADVISORY COUNCIL ON SCIENCE AND TECHNOLOGY

August 12, 1988

Mr. Charles Dasey
U.S. Army Medical Research and
Development Command
Attn: SGRD-PA
Fort Detrick, Frederick MD
21701-5012

Dear. Mr. Dasey:

As per our telephone conversation, I am sending the following comments on the Draft Environmental Impact Statement (DEIS) of the Department of the Army's Biological Defense Research Program (BDRP).

First, the DEIS is too general in its content for specific comments.

However, there are some disturbing aspects of it with respect to its tone and purpose. The tone of the document suggests that anyone who questions the safety of the program are misinformed, ignorant or basing their position on emotion rather than fact.

The DEIS reads as a public relations document rather than an assessment of impacts from continuing the BDRP. Since the BDRP is a Congressionally mandated program, the DEIS does not need to present a defense of its purpose nor does it need to be condescending toward critics and reviewers. Yet it does both.

Another primary concern is that the DEIS presents only two possible alternatives, i.e. terminate the BDRP or the preferred alternative of continuing the BDRP unchanged. The discussion of these two alternatives is confusing. A No-Action alternative, as the DEIS indicates, means to maintain the status quo. The status quo is the ongoing BDRP and is the same as the proposed action. The other alternative of terminating the BDRP is questionable as a viable alternative because of the Congressional mandate to conduct the BDRP.

Lastly, in a discussion of the current BDRP program, the DEIS states that the IAM process identifies areas of potential concern or impact that are found not to be relevant. It identifies these as endangered species, cultural resources, wetlands and habitats, and concludes that they are not measurably affected by the "ongoing BDRP". However, an EIS process must assess the likely or possible impacts associated with all aspects of a proposed action and if a precise analysis of likely events cannot be documented, then a worse case scenario

is constructed to allow assessment of potential impacts. The DEIS dismisses any possible worse case scenario as being unlikely. Therefore, so are the impacts. Thus, the impacts are all reduced to what has already been observed to exist. This does not represent a full analysis of potential impacts.

Based on these few observations, I must conclude that the DEIS is not only too general in its content, but represents an inadequate presentation of the potential impacts of the BDRP.

Respectfully yours,

Randy G. Moon, Ph.D.
State Science Advisor
State of Utah

A14-28b

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STATE OF MARYLAND

DEPARTMENT OF THE ENVIRONMENT
201 WEST PRESTON STREET ? BALTIMORE, MARYLAND 21201
AREA CODE 301 . 225 5385

William Donald Schaeffer
Governor

Martin W. Walsh, Jr.
Secretary

August 18, 1988

Major General Phillip K. Russell
Commander, U.S. Army Medical Research and
Development Command
Fort Detrick
Frederick, Maryland 21701-5012

Dear General Russell:

In my June 16, 1988 letter, I promised to forward our comments on the Draft Biological Defense Research Program (BDRP) Environmental Impact Statement to you by the August 12, 1988 deadline. I apologize for the delay.

I feel that you have adequately addressed the issue of environmental effects of the Biological Defense Research Program and that your research is potentially of great value to public health especially as it relates to the development of vaccine in the future. I understand that you were already involved in the development of Ribovirin for Lassa Fever and that is a major contribution to the research program.

I wish you the best in your undertaking.

Sincerely,

Martin W. Walsh, Jr.
Secretary

MWW:aew

DEPARTMENT OF HEALTH
OFFICE OF THE EXECUTIVE DIRECTOR
228 North 1460 West
P.O. Box 16700
Salt Lake City, Utah 84116-6700

Norman H. Bangerter
Governor

Suzanne Dandoy, M.D., M.P.H
Executive Director

September 30, 1988

Philip R. Russell, Major General
U.S. Army Medical Research and Development Command
Attn: SGRD-PA
Fort Detrick
Frederick, MD 21701-5012

Dear Major General Russell:

Please accept the following comments offered by the Utah Department of Health in reference to the Draft Programmatic Environmental Impact Statement on the Department of Defense Biological Defense Research Program (BDRP), issued in May of 1988.

Sincerely,

Suzanne Dandoy, M.D., M.P.H.
Executive Director

Enclosure.

Statement of the Utah Department of Health
Department Concerning the
Draft Programmatic Environmental Impact Statement
Army Biological Defense Research Program

September 30, 1988

A14-30b

Statement of the Utah Department of Health
Concerning the
Draft Programmatic Environmental Impact Statement
Army Biological Defense Research Program

The Utah Department of Health submits the following comments in response to the May 1988 Draft Programmatic Environmental Impact Statement (DPEIS) regarding the Department of Defense Biological Defense Research Program (BDRP). These comments primarily address two issues surrounding the BDRP: safety and research intent.

Safety

In an appendix to these comments is the "Response to the Draft Environmental Impact Statement: Biological Aerosol Test Facility, Dugway, Utah, submitted by the Utah Department of Health in April, 1988. Attention is called to this appended report, which describes a number of specific safety concerns relevant to the BDRP as a whole.

The DPEIS does not adequately address the need for state and local health officials to be apprised regularly of research involving higher hazard microorganisms. These officials should have knowledge of specific pathogens being tested. The Army should assist state and local health officials to develop contingency plans for protection of the public, in the event of an accident wherein pathogens escape which have potential for causing infection in the community. These plans should be developed even though such accidents are deemed very unlikely. In particular, such plans should be developed for the areas surrounding Fort Detrick, Maryland and Dugway, Utah.

The DPEIS does not describe the decision criteria used when the Army elects to conduct research with a BL4 microorganism. Since such organisms carry highest levels of risk, it would be appropriate for the BDRP to formulate specific criteria to justify research with a BL4 microorganism. The mere existence of a BL4 pathogen may not call for Army research to address it. In some cases, other research centers may be able to conduct research more appropriately.

The statement in the PDEIS (p. 5-20) that there are no unique "areas of significant concern" at Dugway Proving Ground appears false. The operation of the proposed Biological Aerosol Test Facility (BATF), designed to aerosolize pathogens, must be considered an unusual potential hazard. The need to aerosolize high level (BL3) pathogens, as opposed to simulant organisms of very low pathogenicity, has not been explained satisfactorily either in the BATF DEIS or in the BDRP DPEIS. Accidental contamination arising from the handling and aerosolization of BL3 pathogens can pose a risk to BATF workers and their close contacts.

Human errors inevitably occur and not all errors are promptly recognized. The risks vary with each organism, each individual worker and each experiment. These risks cannot be dismissed entirely. Again, consideration should be given to the use of simulant organisms alone in BATF aerosolization experiments.

According to a recent U.S. Army announcement, a decision has been made to build the BATF to BL3, rather than BL4, specifications. The Utah Department of Health endorses this change. A BATF built to BL3 specifications will not support research with highly dangerous exotic or novel pathogens. This substantially reduces the public health risk should microorganisms escape. The final Programmatic Environmental Impact Statement should make note of this change.

Brief mention is made (p. 5-21) of outdoor testing at Dugway Proving Ground using simulant organisms in aerosol form. This program needs further explanation regarding its purposes, the biological species involved, amounts released, sites and conditions of release, and precautions taken to avoid any possible adverse environmental or community health effects. It should be noted that under some conditions in susceptible individuals, even normally non-pathogenic microorganisms can cause infection.

Research Intent

Among representatives of the civilian scientific and medical communities, a central area of concern about the BDRP pertains to the intent and the hazards of biosafety level 3 (BL3) and biosafety level 4 (BL4) research. The DPEIS describes the policy of the United States to continue observing the 1972 Biological Weapons Convention banning offensive research. The DPEIS states, "Development of a more virulent strain of a pathogen is specifically prohibited under any circumstance, and is not the goal of any BDRP effort." (DPEIS p. 5-9) This statement is somewhat reassuring, but does not entirely remove our concerns.

To ensure the proper design and operation of this nation's biological defense research facilities and programs, the following measures should be implemented:

1) The formation of a national committee for BDRP oversight to review all of the BDRP research projects and report to the United State" Congress. This committee should

be comprised of nationally recognized biological and medical scientists who are neither appointed by, nor otherwise associated with, the Department of Defense.

2) Local safety and review committees composed of civilian lay persons as well as biological and medical scientists. These committees would be responsible for monitoring the conduct and safety of research conducted at Fort Detrick, Aberdeen Proving Ground, and Dugway Proving Ground.

3) Construction of a lower-containment level (BL3 instead of BL4) BATF at Dugway Proving Ground. As noted above, this should remove the possibility of conducting aerosol testing with highly pathogenic novel or exotic organisms. This option could produce more trust in the BDRP, in addition to removing some risks to the public health. The DPEIS says very little about the BATF and does not acknowledge the recent decision to build it at a lower containment level.

4) A formal policy whereby neither the nature of BDRP research nor its results are classified as secret, the only exceptions being research on materiel where necessary. It is important that results of BL3 and BL4 pathogen or toxin research not be classified, especially if such research has involved recombinant DNA technologies. The DPEIS falls short of endorsing complete openness in publishing results of biological experiments.

Summary

Issues of safety and intent in the U.S. Army's Biological Defense Research Program remain which are not fully addressed by the Draft Programmatic Environmental Impact Statement. The Utah Department of Health recommends a national committee of oversight for the BDRP composed of independent scientists reporting to the U.S. Congress. We also recommend independent local review committees to oversee the safety and operation of programs at the primary research centers. Maximum openness regarding the nature design of BDRP research is important for state and local health officials and, also, for the public and the larger scientific community. The decision of the Department of Defense to build the Dugway Biological Aerosol Test Facility to BL3 rather than BL4 specifications alleviates some safety concerns regarding future research. We recommend that this decision be acknowledged in the Programmatic Environmental Impact Statement.

Response to the Draft Environmental Impact Statement:

Biological Aerosol Test Facility, Dugway, Utah

Utah Department of Health
April 6, 1988

The following comments are submitted by the Utah Department of Health in response to the Draft Environmental Impact Statement (DEIS) of January 1988, regarding the proposed Biological Aerosol Facility (BATF) to be constructed at Dugway Proving Ground. These comments address issues and impacts under seven subject headings: air emissions control, wastewater treatment, drinking water and sanitation, solid and hazardous waste disposal, emergency response planning, safety procedures, and epidemiological consideration.

I. AIR EMISSIONS

Because of the possibility that highly infectious pathogenic microorganisms will be tested in aerosol media in the Dugway facility, special attention must be given to air emissions control. The air must be fully treated before it is discharged, with adequate safeguards to ensure that no test material which is hazardous is emitted. The methods of accomplishing this must be explained in more detail than that provided by the DEIS (page C-8). Volumes of air exhausted during full operation periods in the laboratory need further detailed explanation. Sources of air, such as incinerators, design capacity of pumps, emission estimates, air pollution control devices, etc., also should be explained.

The measurements of air movement in the laboratory during down time are not addressed in the DEIS. When tests are completed and aerosols have decayed prior to cleanup, chemicals will be used for sterilization, neutralization or heat treatments. During such time, it is not stated if the direction of air movement will change, nor is it clear if there will be periods when air movement reverses or when filters are inactivated, allowing non-treated air to escape the building. At all portals of air discharge from the building, monitoring for particulates should be carried out during the time when systems are partially or totally inactivated to assure that all discharges contain no infectious or toxic materials.

The list of relevant air requirements provided in the DEIS (page F-21) is incomplete. Emissions of any type or quantity from the laboratory will be subject to state New Source Review (NSR) regulations and require a State permit.

II. WASTEWATER TREATMENT

The wastewater system permit process allows the Utah Department of Health's Bureau of Water Pollution Control to review the scope of this project with regard to the potential quantity and quality or wastewater produced, and the water pollution control measures taken. A feasibility report will be requested detailing certain features of wastewater treatment and discharge. Upon approval of the feasibility report, the Bureau will then request construction plan with detailed specifications.

The Bureau of Water Pollution Control raises the following issues with respect to the DEIS proposal:

1) The statement on page G-8 is incorrect. Utah has recently been authorized by the Environmental Protection Agency to administer the National Pollutant Discharge Elimination System (NPDES) Permits Program. Accordingly a construction permit would be issued by the Utah Water Pollution Control Committee following the review of engineering plans and specifications of the proposed wastewater treatment facility by the

Bureau. Any participation of the U.S. Environmental Protection Agency, whether for the construction or the discharge permit, is unnecessary. DEIS Statements an Pages C-8 and A-11, therefore, need correction.

2) The capacity of the evaporative lagoon needs to be evaluated in light of wastewater generation rates. Effluent characterization from chemical decontamination and inactivation systems must be included for review (page D-29). In general, details of the evaporative sewage lagoon need further explanation and evaluation (pages G-3, G-4). It is not clear if the evaporative lagoon mentioned in the report is an existing lagoon. If not, the siting considerations in constructing the evaporative sewage lagoon must be addressed. Finally, criteria for handling, monitoring, and sampling the lagoon need to be described in detail in the DEIS, with mention of the individual and agencies responsible for carrying out these activities.

3) The "Utah State Environmental Health Services Branch" (page F-24) should be referred to as the Utah Division of Environmental Health.

III. DRINKING WATER AND SANITATION

The details of plumbing design are not mentioned. Water sources must be protected. Anti-backflow valves must be installed at sinks, basins, and faucets throughout the laboratory. These valves prevent water from siphoning from sinks when water pressure is reduced in water lines.

IV. SOLID AND HAZARDOUS WASTE DISPOSAL

The descriptions within the DEIS of BATF operations relating to waste disposal which cause concern are as follows:

1) The DEIS vaguely refers to "hazardous chemical waste such as disinfectants, corrosives, acids, or rodenticides/pesticides" (page G-2) without further identification or description. Peracetic acid, used for decontamination, is the only chemical waste specifically named. Solid waste is described as "spent HEPA filters, animal waste, bedding and carcasses, and other disposable material. These descriptions should be more specific.

2) The DEIS is deficient in that it gives no estimate of the quantity of any waste generated.

3) The DEIS states that solid and Squid wastes will be decontaminated/inactivated by . . . heat or chemical treatment" (Pages A-14, G-3) without specifying what chemicals may be used in such treatment, except to describe them as "disinfectants" (page D-29). Incineration is repeatedly mentioned as the treatment and disposal method for "a substantial portion of the solid waste" but no description of the

incinerator or its operation is provided. The DEIS also says that all liquid effluents will be discharged to "dedicated holding tanks" (page D-29), at which point the effluent will be decontaminated by disinfectants or heat treatment. No mention is made of how long this effluent will be stored and no description of the holding tanks is given.

4) Three waste disposal methods are mentioned In the DEIS. These are noted below the comments on the adequacy of the DEIS descriptions:

a) Placement in a sanitary landfill for "treated solid wastes which cannot be incinerated" (page G-3). The DEIS fails in not defining which solid wastes cannot be incinerated and it fails to describe the location of the landfill to be utilized for their disposal.

b) Release of treated liquid waste into an "evaporative sewage lagoon." Criticisms of the DEIS description of this operation are contained in Section II-2 (above) in these comments.

c) Disposal or hazardous chemical waste "as provided in DPG Regulation 420-10 in consonance with the provisions of RCRA" (page G-2). This requires explanation. The specific provisions of DPG regulation 420-10 for disposal of hazardous wastes should be cited with the methods by watch they will be implemented at the BATF.

The DEIS lists required permits and approvals (page C-7). A RCRA permit for a hazardous waste treatment, storage, and disposal facility is not included in this list, and may be required for operation of the BATF. Of particular concern is the operation and maintenance of the sewage lagoon, holding tanks and incinerator.

V. EMERGENCY RESPONSE

The DEIS does not clarify which civilian authorities the Army would contact in the event of an emergency. It is critical to identify specific local and state agencies for notification. Included In the BATF proposal should be the definition of a relationship between officials of Dugway Proving Grounds and officials of the Utah State Government and, specifically, the Utah Department of Health. It is essential that the Department of Health have some oversight of research conducted at Dugway. Specifically, the Utah Department of Health should be apprised of all microorganisms being tested, and should be notified immediately of any accidental pathogen or toxin exposures or releases. The Utah Department of Health, Utah Department of Public Safety, and local health departments should be involved in contingency planning in the event of such accidents.

Should accidental human exposures or infection occur at the BATF, the DEIS describes only two levels of response (pages D-33, D-34): 1) on-site medical treatment and management at Dugway Proving Ground, or 2) air evacuation of the patient to Fort Detrick, Maryland, in an isolation device. These contingency plans are clearly inadequate. There could be occasions when an infection is sufficiently severe to warrant immediate treatment of the patient in a local hospital. It is also quite possible that a BATF worker could be unknowingly contaminated with a pathogen, spreading toxins in the community before the contagion is recognized. The DEIS must address the possibility, if that occurs, that workers, their families, and perhaps members of the larger community may require treatment in nearby civilian hospitals. Should that happen, it must be understood that the attending physicians involved require full access to information regarding the nature of the exposure and the pathogen or toxin involved. Finally, the possible need under some circumstances for community quarantine measures should be considered in the DEIS.

VI. SAFETY PROCEDURES

The DEIS fails to treat several safety issues:

1) The pressures of meeting research deadlines are known to compromise strict adherence to safety principles in some laboratories. Without outside oversight, the BATF may be especially vulnerable to such pressures. This points to the need for independent civilian and state government representation on the laboratory safety committee.

2) No mention is made of an explosive potential when paraformaldebyde is heated to produce formaldehyde vapor, to be used for laboratory decontamination. In general, the explosion and fire risks, with the potential of pathogen release, deserve more serious consideration (pages XI-11. XI-12).

3) Transportation of hazardous biological agents carries some risk; this is discussed only briefly (page D-27). Alternatives to the use of the U.S. Postal Service should be considered.

4) The security of Dugway Proving Ground from sabotage or terrorist penetration should be addressed.

5) A more detailed discussion of circumstances in which the BATF emergency exits would be used is warranted. Should these exits be used, more detailed planning of decontamination procedures appears necessary (Appendix IV).

VII. EPIDEMIOLOGICAL CONSIDERATIONS

The DEIS emphasizes that the laboratory is intended for research requiring no more than Biosafety Level 3 (BL3) containment, and addresses the risks and potential impacts of the facility on that premise. However, this premise appears to be contradicted by a number of descriptions in the DEIS pointing to operations requiring the highest level of containment. Biosafety Level 4 (BL4).* The document also acknowledges explicitly that BL4 research might eventually be conducted (page A-4).

Herein lies a mayor flaw In the DEIS. If a BL4 facility is proposed which may eventually be used for research requiring that highest level of containment, then the DEIS should clearly address the risks and possible impacts of BL4 research.

The DEIS describes laboratory risks with microorganisms requiring BL3 precautions, such as Francisella tularensis, Bacillus anthracis, Coxiella burnetii, and the Venezuelan equine encephalitis virus (page D-30; Appendix VII). BATF workers and their families are exposed to some risk with these specific organisms but, with proper precautions, the risk to the general public appears low. This assessment must be made with caution, however, because the full range of pathogens to be tested is not known, and because the DEIS does not take into account the possibility of asymptomatic pathogen colonization of laboratory workers, especially immunized workers, who could pose a risk to the larger community. Effective means of regular surveillance of workers and their families to exclude a possible pathogen carrier state must be addressed.

BL4 research carries substantially greater risk, both to the workers and to the general public. BL4 research might include the study of virulent exotic microorganisms or novel microorganisms created through recombinant DNA manipulations. Such organisms might not be well characterized, but could potentially be contagions, highly pathogenic, and without effective treatment. With scrupulous adherence to BL4 precautions, the probability of an accidental contamination or release of such an organism may be relatively low, but certainly cannot be ignored. A precise risk assessment is not possible without specific knowledge of each organism to be studied at the

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*Among several examples implicitly indicating that this facility may be used for BL4 research activities are found: a) the use of encapsulating suits for the workers (Page D-20), b) contingency plans to evacuate an infected worker in isolation to the Army Medical Research Institute at Ft. Detrick, Maryland (page D-14). and c) use of the facility for characterizing "potential agents of biological origin" (Page G-2), i.e. unknown biological samples perhaps submitted by intelligence agents.

BATF. If an accidental release of BL4 Pathogens occurred, the possibility exists of disastrous consequences to the larger community. Thus, the potential public health risk of BL4 research must be viewed as serious, and such research cannot be recommended by the Department of Health. Should BL4 level research ever be conducted, a cooperative program with the State of Utah involving epidemiological surveillance of unusual diseases in human and animal populations in regions surrounding Dugway would be advisable.

Given the hazards of both BL3 and BL4 research noted above, the exclusive use of simulants or agents of low pathogenicity in all experiments involving aerosolization would appear to merit more serious consideration than that provided by the DEIS. It should be noted that the term "Biosafety Level" refers not simply to a building or laboratory design, but to a concept of containment. Essential to this concept is the avoidance of aerosolization of pathogenic organisms. Thus, a laboratory designed to aerosolize pathogens intrinsically violates these biosafety principles.

It would be desirable, [before submitting a BATF proposal for final approval,] to commission an overall review of biological warfare defense issues by a panel of independent civilian scientists. This panel could evaluate the need for such research as well as its risks and limitations, and could address in detail the safety concerns raised. At present. the DEIS does not demonstrate that the benefits of such research outweigh its risks.

SUMMARY AND CONCLUSIONS

In summary, this BATF proposal, as described In the DEIS, has serious deficiencies. The document lacks sufficient detail in describing air emission controls, wastewater and drinking water management, and solid and hazardous waste disposal. Because of this, accurate conclusions regarding the environmental impact of this facility are not possible. Emergency planning details in this document are scant, and the need for state and local agency involvement in this planning is ignored. Laboratory safety procedures deserve more attention in the DEIS. State oversight of laboratory research as well as safety programs is needed. The DEIS contains implications that BL4 research may eventually be conducted at the BATF. Though not addressed by the DEIS, such research could carry significant risk to the public health. In view of this, and the failure of the DEIS to demonstrate that the benefits of such research outweigh its risks, the Utah Department of Health can support neither BL4 research nor the construction of a BL4 facility at Dugway.

Date? ?, 1988

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Attached is a copy of an article from the Detroit News stating that the AIDS virus was created in a lab at Fort Detrick, Frederick, Maryland.

Under such research, Dr. Robert Streker, a Los Angeles physician, sent a 40-case report to President Reagan, the vice-president, all cabinet officials and governors, the F.B.I. and the C.I.A.

I would like you to know firsthand what is in this article so I am asking the reader of my letter to please read it for you.

Being a resident of Frederick County all my life and knowing many employees of Fort Detrick, past and present, I must say the study done by Fort Detrick does not do the truth justice. Although what it does contain is enough to alert anyone to the dangers of such facility.

I believe stating that the research being done at Fort Detrick only poses a negligible risk to employees and the general public is false and if an independent study were done, it would be proven so. The risk is far grater than what has been implied in the recent newspaper articles and the study itself, and with the extreme increase of development in Frederick County, the health of the public must be considered now.

Please be informed that I sent a letter, dated June 7, 1988, and a copy of the article from the Detroit News, to Dr. Everett ?, of which I have not received a reply, so I am asking at this time that an investigation be done concerning the information given you today and if this information be true, then charges must be brought against those responsible for such an outrageous act.

Thank you,

Sincerely,

Mrs. Mary Ann Putman
5101 Ballenger Creek Pike
Frederick, MD 21701

AIDS virus was created in lab, spread by vaccines, doctor says

By Hugh McCann
News Staff Writer

Just when you thought at least the origin of AIDS had been pinned down, along comes Dr. Robert Strecker who says the virus was created in a laboratory, and likely distributed in contaminated vaccines.

Dr. , a Los Angeles physician who has more than 60 AIDS patients, is among the first in the United States to support the theory. Overseas, however, the Soviets have been waging a widespread campaign of what the State Department calls "disinformation," claiming the deadly virus originated in a U.S. military laboratory,said Kathleen Bailey, a deputy assistant secretary of state.

"AIDS came from animal viruses," Dr. Strecker said. "They grew them in human tissue and adapted them to humans The people who did this should be tried and, if guilty, convicted of murder."

TO DATE, more than 200 newspaper stories, radio reports and forged documents have surfaced in 71 countries attributing the AIDS epidemic to American military research gone awry, Bailey said.

However, Dr. Strecker, 41, who researched AIDS along with his brother, Theodore A. Strecker, 46, a Los Angeles attorney, denied any association with such a campaign.

"We are as far removed from that kind of myth-information as humanly possible," he said. "We're not pro-communist in any sense of the word."

U.S. OFFICIALS said the Soviet campaign surfaced in 1984 in a letter in the *Patriot*, an Indian newspaper. The letter? attributed to an unidentified American anthropologist? stated that the AIDS virus escaped in the late 1970s from an Army bio-warfare laboratory in Fort Detrick, Md.

Dr. Strecker said a 1972 document of the World Health Organization (WHO) shows authorization for the manufacture of an AIDS-like virus. He also cited a report of a 1970 meeting of the National Institutes of Health suggesting how such a virus could be tested.

"The request for the virus was made in 1972," he said. "Shortly afterward, AIDS appeared in Africa."

He claims that the virus was engineered and could have contaminated a vaccine used by the WHO to wipe out smallpox in Africa.

LAST YEAR, the London Times reported that the WHO was reviewing new scientific evidence suggesting that immunization with the smallpox vaccine might be involved in AIDS.

According to Dr. Strecker, AIDS is a hybrid of sheep viana virus and cattle leukemia virus? a combination that could occur only in a laboratory. But other virologists say that the genetic material in AIDS is unique, and that science has yet to create any living organism with unique genetic material.

Two years ago, the Strecker brothers sent a 40-page report on their findings to President Reagan, the vice-president, all cabinet officers and governs, the FBI and the CIA.

A WHO official declined comment on the Strecker's claims and the Soviets denied the existence of the alleged disinformation campaign.

The United States and the Soviet Union were among nations signing a UN resolution that the AIDS virus was of natural but unknown origin.

DR> JOHN SEALE of England and East German scientists Jab and Lili Segal claim that AIDS was manufactured in an American lab, but Dr. Strecker will not go that far.

After spending more than five researching the published information on AIDS, he said, he concluded that official attempts to explain the virus' origin "just didn't make sense."

7813 Rocky Springs Rd.
Frederick MD 21701
July 14, 1988

U.S. Army Medical R & D Command
ATTN: SGRD-PA
Fort Detrick
Frederick, MD 21701-5012

RE: DEIS Biological Defense Research Program

Gentlemen,

This is to express my comments, concerns and questions on the referenced statement.

The statement should be site specific rather than program specific; i.e., it should consider the impacts of all programs at each site involved rather than just those which derive from the Biological Defense Research Program (BDRP). The impact of the BDRP could be synergistically affected by other unrelated site specific programs, e.g. an explosion at a nearby non-BDRP facility may cause release of hazardous BDRP biological agents.

The purpose of a NEPA impact statement is to inform the public of current and potential environmental damage. There is no way that I, as a neighbor of Ft. Detrick, for example, can come to understand the overall impact of that facility on my family and my environment if each program underway at that site prepares separate impact statements. By proceeding with separate programmatic statements like this, you are defeating the whole public information purpose of the NEPA provisions requiring such statements. It appears that you are employing the oldest of military tactics in order to diffuse public understanding and criticism, viz. "divide and conquer."

The draft statement does not quantify the impact of potential accidents which may result in catastrophic release of hazardous BDRP biological agents. The DEIS should state the statistical degree of risk of such an accidental catastrophic release to the environment and what would be the consequent risk to nearby residents and environment if such a release did occur. The DEIS indicates that there are, indeed, various possible combinations of human error and mechanical failure which, with some degree of probability, albeit "immeasurably low," could result in a catastrophic release of some hazardous biological agent. What is the quantitated statistical risk value that is being dismissed here as "immeasurably low?" Is it immeasurably lower, for example, than the risk of meltdown that is now effectively halting the whole nuclear power industry in the U.S.? The DOE has quantified this nuclear risk. Surely the possible BDRP catastrophic release scenario referred to in the DEIS can be similarly quantified so that reasonable persons can judge if the risk is acceptably low as well as "immeasurably low."

This brings me to another, more general criticism of the draft statement; viz., it does not distinguish between BDRP work at sites in or near highly populated areas from similar work in remote rural areas. Surely, vastly different impact considerations apply to these different areas. The more hazardous programs of other government agencies (e.g., the Department of Energy) are caroled out in very remote sites for this reason. We are aware of your recent unsuccessful efforts to build such a site in a Western State. By not speaking to this population density issue, you infer that the most hazardous materials and experiments can be used and carried out at remote and urban sites with equal impunity and equivalent impact. Is this inference correct? If so, it should be stated.

Finally, the draft statement indicates that solid wastes from BDRP work at Ft. Detrick are buried in a sanitary landfill in accordance with applicable regulations. It acknowledges that "there is a potential for low impact to soils, topography and erosion from the contribution USAMRIID makes to the overall solid waste landfill requirements at Fort Detrick." This terse, unsupported conclusion leaves several questions unanswered. For example, (1) What criteria were used to determine that the impact of the landfill is "low?" (2) What other responsible government agency (state, local, federal) have evaluated this landfill to verify that its impact is "low?" (3) The above quote from the draft statement does not mention any impact on ground water, yet It is well known that waste leachate entering ground water is the predominant impact of most landfills. Several monitoring wells are In place around the Ft. Detrick landfill. Surely there is data which reveals what, if any, leachate migration exists around the site. This matter should be discussed. (4) No mention is made of disposal procedures for radioisotopes. Are any long lived radioisotopes buried in the landfill? If so, have they leached into ground water? (5) Do insects, birds and/or burrowing animals disperse hazardous buried materials from the landfill; e.g., house flies or crows. This would seem to be a very likely and very fast mechanism for dispersal. Has it been investigated? Since I live very close to it, I would like it discussed in the Statement. I realize that the DEIS indicates that no hazardous materials are being burled there now; however some of my neighbors helped bury them there in the past.

Please let me know if any of the above points need clarification. Thank you for the opportunity to comment.

Sincerely,

John C. Dempsey

22 NORTH MAIN STREET
ESSEX, CONNECTICUT 06426
(203) 767-2006
(203) 767-2508

July 14, 1988

Sir:

I would appreciate your substituting this corrected copy of my letter of today.

Sincerely,

David Keppel

22 NORTH MAIN STREET
ESSEX, CONNECTICUT 06426
(203) 767-2006
(203) 767-2508

July 14, 1988

Major General Philip R. Russell
Commander
U.S. Army Medical Research
and Development Command
Attn: SGRD-PA
Fort Detrick
Frederick, MD 21701-5012

Sir:

I received the Draft Programmatic Environmental impact Statement on The Biological Defense Research Program. I understand that written comments are being accepted until August 12, 1988.

In my view, the Statement's conclusion that the Biological Defense Program is both necessary and safe is entirely wrong and misleading. In fact, the Program is both an environmental and a national security threat. It is particularly urgent that all elements of it employing genetic engineering be strictly terminated.

The Statement suggests that public concern about the military and civilian use of genetic engineering is--almost by definition -- irrational, while the verdict of scientists is uniformly reassuring (1.6.3., p.1-12). This is wrong on both counts. The record of mayor technological accidents (Three Mile Island, Bhopal, Challenger, Chernobyl) shows that the public is often nearer the truth than experts who "prove" nothing can go wrong. In addition, however, the record should reflect the serious concern of scientists about the environmental impact of genetically altered microorganisms and the militarization of biotechnology. The Committee for Responsible Genetics, based in Boston, Massachusetts, is one group made up of many concerned professionals. (My comments are as an individual.)

The Army's draft Statement is a disturbing mixture of contradictory reassurances. On the one hand it says:

Genetically engineered microorganisms do not constitute a programmatically defined category per se because genetic engineering is not a discrete object of study but rather is considered a state of the art tool to be applied to attaining specific research objectives. (3.5.2, p.3-14)

This denial that genetic engineering raises any special issues is as fallacious as to say genetically engineered organisms are no different since they are still made of atoms and molecules. The point -- as it concerns environmental impact -- is the rate and degree of difference. Here genetic engineering crosses a watershed. The environmental and military issues it raises are on a different scale from previous technologies. The Statement's cavalier dismissal of this calls into question the good faith and seriousness of the Army's reassurances that it will use biotechnology circumspectly.

The Army seeks to reassure the public with two assertions: its purpose is strictly defensive, and it will use genetic engineering to create weaker, not stronger, pathogens (5.2. 2.1, p. 5-9). These claims are inherently unconvincing.

Biological diversity is astronomical: we cannot hope to foresee the specific pathogen an adversary might use. Yet while neither side can foresee the other's offensive choice, it <u>can</u> prepare inoculation against the specific weapon it plans to use offensively. Rightly or wrongly, a nation might calculate it would be free to launch a biological attack while protecting its troops and possibly its population. No matter what the Army says, this is how objective observers and other nations will interpret the Biological Defense Research Program's pursuit of genetic engineering.

Similarly, the Army's claim that it will use genetic engineering to develop less virulent, not more virulent, strains of pathogen is objectively unconvincing. The research and development on one can be converted into the other -- in far less time than is the case for atomic or conventional weapons problems. The hand-and-glove dilemma described above remains.

There is only one way to prevent a biological arms race: to halt biological warfare programs, particularly ones using genetic engineering, not only at Dugway but anywhere they are being carried out. There is no military defense against biological weapons. Our current program thus undermines the only restraint available: the Biological Weapons Convention.

One must also view with dismay the Army's charges about the activities of other nations. Its unwillingness to substantiate these in public must engender skepticism. Since military defense is not available for reasons stated above, the allegations are in any case invalid as justifications for the U.S. biological warfare program. Moreover, they create an international climate of inevitability about biological warfare and thus weaken inhibitions worldwide.

Any charges must follow a scrupulous and responsible assessment of the evidence, and then must be brought to the appropriate international body and, if confirmed, serve as the basis for severe sanctions. The United States will have no diplomatic credibility in the effort if it itself pursues the Biological Defense Research Program.

Very truly yours,

David Keppel

THE UNIVERSITY OF CONNECTICUT
School of Pharmacy
U-Box 92
372 Fairfield Road
Storrs, Connecticut 06268

July 21, 1988

U.S. Army Medical Research and
Development Command
Attn. SGRD-PA
Fort Detrick
Frederick, MD 21701-5012

Dear Sir:

I am pleased to provide the following comments concerning the draft Environmental Impact Statement on the Army's Biological Defense Research Program (BDRP). Before doing this, however, I should summarize my professional qualifications and interests in the area of biological toxins. As noted in my enclosed Curriculum Vitae I have been a professor of Pharmacology in the Section of Pharmacology and Toxicology at the University of Connecticut, School of Pharmacy since 1968.

I have well over 100 research publications many of them involving the use of snake venom and venom components particularly the enzyme phospholipase A2. My interests and expertise extend. however, over the much broader field of toxins (animal, plant and microbial) as evidenced by the fact that I have been editor since 1970 of TOXICON. the official journal of the International Society on Toxicology (IST) and the only journal devoted exclusively to publishing research dealing with animal, plant and microbial toxins. I am also President-elect and as of August 4, 1988 will be President of the IST. Because of these professional commitments I am familiar with research using natural toxins both by American and foreign scientists. I have also had occasion during the past year to visit the Army's facilities at Fort Detrick and meet with many of Their research scientists. I am also a member of the Life Sciences Committee of the U.S. Army Chemical Research. Development and Engineering Center. I would have wished to attend the meeting on July 25 in Arlington, Virginia to present these comments in person however, because of prior commitments this is not possible. I feel however, so strongly concerning the questions raised in the Environmental Impact Statement of the BDRP that I request your consideration of these comments.

Before commenting on the impact statement per se I want to address the question of the quality and type of research being carried on at the Ft. Detrick facility. I feel confident that any unbiased peer review would comment favorably on the quality of research being conducted at the Army facility. It is as good or better than that being carried on at major universities throughout the world. There has recently been a burgeoning interest in studying toxins which is quite independent of any biological warfare threats. Highly toxic and specifically acting toxins (Ex. tetrodotoxin, α and β bungarotoxin, latrotoxin, botulinum toxin, pertussis toxin, etc.) are extremely useful tools with which to study biological processes. An understanding of the functioning of the nervous system and ultimately diseased states of the nervous system would be much less if scientists had not used in the laboratory tetrodotoxin to block the sodium channel of the nerve, α? bungarotoxin to bind to the acetylcholine receptor, botulinun toxin to block nerve muscle transmission, etc. The group at Ft. Detrick has made major contributions to our knowledge of toxins and I might especially mention in this connection the research carried on by Dr. John Middlebrook and Dr. Leonard Smith. Because of his outstanding scientific contributions to the field of toxicology, I appointed Dr. Middlebrook to the Editorial Council of TOXICON. The focus of their research at Fort Detrick and their ultimate goal is the development of medical and physical defenses measures against biological warfare threats. However, most of their research represents high quality basic research of a similar type being carried on at many universities. The environmental impact and safety problems which they face are not unique and are shared by many laboratories throughout the world. Indeed the Army facility has formalized safety procedures which are better than that in the university community in general. The fact that "accidents" are so few and far between attests to the fact that scientists have voluntarily taken appropriate precautions in order to be sure that they neither poison themselves nor others. It would be a severe blow to the worldwide community of toxicologists if the BRDP were terminated. Genetic Engineering is a vital research tool if we are to understand the action of toxins and design appropriate safeguards against toxins. It would be folly to attempt to separate this part of the Army program from the rest of their program.

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I found the Environmental Impact Statement to be very detailed and to reach conclusions which are justified on the basis of our present knowledge. I do not understand how someone can read this statement with an open mind and call it "completely inadequate". The authors of this document are to be complimented for the thoroughness of their analysis. As I noted above, the army facility is carrying on good science while this Environmental Impact Statement demonstrates that hey are also performing safe science. The BDRP program deserves to be continued.

Sincerely yours,

Philip Rosenberg, Ph.D.
Professor of Pharmacology and
Editor of TOXICON

PR:td

ENVIRONMENTAL DEFENSE FUND
257 Park Avenue South
New York, NY 10010
(212) 505-2100

Frederic D Krupp
Executive Director

5 July 1988

Mr. Charles Dasey
USAMRDC, Attn: SGRD-PA
Fort Detrick
Frederick, Maryland 231701-5012

Dear Mr. Dasey:

Please accept our comments about the Draft Environmental Impact Statement of the Biological Defense Program. We thank you for sending the document to us and look forward further correspondence regarding the program.

Sincerely,

Rebecca Goldburg, Ph.D.
Staff Scientists

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Summary

The draft programmatic environmental impact statement (DEIS) for the biological Defense Research Program (BDRP) was written in response to a suit by the Foundation for Economic Trends, spurred by the massive expansion of BDRP. The DEIS reviews the program as it exists and offers little new information to the decision making process. In these comments, we identify three major flaws. 1. The DEIS fails to fully analyze the possibility of shifting BDRP to one or more civilian agencies. 2. The Department of Defense has neglected other reasonable policy alternatives, particularly the strengthening of centralized safety and environmental oversight. 3. The DEIS also inappropriately limits the scope of organisms that will be studied in the BDRP. As a result, the DEIS is flawed and inadequate. Furthermore, nothing in the DEIS allays our concern that BDRP will metamorphose into an offensive program.

A14-42b

Introduction

In recent years, the Department of Defense (DOD) has greatly expanded its biological warfare program. Called the biological Defence Research Programs (BDRP), its officially stated mission is to develop battlefield defenses against the possible use of biological weapons. These defenses range from vaccines to specialized protective clothing. Over the past six years, BDRP has received a more than five fold increase in funding.[1] The rapid expansion of the programs prompted a challenge from the Foundation on Economic Trends.[2] The Foundation argued that the DOD failed to assess the environmental impact of its programs in accordance with the National Environmental Policy Act.[3] In a court-supervised settlement, DOD agreed to prepare an environmental impact statement for the program. We are commenting upon the draft of that document.[4]

The draft programmatic environmental impact statement (DEIS) for the biological defense research program (BDRP) reviews the program as it exists and offers little new information to the decision-making process. The EIS procedure is intended to force complete

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1. Preliminary Report of the Majority Staff of the Senate Subcommittee on Oversight of Government Management on DOD's Safety Programs for Chemical and Biological Warfare Research, 11 May 1988.

2. Foundation on Economic Trends v. Weinberger(D.C. D.C.) Civil Action 86-2436, 19 February 1987.

3. 42 USC 4321-4370.

4. Draft Programmatic Environmental Impact Statement: Biological Defense Research Program, RCS DD-M (AR) 1327. May 1988.

consideration of all reasonable alternative actions. But the DEIS lacks a credible analysis for shifting all or a substantial part of BDRP management to civilian agencies. However, even in its analysis of the current programs, the DEIS is inadequate. The development of organization-wide environmental and health safeguards is neglected. The latter was a major concern of those individuals and organizations which participated in the "scoping" meeting. Also, DOD improperly limits the scope of organisms covered by the DEIS. These are serious oversights which must be remedied in the final environmental impact statement.

We continue to harbor serious reservations about the wisdom of DOD pursuing the biological defenses program. An aggressive strategy will strain compliance with the 1972 Convention on Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin weapons and on there Destruction. As DOD admits, offensive and defensive biological warfare programs are indistinguishable at the research phase.[5] We believe the United States should maintain a leadership position by avoiding any appearance of noncompliance with the Convention's provisions. The nation's defense posture is not served by weakening the treaty.

Shifting BDRP to a Civilian Agency

DOD argues that shifting the greater part of the program to civilian agencies would result in a loss of efficiency. We find their analysis wanting. The DEIS does not provide a shred of evidence that shifting BDRP to civilian agencies would actually increase costs, and an additional management layer, or weaken our defense posture. In the FEIS, DOD should either abandon these arguments, or support them with greater specificity and care. Additionally, they should identify and discuss the overlaps

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5. DEIS Appendix 8, p. 3.

between DOD's vaccination research and that carried out under the aegis of the National Science Foundation, Centers for Disease Control and the National Institutes of Health. Duplication of effort wastes resources and increases the probability of an accident.

DOD raises the matter of the public's mistrust of military sponsorship. This mistrust is not without basis. There is the well founded concern that DOD may use national security arguments to keep accidents and other problems, as well as possible benefits, free from public scrutiny.

For instance, from 1949 through 1969, DOD conducted secret open air tests over several U.S. cities, including, Washington D.C., San Francisco and New York. DOD acknowledges that open air testing with bacteria and viruses is necessary in BDRP.[6] Professor Cole, in his comments prepared for the "scoping" meeting, reminds us that, even though it is required to notify Congress and local official prior to a test involving humans, DOD narrowly defines test subjects to include only people deliberately exposed to the agent.[7] As a result, during visibility or dispersant tests notification is not required, even though humans may be inadvertently exposed to viruses or bacteria.

By placing responsibility for BDRP In civilian agencies, DOD can defuse the nagging suspicion that crucial parts of the programs are withheld from view. The CDC and NIH are responsible for developing defenses against normally occurring diseases, and thus there is no

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6. DEIS 5-21

7. "Environmental Considerations for the U.S. Army's Biological Defense Research Program." Leonard A. Cole, Presented at Environmental Impact Statement "Scoping" Meeting for BDRP, Sheraton Tyson's Corner, Virginia, 12 August 1987.

reason why they should not protect us from anthropogenic epidemics. In addition, CDC and NIH are responsible for getting the vaccine to people who need them, and they have the information and institutional structure required to accomplish the task efficiently.

Unlike DOD research facilities, the CDC and NIH operate under a competitive grant system. It is generally agreed that a rigorous system of competitive grants assures the highest quality research. As a result, papers which are produced from such research tend to be published by prominent journals in the field rather than being relegated to obscure or secondary publications. Although DOD extols BDRP's contribution to scientific knowledge, it is far from clear that its work measures up to the research generated by CDC and NIH grants. If BDRP's publication record is used to judge the progress, the results are mediocre at best[8].

Thus, the benefits of shifting to a civilian agency are threefold: Fellow scientists will have greater confidence in the work, the results of the research will tend to receive greater exposure in prestigious journals, and citizen will be more confident in DOD's openness.

Environmental and Health Safeguards

Another reasonable course of action is to restructure the current program, addressing the safety and environmental concerns expressed in the "scoping" meeting. This option was not considered in the DEIS. We feel that it should appear in the final programmatic environmental impact statement (FEIS) as a viable policy alternative. The following comments address this omission.

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8. Charles Piller and Keith Yamamoto, Gene Wars: Military Control Over the New Genetic Technologies (New York: William Morrow, 1988)

The Environmental Defense Fund is concerned by the lack of a comprehensive plan for maintaining safety within the program. As it stands now, the unclassified elements of BDRP are governed by a web of regulations, the enforcement of which is the responsibility of numerous agencies. These include the Department of Transportation (Packaging standards, 49 C.F.R. sec. 173), Environmental Protection Agency (Toxic Substances Control Act, 5 U.S.C. secs. 2601-2929; Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. secs. 136-136y), US Department of Agriculture Virus-Serum-Toxin Act: 21 U.S.C. secs. 151-158) Food and Drug Administration (Food, Drug and Cosmetic Act: 21 U.S.C. secs. 301 et seq.) and the Nuclear Regulatory Commission (use of radioactive isotopes, 10 C.F.R. sec. 1). In addition, DOD voluntarily follows the NIH guidelines governing recombinant DNA (rDNA) work (49 Fed. Reg. 40659 (1984)).

Wielding a $90-billion budget in 1986, BDRP is a large program. BDRP research is conducted in three US Army facilities and in 100 independent laboratories.[9] The burden of this research does not fall on all these facilities equally, nor do they all work with materials and organisms which pose the same degree of risk. Nevertheless, the size of the program does call for a clearly articulated programmatic safety policy. It is not sufficient for DOD to rely on the present tangle of regulations and guidelines to insure environmental protection, health and safety. In general, these agencies have strained budgets and are understaffed; DOD cannot assume they will aggressively enforce safety requirements for BDRP. Moreover, we do not see how these agencies could regulate parts of BDRP which may be classified.

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9. DEIS Appendix 3, pp 2-7.

While DOD claims adherence to state of the art biohazard containment protocols, these safety mechanisms can be circumvented if there is only a slight chance that a dangerous event will occur, people tend not to guard diligently against such an event. Personal risk assessment is highly idiosyncratic; while it seems perfectly rational for someone to protect their health to the fullest extent possible, people often, for a variety of reasons, reject safety devices. Seat belt and motorcycle helmet laws provide a good example; in the absence of an active enforcement program, compliance with these laws drops dramatically. A similar situation can exist in a lab without diligent enforcement, lapses in safety protocols can become endemic within the facility.

Given the size and nature of BDRP, we find it puzzling that the DEIS does not mention a central office which sets and, just as importantly, enforces safety and environmental regulations within BDRP. A central office could also investigate problems within DOD labs, and those of its contractors. A serious accident would likely trigger the convening of a formal board of inquiry. However, incidents of lesser significance, which often presage serious events, need some measure of formal review by scientists and safety technicians. While the DEIS does state that, in accordance with the NIH guidelines, BDRP has Institutional Biosafety Committees (IBC's) wherever rDNA work is performed, there is a doubt as to the veracity of this claim.[10] Moreover, as the DEIS repeatedly stresses, the greatest part of the program is devoted to non-recombinant microbial work and, as a result, is beyond the oversight of the IBC's. At any rate, the IBC's work entirely at the local level, so they have no impact upon the program as a whole.

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10. Charles Piller and Keith Yamamoto, Gene Wars: Military Control Over the New Genetic Technologies (New York: William Morrow, 1988) pp 189-190.

DOD may have a formal programmatic environmental and safety system, complete with outside reviewers which we view as crucial to a credible system. If one exists, a description of it should be included in the final programmatic environmental impact statement (FEIS), together with an examination of the structure and effectiveness of the various IBC's at both BDRP's primary sites and its contractors. If none exists, we feel restructuring of the program's health ant environmental safeguards on an organizational level should be evaluated as a reasonable alternative course of action. Organizational charts and reporting procedures should be included in the evaluation.

Furthermore, the DEIS should have had a far more comprehensive section on accidental exposures. Table A8-3 of the DEIS covers 20 "potential accidental exposures" at Fort Detrick since 1983, but there is no information presented for the whole BDRP.

Finally, we challenge the oft repeated statement that using rDNA techniques to engineer a more virulent strain of a pathogen is forbidden. Such work is barred by the NIH guidelines. These guidelines have no force of law and have been adopted voluntarily by DOD. But the only enforcement mechanism behind the guidelines is the withdrawal of research funding if they are not followed, hardly a problem for the BDRP. There is nothing to stop DOD from relaxing or retreating totally from compliance with the guidelines, either selectively for certain elements of the programs or in its entirety. If BDRP were under the authority of a civilian agency, the prohibition would be more credible.

Scope of Pathogens Evaluated

The direction of BDRP's research is influenced by reports from the various intelligence agencies.[11] The renewal of interest in biological warfare was in response to intelligence reports alleging the use of mycotoxins, "Yellow Rain," in Laos and the possibility that the USSR is experimenting with *Bacillus anthracis* in Sverdlovsk.[12] We will not deal with the controversy surrounding these allegations; we only invoke them to illustrate the strong influence such reports can have on the direction of research within BDRP. If, for example, a series of intelligence reports alleged that a hostile group or state was culturing a highly contagious hemorrhagic virus as a biological weapon, the DOD would best likely respond quickly and secretly to the perceived threat. DOD must acknowledge the possibility that it may have to change the scope of its research sometime in the future. We can think of no pathogen category which should be excluded from analysis in the FEIS.

The DEIS toes not cover certain categories of pathogens which, at the present, are not studied in the BDRP. These include the highly contagious microbial diseases spread from human to human, either directly or via inanimate objects.[13] Examples of excluded organisms are Typhoid Fever ant Lassa Fever. Pathogens of this sort are dangerous to the lab workers, and they are difficult to contain even though they are studied under the rigorous biosafety level 4 procedures, when such pathogens escape containment they

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11. DEIS 1-4, 5-6.

12. Summary Scoping Statement for the Biological Defense Research Program Environmental Impact Statement. 5 August 1987

13. DEIS, Appendix 9, pp. 58-59.

are among the most difficult microorganisms to control. Therefore we question the exclusion of any category of pathogenic organisms from the FEIS.

Compliance with the 1972 Convention

DOD repeatedly stresses that the BDRP is only defensive. Yet no definitive barrier stands between defensive and offensive weapons. DOD defines the difference in terms of quantities. With microorganisms, large quantities can be grown very rapidly. We provide the following example.

For the bacterium which causes tularemia, Franciscella tularensis, DOD reports that a research program requires approximately 5 liters of cultured bacteria per week, while an offensive program would require 3634 liters per week.[14] At first glance, it looks like a massive difference, more 726.8 fold to be exact. However, this increase in volume represents less then 14 doubling times. If the doubling times for the bacteria is a day, DOD could be up to offensive capacity in two weeks. In reality, doubling times are such shorter, often on the order of minutes or hours. With modern incubation techniques, culturing large volumes of bacteria can be accomplished with ease. Therefore, we find it impossible to be sanguine about DOD's "defensive" plans.

The rapidity with which offensive quantities of bacterial and viral agents can be generated requires that close attention be paid to the provisions of the Biological Warfare Convention (BWC). Indeed, DOD professes to recognize the importance of complying

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14. DEIS Appendix 8.

with BWC.[15] There is no evidence, however, that In preparing the DEIS the issue of compliance was studied. DOD merely states that it will continue to abide by the BWC's provisions, but does not offer any supporting analysis of the treaty. The preparers of the DEIS lack legal credentials.[16] The DEIS cites several historical documents concerning BWC compliance. Unfortunately, the most recent is an excerpted version of the 26 January 1976 memorandum from President Ford concerning BWC adherence.[17] Since that date the field of microbiology has changed dramatically. Culturing techniques have been greatly refined, and scientists can now insert genetic information from one organism into another. In light of these changes, DOD's assurances carry little weight without clarification of its current interpretation of the BWC.

Conclusion

DOD has preparer a document incomplete in its analysis and fraught with unnecessary redundancy. Rather then the professed "hard look" at BDRP, the DEIS is a "hard sell" of their current stance. We urge DOD to write an environmental statement which offers a thorough and honest evaluation of the BDRP.

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15. DEIS ES-2, 3-10, 5-5.

16. DEIS 8-1

17. DEIS A1-12

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In the 1967-1968 period, a small but vocal group of people began a campaign to bring about the abolishment of the offensive biological program. Their approach to this objective was to flood the media with a steady stream of charges regarding program safety and safety of the community which surrounds Fort Detrick. By 1969, an environment of hysteria had been created which prevent reasoned discussions with these people. I was one of many employees in this program who felt that our research and development were making an essential contribution to the defense of our country. I soon came to realize that these people were not interested in biological safety or any other aspect of the BW programs. President Nixon succumbed to these and other political pressures and abolished the offensive biological warfare program in November of 1969. Thus, the United States surrendered an entire weapons system.

I would like to digress from my prepared statement to address the comment of Dr. Rosenberg regarding the nonpredictability of biological warfare. I wish that the Department of Defense would declassify aerosol data collected in large scale field tests by Deseret Test Center in the 1960s. These data clearly demonstrate that aerosols behave according to the mathematical models developed by Calder and others. Preplanning before an attack is absolutely essential to success. When meteorological conditions are defined, the transport of an aerosol is quite predictable.

Today, some 20 years later, another small but highly vocal group of protesters seem to be targeting the defensive biological warfare programs for abolishment...particularly the medical defensive programs. Once again, safety seems to be their principal buzz word. But let me tell you, ladies and gentlemen, they cannot make it stick. Like one of the speakers at the recent Democratic Convention stated "that dog won't hunt."

During the offensive BW program at Fort Detrick, a small group of dedicated scientists established principles on which modern day safety technology and laboratory design were founded. Scientists such as Arnold G. Weedum, Riley D. Housewright, Charlie Phillips, and Everett Hanel, to name just a few, were truly heroic pioneers, and every person who works in an infectious disease laboratory today, owes these gentlemen a tremendous debt of gratitude. Their contributions are described in somewhat greater detail in Appendix 9 of the preliminary draft, Environment Impact Statement.

During 26 years of offensive BW studies at Ft Detrick, not a single person in the civilian community became infected. This demonstrates quite clearly that even 20 years ago, Ft. Detrick did not pose a safety problem to the surrounding community. Yes...there were infections among the "at risk" laboratory workers...423 of them including three deaths from 1943 to 1970. The important factor here is that these were "at risk" personnel, people who worked in the "hot" areas of the laboratories. By contrast, administrative personnel, people like secretaries, budget analysts and supply clerks, who worked in "clean" areas

did not become sick. This is an important factor because in most instances the clean area was separated from the hot area by a wall in the same building.

The medical defensive program for the entire Department of Defense is performed by and under the general direction of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick. USAMRIID has been able to take full advantage of the safety technologies and laboratory building designs of the defunct biological warfare laboratories and to extend these technologies and laboratory designs to a higher order of safety.

The safety record of USAMRIID is outstanding and is indicative of the safety measures being used in the study of some very nasty organisms. It's true that USAMRIID has had a few infections. No work is risk-free. Their safety record is significantly better than most industrial concerns. There have been no deaths and no disabling injuries. USAMRIID employees work in the most unique and best safety-engineered laboratories in the free world. These laboratories are designed with sufficient safety redundancy to prevent the escape of infectious or toxic products into the surrounding community. If old Fort Detrick labs did not cause infections in the community, you can be assured that the modern laboratories of USAMRIID will not also.

I would like to believe that those or you who oppose the programs of medical defense against biological warfare, do so on the basis of safety and out of concern for the community which

surrounds Fort Detrick. There is a body of logic which can be drawn upon to alleviate your fears. However, if you have other motives such as stopping all defensive studies against biological warfare, I have no sympathy with you or your cause.

In the Iran/Iraq war, chemical warfare agents were used when it was in Iraq's self interest to do so and in spite of international treaties and international public opinion not to do so. BW agents could very well have been employed instead of chemical agents. The big difference between CW and BW is that the number of chemical casualties would have to be multiplied by a factor of 100 to 1000.

Biological defense, and particularly medical defense against biological warfare, remains as our country's only deterrent. If these defensive programs stop or are even reduced, the United States falls into a highly vulnerable position in an essentially hostile and non democratic world.

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COMMENTS ON THE DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT ON THE BIOLOGICAL DEFENSE RESEARCH PROGRAM

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We are fortunate to have several lines of defense against biological weapons. The first line is drawn by the international treaties that outlaw the development, production, possession and use of biological weapons: the Geneva Protocol and the Biological Weapons Convention (BWC). Our second line of defense is deterrence provided by a strong US military position with regard to other types of weapons. And the third line is the biological defense provided by the Biological Defense Research Program for the soldier in the field.

Because of the BWC and our strong military position, BW do not pose a significant strategic threat to the US. Rather, the major threat arises from the possible use of BW by terrorists or psychopaths, or from accidental escape of BW agents from the containment facilities in which they are studied. The latter is one of the topics addressed in the Draft Environmental Impact Statement (DEIS). What is not addressed is the greatly increased danger of accidental escape that would result if there were a proliferation of military facilities studying BW agents around

the world. Once a biological weapons race got started, it would not be constrained by coat or technological accessibility; nor would it be likely to exclude efforts to develop novel agents using genetic engineering. Proliferation is a very grave danger - not just because it could lead to biological warfare, but also because shoestring operations carried out with varying degrees of technical competence and responsibility, in multiple locations and sometimes inadequate facilities, are almost certain to result in breakdown of containment. Against the resulting possibility of global epidemic or the establishment of new diseases, military defenses would be largely Useless. The DEIS does not consider the relationship of the BDRP to such a multiplied threat to the global environment.

When the DEIS says that the BDRP enhances the national defense posture, it is looking at a very narrow segment of national security. It speaks of deterring the use of BW by our protective capacity and protecting troops in the event of BW attack. These are fine goals, but only to the extent that they do not interfere with other aspects of national security-something that is never taken up in the DEIS.

It is important to recall that BW have not been considered militarily useful because of their "massive, unpredictable, land potentially uncontrollable consequences" that could "produce global epidemics and impair the health of future generations"

(according to President Nixon). The new biotechnologies do not alter this. Consequently, it is the population that is at risk, and more at risk than troops because the long delay before microbiological agents take effect makes their battlefield use unlikely. Military defenses cannot protect the public. Therefore it is of primary importance that the military defense program should not undermine our primary lines of defense: the BWC and deterrence by other weapons.

However, international confidence in the BWCis being eroded by suspicions that offensive research, possibly involving the use of genetic engineering techniques to create novel pathogens with weapons potential, is being carried on under the guise of defensive activities.

It behooves the US, and other nations as well, to make every effort to dispel such suspicions. Otherwise, smaller nations may decide that they too must acquire The poor man's nuclear bomb." We are at a critical point in the history of biological arms control. Biotechnology is new, nothing has happened yet, and there is strong international concern and desire to strengthen the treaty regime. The recently undertaken confidence-building measures, involving the exchange of information, are a prelude to the establishment of measures to verify compliance and resolve complaints. The stringent provisions already agreed to in the BWC negotiations provide a model.

But the Department of Defense in recent years has been generating rather than allaying suspicions by its imprudent and

unjustified rhetoric on the military utility of BW and by certain aspects of the BDRP. Various changes in the BDRP could solve this problem, but because the problem is not acknowledged the DEIS casts off all possibilities of change.

The most controversial aspects of the BDRP are threat assessment, the possible development of novel organisms and toxins for that use, large-scale aerosol testing, and field testing. These items, the major sources of suspicion, are scarcely mentioned in the DEIS. This vast document is anything but comprehensive; it appears to be intended as a therapeutic dose of highly repetitive thin gruel. The big questions are avoided or obscured: in what situations simulants are or are a not adequate, and why; when is aerosol testing necessary, with what agents and on what scales could expert consultation perhaps provide new answers? What kind of evaluation and documentation is to be prepared before field testing or novel agent development? Is public input guaranteed? Who will decide? The DEIS has no intellectual content and provides little basis for intelligent evaluation of the BDRP. By contrast, the negative impact of the BDRP, as it now stands, is clear.

One thing that the DEIS does not slight is the benefit of the medical program to science and public health. But these real benefits could better be provided in the civilian sector; they are not acceptable as rationales for a program whose purpose is national defense. The medical work, of course,

provides defense benefits as well, but a medical defense can also be viewed as necessary for offensive use of BW. In addition, suspicions inevitably arise as to whether the medical work produces offensive information as a by-product, or provides a cover for potentially offensive activities such as the development of novel agents. In this light it is clear that the transfer of all medical activities to a civilian agency could provide a reassuring and significant alternative to the present program.

Turning from the medical program to passive defenses (protective devices and decontamination procedures) and detectors, which are developed and operationally tested, according to the DEIS, at the BL1 or BL2 level, the question arises whether any testing of these items against actual BW agents is necessary, and if so whether it must be done with aerosols or on a large scale. The DEIS merely states that limited use of high hazard organisms is necessary (A4-3), implying that small-scale, non-aerosol testing is adequate. It is hard to see why defenses that must work against all possible threats should require specific testing at all. With a little ingenuity it should be possible to devise tests with a series of innocuous agents, possessing a range of relevant properties, that would suffice. (For further discussion of simulants, see my comments on the BATF DEIS, page 5.)

Detectors, too, must have a wide range. It would not be safe to rely on specific detectors there are too many

potential BW agents. But even for detectors based on specific recognition principles (e.g., antigen-antibody reactions, it appears that development is carried out with simulants: verification that specific adaptations actually do work could e accomplished on a very small scale.

The need for field testing is not obvious and is never discussed in the DEIS. Since all medical testing, which unquestionably requires the use of pathogens, is done at USAMRIID (or so the DEIS suggests), there is no clear case for any testing at the Dugway Proving Grounds except with innocuous agents, and indoors. There is however, one brief mention of a function requiring pathogens, listed among other functions (2-7), that may be the major BDRP activity at Dugway: "the laboratory assessment of biological threat agents." If this is an important function, why is it not discussed? Is it really necessary? In the trade-off between public safety and confidence in the BWC, on the one hand, and the ultra-complete testing of materiel and the study of potentially offensive agents on the other, where should the line be drawn? The Army has not come to grips with this question. Perhaps it is more dangerous to conduct secret threat assessment studies than not to do so. And camouflaging threat assessment as materiel testing is no help.

Although the DEIS states repeatedly that all work under the BDRP is unclassified, the DOD Director of Environmental

and Life Sciences, Thomas Dashiell, says "Normally, our threat [assessment and equipment vulnerability work is classified" (Science 226, 1178 (1984)). Furthermore, secret clearance is required for the members of the Dugway Institutional Biosafety Committee (BATF DEIS, VIII-2). The DEIS does admit that "those results which impinge on the national security may be classified." How are the work and the results separated?

It is important to recognize that secrecy or uncertainty I about activities with offensive potential is provocative, regardless of the actual intentions and actions of the Army. The DEIS does not disavow the use of genetic engineering to create novel organisms with weapons potential; it merely confines its discussion of genetically-engineered materials to their use in medical research, thereby creating uncertainty. It does say that no work with genetically engineered microorganisms is performed or planned at Dugway, while acknowledging that the program is ongoing and changes can be expected. A changed policy at Dugway can be anticipated if the proposed BL4 aerosol testing facility is built. Or perhaps not. But so it appears to interested observers around the world. The option remains open to develop genetically engineered novel organisms for ambiguous defensive purposes such as threat assessment, and their development may even now be underway. In such a situation, as Lt. Col. Wyatt Colclasure has said, "You do get information, and like a lot of information, you can put it to different uses" (Science 226,

1178, 1984). Thus, the suspicion of offensive activity.

DOD's interest in threat assessment with novel organisms, including work to be carried out at Dugway, is unequivocal. It is set forth in some detail in the DOD Report to the House Committee on Appropriations, dated May, 1986, which says (in part):

"The threat posed by new biological agents must be established with the greatest degree of certainty possible. This high degree of certainty meat also be established for information on the ramifications of new production and processing technologies as they apply to conventional and novel threat biological agents. The [proposed] biological agent test facility is required to generate basic laboratory data to meet these threat assessment need."

This policy is likely to provoke the very threat that is feared, without actually providing any defense against it ? for, as the DEIS suggests, the number of novel BW agents that could in theory be developed is so vast that the development of specific defenses is impossible. "Generic" approaches are being explored (25). Indeed, truly generic defenses, which could be developed (if at all) without the creation of novel organisms, would be the only logical ones. But, again, the only real defense is a good treaty, good intelligence and military strength in other weapons.

In the event of unexpected BW threats or technological surprises, the safest response would not rely on the "sophisticated (big) technological beam" sought in the DEIS, which can never be adequate to the threat of BW, but on diplomatic action under a strengthened treaty regime. This is particularly true now, when all the old assumptions about our relationship with the Soviet Union are in flux and much of our biological intelligence may be out of date.

The possibility that exploratory research may already be going on at Fort Detrick to determine the military potential of genetic engineering is one that needs to be addressed in the EIS. Either it meat be explicitly disavowed or its environmental impact must be considered. An accident with a novel agent could be far more serious than with a known agent, because of the lack of medical experience with the agent, uncertainty about its effects in humans, lack of tested vaccines, possible built-in insensitivity to treatment, and so forth. Such experimental agents might be designed to persist under adverse conditions, making them difficult or impossible to eradicate. The possibility of starting an epidemic more devastating than AIDS cannot be ruled out.

The DEIS is full of complex quantitative calculations, involving many assumptions, to show that the risk is minute. More relevant is the fact that events of very low calculated

probability do occur. This is important when the consequences are grave. I have discussed this more fully in my comments on the BATF DEIS (pp 3-4).

The risks discussed all concern known, non-communicable (except through vectors) agents. for which vaccines and/or treatments are available. The latter play an important role in the risk determination. However, there is nowhere any disavowal of the use of other kinds of agents. The list of organisms given (A4-3) is not inclusive but merely "representative", and although it is stated that person-to-person spread of the organisms studied is Technically and epidemiologically impossible (5-9), the list includes at least one virus, Ebola, that is highly infective from human to human, highly lethal, and for which there is no vaccine or treatment available. Furthermore, none of the scenarios consider the possibility of a host-vector system becoming established. Finally, there is no mention of plant or strictly animal pathogens. If they are not now in use, what about the future?

The DEIS indicates that all perceived environmental threats are in fact so thoroughly controlled by the BDRP that the only true problem is psychological. The recent preliminary report of Senator Levin's Government Management Oversight investigation of safety in the BDRP finds otherwise. More will be heard from that Subcommittee on the safety issue. Suffice it to say here that the DEIS does not have a tenable basis for ruling out all changes in the existing BDRP.

A14-54b

In the scoping process it was suggested that simulants and innocuous agents be used in place of hazardous agents, and that genetic engineering work be discontinued. Obviously the medical program could not be carried on under those circumstances, but what about the rest of the programs? I have already suggested that the medical program be transferred out of DOD, to allay suspicions. If that were done it would be a simple matter to apply general restrictions to the BDRP; but if not, it is still possible to restrict certain facilities and projects.

Large-scale aerosol testing at Dugway and elsewhere is non-medical. Why could this not be restricted to non-pathogens? Or could testing with pathogens and hazardous materials be restricted to a small, and specified, scale? Is <u>any</u> aerosol testing with pathogens necessary? I would like to see unbiased expert input on these questions, with real scientific discussion, taking up the need for pathogen testing, or not, for each of the various purposes under the BDRP.

Since the BDRP is said to be unclassified, it should not be difficult to find means for making its activities more open. Testing, in particular. It is widely assumed that the main incentives for secret testing are to obtain offensive information and to keep secret the defensive capabilities needed for offensive use of BW. Increased openness, including declassification of results, would be an important step in preventing the erosion of the BWC.

If tests with pathogens continue. advance notice of each test, including the names of the organisms to be used, in the Federal Register would be a safety and confidence-building measure. Outside review by experts (without requiring secret clearance) of each intended use of pathogens or hazardous material, to verify the need, would be reassuring - a way to solve the "psychological" problem! The public has a right to know about every organism that is handled in each facility. At a minimum, annual publication of an exhaustive list is a must. Another must is resolution of the question of novel agents. DOD should renounce, absolutely, any work to develop or use novel agents except for cloning purposes in unclassified medical projects.

In sum, the DEIS shows that the BDRP is narrowly focussed on a small part of the BW problem, and there is no recognition of the need to ensure that the program fits constructively into the larger picture with regard to safeguarding the global environment. A large number of scientists and members of the public are seriously concerned about this. We want to see the BDRP reviewed with an open mind, and modified appropriately, so that it can make an unambiguous contribution to real national security.

A14-55b

7213 Rocky Springs Rd.
Frederick, MD 21701

U.S. Army Medical R&D Command
Ft Detrick
Frederick, Md. 21701-5012

August 4, 1988

Re: DEIS Biomedical Defense Research Program

Gentlemen:

The subject DEIS states that Ft. Detrick and the other BDRP program laboratories rely on either a "thick" estimate remove 99.95% of the particulate from the air extracted from hoods. This filtration science is entirely inadequate to protect the Frederick citizen neighbors of the facility. The 0.05% of the particulate which pass through these filters make up a huge number of particles being dumped into the environment by every hood in the facility.

It is well known that every cubic centimeter of air in our homes and environment, and, presumably, in the Ft. Detrick Fume Hoods, contains from 3000 to 5000 particles. Assuming 4,000 per cm^3 and 5 million of exhaust from a hood, the 0.05% loss figure translates to 200 million particles emitted every minute from every hood. Of course, this simple calculation does not speak to the proportion of biologically active particles interspersed among these escaping particles. This value would, of course, vary with each type of experiment. To suggest that any estimate of the impact of the program on the Ft Detrick environment caused by routine airborne releases must stand with this number. It should be stated in the EIS together with appropriate analysis for each number and type of biologically active particulate which escaped.

The DEIS implies that the 99.95% particulate retention figure is superior to state of the art containment. It is not so. High efficiency filters are now available which capture 99.99999% of the particles. They are routinely used to remove particles from large volume air flows into clean rooms. The EIS must acknowledge this fact and state why this simple means of reducing the release of extremely toxic particles is not employed in the BDRP.

The DEIS authors must acknowledge that Ft Detrick lies within the corporate

executive

limits of a large and growing city and that the risk from these releases is much greater here than from more remote BDRP facilities. The DEIS overlooks this simple fact entirely.

I served as the Program Manager for the airborne waste R&D program for the Department of Energy for several years prior to my retirement. All of the high efficiency filters used by that Department at their nuclear facility are individually tested to assure they are at least 99.97% efficient. Moreover, all of the facilities involved are in very remote locations. Also, few radioactive particles which may escape cannot multiply in the environment as can biological materials. I make this comparison to convince you and the statement authors that the EIS must evaluate the impact of this particle release issue in much more detail. It is a most serious matter.

Sincerely,
John C. Dempsey
John C. Dempsey
John C. Dempsey

Gentlemen: (transcript of Dempsey letter #2)

25-1a The subject DEIS states that Ft. Detrick and the other BDRP program laboratories rely on filter which remove 99.95% of the particulate from the air exhausted from hoods. The filtration efficiency is entirely inadequate to protect the Frederick citizen neighbors of the facility. The 0.05% of the particulates which pass through these filters make up a huge number of particles being dumped into the environment by every hood in the facility.

It is well known that every cubic centimeter of air in our homes and environment and presumably in the Fort Detrick fume hoods contain from 3000 to 5000 particles. Assuming 4000 per cm cubed and 5 m cubed/min of exhaust from a hood, the 0.05% loss figure is translated to 200 million particles emitted every minute from every hood. Of course, this simple calculation does not speak to the proportion of biologically active particles interspersed among these escaping particles. This value would of course vary with each type of experiment. I suggest that any estimate of the impact of the program on the Ft. Detrick environment caused by routine airborne releases must start with this number. It should be stated in the EIS together with appropriate analysis for each number and type of biologically active particulate which escapes.

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Sincerely, John C. Dempsey

The University of Illinois at Urbana - Champaign
College of Law
209 Law Building
504 East Pennsylvania Avenue
Champaign, IL 61820
217 333-0931

August 5, 1988

Express Mail

Phillip K. Russell
Major General, Medical Corps Commander
U.S. Army Medical Research and Development Command
Attention: SGRD-PA
Fort Detrick
Frederick, Maryland 21701-5012

Re: Draft Programmatic Environmental Impact Statement on the Department of Defense Biological Defense Research Program (May 1988)

Dear General Russell:

1. My name is Francis A. Boyle and I am a Professor of International Law at the University of Illinois in Champaign. I am also a member of the Subcommittee on the Military Uses of Biological Research of the Committee for Responsible Genetics. In that capacity, I have been closely involved in the proposed Draft Implementing Legislation for the Biological Weapons Convention of 1972 that is currently pending in Congress. Enclosed you will find a copy of the Testimony I submitted In support thereof to the Subcommittee on Immigration Refugees and International Law of the House Judiciary Committee, dated 23 March 1998, together with a Supplement thereto excerpted from a Memorandum I drafted on that subject dated 1 April 1987. Attached you will also find a 1986 Article I wrote on the Reagan administration's Chemical and Biological Warfare Programs that has been reprinted by the Department of the Air Force. in Current News, Special Edition No. 1586, Chemical Weapons, at 6 (28 May 1987). Finally, a copy of my resume has also been attached for your convenience. I should make it clear, however, that I am writing here only on my own behalf as a recognized expert on the subject of international law and biological warfare.

2. Your 12 May 1988 Circular Letter invited public comment on the Draft Programmatic Environmental Impact Statement on the Department of Defense Biological Defense Research Program (BDRP] (May 1988), that will hereinafter be referred to as the DEIS. In my expert opinion, there are several aspects of the DEIS that raise serious questions as to the BDRP's compliance with the stringent terms of the 1972 Biological Weapons Convention (BWC). Therefore, I would respectfully request that you "tasks someone from your Command to respond to the following comments and questions I have posed on this matter. A prompt forthright, and honest response to these questions will go a long way toward alleviating the concerns held by me and many other members of the Committee for Responsible Genetics about the BDRP.

3. For example right at the very outset of the DEIS, section 1.1 directly raises the issue of BDRP compliance with the BWC In the following words: "The Department of Defense (DOD) cannot ignore completely the possibility that BW threats exist and fail to provide any deterrents to their

potential application much less fail to provide a reasonable level of protection to U.S. forces." (Emphasis added.) (page 1.1). Section 1-1 clearly raises the question of whether or not the BDRP has for Its purpose the development of offensive BW threats to serve as "deterrents" to an alleged or supposed threat by an adversary of the United States. Moreover, section 1.1 makes it quite clear that the development of such "deterrents" is a DOD objective that is quite different from providing "a reasonable level of protection to U.S. forces." Clearly, "protection" is permissible under the terms of the Biological weapons Convention. But since the DEIS distinguishes "protection" from "deterrents," then obviously the ODD Intends to mean that such "deterrents" are something beyond mere "protection." If so, then there exists a distinct possibility that DOD research, development and testing of Such "deterrents" would violate the BWC.

4. For example, in the areas of chemical weapons, nuclear weapons, and conventional weapons. whenever the Department of Defense has talked about developing "deterrents" to their respective uses, it has always meant the research, development, testing and deployment of chemical, nuclear, and conventional weapons that will be used in retaliation in the event an adversary should resort to the first use of such weapons. Likewise, the entirety of the DEIS produces the strong implication that the Department of Defense is seriously contemplating the development of biological weapons in order to serve as "deterrents" to their expected use by an adversary of the United States government. In any event, a reasonable person reading the DEIS could certainly conclude that the Department of Defense is moving toward the development of BW "deterrents" that would be illegal under the terms of the BWC. At the very least, I suspect that is how the Soviet Union will read the DEIS. What concrete assurances can the DOD provide to the American people and to the Soviet Government that this is not the case?

5. Next, DEIS section 2.1 cites the Sverdlovsk incident and allegations of the use of toxins In Southeast Asia and Afghanistan by the Soviet Union as evidence of a resurgence of interest in biological warfare agents by the supposed adversaries of the United States government. Yet all of the scholarly literature written on these subjects agrees on the points that "yellow rain" was nothing more than bee feces and that the Sverdlovsk incident was produced by contaminated cattle feed. Since these matters are discussed at greater length in my 1986 Article and in the recent book by Piller and Yamamoto entitled Gene Wars (1988), I will not bother to review that literature In detail here. Suffice it to say that the Department of Defense can not produce a realistic assessment of the alleged biological weapons threat to the United States of America when its only two unclassified pieces of evidence have been definitively proven to be erroneous. How can the American public rely upon the integrity of the DEIS when it is premised upon such faulty assumptions?

6. The entire DEIS itself has been seriously compromised by dredging up I such unsubstantiated and spurious allegations that have now been completely I discredited by the scientific community. Whoever on your Staff was responsible for drafting these sections of the DEIS did no good service to the Department of Defense in reproducing such disingenuous allegations here. The DEIS's reliance upon these thoroughly debunked allegations simply raises the question of whether the Department of Defense is purposefully creating the specter of a Soviet offensive BW threat in order to Justify its own development of

retaliatory/offensive BW "deterrents" (to use the DOD's own term) under the guise of the BDRP.

7. For example, the DEIS lists my institution, the University of Illinois at Urbana-Champaign, as a secondary research site for the BDRP. I inquired from your Command as to the nature of four contracts that have been let out by the DOD to researchers at the University of Illinois as part of the BDRP To my surprise, I discovered that two of these contracts (viz., DAMD 17B2C2179 and DAMD 1785C5224) relate to tricothecene mycotoxins, which are said to be the active ingredients of so-called "yellow rain." Yet, Since it has already been established that "yellow rain" is nothing more than bee feces, there is absolutely no legitimate reason whatsoever for these researchers to be engaged in toxicological studies related to tricothecene mycotoxins for the DOD. At the very least, it seems to me that this weapons-specific research is what the DOD likes to call "dual-use": that is, it generates results that can be put to both offensive and defensive purposes depending upon the mere Intention of the researchers involved or of the DOD. The fact that there has never been an offensive "yellow rain" threat to the United States ins gates to me that perhaps the purpose of such "yellow rain" research is to generate results that can be put to prohibited uses. What concrete assurances can the DOD provide to the American people and to the University of Illinois community that such is not the case beyond DOD's own self-interested disclaimers?

8. Furthermore, it appears from the public description of the DOD studies at the University of Illinois that mycotoxins and bluegreen-algae toxin are being injected into pigs (viz., DAMD 1785C5224 and DAMD 1785C5241). Nevertheless, DEIS Appendix 3 lists the University of Illinois as a secondary site that falls into Risk Category VII, which is defined as "Other Program Research and Activities*," a term that is further defined as "*Includes either very low risk or non-risk activities which do not fit into the above [I-VI] categories." (page A3-1) Quite frankly, I find it completely misleading to say that the injection of pigs with mycotoxins and bluegreen-algae toxin are "very low risk or non-risk activities" that only require the lowest degree of minimal protections according to BDRP procedures. The DEIS's obfuscation of the weapons-specific type of research that is really going on at the University of Illinois, together with the misleading description of such research as being low-risk or non-risk, call into question the entire categorization scheme for all of the contracts at the so-called secondary sites in the BDRP. This section of the DEIS must be substantially revised and significantly more information on the exact nature of BDRP contracts and secondary site protections must be disclosed to the people inhabiting the nearby vicinities.

9. DEIS section 2.4.1 states with respect to gene cloning of protein toxins: "The general approach is to identify the portions of the protein toxin responsible for eliciting immunity, as opposed to that portion of the molecule responsible for toxicity." (Emphasis added.) (page 2-5). The use of the words "general approach" implies that there are also "other approaches" undertaken by the DOD with respect to this particular type of research. More concretely there is nothing to prevent researchers from cloning the portion of the molecule responsible for toxicity, which they have already implicitly identifies when distinguishing it from the immunogenic portion. The DEIS provides absolutely no assurance or mechanism to guarantee that this is not occurring under the aegis of the BDRP even though the DEIS makes it quite clear that such prohibited research can in fact occur.

10. In this regard, the various federal laws, statutes and regulations mentioned in the DEIS are completely inadequate to implement the strict terms of the Biological Weapons Convention for the reasons explained in my 1988 Testimony and in my 1987 Memorandum that I prepared on behalf of the Committee for Responsible Genetics, copies of which are attached to this letter. Nowhere in the DEIS has your Staff indicated that qualified and Independent legal experts have vetted the BDRP in accordance with the strict terms of the BWC, or that such oversight and examination would be conscientious, continuous and comprehensive. What assurances do the American people have that the Department of Defense is scrupulously adhering to the terms of the Biological Weapons Convention other than the self-exculpating DEIS statements to that effect?

11. I would submit that if the Department of Defense wants to obtain public acceptance and support for the BDRP, then it must establish both external and internal procedures whereby independent lawyers, in addition to independent scientific experts, can guarantee and assure to the American people that the BWC is being strictly adhered to throughout all aspects of the BDRP. Since the BDRP is generally not classified, such procedures should not be too difficult to set up, assuming the DOD really wants to. I would be happy to meet with you and your Staff in order to establish such procedures that might provide some degree of credibility with respect to BDRP/BWC compliance in the eyes of the American scientific and legal communities.

12. DEIS section 4.2.2 states that it would not be appropriate, even if it could be done institutionally, to transfer defense responsibility to another agency or organization." (page 46). Yet that is precisely what has historically been done with respect to nuclear weapons. Originally, the Truman administration decided to establish civilian control, as opposed to military control, over nuclear weapons by means of creating the Atomic Energy Commission. Such governmental supervision over nuclear weapons now resides in the civilian Department of Energy, which is exclusively responsible for the research, design, development and testing of nuclear weapons systems themselves, not the Department of Defense. The same type of civilian function could certainly be performed with respect to the BDRP by the National Institutes of Health, for example. In any event, the DEIS dismissed this alternative out of hand without even bothering to discuss or analyze it. A revised DEIS must contain a detailed analysis of the utility of this civilian alternative by your Staff.

13. Indeed, DEIS Executive Summary section ES.7 dismissed three options for the BDRP out of hand without even bothering to comment upon them: the elimination of aerosol testing; placing a moratorium on research involving genetic-engineered micro-organisms (GEMs); and transferring the management responsibility for the BDRP to a non-military agency. (page ES-4) Whoever was responsible for preparing the DEIS was grossly negligent in not producing a comprehensive analysis as to why either one if not all three of these alternatives should have been seriously considered with respect to all or significant parts of the BDRP. I would respectfully request that you go back to your Staff and demand that they produce a revised DEIS that seriously addresses these three aspects of the problem.

14. Proceeding sequentially through the DEIS, I next have serious concerns with respect to BDRP research going on at secondary sites outside the

territorial jurisdiction of the United States. I would like to know whether or I not and how the Department of Defense is making sure that such research is being conducted in accordance with the strict terms of the Biological Weapons Convention irrespective of whether the host country is a party to the BWC. There is a potential for the Department of Defense to take the position that it is not responsible for absolutely guaranteeing that BDRP research conducted in countries not parties to the BWC is consistent with the terms of the convention. Is this the case or not?

15. For example, I am especially concerned that BDRP research is currently taking place in Liberia, which is not a party to the BWC as indicated in Appendix 3, page A3-4. As you undoubtedly know, Liberia is ruled by a ruthless dictator named Samuel K. Doe, who is kept in power by the Central Intelligence Agency and the DOD Army's Special Forces. What assurances can you provide to the American people that BDRP research currently being conducted In Liberia is in full compliance with the terms of the BWC when Liberia is not a party to the BWC? Such questionable foreign BDRP research contracts create the strong suspicion that the Department of Defense has been purposely letting out BDRP contracts to sources in Liberia and other non-BWC states for the express purpose of circumventing or undermining the stringent controls of the BWC.

16. In this regard, I have also noted in DEIS Appendix 3 that both the Wistar Institute of Philadelphia, Pennsylvania and the Pan-American Health Organization in Argentina are classified as secondary sites for the BDRP. Since that is the case, I would like to know whether or not DOD funding under the aegis of BDRP research or otherwise was behind the controversial experiment developed by the Wistar Institute involving a genetically-engineered rabies vaccine that was injected into animals in Argentina without official sanction by the governmental authorities of that country. Argentinean officials have since charged that the virus spread beyond the animals that had been vaccinated. If DOD funding was behind that Wistar experiment, then it is obvious that DOD quality and safety controls have proven to be completely inadequate. In any event, because of the Argentinean affair, it appears that Wistar should not under any circumstances be allowed to conduct BDRP research. What assurances can you provide to the American people that comprehensive controls will be instituted with respect to all BDRP research occurring at so-called secondary sites whether in the United States or abroad by irresponsible contractors such as Wistar?

17. DEIS section 5.2.1.4 at page 5-6 admits that the BDRP Is engaged in the process of identifying and counteracting so-called "potential threat agents." Yet, once again, the American people have no guarantee that the Department of Defense is using GEMs to produce a vaccine as opposed to the weapon itself. DEIS page 5-9 admits that BDRP uses of recombinant techniques are with the goal of producing "a less virulent strain." But then a portion using the same recombinant techniques, the BDRP can certainly produce a "more virulent strain." What independently verifiable guarantees can the Department of Defense provide to the American people that this is not going to happen under the aegis of the BDRP?

18. DEIS Appendix 4, section 1.3 at page A4-3 provides no rationale whatsoever for the rejection of simulants as an alternative to the use of highly dangerous organisms for various aspects of the BDRP. The use of simulants for a variety of purposes is simply dismissed out of hand. This

section of the DEIS is completely inadequate and slipshod. Your Staff needs to produce a revised DEIS that contains a comprehensive analysis of the potential use of simulants throughout all aspects of the BDRP.

19. DEIS Appendix 4, section 3.2 states that with respect to toxins, research, development and testing activities include: "structural analyses to identify the parts of a toxin responsible for immunity." Yet, since that is the case, then the same "structural analyses" can also be used to "identify the parts of a toxin responsible for" pathogenicity. Once again, Such dual-use studies and activities raise serious questions of BDRP compliance with the BWC. What assurances can the DOD provide to the American People that these "structural analyses" are not being put to prohibited purposes? A similar criticism applies to a DOD contract here at the University of Illinois for The Development of a Toxic Knowledge System (viz., BAND 1787C7114).

20. The above analysis contains most of the major points I wish to make on the proposed DEIS for the BDRP. I do hope that a responsible person under your Command will have the opportunity to provide a formal, written, and Comprehensive response to these questions. If necessary, I will be happy to meet with someone from your Command in order to discuss these concerns. However, unless and until I receive an adequate response to these points and questions in writing, I will remain opposed to the BDRP. In addition, I will also recommend that the Committee for Responsible Genetics use its Considerable influence and prestige within the scientific community and elsewhere to actively oppose the BDRP by all means possible. Finally, I will also have to make a similar recommendation to those lawyers' organizations of which I am a member.

I look forward to hearing from you at your earliest convenience. And thank you very much for your kind attention to this matter.

Yours very truly,

Francis A. Boyle
Professor of Law

FAB/bw
encl's.

cc: The Committee for Responsible Genetics

The University of Illinois at Urbana - Champaign
College of Law
209 Law Building
504 East Pennsylvania Avenue
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217 333-0931

TESTIMONY
IN SUPPORT OF
H.R. 901. 100th CONG., 1st SESS.

A BILL TO IMPLEMENT THE BIOLOGICAL WEAPONS CONVENTION OF 1972

Before

The Subcommittee on Immigration, Refugees and International Law
of the House Judiciary Committee

March 23, 1988

by

Francis A. Boyle

Professor of International Law and

Program in Arms Control, Disarmament and International Security

The University of Illinois at Urbana-Champaign

Counsel, The Committee for Responsible Genetics

A.B. (Chicago: 1971), J.D. Magna Cum Laude (Harvard: 1976),

A.M. and Ph.D. In Political Science (Harvard: 1973 and 1983)

Author: World Politics and International Law

(Duke University Press: 1985)

Good Morning. My name is Francis A. Boyle, Professor of International Law and Member of the Program in Arms Control, Disarmament, and International Security at the University or Illinois at Urbana-Champaign. I am also Counsel to the Committee for Responsible Genetics (CRG) and in that capacity I have directly supervised CRG's project to sponsor the passage of implementing legislation for the Biological weapons Convention of 1972. I should point out that I have not been paid any fee by any individual, group, corporation, or organization-- including the Committee for Responsible Genetics-- for the testimony I am giving here today.

It is generally agreed that the Biological weapons Convention of 1972 applies to recombinant DHA experiments and other techniques of genetic engineering. One of the great loopholes and severe deficiencies of the Convention, however, Is the exception article I thereof has created for biological agents or toxins that are retained "for prophylactic, protective, or other peaceful purposes." Indeed, article X of the Convention makes it clear that parties to the Convention have the right to participate In the fullest possible exchange of equipment, materials, and scientific and technological information for the use of bacteriological agents and toxins for Peaceful purposes. Hence, one of the major problems with the Convention today is the undeniable fact that it becomes almost impossible to conduct genuinely peaceful research Into genetic engineering applications of a Defensive nature (e.g., developing a vaccine) without obtaining results that could readily be put to use for the production of proscribed offensive biological weapons.

The best way to deal with the serious compliance problems created by such intrinsically dual-use genetic engineering research is for the United States Congress to adopt tough implementing legislation designed to guarantee that all

such projects conducted in U.S. territory be undertaken in strict accordance with the terms of the Biological Weapons Convention. In this regard, article IV of the Convention requires each state party to adopt such implementing legislation. Hence the United States government is under an obligation to adopt implementing legislation in order to carry out the terms of the Convention within its domestic legal order to make sure that all U.S. citizens adhere to its terms -- whether persons in the government, government contractors, and especially individuals in the private sector.

The enactment of such implementing legislation would also constitute one of the primary mechanisms for preventing "terrorist" states, groups, or individuals from contracting with U.S. genetic engineering firms for the production of biological weapons that could serve as a relatively inexpensive alternative to the development of nuclear weapons for the threat or use of mass extermination in order to accomplish their terroristic objectives. At this point In time private American DNA genetic engineering firms are perfectly free to ignore the terms of the Convention. So far the Convention can only bind the United States government as a matter of international law in its relations with other state parties to the Convention. The prohibitions of the Convention do not yet bind any private citizen or corporation within the United States of America of their own accord.

Indeed, it would be unconstitutional as a violation of due process of law to prosecute or punish any individual pursuant to the terms of the Convention because it has not yet been implemented by a specific congressional statute that precisely defines the nature of the offense, fixes the penalty, establishes proper venue for the prosecution, etc.See, e.g., The Over the Top Case, 5 F.2d 838, 845 (D. Conn. 1925). Hence, today it would not be criminal for a private DNA genetic engineering firm to contract with a terrorist state

or group or even a private individual to manufacture biological weapons. The only may to stop such a tragic disaster from happening is for Congress to adopt tough implementing legislation now that would make such activity a crime whether committed by a government contractor or someone in the private sector. Although not absolutely foolproof, the imposition of severe criminal penalties would serve as an effective deterrent upon governmental contractors and private sector individuals who are currently conducting genetic engineering research that could be put to such prohibited uses.

In response to these compelling arguments the Reagan administration has adopted the somewhat debatable position that various statutes already on the books could, when considered together, serve the purpose of Implementing the Biological Weapons Convention:viz, the Arms Export Control Act; Export Administration Act; Hazardous Material Transportation Act; Toxic Substances Control Act; Public Health Service Act; Federal Insecticide, Fungicide and Rodenticide Act; and the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules. In the brief time allotted to me here today, I will not have the opportunity to analyze in great detail why this is not so. But In this regard, at the request of the Committee for Responsible Genetics I had drafted a Memorandum at Law entitled The Need for United States Implementing Legislation for the Biological Weapons Convention of 1972 that was dated April 1, 1987. Attached you will find a Supplement to my Testimony that contains the relevant portions of that Memorandum. As you can see, this 1987 Memorandum contains an extensive analysis of these various statutes cited by the Reagan administration, together with a detailed explanation on a point-by-point basis of exactly why these statutes, whether considered individually or collectively, would be completely inadequate to serve for the purpose of implementing the Biological Weapons Convention.

Technically, therefore, the United States government still stands in breach of its solemn international legal obligation under Convention article IV to enact such domestic implementing legislation. By contrast, for example, the British government adopted strict implementing legislation for the Biological Weapons Convention as long ago as 1974. Similarly, France had enacted legislation which it considered far more protective than the Convention in 1972. Belgium adopted legislation to implement the Convention in 1978, and Australia adopted the Crimes (Biological Weapons) Act of 1976. Japan, Nigeria, the Netherlands and Sweden, inter alia, also have domestic legislation dealing with such matters. In Communist states such as the Soviet Union and China where there is no private sector as a matter of law, the terms of the Biological Weapons Convention would apply directly to all agencies and instrumentalities of the government as well as to all government employees, which would presumably include anyone who might conceivably be engaged In such genetic engineering research. Also, other states in the world community do not specifically require domestic implementing legislation in order for treaty obligations to be directly binding upon their private citizens.

The proposed implementing legislation would place the U.S. government on the same legal footing as many of our friends and allies and thus strengthen the Convention's strict regime. In addition, such implementing legislation would drastically curtail the ability of terrorist states, groups or individuals to contract with American DNA genetic engineering firms for the production of biological weapons for their own nefarious purposes. Such implementing legislation would also serve notice to government contractors and private sector individuals that there exists a bright red line demarcating felonious behavior that they had better not cross or even nibble around the edges of anew it comes to self-styled "peaceful" or "defensive" research into

biological weapons and biological warfare capabilities. Finally, Such implementing legislation would certainly help assuage some of the serious concerns held by other state parties to the Convention about the purpose of the new aerosol test facility at the Dugway Proving Grounds and thus prevent the development of a de facto biological weapons race under the guise of "defensive" research.

For all of these reasons then, I believe it would be extremely important for the United States Congress to adopt such strict implementing legislation immediately. Thank you very much for your kind consideration. It has been most appreciated.

Yours very truly,

Francis A. Boyle

Professor of Law
and Program In Arms Control,
Disarmament and International Security
Counsel, Committee for Responsible Genetics

FAB/bw

TESTIMON.BWC

COMMENTS OF JEREMY RIFKIN, AND THE FOUNDATION ON ECONOMIC TRENDS ON THE DEPARTMENT OF DEFENSE'S DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT FOR THE BIOLOGICAL DEFENSE RESEARCH PROGRAM

AUGUST 8, 1988

A14-64a

I. INTRODUCTION

These comments are submitted by Jeremy Rifkin, President of the Foundation on Economic Trends (Foundation). The Foundation is a public interest organization which assesses the economic, environmental and ethical risks involved in emerging technologies. Over the past several years a major focus of the Foundation has been the regulation of developments in biotechnology. A particular concern of the Foundation has been the use of biotechnology and genetic engineering in biological warfare research.

The Foundation on Economic Trends has in the past engaged in actions which temporarily halted certain biological warfare research work. We have focused public attention on the military application of genetic engineering technology, and we have forced the Department of Defense (DOD) to prepare environmental impact statements (EISs) on the health and environmental implications of the biological defense research program (BDRP).

In December 1984, the Foundation and other plaintiffs filed a motion for preliminary injunction to enjoin the construction of the proposed aerosol biological warfare testing facility (BATF) at Dugway, Utah. We maintained that the Army had not prepared an environmental assessment (EA) for the facility and wee therefore not in compliance with the National Environmental Policy Act (NEPA). Approximately one month later, the Army released an EA for the BATF. Contending that the EA wee grossly inadequate, we quickly moved for a permanent injunction on the facility.

On May 31, 1985, Federal District Court Judge Joyce Hens Green permanently enjoined the construction of the lab citing the "serious and far-reaching risks involved in its operation. Judge Green held that the EA was "clearly inadequate" and a "substantive violation" of NEPA. She concluded that "[g]iven the deadly nature of the material being tested, considerations of the larger interests of society-particularly concerns for public health and safety--militate heavily in favor of enjoining construction." See Foundation on Economic Trends et al. v. Caspar W. Weinberger et al., 610 F. Supp. 829 (D.D.C. 1985). The Department of Defense released the BATF draft EIS in January of 1988. The Foundation has submitted comments on the draft EIS, outlining its substantial procedural and substantive inadequacies.

In September of 1986, the Foundation filed another law suit against the DOD calling for a programmatic environmental impact statement (EIS) on the entire Biological Defense Research Program. On February 17, 1987, the U.S. District Court of the District of Columbia ordered the DOD to undertake the preparation Of a programmatic (EIS) covering all private and military laboratories which conduct biological warfare research. On August 12, 1987 the Foundation participated in the "scoping" of this EIS. We initiated that major concerns about the efficacy Or the biological warfare program, its security, and its environmental effects be included in the court ordered environmental documentation.

II. THE BDRP EIS

The two major purposes of an EIS are to 1) provide decisionmakers with enough information to aid in the substantive decision whether to proceed with the project in light of its environmental consequences; and 2) provide the public with information and an opportunity to participate in gathering information. SeeCitizens for a Better Henderson v. Model, 768 F2d, 1051, 1056 (9th Cir. 1985). The form and content of an EIS must therefore foster both informed decisionmaking and informed public participation. Crucial to fulfilling this purpose is that an EIS "provide full and fair discussion of significant environmental impacts and . . . inform the decisionmakers and the public of the reasonable alternatives which would avoid or minimize adverse impacts . . ." (40 C.F.R. 1502.1)

The BDRP EIS fails in both these purposes. It does not adequately address the environmental consequences of the proposed action nor does it provide a full and fair description of possible alternatives to the current BDRP scope and implementation. Moreover, the findings in the BDRP on environmental impact are conclusory and unsupported.

The Council on Environmental Quality (CEQ) regulations do not allow for such conclusory and unsupported findings in an EIS. They stipulate that "Agencies shall insure the professional integrity, including scientific integrity, of the discussions and analyses in environmental impact statements. They shall identify any methodologies used and shall make explicit reference by footnote to the scientific and other sources relied upon for conclusions in the statement." 40 C.F.R. 1502.24 Throughout the BDRP EIS is in violation of this and other NEPA regulations.

III. ENVIRONMENTAL AND HEALTH IMPACTS OF THE BDRP

The BDRP is devoted to research in "militarily significant" bacteria, viruses and toxins. These pathogens can be used to destroy animals, crops, and people. Biological agents can mutate, reproduce, multiply and spread over a large geographic areas by wind, animal, and insect transmission. Once released, many biological pathogens are capable of developing a viable niche and maintaining themselves in the environment indefinitely. Traditional biological agents include Yersinia pestis (the plague), anthrax, botulism, snake venom, tularemia, rift valley fever, Coxiella burnetii (Q fever), eastern equine encephalitis, and small pox. These pathogens are selected for research because they have potential use as warfare agents due to, inter alia, their pathenogenicity, quick infectivity, and ability to rapidly disseminate.

Moreover, the BDRP is involved in large scale genetic engineering of biological warfare agents. In a May 1986 report to the Committee on Appropriations of the United States House of Representatives, the Department of Defense pointed out that recombinant DNA and other genetic engineering technologies are finally making biological warfare an effective military option. Genetic engineers are cloning previously unattainable quantities of "traditional" pathogens. The DOD report states that:

potent toxins which until now were available only in minute quantities, and only upon isolation from immense amounts of biological materials, can now be prepared in industrial quantities after a relatively short developmental period. This process consists of identifying genes, encoding for the desired molecule and transferring the sequence to a receptive micro-organism which then becomes capable of producing the substance. The recombinant organisms may then be cultured and grown at any desired scale...Large quantities of compounds, previously available only in minute amounts, thus become available at relatively low costs. 1

Using recombinant DNA technology, it is now possible to develop a nearly infinite variety of "novel" designer biological warfare pathogens never before seen. The DOD report summarizes:

[new advances in biotechnology]...permit the elaboration of a wide variety of 'novel' warfare materials...The novel agents represent the newly found ability to modify, improve or produce large amounts of natural materials or organisms previously considered to be militarily insignificant due to problems such as availability, stability, infectivity and producibility. 2

Recombinant DNA "designer" weapons can be created in many ways. The new technologies can be used to program genes into infectious micro-organisms to increase their antibiotic resistance, virulence, and environmental stability. It is also possible to insert lethal genes into harmless microorganisms resulting in biological agents that the body recognizes as friendly and does not resist. It is even possible to insert genes into organisms which affect regulatory functions that control mood and behavior, mental status, body temperature, and other functions. Scientists any they may be able to clone selective toxins to eliminate specific racial or ethnic groups whose genotypical make-up predisposes them to certain disease patterns. Genetic engineering can also be used to destroy specific strains of agricultural plants or domestic animals if the intent is to cripple the economy of a country. In recent months advances have been made in the creation of genetically engineered microbes which are designed to self destruct after a given period of time. In sum, the implications of this, and other advances in genetic engineering, are extraordinary and frightening.

Due in part to genetic engineering the BDRP has expanded 500% over the last 6 years. In 1981, the Pentagon budget for "defensive" biological warfare research was only $15.1 million.

In fiscal 1982 it rose to $21.6 million. In fiscal 1983 it jumped again to $38.8 million. In 1984 it rose still higher to $39.1 million. In 1985 the DOD budget grew to $50 million and in 1986 to $90 million. The 1987 expenditures are estimated to be close to $70 million. 3

The BDRP has the potential for significant adverse effects on the environment and public health. According to the DOD biological warfare research is ongoing in more than 19 government labs, 50 non-governmental research labs and institutions, and over 85 colleges and universities.4 As noted, this research involves numerous bacteria strains such as Salmonella marcescenes, and Yersinia testis, numerous viruses including Rift Valley Fever, Yellow Fever, poliovirus, Ebola and Marburg viruses and human retroviruses; and more than seventy toxins, including T2 mycotoxin, Scorpion toxin, and Motive rattlesnake toxin. The BDP has also conducted over 75 recombinant DNA experiments. 5

The environmental concerns about this research include 1) effects on the general public from potential exposure to biological warfare agents during normal operations or due to advertent or inadvertent release of the hazardous organisms (i.e. human error, equipment failure, terrorism, or natural disasters); 2) effects on DOD personnel from potential exposure to biological warfare agents nonbeing researched; 3) impacts on the thousands of national and international volunteers being used in BDRP projects; 4) impacts on air, and water quality and biota from BDP operations or accidents; 5) laboratory security; 6) risks involved in decontaminating facilities; 7) treatment and disposal of BDP research wastes, 8) economic and social impacts to areas adjoining BDP sites, and 9) transportation and shipping of BDP pathogens.

The BDRP EIS fails to adequately address these concerns. The EIS does not even provide full relevant data on all facilities involved in BDRP research. To be adequate, the EIS should describe what pathogens are being researched at each facility and what type of research is being conducted. Additionally, safety and security measures, inventory, emergency medical procedures and other similar protocols should be described for each mite. The EIS in selecting only a few sites for any extensive review leaves the impression that those preparing the EIS did not have full information as to all facilities or even full access to the legal pleadings which led to the preparation of the EIS.

The EIS also makes it clear that the BDRP has never instituted a comprehensive study on accidental exposures and other hazards of the BDRP. The DOD has admitted that there have been approximately 20 "potential accidental exposures" at Fort Detrick since 1983 put the DOD has not provided information on the rest of the BDRP.6 There have also been widely reported cases of fires and other accidents at Fort Detrick including missing quantities of viruses One of the moat recent incidents is the loss of a sample of Crimea Congo hemorrhagic fever en route from the Center for Disease Control to the BDRP lab at Fort Detrick, Md. According to the

National Institutes of Allergy and Infectious Diseases the Congo fever virus is so "highly infectious that most labs won't work on it." 7 With this virus, and many others being worked on in the BDRP labs even small amounts of the pathogen if dropped from a plane or truck or dumped into the water supply, could have devastating effects.

Additionally, the danger of experimentation with pathogens is highlighted by the reporting of several NIH research experiments, not related to the BDRP, which have led to the infection of workers with the pathogens ranging from pertussis to AIDS. One internal NIH report on such accidents pointed to the need for upgraded standards when dealing with large scale research activities with pathogens because of, inter alia, "the potential for introducing infective agents into the community outside the laboratory." 8 The BDRP EIS makes no analysis of how these NIH accidents relate to the hazards in BDRP research.

The dangers of BDRP research have been noted by many in Congress and the public health sector. Senator Orrin Hatch (R-UT) has maintained that BDRP research in populated areas constitutes "reckless endangerment" and has advocated "a remote island for any future biotoxin work." 9 Dr. Anthony Robbins past President of the American Public Health Association has summarized, "[w]eapons designed and built with modern biotechnology will leave us no reasonable opportunity to protect the public. This is true whether the public is exposed by military attack; by accident; or by terrorism. Advances in genetic engineering and other new techniques of biotechnology have magnified both the theoretical lethal capabilities of biological agents, and their potential to create public health catastrophes." 10

The recently released Department of Defense Annual Report on the BDRP (October 1986 through September 1987) demonstrates that the BDRP is expanding in many important arena. The Annual Report demonstrates that the BDRP is continuing to aggressively investigate, purify, propagate, clone and alter traditional and new pathogens. The BDRP is also expanding its vaccine program to include large numbers of national and international volunteers. The 1987 Annual Report states that the BDRP has "established protocols for field testing efficacy of Argentine hemorrhagic fever vaccine in 3,000 volunteers residing in endemic disease areas." The increase in the number and type of pathogens being investigated by the BDRP and the expanded use of international volunteers in BDRP programs causes a growing potential for health and safety risks. The expansion of the international research in the BDRP comes at a time when the NIH is still undecided as to how its research Guidelines apply to research done abroad.

Even as the BDRP expands, an internal Army Science Board report evaluating the BDRP (July 1987) states that "there is a serious lack of clear-cut assignment of responsibility together with authority to control the program's direction and outputs. The report concludes that "there does not presently exist within

the Army an adequate mechanism for assuring the systems integration of the total BD program." 12

This lack of integration and coordination is particularly evident in the DOD's apparent inability to assess and minimize the environmental and health impacts of the BDRP. The DOD is content to allow the BDRP's impacts to be governed and monitored by a series of regulations, the enforcement of which is the responsibility of numerous agencies. These include the Department of Transportation (Packaging standards, 49 C.F.R. sec. 173), Environmental Protection Agency (Toxic Substances Control Act, 5 U.S.C. secs. 2601-2929: Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. secs. 136-136y), US Department of Agriculture Virus-Serum-Toxin Act: 21 U.S.C. sees. 151-158), Food and Drug Administration (Food, Drug and Cosmetic Act: 21 U.S.C. secs. 301 et seq.) and the Nuclear Regulatory Commission (use of radioactive isotopes, 10 C.F.R. sec. 1). In addition, DOD voluntarily follows the NIH guidelines governing recombinant DNA (rDNA) work (49 Fed. Reg. 4065g (1984)).

The BDRP makes no analysis of the Army Science Board finding nor how such an uncoordinated research program can rely for its safety on the enforcement of the regulatory tangle cited above.

IV. ALTERNATIVES

The consideration of alternatives is generally accorded the role of "linchpin" for any EIS. A full and detailed discussion of the alternatives to a proposed action is essential for a legally adequate EIS. An alternative may not be given short shrift because it is outside the jurisdiction of the agency or is contrary to existing agency policy. In sum, the discussion of alternatives must demonstrate that the agency has taken a "hard look" at the environmental consequences of its proposal and those of possible alternatives. See, Baltimore Gas & Electric Corp. v. NRDC, 462 U.S. 87, 97 (1983); California v. Block, 690 F. 2d 753, 761 (9th Cir. 1985).

In the BDRP EIS, the DOD has wholly failed to adequately address the alternatives to its proposed action. Its discussion of alternatives is replete with sweeping conclusions unsupported by facts and scientific studies. As noted, the CEQ regulations specifically forbid such vague, conclusory and unsupported discussion of alternatives to a proposed action. See 40 C.F.R. 1502.24. The three most important alternatives which are not adequately addressed are 1) the consideration of options to replace aerosol testing, 2) a moratorium on research involving genetic engineering, and 3) the transfer of the management of the BDRP to a non-military agency. Additionally, the BDRP EIS does not adequately address the need for the use of simulants to replace the use of dangerous pathogens.

The BDRP EIS rejects all these alternatives in just over two pages. (4-4,6) The DOD admits that "no detailed study" has been

made of theme proposals despite the fact that they would significantly eliminate the environmental impacts of the BDRP program. The EIS also fails to look at these alternatives in conjunction with each other. For example, the DOD could declare a moratorium on genetic engineering research and transfer any truly necessary recombinant research to the National Institutes of Health or other agency which, unlike DOD, are required to follow the NIH Guidelines for such research.

The simulant alternative has been much discussed for several years, yet the DOD continues to avoid any real discussion of its actions in this area. Any "hard look" analysis of the use of simulants should include, inter alia: 1) a listing by the Army of how many simulants have been approved by the Army for use and for what uses; 2) an explanation by the Army of its procedures for developing simulants or surrogates for testing, including a description of its program, if any, for developing such simulants, including facilities, personnel and funds dedicated to such purposes and what priority the Army has given to their development; 3) a precise description of which teats, and for which pathogenic organisms, simulants are ineffective; 4) an explanation and description of what specific characteristics in each of the pathogenic microorganisms will be useful for tests to be performed in the facility and to what extent those characteristics may be developed (or retained) in such simulants; 5) an explanation of why simulants in the form of attenuated strains, vaccine strains or related not-pathogenic species are not suitable for various contamination and decontamination tests, including specific characteristics of each specific simulant which do not make tub useful in such tests.

V. CONCLUSION

In sum, the BDRP EIS is shoddily prepared, grossly inadequate and in clear violation of NEPA and its relevant regulations. The BDRP EIS fails to adequately assess the human health and environmental risks of the BDRP and also fails to conduct a full discussion of possible alternatives. The EIS is a wholly inadequate document to inform either decisionmakers or the public on the BDRP.

As described the EIS should have adequately examined the need for alterations in the BDRP to avoid risk to human health and the environment. As noted these alterations would have to involve change in the conduct, type and scale of BDP activities. In review, the first step in improving the conduct of BDRP activities would be to shift the recombinant research currently ongoing at the BDRP to civilian agencies. The DOD should declare a moratorium on the use of recombinant DNA research and shift research which has public value to the civilian agencies such as the NIH or CDC. Other changes should include the establishment of an independent (non-DOD) review committee to assess the environmental and health implications of BDRP research. Additionally, there should be

mandatory reporting of all BDRP accidents with full investigation (of any such accident by independent (non-DOD) investigators. Moreover, the BDRP should make available to the public an updated list of all pathogens being researched, the location of such research, and the safety and security measures, including emergency protocols, for all such locations. All new and/or controversial research should be published in the federal register for full notice and comment. Finally, changes in BDP activities should include a total commitment to the use of simulants rather than the toxic materials currently in use.

An important change in the scale of the BDRP would be the requirement that all BDRP researchers and research location keep a careful inventory of all BDRP pathogens. Additionally, no new pathogens should be investigated by the BDRP unless there is some intelligence that there is a real need for defensive research into such pathogens.

Finally, the environmental impacts of the BDRP program could be minimized through a change in the location of BDRP operations. Such research should not be dispersed through the several dozen laboratories currently in use. Instead any BDRP research found absolutely necessary should be located at remote sites away from populations. Environmental and safety consideration should, and legally must, be included in the decision as to which facilities will conduct which parts of the BDRP.

Given the above, unless both the form and content of the BDRP EIS are significantly revised and expanded the Foundation will once again file suit in Federal court to enforce NEPA compliance by the DOD in the operation of the BDRP. Such a suit would almost certainly call for substantial injunctive relief, especially as regards the closing down of the major BDRP facilities.

Sincerely,

Jeremy Rifkin

FOOTNOTES

1. Department Of Defense Biological Defense Program, Report to the Committee on Appropriations House Representatives, May 1986, p. 4.

2. Ibid., p. 8.

3. Department of Defense, Annual Report on Chemical Warfare Biological Defense Research Program Obligations, 1 October 1986 through 30 September 1987. p.1.

4. see list of laboratories involved in BDRP research in Draft Programmatic Environmental Impact Statement, Biological Research Defense Program, May 1988, Appendix 3.

5. See partial list of BDRP pathogens Answer to Plaintiff's Interrogatory No. 4, Foundation on Economic Trends et al v. Weinberger et al., Civil Action No. 86-2436.

6. See Programmatic Environmental Impact Statement, Biological Research Program, Appendix 8..

7. Associated Press Wire Report, The News, Frederick, H.D Saturday May 30, 1987, A-5.

8. NIH Draft Report "Laboratory Acquired Pertussis Associated With Pilot Plant Production," (11/20/86), p.5.

9. "Hatch Proposes Island Location for Germ Warfare Testing, Press Release, Office of Sen. Hatch, March 25, 1988.

10. Statement of Anthony Robbins M.D. to the Committee on Interior and Insular Affairs, Subcommittee on Energy and the Environment Committee on Foreign Affairs Subcommittee on Arms Control; International Security and Science Committee on Armed Services, Subcommittee on Military Installations and Facilities, May 3, 1988.

11. p. 61.

12. Department Of the Army, Army Science Board, "Final Report of the Ad Hoc Subgroup on Army Biological Defense Research Program n July 1987. p. 5.

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A.J. Martinez
2500 East 2900 South
Salt Lake City, UT 84109

August 1, 1988

Commander
U.S. Army Medical Research and Development Command
ATTN: SGRD-PA
Fort Detrick
Frederick, MD 21701-5012

Sir:

Thank you for the opportunity to review the Draft programmatic EIS on the DOD Biological Defense Research Program.

I find the document to be vague and inconclusive in assessment of potential hazards to the public from the accidental release of the toxins and biological agents stored and tested at Dugway Proving Grounds. I seriously question the integrity of the data used to support the proposed action. I feel that the real issues were obscured by generalities and program specific "buzz" words making the document incomprehensible to the average reader. The document seems to he inconsistent and in some cases inaccurate, again lowering my comfort level and trust concerning the validity of the document. A small but significant example is the statement in section 5.3.3: "The installation includes more than 800,000 thousand acres in Tooele and Juab counties...". Juab County does not host DPG to the best of my knowledge.

I believe in a strong (non-nuclear) defense. I find the testing and potential use of these agents to be morally and ethically wrong, and do not agree that we must test biological agents because some nations have allegedly violated the testing treaty; however, I concede this decision and the responsibility for accidental and/or intentional exposure of the general public to the "experts". In doing so, I retain the right to demand that documents concerning this issue be hones, simple and to the point; conditions not found in the draft EIS.

While I disagree with the proposed action and find the idea of this type of warfare to be a crime against humanity, I do thank you for the opportunity to review this document. I thank you in advance for placing me on your mailing list.

186A South Street
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COMMITTEE FOR RESPONSIBLE GENETICS

August 8, 1988

Commander
U.S. Army Medical Research and Development Command
Attn: SGRD-PA
Fort Detrick
Frederick, MD 21701-5012

Dear Sir:

I am pleased to submit the following response of the Committee for Responsible Genetics (CRG) to the Draft Programmatic Environmental Impact Statement (Draft EIS) for the Biological Defense Research Program. The Committee for Responsible Genetics represents a group of scientists, public health and public policy professionals, trade unionists, environmentalists, and other concerned citizens committed to seeing the positive benefits of the life sciences instituted safer, and responsibility in our society.

The following considerations are relevant to our discussion of the present policy underlying the BDRP and of alternative policies:

1. Since 1980, the Biological Defense Research Program has expanded greatly. As a result of this expansion, the Army has initiated extensive research and development activities that involve investigation of the properties of lethal biological agents, open-air testing, and testing of large aerosols of biological agents. Future plans include exploration of the properties of genetically modified pathogens. As the Army's Draft EIS for the Biological Aerosol Facility at Dugway Proving Ground stated, there is a "need for the development of test methods to match new features of biological defense that ate finder development to meet newly perceived types of threats."

As the Draft EIS notes. the rationale for this expansion is based on claims that i) the Soviet Union maintains on offensive biological warfare capabilities; ii) the Soviet Union has produced toxin Weapons for use in Afghanistan and Southeast Asia; iii) that anew biogenetic technologies such as genetic engineering could be used to construct novel biological agents And toxins.

The Draft EIS makes no mention of the fact that claims i) and ii) are both highly controversial and are not presently supported by

any other nation. The soviet Union has recently provided medical evidence against the U.S. claim that the outbreak of anthrax in Sverdlovsk was caused by a release of the organism from a biological warfare facility. Many experts see the second claim as entirely discredited at this point as a result. in part. of new evidence generated by the United States government and other governments. The Draft EIS exhibits considerable bias in using sources that support claims i) and ii) while ignoring entirely the body of evidence against those claims.

2. Since 1980s, the Department of Defense has moved toward development of specific (as opposed to generic) defenses against "conventional" (that is, naturally occurring) biological warfare agents; it has also strongly implied a need to move in the future towards development of specific defenses against genetically modified organisms and novel toxins. However, the range of conventional biological warfare agents is large; moreover the possibility of use of genetically engineered organisms multiplies the uncertainties almost infinitely. Thus, the concept of a specific defense is untenable and is leading since such defense can always be circumvented by the use of a different biological warfare agent.

The only scientifically persuasive rationale for developing specific prophylactic measures is to protect personnel in defense laboratories and troops in combat in preparation for development and use of biological warfare agents. For this reason. this emphasis of the BDRP is provocative and destabilizing since it is likely to be construed by other nations as evidence for offensive intentions.

The National Environmental Policy Act requires that an Environmental Impact Statement examines a full range of policy options and their relative impacts in order to defend a chosen policy. However, the present statement addresses only two policy options in depth: (1) continuation of the program, in its present form: (2) termination, (ES.4-ES.5, 4.6-4.8.) before concluding that (1) is the preferred alternative.

The CRG finds the Draft Environmental Impact Statement inadequate for two main reasons:

A. The environmental impact statement fails to address the full implications of continuation of the present policy:

B. The environmental impact statement fails to address the full range of possible alternative policies.

Our detailed reasons for these positions are developed below.

A. Failure to address the full implications of continuation of the present Biological Defense policy.

The investigation of dangerous pathogens for biological warfare purposes differs from their investigation for peaceful purposes since the former will almost certainly involve interest in exploring properties of increased survivability and decreased sensitivity to treatment. The CRG believes that a complete ETS must take into account all the possible risks of every phase in any action that explores the properties of lethal biological agents including strong indications that pathogenic microorganisms modified for military objectives will be investigated. The character of biological warfare--the intentional development of pathogenic agents and organisms that are difficult to control--raises much deeper uncertainty, and therefore greater concern than would use of the same agents for civilian purposes.

Specific issues related to the BDRP's use and testing of dangerous biological agents are addressed below.

1. Use of genetically engineered organisms in the BDRP

The Draft EIS argues that use of genetically modified organisms in the BDRP will be safe because "genetic engineering techniques and genetically modified microorganisms, when utilized under the conditions recommended in the NIH guidelines, present no risk to the human environment" (A-47) and because the NIH has "published an environmental impact statement and environmental assessments of the potential impacts of research with genetically engineered microorganisms" (A-47). There are several problems with this argument:

First, the Department of Defense is not legally required to use the NIH Guidelines. It does so on a voluntary basis. It is conceivable that it could invoke national security interests for not revealing details of its procedures to the NIH Recombinant DNA Advisory Committee.

Second, the NIH Guidelines were assessed for their environmental impacts in 1976 and in 1978. Since 1978, however, two fundamental changes in the guidelines have occurred. First, the NIH Guidelines have been undergone several major revisions. Second, the NIH Guidelines have been expanded to encompass large-scale uses of genetically engineered organisms. Yet no further Environmental Impact Statement or Assessment has been developed. Therefore, it has not been demonstrated that the 1986 NIH Guidelines now in effect provide adequate protection of the environment and human communities.

Third. the containment of deliberately generated aerosols has never been addressed by the NIH Recombinant DNA Advisory Committee since the operating assumption of this committee was that generation of aerosols should be avoided as much as possible.

Therefore, the fact that the U.S. Army may follow the 1986 NIH Guidelines is

not a sufficient guarantee that its activities involving genetically engineered pathogens and toxins can be performed safely.

2. Field Testing of Dangerous Biological Agents

Open-air testing of dangerous biological agents is carried out at the U.S. Army Dugway Proving Ground. The Draft EIS acknowledges that this is a "significant area of concern to the locale because of the perceived high hazard associated with it." However, we have not been able to find any discussion of the environmental impacts of open-air testing of dangerous biological agents. Clearly this is a major omission since such organisms could be disseminated in the air or water or through animal rectors to surrounding communities.

3. Use of Aerosols of Dangerous Biological Agents

The CRG has addressed the environmental impact of the use of large aerosols of dangerous biological agents in its comments on the Draft Environmental Impact Statement for the Aerosol Test Facility. Dugway Proving Ground, March 14, 1988. We found the Draft EIS for the Aerosol Test Facility to be inadequate because i) it did not address the risks of using genetically engineered organisms designed for Military purposes in the facility; ii) the description of the range of organisms to be used in the facility appears to be in conflict with the public testimony of Department of Defense officials before Congress; iii) there are no provisions for protection of personnel other than those directly engaged in aerosol tests in the facility; iv) there are no provisions for monitoring disease outbreaks in hospitals and clinics throughout Utah; v) there is a contradiction between claims that Dugway provides a natural barrier to possible environmental or public health dangers and the documentation provided In the Dugway EIS of the presence in the area of animals and insects that may act as carriers of disease.

4. Psychological Impact of the Testing of Biological Warfare Agents

It is clear that there is great public anxiety in certain communities concerning the possible impact of the use and testing of agents of biological warfare. Plans for the construction and use of the Aerosol Test Facility at Dugway Proving Ground, Utah, have aroused widespread public concern. Yet the question of the psychological impact of use and testing of biological warfare agents is not addressed in the Draft EIS.

B. Failure to address the full range of possible alternative policies

The CRG contends that the testing of aerosols of biological warfare agents. The open-air testing of biological warfare agents, and the construction of novel biological agents under the BDRP should be discontinued on the grounds that a) these activities are provocative, destabilizing and may be reasonably

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perceived to undermine the 1972 Biological Weapons Convention: b) these facilities pose hazards to the environment and surrounding communities in the areas where they are conducted that have not been satisfactorily addressed by the Draft Environmental Impact Statement.

The CRG also contends that the Draft EIS fails to consider the following elements of an alternative biological defense policy that provides for generic defense against biological warfare agents while avoiding activities that are environmentally hazardous as well as politically provocative:

1. Open-air tests should be conducted only with biological warfare simulants. All other open-air testing should be terminated.

2. Aerosol tests should be conducted only with biological warfare simulants. All other resting of aerosols should be terminated.

3. Where there is a recognized medical need for activities involving the construction of novel biological agents, these activities should be transferred to civilian agencies. Non-medical activities involving construction of novel biological agents should be terminated.

4. All biological warfare activities should be required to be unclassified. All research should be publicly disclosed and all results should be publicly reported. This will ensure full public access to activities conducted under the Biological Defense Research Program and, at the same, provide reassurance to other nations that the United States is in fully complying with the provisions of the 1972 Biological Weapons Convention.

Sincerely,

Susan Wright, Ph.D.
Co-chair, Subcommittee on Military Use of
Biological Research, Committee for
Responsible Genetics

1. Draft Environmental Impact Statement, Biological Aerosol Test Facility, Dugway Proving Ground.

2. For a review of the literature on the Sverdlovsk anthrax outbreak and on the "yellow rain" charges, see Elisa Harris, "Sverdlovsk and Yellow Rain." International Security 11 (Spring 1987). 41-95. For a discussion of the case against the yellow rain charges, including the evidence produced by the governments of the United States and Britain, see Julian Robinson, Jeanne Guillemin and Matthew Meselson, "Yellow Rain: The Story Collapses." Foreign Policy 68 (Fall 1987). 100-117.

UTAH MEDICAL ASSOCIATION
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Philip K. Russell
Major General, Medical Corps
Commander, U.S. Army Medical Research
and Development Command
Attention: SGRD-PA
Fort Detrick
Frederick, Maryland 21701-5012

Dear General Russell:

As you are aware, the Environmental Health Committee of the Utah Medical Association hers closely examined the Draft Environmental Impact Statement (DEIS) examining the Biological Defense Research Program (BDRP) of the Department of Defense. The Committee has presented a statement regarding the DEIS which expresses some concerns regarding the overall scope and safety of the program, as well as some specific suggestions to help address those concerns.

On September 20 and 21, the Committee presented this issue to the Utah Medical Association's annual House of Delegates. This is the highest policymaking body of the Association and consists of 280 physicians from all areas of the state. After opportunity for debate and discussion, the House of Delegates adopted the report with commendation and asked that you be notified that we all share the concerns initially expressed by our Environmental Health Committee, and we would like to help work with the Department of Defense to assure that the BDRP can proceed in a safe manner.

Accordingly, you will find enclosed a copy of the statement which has been modified to reflect the support of the entire Utah Medical Association. We would request that you accept the statement as official comment on the programmatic DEIS of the overall BDRP. You will also note a second change, which Mr. Richard S. Pertzel of your staff has clarified for us, on page 2, paragraph 3. The actual funding amounts for 1981 and 1987 have been corrected to 314.9 million and $73.2 million, respectively, which removes the funds for chemical warfare research from the combined figures we had available to us. While this change in absolute dollars is large, the point that the activity has been greatly increased over the past eight years (five-fold using either set of figures) remains unchanged.

Also in accord with the wishes of the UMA House of Delegates and of the UMA Environmental Health Committee, we would like to express our thanks to you for allowing the deadline for public comment on the DEIS to be extended and for arranging to hold a public hearing in the state of Utah. We appreciate your willingness to hear both our concerns and those of the people of Utah, and we look forward to continued cooperation in addressing those concerns.

Thank you again for your consideration.

Sincerely,

CRAIG L. BOOTH, M.D.
President

CLB/vp

Enclosure

cc/Governor Norman H. Bangerter
Suzanne Dandoy, M.D., Director, Department of Health
Senator Orrin Hatch
Senator Jake Garn
Representative James V. Hansen
Representative Howard Nielson
Representative Wayne Owens
C. Everett Koop, M.D., U.S. Surgeon General
James E. Davis, M.D., President, American Medical Association

UTAH MEDICAL ASSOCIATION
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A Statement of the
Utah Medical Association
concerning the
Draft Programmatic Environmental Impact Statement
of the
Department of the Army
Biological Defense Research Program

September 30, 1988

A14-74a

As members of the Utah Medical Association, and as physicians who live and practice medicine in the state of Utah, we have an obligation to help maintain and protect the public health of the citizens of our state. This obligation applies to potential local and regional adverse health exposures, but also in a more general sense, we share the concern of the Department of the Army that it is important to maintain strong defensive programs to help protect all the citizens, not just of Utah, but of the entire United States of America.

We have reviewed the Draft Environmental Impact Statement (DEIS) of the Department of the Army's Biological Defense Research Program (BDRP), as well as the report of the United States Senate Subcommittee on Oversight of Government Management majority staff report regarding the Department of Defense's safety programs for chemical and biological warfare research. After reviewing these documents, we have some serious concerns which we feel must be more thoroughly addressed and/or modified, to help assure that unforeseen and tragic consequences will not arise from the operations of the BDRP.

Our major concern regarding the programmatic DEIS relates to the proposed and discussed alternatives which are limited to: 1. continue the BDRP unchanged (the preferred alternative), or 2. terminate the BDRP (page ES-5, 4.2 to 4.8). The DEIS rightfully points out many of the benefits which accrue from the continuation of the BDRP, not the least of which is that "the DOD cannot ignore completely the possibility that biological warfare threats exist and fail to provide any deterrents to their potential application"...(page 1-1). This alone is a strong argument, with which we completely agree. However, if the only other possible option is to completely eliminate the BDRP, thus losing all capability to maintain an adequate defense program, the Department of the Army has unjustifiably eliminated the opportunity for public input and discussion of the overall safety of the program, and means by which the program can still continue but with adequate safeguards for the public health. He are particularly concerned with the attitude expressed throughout the DEIS that opposition to the BDRP as currently operative is based more on public perception of risk than on true risk, when in fact the problem seems to be more one of how do we assess and quantify these potential risks in order to compare them to the more easily quantified benefits. The attitude appears throughout the statement that those who question the safety of the program are operating on misinformation, emotion, ignorance, or other less than admirable motives. ("An evaluation complexity arose, however, because virtually all of the significant adverse impacts were either perceived, rather than actual, or were associated with a potential accident or incident. Professional scientific scrutiny by the inter disciplinary team did not lend credence to the expressed fears or hypothetical risks", (page 1-15 to 1-16; see also pages ES-5, 4-2, 4-3, 6-8, A6-6, among others)). An entire appendix (appendix 6) is devoted to explaining the means by which most of the relevant safety concerns were able to be categorized as not significant so that they did not need to be addressed, while only one paragraph (paragraph 1, page 4-4) wee required to discuss the option of continuing the defensive studies of the BDRP Using simulant, or low pathogenicity, organisms.

Although the Department of the Army's group of expert professionals are confident that little or no safety hazards and that adequate safety and regulatory controls exist to assure are in place to assure that no accidents will happen (page 3-5 to 3-9), the Senate subcommittee on Oversight of Government Management

apparently does not agree: "With respect to research involving BW agents, DOD's safety protections appear to be fragmented and, particularly for BDP contractors, completely inadequate. there is no comprehensive set of safety regulations for research with BW agents and toxins, no emphasis on safety in the contractor program, and no office that monitors contractor safety." (page 8 Senate Subcommittee Report).

As we pointed out in an earlier statement regarding the Biological Aerosol Test Facility proposed for the Dugway Proving Ground, we continue to be concerned with an apparent lack of advance planning for the management of a potential release or organisms or toxins into the environment. We are impressed with and commend the Army on an impressive safety record in the testing and handling of these agents over many years of both offensive and defensive research (appendix 8). However, as is clearly outlined in Table AS-3 (page A8-10), this safety record is not perfect, nor are all the accidents remote history.

Finally, again in the spirit of public safety nut just in Utah but throughout the United States, we are concerned about the entire scope and direction which the BDRP has taken over the past few years. The United States has formally renounced the use of biological warfare agents since 1969, and joined with more than 100 other nations in signing the 1972 Biological Weapons Convention, which prohibits any stockpiling of or offensive research on BW agents. We do believe that the Department of the Army has no plans for offensive BW research; however, spending on BW research has increased from $14.9 million dollars in fiscal 1981 to $73.2 million dollars in fiscal 1987. We feel that the justification given for this massive increase is not valid, and we fear that other nations, when viewing our greatly increased activity, will respond in kind and set off a new round of arms escalation.

We feel that much of the defensive nature of the BDRP can be continued by testing detection and protection devices using low pathogenicity, simulant organisms. We also feel that the vaccination programs could be maintained. Both of these could continue without the increased risk of inducing tear and suspicion among the world communities who look to us for guidance and leadership in moral as well as military matters.

With all this in mind, the Utah Medical Association would like to go on record with the following recommendations concerning the Draft Programmatic Environmental Impact Statement of the Biological Defense Research Program, and concerning the BDRP itself:

1) A final environmental impact statement must include a compromise alternative or alternatives to continuing the program as is versus termination of the program. Many qualified scientists feel that there is no adequate justification for the use of actual biological warfare agents for conducting tests of detection and protection devices, since low pathogenicity simulant organisms can be used with equal or improved of efficacy. Thus the use of simulant organisms, <u>particularly</u> for any aerosol testing, should be a valid means by which our concerns for public safety can be balanced with our concerns for a strong national defense.

2) Although the potential for accidental release or exposure to surrounding communities is admittedly very small, the consequences of such of an event could be disastrous. Thus, as stated in our prior recommendations regarding the proposed Biological Aerosol Test Facility at the Dugway Proving Grounds, the BDRP must have improved plans for manaqinq such a release. It must also incorporate a civilian scientific surveillance committee, which should include members of the academic biology research community, the National Academy of Sciences, the National Institutes of Health, the Centers for Disease Control, and members from the local medical associations and state health departments in areas where major BDRP activities are carried out.

3) Any allegations of non-adherence to the 1972 Biological Weapons Convention should be turned over to an appropriate international agency, the United Nations Security Council, as provided for in Article VI of that treaty, for open investigation. It is unfair and unjust to make such allegations as justification for increased BW research activities, yet to refuse to back-up the allegations by claiming that the information to do so is classified.

4) The terms of the 1972 Biological Weapons Convention should be reviewed and strengthened, particularly in light of new capabilities for genetically engineering biological warfare agents and organisms. We must not lose this valuable start towards the elimination of an entire means of waging war against our fellow man simply because we continue to amplify mistrust out of fear or ignorance.

Thank you very much for the opportunity to comment on the Army's Biological Defense Research Program. We appreciate the chance to work with you toward ensuring that we can maintain a strong national defense, but not at the expense of the health and safety of those who live and work in proximity to the defense programs. We have an obligation to assure that the environmental and pubic health of the people of the state of Utah is a foremost consideration in any decisions and management of these programs, and we will continue to work with you to that end.

down winder

966 East Wilson Avenue, Salt Lake City, Utah 84105

August 12, 1988

U.S. Army Medical Research and Development Command
Attn: SGRD - PA
Fort Detrick, MD 21701-5012

Sirs:

We wish to submit for the record the following comments on the Draft Environmental Impact Statement for the Biological Defense Research Program.

First, we reiterate our complaint that the Department of the Army has completely honored repeated requests by Downwinders, Utah elected officials, and Utah citizens, both ill public and in writing, for public hearings in our state on the DEIS. To our knowledge, the Army has never ever officially responded to those requests; certainly, DOA has never informed Downwinders of its position regarding Utah hearings. One DOA official was quoted in the Salt Lake Tribune that holding hearings in Utah was not "convenient" for the Army. This blatant disregard for the rights of Utah citizens to participate in this process of decision-making on a program that has enormous implications for our future is arrogant and unacceptable.

We also note that the Army hate thoroughly botched the environmental review process for the BDRP and the proposed BATF by conducting these analyses backwards. DOA should, according to NEPA regulations, proceed from the general to the specific in its analyses, not the other way around, as it has done with these two DEIS's. Downwinders pointed this out to DOA in a letter dated March 13, 1988. We received no reply and DOA failed to take any corrective action to comply with NEPA regs.

Since the proposed BATF at Dugway is a critical part of the BDRP, we suggest that all public comments, verbal and written, that were submitted in the DEIS process for the BATF be included as official comments on the BDRP DEIS as well.

As for the DEIS document itself, we object to the narrowing of program options to the no action alternative (eliminate BDRP) Or the preferred alternative (business as usual). The rationale offered to reduce alternatives to this all or nothing choice is thin and specious. In light of recent Senate OGM reports and hearings and GAO investigations pointing out numerous, serious deficiencies in the Army's CBW programs and making more than a dozen serious, intelligent recommendations for improvements in those programs, we find the Army's posture on alternatives absurd and condescending. There are other alternatives: the Army simply refuses to seriously examine them. This is a fatal flaw in this DEIS.

We consider the Army's contention that the preferred alternative means maintaining the status quo to be a distortion of the truth. In reality, the BDRP is experiencing rapid expansion? it is nowhere near a static or stable program. The proposed Dugway aerosol testing lab is just the most obvious example of program expansion. The budget for BW has increased nearly 500% since 1980, and more of that budget (60%) is contracted to private and university labs than ever before. Research into GEMs is increasing. All of this puts the lie to the Army's position that they only seek to maintain the status quo with the preferred alternative. The "real", underlying preference is to continue to expand research facilities, budgets, contracts, and research into GEM warfare agents. The Army's failure to admit the obvious, and to give the public a chance to review the real preferred alternative: massive BW expansion, turns this entire document into a sham.

We could list page after page of additional problems with this document, but will list only a few at this time. We reserve the right to submit additional comments when the Army agrees to conduct public hearings in Utah, when the final EIS is issued, and in court.

- DEIS fails to address, except in the context of the BW Convention, the absence of a no first use policy for BW agents

- DEIS fails to justify DOA rejection of suggested controls and procedures suggested by independent scientists and other government agencies

- DEIS fails to explain the rationale for increased contracting of BW research

- DEIS inadequately explains DOA rejection of elimination of aerosol testing of BW agents (pathogens) as an alternative

- DEIS does not address provisions for release of information to the public about BDRP or provisions for scientific peer review of BW research activities

- DEIS makes no provisions for evacuation of citizens near DOA facilities or BDRP contractors conducting BW research in the event of an accident, or for informing local health authorities in the event of an accident

- DEIS fails to address plans and alternatives for clean-up of contaminated facilities used for BW research and testing

One final comment. The DEIS makes repeated mention of "exaggerated" public fears and perceived risks, and public controversy as the most serious problems jeopardizing the BDRP. The DEIS utterly fails to address the reason for fears and controversy- the U.S. military's and the CIA's horrific record

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of lies, cover-ups, incompetent, immoral and illegal actions in the conduct of its CBW programs since the 1940's. Until the Army comes clean on its past, and can make ironclad, independently verifiable assurances that the past will not be repeated in the future conduct of the BDRP, those fears and that controversy will remain valid and prudent.

Submitted by Steve Erickson for Downwinders

Department of Biology
University of Utah
Salt Lake City, Utah 84112
August 10, 1988

U.S. Army Medical Research and Development Command
Attn: SGRD-PA
Fort Detrick, Frederick, MD 21701-5012

Dear Sirs:

We in the Salt Lake City community of medical and biological professionals have considered at some length the May, 1988 DPEIS on D.O.D.'s Biological Defense Research Program. In no way are we convinced that this is a program that will contribute to our national well being.

The accompanying petition states our concerns in succinct but well considered terms. It has been signed by 139 faculty and research personnel with Ph.D., M.D. or D.V.M. degrees (and by 9 graduate students, a level that was not actively solicited). The signatories include at least 4 department chairmen, and represent some ten departments. 85% of the faculty in the Biology Department have signed.

We therefore respectfully request that the activities proposed in the May, 1988 DPEIS be carefully reconsidered and not permitted to procede as projected.

Sincerely yours,

Naomi C. Franklin
coordinator

BIOLOGISTS' PETITION with regard to D.O.D.'s BIOLOGICAL DEFENSE PROGRAM 7/7/88

The undersigned physicians and biological scientists petition our representatives to review DOD's Biological Defense Program in general, and in particular their plan to build at Dugway Proving Grounds a Biological Aerosol Test Facility at the highest level of biological containment. Their request for such a high containment facility anticipates the testing of genetically engineered biowarfare agents. We biologists are committed to using the new genetic technology for diagnosing, curing and preventing disease, not causing it, as well as for such purposes as the improvement of agricultural crops, reversal of genetic disease, provision of rare biochemicals and the unravelling of biological mechanisms. We abhor the use of biological agents as offensive weapons by any nation, in accord with the many nations who signed the 1972 International Convention banning the use or stockpiling of biological weapons.

32-1a, 32-1b, 32-1c, 32-1d, 32-1e

Although we recognize DOD's responsibility to provide defense against possible biological attack, we find their program tobe flawed, hazardous and likely to break the constraints of the 1972 Convention. In the first place, any use of actual pathogens, particularly in aerosols, will present a hazard to workers, their families and the community at large; even endemic agents of such diseases as anthrax, tularemia and plague, normally poorly transmissible, will become highly dangerous when aerosolized. In the second place, an infinite variety of potentially lethal agents already exists or could be produced by genetic engineering; engineered organisms raise the specter of epidemics that can be neither diagnosed nor treated. In view of the variety of agents possible, it is essential that defense be general rather than specific, if it is to provide protection of wide scope that will not soon become obsolete. On both counts DOD's need to provide detection, protection and decontamination will best be served by testing with harmless simulant organisms. In any case it is unconscionable that DOD be allowed the capacity to develop new pathogens in order to test our defenses against them.

32-2, 32-3

To allay all suspicion and to reduce worldwide the vulnerability to biological warfare, it will be most valuable to make the DOD program *open: reviewed and subject to approval* by a non-military committee of physicians, scientists and citizens. By renouncing military research on genetically engineered organisms, while conducting defensive research in full view, DOD will contribute to reducing rather than escalating the risk of biological warfare.

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contribute to reducing failure [illegible]

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MOSS **** U.S. Senate

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Testimony on U.S. Army Biological Defense Research Program
September 19, 1988

As a Utah citizen, and as a candidate for the United States Senate, I feel compelled to take a firm stance against the research of biological weapons, in Utah or anywhere else.

It is not enough to oppose germ warfare testing in Utah. That attitude contains a "contaminate the other guy" mentality which is immoral and politically dangerous. It also fails to recognize the inherent danger of biological weapons testing and, even worse, it fails to remember that we are a global family. When we contaminate any part of the world with disease or genetically engineered germs, we harm are entire planet and all of its people.

The army's biological weapons testing program is dangerous because the entire concept of germ warfare is dangerous. It opens up a Pandora's Box of new weapons proliferation that we may never be able to close.

We should not be confused by tactics which suggest that this testing is necessary to defend our country against germ warfare by other nations.

First, there is a good possibility that tests could be done with less-dangerous simulants, rather than genetically-engineered germs for which we may never have a cure. That approach to "defense" has not been adequately explored by the army.

Second, we must realize that when we are dealing with dangerous toxins, bacteria and viruses, the lines between offense and defense are easily blurred. If someone in your family is killed or mutilated by germs created for military purposes, it doesn't really matter whether they were spawned for "offense" or for "defense."

Finally, if you read the Salt Lake Tribune this morning, you understand that the army--according to its own Science Board ad hoc subgroup--has not been able to demonstrate any threat from foreign germ warfare.

As a Utahn and as a citizen of the United States and the planet earth, I urge the army to abandon its biological weapons testing program. I firmly believe that the health of our nation's people and the future of our human family depends on it.

9/19/88 statement by Naomi C. Franklin with regard to DEI5 May, 1988 on DOD's Biological Defense Program:

I have already submitted, to meet the August 12 deadline, a petition of concern over DOD's Biological Defense Program. That petition was formulated by over a dozen SLC physicians and faculty in the Biological Sciences at the Univ. Of Utah. It was signed by over 140 holders of PhD and MD degrees in the SLC community of professional biologists. These included over 85t of the faculty in Biology over 751 of the faculty in Cellular, Molecular and Viral Biology, a large proportion of the faculty in Infectious Diseases. Eight of the departments were also represented. The text of the petition is as follows: Appended.

There are a few comments of my own that I would like to add.

There was a news article in the Washington Post on 7/28/88, headlined "Pentagon Planning Biological War Games". "The Army said ... that it is attempting to define the role of such (biological) weapons in U.S. military strategy, ...to take away the mystery about the weapons" through more effective public relations. Such news does not say to me that the Army is concerned only with Defense against Biological weapons.

I understand that there is valuable research being conducted by the Army in development of vaccines. These vaccines are valuable is protecting the health of our personnel in different parts of the world. I would think that such a program would more appropriately be conducted by the National Institutes of Health, whose mission, after all is <u>health</u>. The very presence of this program under DOD raises concerns. Especially when one learns that modern genetic technology is being used to separate pathogenic characters from immunologic characters, in order to have safe organisms for use in immunizing. Unfortunately, the same steps used to separate an also be used to reassemble, in new and unpredictable combinations. If the Army contract out innocent parts of the operation to innocent scientists in universities and industry, we do not know how the innocent parts may be reassembled when they are returned to Army labs.

As a consequence of the Dugway track record, the Army's need for secrecy and the nature of the Army's mission, I do not feel secure when this research with deadly biological agents is in Army hands. Would it not be reasonable to let this research be conducted under auspices of NIH, in an open fashion, with review by free scientists? Vaccines could be developed for DOD upon request. Simulant pathogens could be provided to DOD for testing. My suspicions, and those of our adversaries would not then become exercised, causing escalatory measures to be undertaken.

In thinking about the state of infectious diseases in our present world, we can observe the eradication of such scourges as smallpox, the result of worldwide effort by WHO. We can also note the arrival in our consciousness of several new diseases during only the past decade: Giardia, lime disease, Legionnaire’s disease, canine distemper in North Sea seals, and even AIDS. All biological systems have this fascinating characteristic: the potential to multiply and to change. Each mortal change has required at least a few years of research to become understood. I would be more comfortable if I knew that research on theses biological agents was left in the hands of those dedicated to Health.

THE ENEMY

Testimony given by Professor Edwin B. Firmage
before the United States Army Hearings
Tooele, Utah
Monday September 19, 1988

All that most maddens and torments; all that stirs up the lees of things; all truth with malice in it; all that cracks the sinews and cakes the brain; all the subtle demonisms of life and thought; all evil to crazy Ahab, were visibly personified, and made practically assailable in Moby Dick. He piled upon the whale's white hump the sum of all the general rage and hate felt by his whole race from Adam down; and then, as if his chest had been a mortar, he burst his hot heart's shell upon it.

Herman Melville, *Moby Dick* (1851)

The proposal that we increase our capacity in research into biological agents to be used as weapons or defenses reveals the insanity of our situation. Since the development of recombinant DNA, we must know that there is no defense possible to the use of biological agents. Recombinant DNA can be the Manhattan Project of biological weaponry. We must not allow that to happen.

By genetic engineering -- gene splicing - we can produce an endless spectrum of biological agents for which no conceivable vaccine or antidote would be possible. Many simple means exist to distribute or deliver such agents. means so utterly pervasive as to make defense impossible. Aerosols of great variety can spread dread plagues across a nation. No amount of exotic clothing. masks, or vaccines can really be expected to protect troops in the field. No conceivable means exist or could ever be developed to protect civilian populations throughout a nation. No continental astrodome can protect our air, our water, our people.

Yet real defenses do exist against the use of biological agents as weapons. These defenses, however, are hurt -- not helped -- by continued research on the use of biological agents as weapons or defenses against such agents, the distinction between such offensive or defensive use being impossible to maintain.

Most immediately and least important, there simply is not a realistic situation in which an enemy of the United States would use biological agents against us when other and better weapons are readily at hand. Biological agents would not immediately immobilize our forces. Our reaction, even after infection, could be swift and lethal with conventional or nuclear weapons. Second, biological agents are not reliable nor containable. Perhaps such agents would be rendered impotent by any one of many environmental factors: heat, cold, rain, wind. If lethal against an enemy, within a short time such a plague would incapacitate friends of the aggressor state and then that country as well. The effects of such agents cannot be controlled or contained.

The potential users of such heinous weapons who might not be deterred by such practical considerations are terrorist groups or completely irresponsible, dangerous states with little to lose at the spectra of mart uncontrolled carnage, Our own research, with that of the Soviet Union and other nations, simply adds to the information ultimately available to other states and other groups. The notoriety our own actions give by the continued development of biological agents as weapons make their acquisition and eventual use by some terrorist group or terrorist state more likely, not less so.

Meanwhile, the immediate cost to those of us nearby -- the possibility of accident, natural disaster through earthquake, or targeting by foreign enemy or terrorist group-- is substantial. In other words, we bear the burden of possible great harm, intentional or accidental, while the result of this effort provides our country with less security, not more.

Far more important, however, is the harm we inflict upon ourselves in participating in this particularly senseless system of most gruesome mass death. Our greatest hope against biological agents being used easiest us is that the huge mass of humanity recoils at the suggestion that we would inflict such horror upon each other, fellow human beings. As we continue research into such monstrous weapons we make ourselves and each other less human. We lose the serrate qualities of our own humanity. We assume that others will let loose upon us plagues that might destroy millions of human beings. By projecting our fears onto others, we then justify our own actions that otherwise would be abhorrent and inconceivable to our own humanity.

We must overcome our own fear. I fear our fear. I fear our fear more than I fear Russians or Chinese or Libyans. When I fear the worst, my own consequent actions fulfill the worst fears of my enemies. Then their actions fulfill my own first perceptions. And so on.

The answer is not in developing still more weapons of mass destruction--biological plagues to take their place in a ghastly gallery alongside mustard gas and nuclear weapons. Instead, somehow, we must learn how we might define ourselves without the use of an enemy, the Other, without whom we seem to have no content and no purpose. As individuals and as a nation, we must discover at our own core, our center, our identity: an identity so wonderfully human that we see purpose and direction without fearful projection onto another.

We beg your pardon for tasking that you speed part of your lives in developing such use of biological agents, or the impossible task of inventing defenses against such agents, on our behalf.

For your own humanity and for ours as well, we ask that you stop.

A14-85b

September 19, 1988

Philip K. Russell
Major General, Commander
U. S. Army Medical Research
and Development Command
Fort Detrick
Frederick, MD. 21701-5012

Dear Major General Russell:

Thank you for honoring requests to have a Utah Hearing on the Draft Environmental Impact Statement for the bioweapons research efforts of the U. S. Army. Unfortunately, the approximately two weeks notice of the Hearing meant that a number of us could not change our schedules to be present. This is an attempt to express our objections to the program in letter form.

36-1a 1. We fear that other countries will suspect that U. S. intentions are to develop offensive weapons because of the building of a BL 4 facility. Thus they will embark on or expand bioweapons development of their own.

36-1b 2. Because of the potential for unlimited varieties of biological agents, we agree with scientists who claim that the idea of defensive biological warfare is misleading.

36-2 3. We believe that the production of real disease-causing germs in the research is inappropriate given that credible members of the scientific community claim that simulants would serve defensive purposes.

4. We pledge ourselves to increase both our level of knowledge and that of our representatives in Congress on this sensitive issue.

Sincerely,

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A14-36

UTAH STATE UNIVERSITY
College of Agriculture
DEPARTMENT OF ANIMAL DIARY AND VETERINARY SCIENCES
ANTIVIRAL PROGRAM
Logan, Utah 85433-5600

September 20, 1988

U.S. Army Medical Research and
Development Command
ATTN: Mr. Charles Dasey, SGRD-PA
Fort Detrick
Frederick, MD 21701-5012

Dear Mr. Dasey:

Enclosed is my written comments essentially as they were presented at the Public Meeting on the Draft Environmental Impact Statement for the Department of Defense Biological Defense Research Program.

I trust they will be of value to you.

Yours sincerely,

Robert W. Sidwell, Ph.D.
Professor of Virology and Director,
Antiviral Program

Enclosure

A14-87a

Statement made at the Public Meeting on the Draft Environmental Impact Statement for the Department of Defense Biological Defense Research Program.

Submitted by: Robert W. Sidwell, Ph.D.
Utah State University

I represent a research group which is an Army contractor. We have been conducting research at Utah State University on developing new drugs to cure virus infections of man. I should point out that much of the recent increase in Army expenditures on BDRP has been for the development of drugs? ? a most defensive (in opposition to offensive) research attitude.

I wish to make a statement regarding the safety aspects of our research, and the Army's interaction with us in this regard.

1. The disease we wish to cure is Rift Valley Fever--this is caused by a highly dangerous pathogen often lethal for man. At the Army's suggestion, we are using Punta Toro virus in our research. This is a less pathogenic, look-alike virus which is classified in the BL-2 category. Thus we are using a "substitute" pathogen as has been recommended tonight by several speakers.

2. Before we could work with this organism, I was invited, at Army expense, to visit Fort Detrick and meet with Dr. Ralph Kuehne, the Safety Engineer for that facility. I did so, accompanied by our campus architect. We were given an extensive tour of that facility, including many "behind the scenes" areas, in order to help us design an appropriate facility for our Research.

3. Such a facility was then constructed on our campus. It is a designated BL-3 facility, with negative air, HEPA filters, pass-through autoclaves and total restriction of all but fully trained personnel. Again, I should stress that all organisms with which we are working are designated BL-2 agents, but all are being handled under full BL-3 conditions at the Army's request.

4. Our facility was inspected during construction by Dr. Gary Resnick of Dugway and later by Dr. Peter Canonico and Dr. Dominique Pifat of Fort Detrick. All concluded the laboratory was an acceptable BL-3 facility. Before opening it for research, we held an open house in which campus administrators, campus and Logan City police and fire department officers, and City officials were invited to tour the facility and ask questions about it.

In summary, we were impressed with the interest and concern of the U.S. Army Medical Research and Development Command for our safety and proper conduct of research they were sponsoring. Our group was never contacted by the Congressional Sub-Committee who investigated the Army's safety practices, so I must conclude the report was cursorily prepared and is not completely correct.

THE UNIVERSITY OF UTAH

Mr. Charlie Dasey, SGRD-PA
U.S. Army Medical Research and Development Command
Fort Detrick, MD 21701-5012

September 25, 1988

I would like to make several objections to both the draft EIS which has been prepared by the BDRP (May 1988) and to the research program in general.

1. The main issue which has not been seriously considered is the distinction between defensive and offensive research. Offensive research is anything which gives that appearance to foreign powers, and which is not directly necessary for protection of our own troops. In addition to being against the treaty, offensive research is dangerous and pointless. Aerosol research on pathogenic organisms with no known cure, or on genetically manipulated organisms is difficult to justify as defensive research. There is no way to anticipate the particular organism used by enemies, so vaccines or detection systems cannot be developed.

2. Given that there are problems in anticipating what pathogen with what surface properties will by used by enemies, any defensive research should focus on more general properties of organisms. The army has never satisfactorily answered why simulants could not be used in this type of defensive research.

3. The safety features in the BDRP are impressive, but not good enough for work with incurable pathogens, and certainly not with aerosols. The problem of nuclear power industry, human error and machine malfunction are unavoidable. For example, there are several fairly well documented examples of "mistakes" as potential risks, if this type of research continues, are of such magnitude as to warrant more serious consideration.

4. Ecological theory and epidemiological studies have shown that population growth, or the spread of a disease has an initial lag phase where abundances are low and difficult to detect. This is followed by an exponential growth phase where populations increase extremely rapidly. Once in this phase, a disease may be impossible to control, even if cures exist. If there is a latency period before symptoms are obvious, control becomes even more difficult.

Department of Biology
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A14-88a

5. The secrecy with which research decisions are made is not healthy. All research goals should be formally reviewed by a panel of respected non-military scientists, for example, National Academy members. This is partly to insure scientific quality, as is done by NSF and NIH, and partly to allow a reasonable watchdog evaluation. This would greatly improve the government's credibility. What are the objections to this type of review?

6. Why can the US and USSR not establish a mechanisms for mutual monitoring of biological warfare research? This appears to be working with nuclear arms research. Similarly, it would seem to be the best way to insure that biological agents were not developed or used for warfare purposes, a goal that should be universal.

7. In the evaluation of safety factors at Dugway, the abundance and diversity of rodents was not given sufficient consideration. Desert communities are well known for having large rodent populations, and Dugway is not exception. Army surveys show high trap success (50%) and high diversity of flying and non-flying mammals. These are potential reservoirs for pathogens. Populations are not monitored, and the potential for infection from accidental releases may be very high.

I hope the Army gives serious reconsideration to their BDRP in light of the enormous risks, both medical and political, that could arise from offensive research.

Sincerely,

Phyllis D. Coley, Ph.D.
Biology Department
University of Utah

A14-88b

David S. Thaler Ph.D.
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University of Utah
Salt Lake City, UT 84112
801-581-3618

28 September 1988

Statement on the Proposed Biological Warfare "Defense" program of the US Army

The key issue regarding biowarfare is that the US and USSR are on the verge of an arms race in a new area. This new arms race threatens to corrupt molecular and microbiology, disciplines which have so far been linked to applications in medicine and agriculture for beneficial ends. It would be an act of integrity and decency for practitioners of molecular and microbiology to foster a world in which the fruits of our discipline are not abused by being dragged into the arms race. In fact we want a world in which our discipline is an example of openness in the search for truth for its own sake and for human benefit in its applications. Biology is at a crossroads, a point at which it is vital to set the direction for the future.

On the surface the situation regarding biological warfare is good. Both the US and the USSR have signed a treaty pledging, amongst other things, that they will not pursue offensive biological warfare. Unfortunately, the integrity of the treaty is being threatened by the new developments in the Biological Warfare "defensive" research program in the US and possibly within the USSR as well.

US military Biological Warfare research conducted under the rubric of threat assessment contains elements that would form part of a program aimed at establishing an offensive capacity, this constitutes a de facto violation of the treaty irrespective of intent. Actions that appear to violate the treaty could easily inspire counter actions and soon degenerate into a new arms race.

The new test facility proposed for Dugway and the entire Biological Warfare program could easily appear to be directed towards actions that are a violation of the treaty. The program's advocates claim that only work within the confines of the treaty will be conducted, but the program as proposed appears ideally suited for work that is not within the confines of the treaty. Even if the program is honest in its intent, the facility could frighten the Soviets into noncompliance which in turn would engender US response and so on.

The INF treaty has demonstrated the potential for new levels of cooperation between the superpowers to assure compliance with arms control measures. The phrase "Trust but verify" has become a part of the national vocabulary. Molecular biological research is particularly suited to this kind of strong verification because at this time there is no new developed military application, only research. Both the US and USSR have pledged to forgo offensive biological warfare. However the institutional measures necessary to prevent the development of offensive biological warfare are inadequate, both inside the US and the USSR. Because biological warfare is forbidden by treaty, because there is as of yet no newly developed application and because the fields of biology, agriculture and medicine have deep roots in aiding the human condition, the area is ripe for actions to insure that the treaty remains enforced in both countries.

In the case of biological warfare the best defense is not a good offense. The best defense would be for the US and USSR to honor their treaty obligations and to be well assured that the other superpower is honoring the same obligations. To accomplish this goal the US and the USSR ought to forego any classified work in molecular biology (including exotic technologies not envisioned at the time the treaty was negotiated). A joint program on truly defensive biological work could be instigated. Jointly created and shared protective technology would deter offensive warfare by any party. Improvements in protective technology might also be of civilian benefit for health care workers and scientists who work with pathogens. Because there is as yet no new offensive technology in existence it is a very practical time to end military secret research and to be open about defensive technologies that are developed. A commitment to open research as the alternative to an arms race might be understandable to the Soviet political

establishment and might help to open up the Soviet scientific community both internally and to international collaboration.

In summary: The greatest danger posed by biological warfare at this time is the danger of a new arms race. The program proposed is not as likely to counter or anticipate new threats as it is to cause them, both directly and via a self fulfilling prophesy.

A few other points need to be addressed in relation to the Impact Statement:

1. One component of the proposed program involves aerosol testing under so called BL3 and BL4 conditions. BL3 and 4 are said to correspond, respectively, to P3 and P4 under the N.I.H. guidelines for recombinant DNA research. However one of the key points in the N.I.H. guidelines is that pathogens should not be aerosolized. Thus the proposed BL3 and BL4 facilities do not correspond to P3 and P4. Work with aerosolization must be considered more hazardous than work in which aerosolization is prohibited.

2. There is no need to aerosolize pathogens if the program is trying to develop "gas mask" type filters or protective clothing. There are many microorganisms that are just as small and easy to detect as any pathogens. Such "simulants" are completely adequate to test penetration.

3. The main use of an aerosol test involving pathogens could be to assay the efficacy of novel organisms as biowarfare agents.

4. The development and the testing of novel organisms is justifiable under the programs defensive rubric as follows: "If we develop a novel organism and develop defenses to it, then if the enemy develops the same organism we will already have a defense."

5. The statement quoted in 4 above has problems:

a.) One of the routes to be pursued in defense against novel organisms is via the development of vaccines. Vaccines are quite specific. The target of vaccines is one of the targets that might be varied via genetic manipulations. It would be hard to anticipate the target changes that an adversary would make, relatively easier to make your own.

If one side uniquely possesses a novel pathogen and the vaccine to it, that side has an offensive weapon. Vaccines are likely to be more useful for the offense than the defense.

b.) The criticism of vaccine development by the military or under contract to the military applies also to biosensor development for specific pathogens.

6. In the context of the arms race and the information age, knowledge of pathogenic organisms and their treatment is a potential weapon if that knowledge is held exclusively by one side.

7. The program includes a large non-classified component which is to involve contracts administered by the army and for which it has been argued that these contracts are essentially as benign as those administered by the National Institutes of Health or the National Academy of Science.

8. Army contracts typically include a clause which requires the contracted to submit to the army a summary or a copy of work before that work is to be published or presented at a meeting. The contracts specifically retain for the army the right to classify or to otherwise prohibit public dissemination of the information.

9. Pre-publication notification is never a requirement for money awarded from the N.I.H. or N.S.F.

10. The ability to prohibit public dissemination of information (contained in each contract to be issued under the proposed program) gained in the Biowarfare program would allow a defensive program to shift into weapons development at a moments notice, with no external control on that decision. External agencies, domestic or foreign, would have no way of knowing if information was being censored.

11. The argument has been made by Amy spokesmen that the proposed program will not involve weapons development for anything like thaw because the quantities of pathogens involved is anticipated to be "quite small". This argument is specious because microorganisms grow rapidly.

In the correct facility, a single organism could be grown into several tons in a matter of days. Such facilities are common in the context of pharmaceutical production.

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12. A deep impact of the proposed program would be to create a group within the military whose career interests would be served by expanding the Biowarfare horizons and whose personal interests would be ill served by restraint on this potential new sort of arms race. Such a development would not be in the national interest. The potential of such a development should not be overlooked. Analogous situations currently exist in nuclear weaponry and in the Star Wars (S.D.I.) program.

13. The proposed program is likely to have adverse economic effects and adverse effects on the public health via the redistribution of resources and research talent in the biological sciences. Biotechnology is currently a very bright spot in the U.S. economy and has great potential. Military involvement is likely to distort the competitive market, i.e. to condition what types of projects are worked on and thereby channel resources away from projects which I would otherwise receive more attention. The Biowarfare programs advocates will doubtless mention the possibility of spin-offs. The military is not however the most competent agency to direct Biotechnology in this country, far more expertise exists in the N.I.H and the N.S.F.

14. The proposed program would be highly divisive in the community of Molecular biologists. Many would refuse to cooperate with the proposed program and even with fellow academics or industrial microbiologists who take part in it. The effects of this loss of synergy on the research community would be hard to quantify, but they would be large. The result would be a less productive scientific community as a whole, a relative loss of economic advantage and quite possibly a lessened ability for the accomplishment of those goals of the proposed program that are benign and within the confines of the treaty prohibiting Biowarfare.

Utah Peace Test
P.O. Box 11416
Salt Lake City, Utah 84147

October 1, 1988

To Chuck Dasey,

Utah Peace Test is an organization committed to nonviolence and peaceful approaches to conflict resolution. We strongly object to the U.S. Army's proposal to continue testing biological weapons for defensive, or any other purposes.

Enclosed is a petition prepared by Utah Peace Test and signed by nearly 200 Utah citizens. Although the petition was prepared in response to the proposed level IV aerosol test facility at Dugway Proving Ground, we believe the concerns it raises directly apply to all defensive biological weapons testing by the U.S. Army. Therefore, we ask you to include the contents of this petition and the collected signatures in your final DEIS for the BDRP.

Sincerely,

Utah Peace Test
c/o Paige Wilder

Utah Peace Test
c/o Paige Wilder

A14-92

LETTER IN OPPOSITION TO THE BIOLOGICAL AEROSOL TEST FACILITY

We recognize that the current arms race endangers the entire world. It imperils the existence of all living creatures. We have reached a precipice from which we must act. It is only through reducing the arms race and developing peaceful means of resolving conflicts that we can move away from the danger.

40-1 Therefore, we strongly oppose the building of the proposed Biological Aerosol Test Facility at the Dugway Proving Ground. It would move us in the wrong direction. We would be escalating the arms race to a frightening new level. It is a morbid misventure with deadly implications.

40-2 Furthermore, we oppose the construction of the biological warfare lab because the public could be exposed to numerous environmental health and safety risks. The facility will be used for testing highly contagious germs and possibly non-curable diseases. If the general public were exposed to these agents, there could be a massive epidemic. There is no certainty that this will not happen. In addition, the Army has not developed adequate preventative measures to assure the public that workers, small animals, wind-drifts, and other materials will not transmit such deadly germs as anthrax, Q fever, tularemia, and rift valley fever to the general population.

40-3 The Army claims they need this facility to develop antidotes to deadly germs that could be used against our troops. While on the surface this motive may appear sound, in reality it is folly. First, pathology experts have testified that it is virtually impossible to create antidotes for even a small portion of the various strains of a virus. Second, to create antidotes for new viruses means creating new viruses for offensive use in violation of the Geneva Accords of 1972.

40-1 The essential point is that the building of this facility will only heighten the fears and tensions that exist between nations. Meanwhile, the people of this country and the world yearn for peaceful cooperation and understanding between nations. It is inexplicable as to why our government would take this regrettable step in defiance of the public's will.

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A14-93

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[illegible]	[illegible]	
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Gary Doty	645 Hollywood Ave. SLC 84105	Gary Doty
Gingfeng Xu	645 S [illegible] SLC	Gingfeng Xu
Rosemary Johnson	149 E 4th So. SLC UT	
[illegible]	717 [illegible]	
Christina Taylor	160 Kinsella St. SLC UT 84102	Christina Taylor
SANDY SHELTON	576 E Vine #2-B Murray 84107	Sandy Shelton

Name	Address	Signature
Rolf Kastrup	87 Q St #2 SLC UT 84103	Rolf Kastrup
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	2-118 Elizabeth St #2, SLC UT	
[illegible]	1767 [illegible] SLC	
Susan Paris	834 E. 3950 So. #H SLC 84107	Susan Paris

Name	Address	Signature
James Wilde	Emigration Can	James Wilde
Shauna Bona	5464 So McClelland	Shauna Bona
T. BEHREND	710 6th Ave SLC	
MARC HOENIG	2539 S Park	
Milton Braselton	328 So. 8th E.	Milton Braselton
[illegible]	6711 S. 3rd C	Midvale UT

A14-95

Name (PLEASE PRINT)	Address	Signature
Russ Fish	736 Windsor St, SLC	Russell D. Fish
M. Hiatt (Merle Hiatt)	159 Relay Dr. S.L.C.	M Hiatt
Liliana Lemus	649 Wilson Ave	[illegible]
Mike Nakamura	1307 South 13th East	Mike Nakamura
Susan Browning	2597 Nottingham Way SLC	Susan Browning
Gordon L. Remington	305 Third Ave #8 SLC UT 84103	[illegible]
Michaela Condit	1909 Texas St. SLC UT 84108	[illegible]
Lin Esther	460 6th Avenue SLC 84103	Lin Esther
June Viavant	2590 E Kensington Cove SLC 84124	June Viavant
[illegible]	510 E 4th Ave SLC 84103	[illegible]
Marilyn Felton	3936 Meadow Green Cove #72 West Valley City 84120	[illegible]
Craig Sanders	1424 University Way SLC UT 84108	[illegible]
[illegible]	1424 Univ. Way SLC Utah 84108	[illegible]
Kirsten Clark	452 9th Ave SLC	Kirsten Clark
John Wiskoski	1805 S 500 E SLC	[illegible]
[illegible]	1445 [illegible] SLC	[illegible]
Pat Fish	736 Windsor St	Pat Fish
[illegible]	1708 E [illegible] SLC UT	[illegible]
Clark O. Leonard	1445 Western Way SLC, UT	Clark O. Leonard

Name	Address	Signature
Steven J. Pomeranz	Bennion, UT. 5702 Dynasty Cove Cir S.L.C. Utah 84104	[illegible]
Laura Fleming	829 Arapahoe Ave SLC Utah	[illegible]
Stephen S. Fleming	829 Arapahoe Ave SLC Utah	[illegible]
[illegible]	2812 1300 S #6 SLC UT	[illegible]
Susan Allan	3251 S 50 W #180 SLC Utah	[illegible]
Michael S. Carter	64 E St SLC, UT 84103	[illegible]
[illegible]	252 Douglas St SLC, UT 84102	[illegible]
[illegible] Fitz	1057 Denver SLC UT 84111	[illegible]
Lewis E. Gulway	638 No. 900 W. S.L.C. UT 84116	[illegible]
Frank Fay	360 E Stonehedge Dr #131	[illegible]
Francine Brennan	1750 Jefferson Ave	[illegible]
R. Lee Guthrie	7124 Turnagain Cove SLC 84121	[illegible]
Greta Belanger de Jong (Greta Belanger deJong)	140 McClelland St. SLC UT 84102	[illegible]

		Signature
Heather Hirsaki	1434 S 1700 S.	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
Cynthia L. Cook	2200 S. 4800 S. #135	[illegible]
[illegible]		Tonya Mason
Stephen David Whitbeck	Woodscross 11670 19605	[illegible]

A14-96

Name	Address	Signature
Joseph Hennelly	1735 So. Main St SLC UTAH 84115	Joseph F Hen
Steve Settles	380 Richard St.	Steve Settles
James Ray Pratt	931 So 900 E Salt Lake City	[illegible]
MASON W. RANKIN	4108 So 670 E # SLC, UT 84116	Mason W Rankin
KURT WALL	836 FIGTREE PL #1024 SLC, UT 84123	Kurt Wall
Jerry CHAMFR	1156 W. Clubhouse Dr Apt 2014 SLC UT 84123	[illegible]
Deena Borozy	206 K St, SLC, UT. 84103	Deena Borozy
Dean Ehrman	3247 BON VIEW DR.	DEAN EHRMAN
MATTHEW HEIN	1327 Lincoln St. #1 84105	Matthew Hein
[illegible]	055 Denver 84111	[illegible]
CESAR CABRALES	1302 S. 500 E SLC, UT 84115	Cesar Cabrales
[illegible]	3315 Hectel WVC Utah 84119	

A14-97

...ge... stop in defiance of the public's will.

Name	Address	Signature
Steve Olson	826 S 3rd E	Steve Olson
Debbie Collmer	804 E 3rd S	Debbie Collmer
[redacted]		
Gerald F Kahley	P.O. Box 9455 SLC	Gerald Kahley
Terry Hardy	667 E So. Temple SLC	Terry Hardy
Carolyn Thompson	138 East 1300 So. SLC	Carolyn Thompson
Barbara B. Wardle	3290 E 4800 So #118 SLC	Barbara B Wardle

Sue Goodwin	P.O. Box 655 Franklin Id 83237	Susan Goodwin
Tawni J. Anderson	454 F Street SLC, UT 84103 Box 21 Reed College Portland, OR 97202	Tawni Anderson
JEANEAN L SANTINI	674 S. 10 E SLC, UT 84102	Jeanean Santini
[illegible]	168 16th Ave. SLC, 84103	Carol Littlefield
MYCES HARTHUN	1135 1ST AVE #7 SLC 84102	[illegible]
Steve Lieser	78 So. Wolcott SLC 84102	[illegible]
Cynthia Vogt (Cynthia Vogt)	1589 So. 700 East SLC 84105	Cynthia Vogt
Eric Robinson	240 So. Main SLC 84101	Eric Robinson
LETITIA Archuleta	54 L Street SLC 84103	Letitia Archuleta
RICHARD H MILLER	1125 E 900 So SLC	R H Miller
MARIO MURALES	727 E 1st AVE	Mario Morales
MARYSE CÔTÉ	823 - 1st AVE SLC.	Maryse Côté
Erique Price	353 E. Woodlake Dr. #32 SLC 84107	Enrique Price
Susan Northington	1241 E. 5600 So SLC	Susan Northington
ANNE QUIGLEY	29 Virginia ST	Anne Quigley
Chris Ivory	370 E. S. Temple #500	Chris Ivory
[illegible]	331 [illegible]	[illegible]
Glenn M. Goffin	124 N. Canyon Rd. SLC	Glenn M. Goffin
[illegible]	424 J ST SLC	[illegible]
J. Terrell Dougan	1813 Fort Douglas Circle	J. Terrell Dougan
Jeff & Susan Moore	866 W. End. Ave	Jeff Moore
Bonnie Mangold	326 Almond St. SLC, UT. 84103	Bonnie Mangold

A14-98

9/30/88

I am writing in strong opposition to the proposal to continue research into biological weapons. There are several critical points which must be considered in the final EIS.

1. Immediate safety. the record of the army's research program is abysmal. Countless Utahns can attest to the inability of the army to contain its research. As an experienced lab worker I am convinced that eventually human error will lead to deadly consequences if deadly biological weapons are developed for research purposes. The nebulous "benefits" of biological weapons research do not justify placing civilians or military personal weapons are developed for research purposes. The nebulous "benefits" of biological weapons research do not justify placing civilians or military personal at risk. Animal vectors such as the highly diverse rodent population around the Dugway research facility make the spread of dangerous organism potentially rapid, widespread, impossible to monitor, and unstoppable.

2. Need. If dangerous research is to be justified, some need must be shown. There has never been any verifiable and believable evidence suggesting offensive biological weapons are being developed by other countries. Phenomena cited as evidence of biological weapons testing have been repeatedly shown to be bogus. An example is "yellow rain". I was appalled to find the "scientists" at the Tooele hearings had not heard of Meselson's review which showed irrefutably that yellow rain is/was a natural phenomenon and not the result of biological weapons testing. The treaty of 1972 banning the development of biological weapons has so far been honored by both sides. We need to continue to strictly adhere to the treaty in order to avoid sparking a new arms race (see point 4).

3. Ineffectiveness. As I have studied molecular biology, I have become convinced that research into defenses against genetically engineered pathogens is futile. The almost infinite number of possible mutations in viral coat proteins, as an example, makes the development of effective vaccines nearly impossible. Filtration and other methods of preventing organisms from infecting a host already exist, and dangerous recombinant or natural organisms do not present any new external features not found in "safe germs" to these generalized defenses. thus research using dangerous and recombinant organisms is pointless.

4. Political consequences. Any secret research into biological weapons will enhance tensions between competing nations, increasing the likelihood of a biological arms race. As long as all research is absolutely shared among countries, and as long as there is no perception that offensive

biological weapons are being researched, then perhaps we can avoid such an arms race. Offensive and defensive research can not be distinguished in most cases, thus any research can be perceived as potentially offensive. Lets take a stand and renounce **all** biological weapons research. We should take every opportunity to prevent the development of weapons which every sane person agrees have no place on this earth. The DEIS refers to the BDRP as a research and development program. As such it must be stopped.

Please address each of these issues in the final EIS.

Sincerely,

Rolf Karlstrom
87 Q St. #2
Salt Lake City, UTAH 84103

A14-99b

UPHA
UTAH PUBLIC HEALTH ASSOCIATION

October 4, 1988

Mr. Charles Dasey
US Army Medical Research & Development Command
ATTN: SGRD-PA
Fort Detrick, Frederick. MD 21701-5012

Dr. Mr. Dasey:

Enclosed is a copy of a resolution passed by the membership the Utah Public Health Association at its annual (1988) conference. The language and intent of the resolution, I believe, is quite compatible with the "Statement of the Utah Department of Health Concerning the Draft Programmatic Environmental Impact Statement Army Biological Defense Research Program", submitted to you on September 30, 1988.

1 hope and trust you will earnestly and favorably consider the position of the Department of Health and our association.

Sincerely,

Suzanne Kirkham, President

Enclosure

PO Box 16650-CHS 20
Salt Lake City, Utah 84116-0650
(801) 538-6140

PASSED 6/3/88

RESOLUTION ON THE DUGWAY BIOLOGICAL AEROSOL TEST FACILITY
UTAH PUBLIC HEALTH ASSOCIATION
SUBMITTED MAY 11, 1988 BY THE UPHA PEACE CAUCUS

WHEREAS the United States Army proposes the construction of a biological aerosol test facility at Dugway, Utah, for the purpose of conducting defensive research in biological warfare,

WHEREAS this facility would be designed for the highest level of biological containment possible, designed for research using extremely pathogenic microorganisms, possibly exotic and genetically-engineered organisms,

WHEREAS the proposed facility exposes its workers and the general population to an unknown but unacceptable risk of epidemic disease from accidental pathogen contamination or release,

WHEREAS such research could further provoke the international arms race in biological warfare, and

WHEREAS the benefits of this level of research have not been demonstrated to exceed the associated risks,

THEREFORE, BE IT RESOLVED that the Utah Public Health Association (UPHA) oppose the construction of this biological aerosol test facility, and

BE IT FURTHER RESOLVED that UPHA oppose research in biological warfare using exotic or genetically-engineered agents of potentially high pathogenicity, and

BE IT FURTHER RESOLVED that UPHA instruct the UPHA Board of Directors to join with other organizations opposing this facility, to promote public education and to provide legislative or judicial testimony pertaining to this issue as needed, emphasizing the negative public health impacts or such a facility and such biological warfare research.

Pat Johnson

A14-100b

Tim Scherer
1765 Willowbrook Drive Provo Utah 54604

September 26, 1988

U.S. Army Medical Research &
Development Command
Attn: SGRD-PA
Fort Detrick, Frederick. MD
21701-5012

To those it should concern:

As are most citizens in America, I am opposed to the development and use of biological weapons.

I realize, as Ollie North stated in the Iran/Contra hearings, that "we live in a dangerous world," and that, as a result, we must maintain a constant state of readiness to defend ourselves against any act of aggression. But I can't think of one such act that would require retaliation with biological weapons.

There is no such thing as defensive war, but only retaliation since first strikes are called retaliations for some great injustice, and since all actions in war are offensive, we are therefore in violation of the treaty governing of offensive biological weapons when we create arguments in favor of the proliferation of defensive biological weapons. War may be a game to play, but we should not trifle with the treaty-making process, since trust, above all, is the basis for all world peace.

Due to their very nature, biological weapons are immoral: aggression against civilian population, especially in the case of genetically involved biological weapons, is not war, but genocide. There may be no proud soldiers in acts of violence with biological warfare. And quite glibly, may I add, what is war without pride? What good is world domination if we can't feel glad about having it. What fun was it for Oppenheimer when, after being heralded for his advancement of nuclear technology and after the bombing of Hiroshima and Nagasaki he repented of his involvement in nuclear research

Being less than an idealist, and knowing that governments are lastly concerned with wisdom, I understand that Utah will long be the home of the production and development of biological weapons. This being the case. I see it as essential that we maintain a thorough and constant state of readiness against local contamination from all strains stored in the state. We must be made aware of the risk to public safety should a leak of any level occur; our doctors mull he made prepared to deal faith all catastrophies.

However, this does not mean I will use any less of my power to defeat the proponents of biological weapons.

Sincerely,

Tim Scherer

A14-101b

DCED
Division of State History
(Utah State Historical Society)
Department of Commerce and Economic Development

July 20, 1988

U.S. Army Medical Research and Development Command
Attn: SGRD-PA
Fort Detrick, Frederick, MD 21701-5012

RE: Draft Programmatic Environmental Impact Statement, Biological Defense Research Program

In Reply Please Refer to Case No. K390

Dear Sirs:

The staff of the Utah State Historic Preservation Office has received for review the above referenced Environmental Impact Statement. It is unclear from the document whether there will be any new construction at the Dugway Proving Grounds in Utah. If there is to be new construction as a part of this program, our office hopes that the Defense Department identifies and evaluates any historic properties that might be affected by the project as specified in the National Historic Preservation Act of 1966, as amended.

Please let us know if our office may assist the Defense Department in complying with federal historic preservation regulations.

Sincerely,

A. Kent Powell
Deputy State Historic
Preservation Officer

DC:K390/5816V OFR

SALT LAKE CITY CORPORATION
OFFICE OF THE MAYOR
324 SOUTH STATE STREET
FIFTH FLOOR, SUITE 500
SALT LAKE CITY, UTAH 84111

PALMER DePAULIS
MAYOR

July 29, 1988

U.S. Army Medical Research and Development Command
Mr. Charles Dasey
Attn: SGRD-PA
Fort Detrick, Frederick, MD 21701-5012

Dear Sir:

The Health Interim Committee of the Utah State Legislature recently requested that the Department of the Army conduct public hearings in the State of Utah on the Draft Environmental Impact Statement for the Biological Defense Research Program (BDRP). I concur in that request.

I agree with the Committee that the people of Utah should be allowed ample and equal opportunity to review and comment on the BDRP DEIS and to participate in the decision -making process on the future of this program. This is especially important since the Dugway Proving Ground is one of the three main facilities in the U.S. for biological warfare research, and Dugway is the site selected for a proposed new aerosol test facility which has generated considerable controversy in our state.

I believe it is important that the general public have the benefit of seeing "the big picture" of the Army's biological weapons program before any decisions are made regarding the proposed Dugway aerosol testing lab.

I ask that the Army respond promptly and favorably to the Committee's request for hearings and if necessary, extend the August 12 comment deadline for the BDRP DEIS to accommodate Utah hearings.

Respectfully,

Mayor

cc: Governor Norman Bangerter
Utah Congressional Delegation
Commander, Dugway Proving Ground
Senator Ivan M. Matheson, Senate
Representative Joseph M. Moody, House

CONGRESSMAN OWENS: THANK YOU VERY MUCH. MR. MODERATOR, DISTINGUISHED GUESTS, LADIES AND GENTLEMEN, I AM PLEASED TO BE HERE. I AM FIRST OF ALL GRATIFIED BY YOUR ANNOUNCEMENTS EARLIER THIS AFTERNOON THAT YOU'RE REVISING THE PLAN FOR DUGWAY TO ELIMINATE PREPARATIONS FOR BIOSAFETY LEVEL 4 TESTING. THIS WAS REQUESTED BY A NUMBER OF US OVER THE PAST SEVERAL MONTHS, THE PURPOSE OF A HEARING HELD IN WASHINGTON LAST SUMMER, AND I AM GRATIFIED BY THAT DECISION. I THINK IT SAVES AN IMMENSE AMOUNT OF CONTROVERSY AND DOES NOT ROB YOU OF ANY FUTURE OPTIONS, MY CONCERN FIRST FOR THE SAFETY AND SECOND FOR THE

PUBLIC SCOPING MEETING FOR THE PROGRAMMATIC DRAFT ENVIRONMENTAL IMPACT STATEMENT REGARDING THE DEPARTMENT OF DEFENSE, BIOLOGICAL DEFENSE RESEARCH PROGRAM

TOOELE ARMY DEPOT

SEPTEMBER 19, 1988

7:00 P.M. TO 10:00 P.M.

A14-103b

INTERNATIONAL IMPLICATIONS OF PREPARING FOR THAT LEVEL OF TESTING CAPABILITY AND THE DISCORDANT NOTE INTERNATIONALLY WHICH IT FOUNDED.

THE CLEAR INDICATIONS THAT IT WOULD CAUSE OTHER COUNTRIES PARTICIPANTS IN THE 1972 BIOLOGICAL TREATY, WARFARE TREATY, CAUSED THEM TO BE CONCERNED ABOUT WHAT WERE AMERICA'S GOALS, WHAT AMERICANS ACTIONS WERE. MUCH OF THAT CONTROVERSY NOW, I THINK, CAN BE MITIGATED BY YOUR DECISION OF TODAY AND I COMMEND YOU VERY SINCERELY FOR THAT.

WE DO LOOK FORWARD TO THE COMPLETED ENVIRONMENTAL IMPACT STATEMENT WHICH I AM HIGHLY CONFIDENT WILL TAKE INTO CONSIDERATION MANY OF THE SAFETY ISSUES RAISED EARLIER IN MEETINGS HERE IN UTAH AND ELSEWHERE BY MANY PUBLIC OFFICIALS AS WELL AS BIOLOGICAL RESIDENTS AND MANY BIOLOGICAL EXPERTS NATIONWIDE. SO WE LOOK FORWARD TO THAT STATEMENT THAT WILL BE VERY, VERY IMPORTANT TO US HERE.

THIS HEARING, OF COURSE, DEALS WITH THE PROGRAMMATIC DRAFT ENVIRONMENTAL IMPACT STATEMENT AND I COMMEND YOU AGAIN, VERY SINCERELY, FOR YOUR WILLINGNESS TO COME HERE TO TOOELE, AT MY REQUEST, AND THE REQUEST OF OTHERS, TO BE RESPONSIVE TO THOSE OF US IN UTAH WHO FEEL SO CLOSELY TOUCHED BY THE BIOLOGICAL DEFENSE RESEARCH PROGRAM. I THINK THAT HERE, AS IN VERY FEW OTHER LOCATIONS THROUGHOUT THE COUNTRY, WE HAVE VERY GREAT SENSITIVITY TO THESE ISSUES

AND I FIND THAT YOUR COMING HERE, I BELIEVE TO BE VERY RESPONSIVE AND SENSITIVE AND I COMMEND YOU FOR THAT.

I NOTE THAT THERE ARE AT LEAST TWO VERY SERIOUS STUDIES DONE WHICH QUESTION THE ADEQUACY OF THE DRAFT PROGRAMMATIC ENVIRONMENTAL STATEMENT. THE GAO AND THE SENATE SUBCOMMITTEE ON THE OVERSIGHT OF GOVERNMENT MANAGEMENT HAVE RECENTLY INVESTIGATED THE BIOLOGICAL CHEMICAL DEFENSE PROGRAM AND NEITHER SUPPORTS THE OPTIMISTIC SCENARIO [WHICH HAS BEEN LAID OUT HERE TONIGHT AND]IN YOUR STATEMENT, AND THOSE ISSUES MUST, OF COURSE, BE CAREFULLY ADDRESSED BEFORE THIS FINAL STATEMENT IS ISSUED AND THE PROGRAM GOES FORWARD.

THE GAO, FOR EXAMPLE, WARNED OF THE UNCERTAINTIES THAT SURROUND THE ADEQUACIES OF THE SAFEGUARDS TO THE PROGRAM. MORE ALARMINGLY, REALLY, THE SENATE REPORT OMINOUSLY WARNS THAT DOD'S SAFETY PROTECTIONS APPEAR TO BE FRAGMENTED AND COMPLETELY INACCURATE. THE REPORT GOES ON TO DISCUSS EXAMPLES OF FIRES, MISPLACED VIALS OF BE AGENTS, LABORATORY SPILLS AND EMPLOYEE EXPOSURES TO BE AGENTS. HOW DOES THIS SQUARE WITH THE IMPRESSIVE RESEARCH HISTORY WHICH THE ARMY SPEAKS OF IN ITS DRAFT ENVIRONMENTAL IMPACT STATEMENT? WE SEE MANY OF THE SAME CHARGES FROM VERY RESPONSIBLE PEOPLE MADE ON THE PROGRAMMATIC BIOLOGICAL RESEARCH PROGRAM, NATIONWIDE PROGRAM, NATIONAL PROGRAM, THAT WERE RAISED ON THE INITIAL DRAFT ENVIRONMENTAL IMPACT

STATEMENT FOR THE NEW DUGWAY FACILITY.

THERE IS A QUESTION HERE ABOUT WHETHER THE ARMY SHOULD CONTROL THIS ENTIRE PROGRAM, AND I READ WITH INTEREST THE MATERIAL FACTS TO ME OUT HERE FROM MY WASHINGTON OFFICE THIS AFTERNOON, AND THEN LISTENED AS THE GOOD DOCTOR PRESENTED HIS REMARKS TONIGHT, THAT YOU CONSIDER THE POSSIBILITY OF MOVING SOME OF THE BIOLOGICAL DEFENSE RESEARCH PROGRAM THROUGH NONMILITARY CONTROLS. I ASSUME THE PANEL IS AWARE THAT I HAVE INTRODUCED JUST SUCH LEGISLATION SEVERAL MONTHS AGO. I BELIEVE THAT WE SHOULD PLACE INTO CIVILIAN HANDS THE NATIONAL INSTITUTES OF HEALTH, THE CONTROL FOR THE RESEARCH AND DEVELOPMENT UNDER THE BIOLOGICAL DEFENSE RESEARCH PROGRAM, THE TESTING. I THINK PROPERLY DONE BY THE ARMY AND I THINK, HOWEVER, IN ITS RESEARCH AND DEVELOPMENT, GIVE WAY TO MILITARY-NONMILITARY CONTROL, SO I TAKE DIRECT ISSUE WITH THAT DECISION WHICH YOU HAVE MADE AND WHICH YOU HAVE JUST ANNOUNCED.

I THINK THAT THE DECISIONS -- THE DECISION TO GIVE THIS RESEARCH AND DEVELOPMENT ASPECT TO THE NATIONAL INSTITUTE OF HEALTH WOULD BE SUPPORTED BY TWO PRIMARY FACTORS, TWO PRIMARY REASONS. THE FIRST BEING A MUCH GREATER RECORD OF SAFETY AS I GATHER FROM READING THE REPORTS ON THE ARMY'S PROGRAM. SECONDLY, PERHAPS MOST IMPORTANTLY, CIVILIAN CONTROL OVER THE PROGRAM WOULD GO ALONG WAYS TO OUTLINE ANY SUSPICION OR CONCERNS THAT THE WORLD HAS ABOUT

AMERICA'S GOAL. SO IT WOULD BE DONE, I THINK, WITH GREATER SAFETY, GIVEN THEIR SAFETY RECORD, AND THEIR BACKGROUND AND THEY ARE MUCH MORE SCIENTIFICALLY-BASED FACILITIES AND SECONDLY, THE 72 BIOLOGICAL WARFARE TREATY, THE CONVENTION IS VERY WEAK IN ENFORCEMENT CAPABILITY AND I THINK THIS COUNTRY NEEDS TO LEAD IN AVOIDING SECRECY WHEREVER POSSIBLE AND IN ASSURING THE WORLD THAT CIVILIANS ARE IN CONTROL OF OUR RESEARCH PROGRAM AND, HENCE, I THINK THAT LEGISLATION, WHICH I INTEND NEXT YEAR TO BRING TO HEARINGS AND HOPEFULLY TO FRUITION AND WHICH DIRECTLY CONTRADICTS ONE OF THE MAJOR DECISIONS YOU HAVE MADE AND WOULD HAVE IMMENSE IMPACT, OF COURSE, ON THE PROGRAM THAT THE MILITARY IS HERE SCOPING FOR US TONIGHT, THAT LEGISLATION I HOPE AND EXPECT WILL MOVE NEXT YEAR.

SO IN THAT SENSE, I AM DIRECTLY AT ISSUE WITH THAT CONCLUSION THAT YOU HAVE MADE. IN CLOSING, I AM GRATEFUL FOR YOUR INTEREST IN COMING HERE TONIGHT AND WILL STUDY CAREFULLY, LISTEN CAREFULLY, TO YOUR PRESENTATIONS THIS EVENING AND STUDY CAREFULLY THE DOCUMENTS THAT WHICH WE NOW HAVE AND PERHAPS AT A LATER TIME HAVE MORE COMMENTS, BUT I AM GRATEFUL THAT YOU'RE HERE AND GRATEFUL FOR THE SINCERE GOOD EFFORTS YOU ARE MAKING TO HEAR WHAT LOCAL PEOPLE FEEL ABOUT THIS ISSUE WHICH TOUCHES US IN A VERY PERSONAL WAY. THANK YOU VERY MUCH.

MR. DASEY: THE NEXT SPEAKER IS DR. RANDY MOON,

REPRESENTING THE GOVERNOR OF UTAH.

DR. MOON: I WOULD LIKE TO READ A STATEMENT THAT GOVERNOR BANGERTER HAS ISSUED REGARDING THE PUBLIC HEARING TONIGHT. HE WAS EARLIER TODAY AND PARTICIPATED IN A PRESS CONFERENCE REGARDING THE DECISION TO THE PREFERRED ALTERNATIVE, OF THE BL3 LABORATORY AND IF YOU WANT ME TO FOCUS THESE COMMENTS, I AM GOING TO HAVE A REAL HARD TIME BECAUSE ALL I AM GOING TO DO IS READ THEM AS HE WROTE THEM AND EDITED THEM WHILE HE WAS HERE.

HE SAYS: "I APPRECIATE THE OPPORTUNITY TO PARTICIPATE IN THIS PUBLIC PROCESS AS WE REVIEW THE DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT ON THE ARMY'S BIOLOGICAL DEFENSE RESEARCH PROGRAM. I WANT TO THANK THE ARMY FOR CONSIDERING OUR REQUEST TO HOLD A PUBLIC HEARING MEETING ON THE BDRP IN THE STATE OF UTAH. I STRONGLY SUPPORT THE PUBLIC PROCESS WHICH PROVIDES AN OPPORTUNITY FOR INTERESTED PARTIES, LIKE YOU AND I, TO COMMENT ON THIS PROPOSED ACTION AFFECTING OUR STATE AND OUR CITIZENS. I HOPE THAT THE PURPOSE OF THESE HEARINGS WILL BE TO CONSIDER THE OPTIONS VERY CAREFULLY. ALL QUESTIONS RAISED MUST BE ANSWERED, EVEN THE HARD ONES. THEN AND ONLY THEN WILL THE PUBLIC PROCESS RESULT IN THE CORRECT DECISION REGARDING THE ARMY'S RESEARCH PROGRAM AND ULTIMATELY DUGWAY'S FUTURE IN UTAH.

"I STRONGLY SUPPORT A NATIONAL DEFENSE AND STATED

SO AT THE PUBLIC MEETING HELD AT SALT LAKE CITY ON MARCH 22ND OF THIS YEAR. AT THAT TIME, I ALSO STATED I OPPOSED THE CONSTRUCTION OF A BL4 LABORATORY AT THE DUGWAY PROVING GROUND. WITH TODAY'S ANNOUNCEMENT THAT THE ARMY WILL DESIGNATE THE BL3 LAB AS A PREFERRED ALTERNATIVE, I COMMEND THE ARMY ON THEIR CHANGE OF ATTITUDE REGARDING THE BIOLOGICAL AEROSOL TEST FACILITY. THIS CHANGE WILL PREVENT THE TESTING OF DANGEROUS ORGANISMS FOR WHICH THERE'S NO KNOWN CURE.

"I APPRECIATE THE ARMY'S NEW FOUND WILLINGNESS TO COMPROMISE WITH THE PEOPLE OF UTAH AND TO NEGOTIATE WITH ME AS GOVERNOR ON MATTERS WHICH AFFECT THE STATE AND ITS CITIZENS. I PARTICULARLY APPRECIATE THE HELP OF CONGRESSMAN JIM HANSEN IN COMMUNICATING OUR CONCERN TO THE ARMY AND HELPING ASSURE THAT THE ARMY RESPONDS TO OUR CONCERNS.

"MY OFFICE HAS ALSO WORKED COMPLETELY WITH SENATOR GARN, WHO IS A MEMBER OF THE MILITARY CONSTRUCTION'S APPROPRIATIONS COMMITTEE, AND AS A MEMBER, HE HAS BEEN WORKING TO ENSURE THAT THE SAFETY CONCERNS AND THE NEED FOR DEFENSIVE BIOLOGICAL TESTING ARE BEING COORDINATED WITH MY OFFICE. SENATOR GARN HAS CLOSELY FOLLOWED THIS PROCESS FOR THE PEOPLE OF UTAH AND WE APPRECIATE HIS EFFORTS.

"MY NUMBER ONE CONCERN HAS-ALWAYS BEEN THE HEALTH AND SAFETY OF THE PEOPLE OF UTAH. I WILL CONTINUE TO WORK CLOSELY WITH THE ARMY TO ENSURE THAT THE HEALTH AND

SAFETY OF THE PEOPLE OF THIS STATE ALSO REMAINS ONE OF THE ARMY'S PRIMARY CONCERNS AND THEY EVALUATE THE BIOLOGICAL RESEARCH DEFENSE PROGRAM. I WILL INSIST THE OPEN PROCESS CONTINUE AND THAT THE ARMY SHARES WITH THE PEOPLE IN THE STATE INFORMATION REGARDING TESTING THAT IS BEING PERFORMED IN UTAH. THE ARMY HAS TOLD ME OF THEIR WILLINGNESS TO ACCOMMODATE A UTAH SCIENTIFIC CIVILIAN REVIEW COMMITTEE THAT I FIRST PROPOSED DURING THE MARCH 22ND HEARING. I, ALONG WITH OTHERS, PROPOSED THE NATIONAL REVIEW COMMITTEE OF THE WORLD'S LEADING EXPERTS, BUT I AM CURRENTLY FORMULATING A LIST OF MEMBERS FOR THE UTAH COMMITTEE AND WILL CHARGE THEM TO MONITOR AND EVALUATE TESTING ACTIVITIES AT THE DUGWAY PROVING GROUND. I COMMEND THE ARMY AND THE INDIVIDUALS OF DUGWAY FOR THE OPEN COMMUNICATIONS THAT HAVE BEEN ESTABLISHED. I LOOK FORWARD TO WORKING WITH THE ARMY SUCH THAT THEY MAY ACCOMPLISH THEIR MISSION AND IN SO DOING PROTECT THE HEALTH AND SAFETY OF THE CITIZENS OF THE UNITED STATES."

THAT CONCLUDES GOVERNOR BANGERTER'S COMMENTS. I WOULD LIKE TO ALSO ADD THAT AS THE SCIENCE ADVISOR IN THE STATE OFFICE OF PLANNING AND BUDGET, OUR DIRECTIVE IS TO FORMULATE THE RECOMMENDATIONS FOR THE COMMITTEE THAT WILL MONITOR AND EVALUATE DUGWAY ALONG WITH INPUT FROM THE CONGRESSIONAL OFFICES AND OUR SENATORS. THOSE NAMES ARE NOW BEING FINALIZED FOR THIS COMMITTEE. OUR FIRST TOUR OF THE DUGWAY FACILITY WILL OCCUR THIS FRIDAY AND THEN FOLLOWING

THAT, THERE WILL BE REOCCURRING MEETINGS OF THE SCIENTIFIC AND CIVILIAN COMMITTEE. THANK YOU.

MR. DASEY: THANK YOU, DR. MOON. THE NEXT SPEAKER WILL BE DR. GUBLER, THE CHAIRMAN OF THE TOOELE COUNTY COMMISSION.

DR. GUBLER: I DON'T HAVE ANY PREPARED STATEMENT, I HAVE ONLY A COUPLE OF COMMENTS I WOULD LIKE TO MAKE. I FIND IT DEPLORABLE WHEN KSL TV, UNDER THE GUISE OF REPORTING THE NEWS, TAKE THAT OPPORTUNITY TO EDITORIALIZE IT AGAINST DUGWAY. I THINK THAT IS REALLY AN ABUSE OF THE JOURNALISTIC LICENSE. SECONDLY, I FIND IT DEPLORABLE THAT MANY OF OUR CITIZENRY WOULD APPEAR TO GIVE GREATER CREDIT TO FOREIGN POWERS THAN TO OUR OWN UNITED STATES GOVERNMENT AND TO OUR OWN MILITARY. LASTLY, I WOULD LIKE TO SAY THAT I AM SORRY THAT THE ARMY DID ROLLOVER AND GIVE INTO THE PRESSURES OF THE NEWS MEDIA AND SOME OF THE POLITICIANS IN CHANGING TO A BL3 RATHER THAN 4. I THINK THE CREDIBILITY OF THE MILITARY IN THE PAST AND PROTECTION OF OUR COUNTRY AND OUR SECURITY CERTAINLY IS NOT BEYOND TOTAL CRITICISM, BUT BY AND LARGE IT HAS BEEN VERY EXEMPLARY. I AM VERY SUPPORTIVE OF THEM, I FEEL IT'S WRONG FOR CONGRESSMAN OWENS TO COME ACROSS THE OAKRIDGE, HE OUGHT TO STAY OVER IN THE WASATCH FRONT AND SEE IF HE CAN'T HOOD WITH HIS CONSTITUENTS THERE.

MR. DASEY: THANK YOU, SIR. THE NEXT SPEAKER IS BRIAN MOSS.

MR. MOSS: I AM BRIAN MOSS AND I AM A CANDIDATE FOR THE UNITED STATES SENATE, BUT MORE IMPORTANTLY I AM A CITIZEN OF THE STATE OF UTAH AND I HAVE BEEN IN THE STATE LONG ENOUGH TO HAVE A LONG MEMORY OF MANY THINGS THAT HAVE TAKEN PLACE AND I THANK YOU FOR COMING HERE FOR THIS HEARING

I WROTE A LETTER ALONG WITH MANY OTHER CITIZENS IN THIS STATE AND ELECTED OFFICIALS REQUESTING THIS HEARING AND I AM VERY PLEASED THAT YOU HAVE LISTENED TO THAT REQUEST AND CAME HERE AND LISTENED TO THE PEOPLE IN THE STATE OF UTAH.

ONE OF THE VERY GREAT CONCERNS WE ALL HAVE, AS I MENTIONED MY MEMORY, IS THE MEMORY OF 8,000 SHEEP MYSTERIOUSLY DYING OUT IN THE DESERT. WE HAVE A MEMORY OF CLOUDS OF DUST ROLLING ACROSS THE SOUTHERN PARTS OF OUR STATE. WE HAVE A MEMORY OF WANTING TO BE THE NUCLEAR DUMPING GROUND OF THE NATION. AND QUITE FRANKLY, THAT'S A SERIOUS CONCERN OF THE PEOPLE OF UTAH. WE FEEL LIKE WE HAVE BEEN DUMPED ON, SPRAYED OVER, WE HAVE HAD CLOUDS ROLL OVER US, AND WE HAVE CITIZENS WHO ARE DYING IN THE SOUTHERN PARTS OF OUR STATE, AND WE HAVE MANY OTHER THINGS THAT THE GOVERNMENT SAID, QUITE FRANKLY, WERE NOT OF CONCERN AND WERE NOT SOMETHING WE HAD TO WORRY ABOUT.

I THINK THERE IS A CREDIBILITY PROBLEM WITH MANY OF THE CITIZENRY IN THE STATE OF UTAH AND THAT'S A PROBLEM THAT YOU HAVE AND YOU NEED TO ADDRESS VERY SQUARELY.

QUITE FRANKLY, I'M NOT SURE OF THE ABSOLUTE NEED FOR THE BIOLOGICAL TESTING. AS I READ FROM THE TRIBUNE STORY THIS MORNING, THE MILITARY HAS YET TO PROVE AN ACTUAL NEED FOR ALL OF THIS DEFENSIVE TESTING. MORE IMPORTANTLY, IT MEANS YOU HAVE TO BUILD THE OFFENSIVE GERMS, THE OFFENSIVE WEAPON IF YOU WILL, AND THAT LEADS TO A VERY SERIOUS CONCERN OF GENETIC TINKERING THAT CREATES VIRUSES AND GERMS THAT MAY, IN FACT, ESCAPE AND GET OUT INTO THE ATMOSPHERE AND THAT'S THE GROUP PROBLEM I THINK YOU HAVE WITH THE PEOPLE OF UTAH AND THAT'S WHY I OPPOSE THE DEVELOPMENT OF THIS BIOLOGICAL TESTING LAB HERE. IT'S ONE MORE INSTANCE WHERE THE PEOPLE OF UTAH HAVE TO FACE ANOTHER THREAT UPON US AND I DON'T REALLY THINK IT NEEDS TO GO ANYWHERE ELSE EITHER, BUT THAT IS MY OWN PERSONAL OPINION, BUT I STAND HERE TO SPEAK FOR THE MANY THOUSANDS OF UTAHNS WHO BELIEVE AS I DO, THAT THIS IS ONE MORE INSTANCE WHERE YOU MAY THREATEN THE HEALTH OF OUR PEOPLE HERE IN THE STATE AND WE ARE NOT FIRMLY CONVINCED, DESPITE THE ASSURANCES GIVEN, THAT YOU WILL BE ABLE TO PROPERLY PROTECT US AGAINST AN ESCAPE OF THESE GERMS OR AEROSOLS-- I AM NOT A SCIENTISTS, I DO NOT KNOW ALL THE MAGIC WORDS TO SAY, BUT WE ARE NOT SURE YOU CAN PROTECT US AND WE ARE NOT SURE THAT WE WILL BE ABLE TO SURVIVE IF THIS PLANT HAS SOME SORT OF CATASTROPHIC ESCAPE, AND THAT ESCAPE CAN MOVE OVER THE OAKRIDGE AND CAN AFFECT ALL OF THE WASATCH FRONT AND ALL OF THE AREAS.

I SAY THIS IN ALL HONESTY AND HONOR AND I APPRECIATE YOU BEING HERE AND I HOPE YOU WILL TAKE THOSE CONCERNS INTO THE REPORT AND INTO THE ISSUES CONSIDERED BY YOUR COMMITTEE. THANK YOU VERY MUCH.

MR. DASEY: THANK YOU, SIR. A REMINDER, THAT WE ARE DISCUSSING THE BIOLOGICAL DEFENSE RESEARCH PROGRAM DRAFT ENVIRONMENTAL IMPACT STATEMENT. THE NEXT SPEAKER IS MR. STEVE ERICKSON REPRESENTING THE DOWNWINDERS.

MR. ERICKSON: I'VE NEVER SPOKEN INTO ONE OF THESE BEFORE, AND I WILL GIVE IT MY BEST.

FIRST OF ALL, I WOULD LIKE TO ACKNOWLEDGE THE ARMY FOR DECIDING TO HOLD THIS PUBLIC HEARING. I KNOW IT TOOK A LITTLE PRESSURE, AND I GUESS YOU GUYS ARE A LITTLE SENSITIVE TO PRESSURE RIGHT AT THE MOMENT. I REALLY THINK IT WAS NEAT OF YOU TO ORGANIZE THIS HEARING ON A SCHOOL NIGHT, WORK NIGHT, AND TO GET MOST OF US TO DRIVE ABOUT AN HOUR AND A HALF IN ORDER TO GET HERE, A ROUND TRIP. I THINK IT WAS A REAL FINE GESTURE ON YOUR PART. AND, BY THE WAY, IS THERE ANYONE FROM THE TOOELE ARMY DEPOT REPRESENTED IN THIS PARTICULAR PANEL? NO, OKAY.

I UNDERSTAND THAT THIS AFTERNOON, WHEN THE GOVERNOR AND JIM HANSEN ATTEMPTED TO MAKE A LITTLE POLITICAL HAY OUT OF YOUR CAVE-IN ON THE BL4, THAT THE UNDERSECRETARY OF THE ARMY WAS NOT ALLOWED ONTO THE BASE AND THAT'S BECAUSE THE TOOELE ARMY DEPOT DIDN'T WANT TO BE

IDENTIFIED WITH THE PURE POLITICS THAT THE DUGWAY PROVING GROUND APPARENTLY FELT WAS APPROPRIATE FOR THIS EVENING AND I WANT TO THANK THE COMMANDANT IN ABSENTIA FOR THAT PARTICULAR MOVE, THAT IS MOST APPROPRIATE.

YOU KNOW, I THINK THAT YOUR ENVIRONMENTAL IMPACT STATEMENT HAS SOME VERY SERIOUS PROBLEMS, BUT I THINK IN COMPARISON TO YOUR CREDIBILITY PROBLEM, THE COMMISSIONER HERE SAYS THAT BY AND LARGE THE ARMY HAS DONE A PRETTY GOOD JOB OF BEING CREDIBLE. I THINK THAT PERHAPS WE OUGHT TO REVIEW A FEW DOCUMENTS BEFORE WE PROCEED ANY FURTHER ON THE CREDIBILITY ISSUE.

ACCORDING TO RECENT REPORTS FROM FREEDOM INFORMATION REQUEST, RECENTLY RELEASED DOCUMENTS, IN 1977 THE ARMY PRESENTED A LENGTHY AND SUPPOSEDLY VERY THOROUGH DOCUMENTATION OF ALL THE TESTS THAT TOOK PLACE IN THE DUGWAY PROVING GROUND. WELL, HOW THOROUGH WAS IT IS THE QUESTION. NOT INCLUDED IN THAT ANALYSIS WAS THE FACT THAT THE ARMY SPLATTERED 450 GALLONS WORTH OF BIOLOGICAL FOG ALL OVER THE WEST DESERT FROM AN AIRCRAFT AND THIS APPEARED TO BE ONLY ABOUT A QUARTER OF WHAT WAS ACTUALLY DONE AND WE ARE STILL TRYING TO SOLVE THE PROBLEM OF THE NEW GLASNOST OF THE DUGWAY PROVING GROUND. WE ARE NOT IMPRESSED AT THIS JUNCTURE.

YOU KNOW, A SINGLE ORGANISM OF "Q" FEVER CAN CAUSE SIGNIFICANT HEALTH PROBLEMS, POSSIBLY DEATH. WELL,

THERE ARE THOUSANDS AND THOUSANDS OF ORGANISMS WITHIN ONE SINGLE DROP OF "Q" FEVER. THE ARMY SAW FIT, IN A 1968 TEST, TO DROP 40 GALLONS WORTH OF "Q" FEVER ALL OVER THE PLACE FROM AN F-100A JET TRAVELING AT NEAR SUPERSONIC SPEED. AT LEAST 69 FIELD TESTS CONDUCTED OVER 18 YEARS WERE LEFT OUT OF YOUR CONGRESSIONAL TESTIMONY IN 1977, WHEN YOU ATTEMPTED TO TELL CONGRESS HOW SAFE IT ALL IS.

WE HAVE RECENTLY FOUND OUT THAT YOU DIDN'T KNOW WHETHER "Q" FEVER WAS NATIVE TO THE AREA, WHETHER IT WAS ENDEMIC, WHEN YOU FIRST STARTED SPLATTERING THAT AROUND THE DESERT, OF COURSE. NOW, IT'S TOO LATE TO COME UP WITH ANY LOGICAL CONCLUSION OF WHETHER IT WAS THERE IN THE FIRST PLACE, OF COURSE, YOU HAVE ALSO SAID TO THE CONGRESS THAT THIS NEVER CREATED ANY PARTICULAR PROBLEM, DESPITE THE FACT THAT YOUR OWN DOCUMENTS SHOW THAT THERE WAS AN EPIDEMIC IN THE WILDLIFE OF "Q" FEVER IN 1959 AND 1960, THAT HASN'T GONE AWAY.

IN YOUR EIS, I RECALL ON THE BIOLOGICAL AEROSOL TEST FACILITY YOU SAID THAT THERE WAS SOMETHING TO THE EFFECT THAT YOU WOULDN'T TEST IT IF THE WINDS WERE OVER SIX MILES AN HOUR, AND I CAN REMEMBER COMMENTING THAT IT'S RARE THAT THE WINDS ARE LESS THAN SIX MILES PER HOUR IN THIS PART OF THE STATE OF UTAH. WHILE IN THE PAST YOU HAVE CONDUCTED WIND SPEED TESTS WITH BIOLOGICAL AGENTS WHEN THE WIND WAS 30 TO 60 MILES AN HOUR. IT SEEMS THAT YOU HAVE

DROPPED BOMBS CONTAINING AGENT US, WHICH NO ONE SEEMS TO KNOW WHAT THAT IS, APPARENTLY IT IS ONE OF YOUR PATHOGENS FROM A 25,000 FOOT ELEVATION OUT OF AN AIRPLANE TO DETONATE AT 10,000 FEET. SO MUCH FOR YOUR METEOROLOGICAL CONTROL. I BELIEVE WE COULD ALSO GO INTO THE FACT THAT YOU HAVE LEAKED AGENTS ALL OVER YOUR RUNWAY BEFORE OUT HERE, THAT YOU HAVE ALLOWED ANTHRAX SPORES TO CROSS I-80 WHICH AT THE TIME WAS I-40. THAT'S JUST A FEW THINGS. THEN THERE IS A SCIENCE, AN ARMY SCIENCE REPORT, WHICH I WOULD LOVE TO HEAR AN EXPLANATION FROM OUR DISTINGUISHED GUEST UP ON THE PODIUM ABOUT THE QUALIFICATIONS OF PERSONNEL, THE INADEQUATE NUMBER OF DOCTORATE LEVEL PERSONNEL, TO CONDUCT THIS PROGRAM, AND THE INADEQUATE TRAINING OF THE REST OF THE PERSONNEL INVOLVED. I THINK WE COULD ALSO REFER TO THE FACT THAT NO LEGITIMATE AND ADEQUATE THREAT ASSESSMENT HAS BEEN CONDUCTED. SO, SO MUCH FOR YELLOW RAIN AND FOR ANTHRAX OUTBREAKS IN THE SOVIET UNION, IT'S CLEAR THAT THE ARMY, WITH ITS OWN EVALUATION, DOESN'T UNDERSTAND JUST WHAT THE THREAT IS. SO WHAT IS IT THAT WE ARE DOING THIS DEFENSE AGAINST? I WAIT FOR AN ANSWER FROM THE ARMY ON THAT ONE. I THINK ALSO IN THIS, IT'S IMPORTANT TO NOTE THAT ONE OF THE KEY POINTS THAT THE ARMY IS TRYING TO MAKE IS THAT THEY NEED TO DEVELOP A PUBLIC RELATIONS PROGRAM THAT WILL CONVINCE US ALL THAT WHAT THEY ARE DOING IS SAFE. I SUGGEST THAT THEY HAVE A WHOLE LOT OF WORK TO DO IN THAT AREA,

PARTICULARLY BEFORE GIVEN THESE NEW REVELATIONS ON DOCUMENTS THAT THEY HAVE KEPT SUBMERGED FOR DECADES AT THIS POINT IN TIME. IT'S ALSO INTERESTING TO NOTE THAT WE ARE THROWING MONEY AT AN UNPRECEDENTED RATE AT THE BIOLOGICAL DEFENSE PROGRAM. IN FACT, WE HAVE SEEN AN INCREASE OF 500 PERCENT SINCE RONALD REAGAN TOOK OFFICE AND THE ANALYSIS OF THE INTERNAL DOCUMENT, ARMY DOCUMENT, SAYS, "WE CANNOT ASSESS WITH CONFIDENCE WHETHER THE ARMY ASSIGNED ADEQUATE PRIORITIES TO BIOLOGICAL DEFENSE COMPARED TO OTHER NEEDS."

WELL, IT SEEMS THAT THE MONEY TRAIL THAT IT INDICATES THAT YOU HAVE THROWN AN AWFUL LOT OF EMPHASIS ON THIS PROGRAM WITHOUT REALLY KNOWING WHERE IT IS GOING.

ANOTHER EVALUATION IN THIS PARTICULAR DOCUMENT IS THAT THERE IS NO INTEGRATION AND NO CONTROL, SO WHERE'S THE PROGRAM GOING. I DON'T THINK THAT ANYONE IN THE ARMY HAS BEEN ABLE TO ANSWER THAT QUESTION WITH REGARDS TO BL4 AS OPPOSED TO A BL3. I THINK THAT THE IMMEDIATE REACTION OF THE PUBLIC IS SO WHAT, YOU ARE GOING TO DO WHAT YOU WANT TO DO ANYWAY, AREN'T YOU, OUT HERE? AS LONG AS NO ONE GETS A CHANCE TO LOOK INTO IT, AS LONG AS YOU ARE DENYING REPORTERS THE OPPORTUNITY TO REVIEW DOCUMENTS, AS LONG AS YOU ARE FAILING TO RESPOND TO TWO SEPARATE FREEDOM OF INFORMATION REQUESTS BY DOWNWINDERS, ONE IN WHICH YOU DIDN'T EVEN GIVE US A LETTER BACK, THE OTHER WE ARE IN THE MIDDLE OF A BIG RUN-AROUND. I THINK WE HAVE TO QUESTION THE CREDIBILITY OF

THE PEOPLE WHO ARE IN CHARGE OF THIS PROGRAM. YOU KNOW, THE CREDIBILITY ISSUE IS CRITICAL OF ALL OF THIS AND I DIDN'T SEE IT ANYWHERE IN THE EIS. I THINK ANOTHER ISSUE THAT IS CRITICAL IS WHAT ABOUT THE MESS YOU HAVE ALREADY GOT OUT THERE? WHERE ARE YOUR ANTHRAX SPORES. THERE'S AN ISLAND OFF SCOTLAND THAT IS OFF LIMITS TO HUMAN BEINGS FOR THE NEXT 100 YEARS AND THAT'S BECAUSE THERE ARE ANTHRAX SPORES SPREAD ALL OVER BY BIOLOGICAL TESTS DONE BY THE BRITISH. IS DUGWAY OFF LIMITS? I DON'T THINK SO. I HAVE HEARD STORIES OF PEOPLE DRIVING PICKUP TRUCKS ACROSS THERE AND NEVER GETTING STOPPED. STORIES OF TRANSIENTS WANDERING FROM WENDOVER ALL THE WAY TO SALT LAKE CITY AND BEING STOPPED AT THE GATE ON THE EAST END GOING OUT OF THE DUGWAY PROVING GROUND AND OUR FREEDOM OF INFORMATION REQUEST, ALL WE WANTED TO KNOW IS WHERE IS YOUR CONTAMINATION?

NOW, I UNDERSTAND THAT YOU HAVE ABOUT $10 MILLION TO CLEAN IT UP, YOU DON'T EVEN KNOW WHERE TO START. WHAT KIND OF CONCLUSIONS ARE THE UTAH PUBLIC SUPPORT TO MAKE FROM THAT KIND OF TRACK RECORD?

NOW, ALL OF A SUDDEN WE ARE EXPECTED TO FEEL THAT THIS IS SAFE, THAT YOU ARE GOING TO GO AHEAD AND BILL OUT THE MONEY AROUND THE COUNTRY FOR VARIOUS LABORATORIES TO CLONE GERMS SO THAT YOU CAN SEE WHETHER THEY WILL GET THROUGH A GAS MASK. I THINK THIS ABSOLUTELY STRETCHES ANYONE'S CREDULITY AND I THINK THE ARMY HAS AN AWFUL LOT OF

EXPLAINING, NOT ONLY ON THE SUBJECT OF BL4 AND THE BL3 ISSUE, THAT'S AN IMPORTANT ONE, WE ARE REALLY PLEASED THAT YOU FOLKS HAVE COME TO YOUR SENSES, I'M SURE THAT A LITTLE BIT OF PUBLIC PRESSURE HAD SOMETHING TO DO WITH IT, BUT A BL3 OR A BL3 ISN'T GOING TO CUT IT AS LONG AS THAT OFFERS THE OPPORTUNITY FOR AEROSOLIZED TESTING OF PATHOGENS. THERE IS NO PARTICULAR REASON-- I HAVE NEVER HEARD A GOOD ARGUMENT OUT OF THE ARMY OF WHY YOU CAN'T USE ATTENUATED VIRUSES WHY YOU CAN'T USE SIMULANTS, AND ALL WE HEAR BACK IS IT IS NECESSARY THAT-- IT'S FOR NATIONAL SECURITY. THAT NO LONGER CUTS IT IN THIS UTAH PUBLIC. I THINK YOU SHOULD HAVE LEARNED YOUR LESSON, YOU SHOULD HAVE PAID ATTENTION TO HOW THE AIR FORCE HAD TO LEARN ITS WAY THROUGH THIS PARTICULAR GAME IN THE EARLY PART OF THE DECADE WITH THE MX. THIS KIND OF PERFORMANCE BY THE ARMY, I THINK, SHEDS A BAD LIGHT ON WHAT IS OTHERWISE A VERY IMPORTANT ASPECT OF THIS COUNTRY AND THAT IS NOT TO CAST DISPERSIONS OF THE ENTIRE U.S. ARMY. I DON'T WANT THAT IMPRESSION TO BE LEFT, BUT WITH YOUR PARTICULAR BEHAVIOR ON THIS BIOLOGICAL DEFENSE RESEARCH PROGRAM, YOU HAVE AN AWFUL LOT OF EXPLAINING TO DO, YOU HAVE SOME CLEANING UP OF YOUR FACILITY TO DO BEFORE YOU WILL BE ALLOWED BY THE PEOPLE OF THIS STATE TO PROCEED WITH ANY ADDITIONAL LABORATORY WHETHER IT'S A BL3, 4, OR WHATEVER YOU MIGHT CONCOCT AND WE INTEND TO STAY VERY CLOSELY ON TOP OF THIS. THERE IS ONE COMMENT THAT I WILL FINISH WITH. IN

THIS PARTICULAR DOCUMENT THAT SAYS, "HAD WE KNOWN OR HAD WE THOUGHT ABOUT THIS A LITTLE EARLIER, MAYBE IN HINDSIGHT, MAYBE WE WOULD HAVE DONE THINGS DIFFERENTLY AND WE WOULDN'T HAVE HAD ANY TROUBLE WITH THE BL4, BUT NOW THAT IT'S ALL OVER, WE WILL EVALUATE AND LEARN OUR LESSON." THE MESSAGE IS THAT IT ISN'T OVER BY A LONG SHOT. WE ARE GOING TO BE AROUND HERE, WE ARE GOING TO KEEP THE PRESSURE ON YOUR PEOPLE UNTIL WE SEE A CHANGE IN BEHAVIOR THAT IS ACCEPTABLE TO THE PEOPLE OF THIS STATE AND YOU ARE GOING TO HAVE YOUR HANDS FULL TRYING TO GET THE MONEY OUT OF THIS CONGRESS AS LONG AS WE HAVE A FEW PEOPLE WHO ARE WILLING TO STAND UP AND SAY NO TO A BIOLOGICAL ARMS RACE. THANK YOU.

MR. DASEY: THANK YOU, MR. ERICKSON. IT IS NOW 7:54, WE WILL TAKE A 10-MINUTE BREAK.

(RECESS TAKEN.)

MR. DASEY: OUR NEXT SPEAKER IS JAY TRUMAN FROM DOWNWINDERS.

MR. TRUMAN: I WOULD LIKE TO MAKE A COUPLE OF POINTS ABOUT THE PROCESS THAT HAS GONE ON IN DISCUSSING WHAT THE FUTURE OF THE BIOLOGICAL PROGRAM IS GOING TO BE.

THE MAIN COMMENT I WOULD LIKE TO MAKE, AND I THINK CANNOT BE IGNORED A LITTLE TOO MUCH, IS THAT WE HAVE HEARD A LOT THE LAST FEW MONTHS ABOUT NEW OPENNESS IN THE ARMY, NEW CONCERNS FOR THE FEELINGS AND SENTIMENTS OF THE PUBLIC AND NOW THE ARMY IS TRYING VERY HARD TO ALLOW THE PUBLIC TO

HAVE ITS APPROPRIATE INPUT. I THINK THAT'S WHAT'S WRONG WITH THE WHOLE PROCESS THAT WE ARE HERE TONIGHT AS PART OF. AND THAT IS THAT THE PROCESS IS A LITTLE MORE THAN A MESS. I THINK IT'S IMPORTANT TO REALIZE THAT THE DUGWAY FACILITY WAS PROPOSED AND ORIGINALLY PLANNED, AND THERE WOULD HAVE BEEN NO HEARING OUT HERE FOR THE PUBLIC T HAVE ANY KIND OF INPUT. THE ONLY REASONS WE HAD HEARINGS IS BECAUSE YOU GOT YOURSELVES INTO COURT AND A FEDERAL JUDGE SAID YOU HAD TO MEET CERTAIN CONDITIONS AND ONE OF THOSE WAS TO ALLOW THE PUBLIC TO HAVE ITS INPUT.

I KNOW IT'S ALSO IMPORTANT TO REALIZE THAT ONE OF THE REASONS WE ARE HERE TONIGHT IS NOT BECAUSE THE ARMY IS CONCERNED ABOUT WHAT THE RESIDENTS OF THE STATE HAVE TO SAY ABOUT YOUR OVERALL BIOLOGICAL PROGRAM, BUT BECAUSE A FEW POLITICIANS IN THIS STATE DEMANDED THAT YOU HOLD SOME HEARINGS, AND IT WOULD HAVE BEEN BAD PUBLIC RELATIONS FOR YOU TO DO OTHERWISE AND I THINK THAT-- ANOTHER POINT THAT I THINK IS VERY RELEVANT, AND THAT IS THE WHOLE QUESTION OF YOUR CREDIBILITY. I AM A LIFE-LONG RESIDENT OF THIS STATE AND ONE OF THE FIRST THINGS I REMEMBER SAYING, I DIDN'T LIKE KINDERGARTEN CLASS IN A LITTLE TOWN CALLED ENTERPRISE, AND WATCHING A PANEL IN UNIFORMS AND MEDALS TELL US WHY WE HAD TO PUT UP WITH NUCLEAR TESTING NEXT DOOR IN NEVADA AND HOW SERIOUS THAT WAS AND HOW WITHOUT IT THE RUSSIANS WOULD BE HERE IN THE MORNING AND WE WOULD

ALL BE DEAD. SOME 30 YEARS LATER THE RUSSIANS STILL AREN'T HERE AND A HELL OF A LOT OF US ARE DEAD. THE PHRASE THERE IS NO DANGER IS AN APPROPRIATE EPITAPH TO PUT ON A LOT OF UTAH HEADSTONES AND WE HERE TONIGHT HAVE THAT. IT'S SUCH A VICTORY THAT THE ARMY WILL GIVE US A BL3 INSTEAD OF A BL4, BUT IT REALLY DOESN'T MATTER WHAT YOU GIVE US. IT'S NOT GOING TO CHANGE MUCH. A LOT OF THE PEOPLE SAY THIS IS A GREAT VICTORY FOR THE RESIDENTS OF THE STATE OF UTAH. WHAT VICTORY AND FOR US OR FOR YOU? IT'S NOT EVEN GOING TO BE THE PUBLIC RELATIONS TRIAD AS YOU FIGURED IT IS. THE PUBLIC CONCERN ABOUT DUGWAY IS Not BASED ON YOUR FACILITY THAT YOU ARE PROPOSING TO BUILD. THE CONCERN OVER DUGWAY IS BASED ON A THREE DECADE LONG LEGACY OF LIES AND DECEIT BY THE UNITED STATES GOVERNMENT AND DEFENSE INDUSTRY TO THE CITIZENS OF THIS STATE.

THE WORDS ABOUT HOW THE BL3 FACILITY WILL PROVIDE ENOUGH SAFETY AND HOW THERE WILL NEVER BE ANY BL4 WORK DONE IS A LITTLE MORE THAN IDLE WORDS AND BROKEN PROMISES. THE SAME TYPES THAT HAVE GREETED UTAHNS WITH EACH NEW DEADLY DEFENSE PROGRAM OVER THE LAST THREE DECADES. WHAT WE HAVE BEEN ASKED FOR THOSE THREE DECADES, TO GIVE OUR SUPPORT AND TO BE PATRIOTIC AMERICANS AND TO SUPPORT WHAT IS NEEDED TO PROTECT THIS COUNTRY AND WHAT HAVE WE GOT FOR OUR PATRIOTISM AND SUPPORT, WE'VE BEEN A-BOMBED, NERVE GASSED AND WE'VE BEEN LIED TO, AND WHEN WE HAVE BEEN HURT BY YOUR PROGRAMS,

WE HAVE WATCHED YOU QUICKLY AND RAPIDLY FIRST DENY THAT YOU HAD ANYTHING TO DO WITH IT AND THEN SMILINGLY INFORM US THAT YOU ARE IMMUNE FROM ANY AND ALL ACCOUNTABILITY.

TODAY, SADLY, NOTHING HAS CHANGED. WHAT DIFFERENCE DOES IT MAKE? A CONTAINMENT LEVEL ON A BUILDING DOES NOT ALTER A TRACK RECORD OF LIES AND DECEITS. THE ONLY PROTECTION THE PUBLIC HAS IN ANY REALITY IS THEIR OPPOSITION TO YOUR DEADLY PROPOSAL. PUBLIC OPPOSITION HAS FORCED YOU TO DOWNGRADE YOUR FACILITY TO A BL3 LEVEL. YOU WERE RUNNING SCARED FROM PUBLIC OPPOSITION. IT IS OUR SINCERE HOPE THAT YOU WILL CONTINUE TO KEEP RUNNING BACK TO WASHINGTON, D.C. WE HAVE BEEN HELPLESS GUINEA PIGS IN YOUR DEADLY EXPERIMENTS LONG ENOUGH. ENOUGH IS ENOUGH. THANK YOU.

MR. DASEY: THANK YOU, MR. TRUMAN. ONCE AGAIN, WE ARE DISCUSSING THE DRAFT ENVIRONMENTAL IMPACT STATEMENT ON THE BIOLOGICAL DEFENSE RESEARCH PROGRAM AND NOT THE SPECIFIC PROPOSAL TO BUILD THE NEW LAB AT DUGWAY. THE NEXT SPEAKER IS DR. KEN BUCHI FROM THE ENVIRONMENTAL HEALTH COMMITTEE OF THE UTAH STATE MEDICAL ASSOCIATION.

DR. BUCHI: THANK YOU, MR. DASEY, DR. OSTERMAN AND MEMBERS OF THE PANEL.

THE ENVIRONMENTAL HEALTH COMMITTEE OF THE UTAH MEDICAL ASSOCIATION WOULD FIRST LIKE TO EXTEND OUR THANKS TO YOU FOR AGREEING TO HOLD THIS HEARING. WE THINK IT'S VERY IMPORTANT THAT THE PEOPLE OF UTAH HAVE A CHANCE TO GIVE

YOU THEIR VIEWS OF THIS OVERALL PROGRAM. I DO HAVE A PREPARED STATEMENT THAT I WOULD JUST LIKE TO READ FOR YOU THAT HAS BEEN DEVELOPED BY THE ENVIRONMENTAL HEALTH COMMITTEE.

OUR COMMITTEE HAS REVIEWED THE DRAFT ENVIRONMENTAL IMPACT STATEMENT OF THE DEVELOPMENT OF THE ARMY'S BIOLOGICAL DEFENSE RESEARCH PROGRAM, AS WELL AS THE REPORT TO THE UNITED STATES SENATE SUBCOMMITTEE ON OVERSIGHTS OF GOVERNMENT MANAGEMENT MAJORITY STAFF REPORT REGARDING THE DEPARTMENT OF DEFENSE'S SAFETY PROGRAMS FOR CHEMICAL AND BIOLOGICAL WARFARE RESEARCH.

AFTER REVIEWING THESE DOCUMENTS, WE HAVE SOME SERIOUS CONCERNS WITH WHICH WE FEEL MUST BE MORE THOROUGHLY ADDRESSED AND/OR MODIFIED TO HELP ASSURE THAT UNFORESEEN AND TRAGIC CONSEQUENCES WILL NOT ARISE FROM THE OPERATIONS OF THE BDRP. OUR MAJOR CONCERN REGARDING THE PROGRAMMATIC DEIS RELATES TO THE PROPOSED AND DISCUSSED ALTERNATIVES WHICH, AS WE HEARD EARLIER TONIGHT, ARE LIMITED TO, NUMBER ONE, CONTINUE THE BDRP UNCHANGED, WHICH HAS BEEN IDENTIFIED AS THE PREFERRED ALTERNATIVE, OR, NUMBER TWO, TERMINATE THE BDRP. THE DEIS RIGHTFULLY POINTS OUT MANY OF THE BENEFITs WHICH ACCRUE FROM THE CONTINUATION OF THE BDRP NOT THE LEAST OF WHICH IS, AND I QUOTE FROM THE REPORT, "THE DEPARTMENT OF DEFENSE CANNOT IGNORE COMPLETELY THE POSSIBILITY THAT BIOLOGICAL WARFARE THREATS EXIST AND FAIL TO

PROVIDE ANY DETERRENTS TO THEIR POTENTIAL APPLICATION." THIS ALONE IS A STRONG ARGUMENT WHICH WE COMPLETELY AGREE. HOWEVER, IF THE ONLY OTHER POSSIBLE OPTION IS TO ELIMINATE THE BDRP, WITH US LOSING ALL CAPABILITIES TO MAINTAIN AN ADEQUATE DEPARTMENT OF THE ARMY HAS UNJUSTIFIABLY ELIMINATED THE OPPORTUNITY FOR PUBLIC INPUT AND DISCUSSION OF THE OVERALL SAFETY OF THE PROGRAM AND MEANS BY WHICH THE PROGRAM CAN STILL CONTINUE, BUT WITH ADEQUATE SAFEGUARDS FOR THE PUBLIC HEALTH. WE ARE ALSO PARTICULARLY CONCERNED WITH THE ATTITUDE EXPRESSED THROUGHOUT THE DEIS, THAT OPPOSITION TO THE BDRP, AS CURRENTLY OPERATIVE, IS BASED MORE ON PUBLIC PERCEPTION OF RISK THAN ON TRUE RISK. IN FACT, THE PROBLEM SEEMS TO BE MORE ONE OF HOW DO WE ASSESS AND QUANTIFY THESE POTENTIAL RISKS IN ORDER TO COMPARE THEM TO THE MORE EASILY QUANTIFIED BENEFITS. THE ATTITUDE APPEARS THROUGHOUT THE STATEMENT THAT THOSE WHO QUESTION THE SAFETY OF THE PROGRAM ARE OPERATING ON MISINFORMATION, EMOTION, IGNORANCE OR OTHER LESS THAN ADMIRABLE MOTIVES.

AN ENTIRE APPENDIX IS DEVOTED TO EXPLAINING THE MEANS BY WHICH MOST OF THE RELEVANT SAFETY CONCERNS WERE ABLE TO BE CATEGORIZED AS NOT SIGNIFICANT, SO THAT THEY DID NOT NEED TO BE ADDRESSED. WHILE ONLY ONE PARAGRAPH WAS USED TO DISCUSS THE OPTIONS OF CONTINUING THE DEFENSIVE STUDIES OF THE BDRP USING SIMULATE OR LOW PATHOGENICITY ORGANISMS.

OUR OTHER DEPARTMENTS OF THE ARMY'S GROUP OF EXPERT PROFESSIONALS ARE CONFIDENT THAT LITTLE OR NO SAFETY HAZARDS EXIST AND THAT ADEQUATE SAFETY AND REGULATORY CONTROLS DO EXIST AND ARE IN PLACE TO ASSURE THAT NO ACCIDENTS WILL HAPPEN.

THE SENATE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT APPARENTLY DOES NOT AGREE AND WE HAVE HEARD ABOUT THAT ALREADY TONIGHT. AS WE POINTED OUT IN AN EARLIER STATEMENT REGARDING THE BIOLOGICAL AEROSOL TEST FACILITY PROPOSED FOR THE DUGWAY PROVING GROUND, WE ALSO CONTINUED TO BE CONCERNED WITH AN APPARENT LACK OF ADVANCE PLANNING FOR THE MANAGEMENT OF THE POTENTIAL RELEASE OR ORGANISMS OR TOXINS INTO THE ENVIRONMENT. WE ARE IMPRESSED WITH AND COMMEND THE ARMY ON AN IMPRESSIVE SAFETY RECORD IN THE TESTING AND HANDLING OF THESE AGENTS OVER MANY YEARS OF BOTH OFFENSIVE AND DEFENSIVE RESEARCH.

AS OUTLINED IN APPENDIX A OF THE DEIS, HOWEVER, AS IS CLEARLY OUTLINED IN TABLE AS3, IN THAT APPENDIX THIS SAFETY RECORD IS NOT PERFECT NOR ALL THE ACCIDENTS IN THE REMOTE HISTORY -- REMOTE PAST.

FINALLY, AGAIN IN THE SPIRIT OF PUBLIC SAFETY, NOT JUST IN UTAH BUT THROUGHOUT THE UNITED STATES, WE ARE CONCERNED ABOUT THE ENTIRE SCOPE AND DIRECTION WHICH THE BDRP HAS TAKEN OVER THE PAST FEW YEARS. THE UNITED STATES HAS FORMALLY RENOUNCED THE USE OF BIOLOGICAL WARFARE AGENTS

SINCE 1969 AND JOINED WITH MORE THAN 100 OTHER NATIONS IN SIGNING THE 1972 BIOLOGICAL WEAPONS CONVENTION WHICH PROHIBITS ANY STOCKPILING OF OR OFFENSIVE RESEARCH OF BIOLOGICAL WARFARE AGENTS. WE DO BELIEVE THAT THE DEPARTMENT OF THE ARMY HAS NO CURRENT PLANS FOR OFFENSIVE BIOLOGICAL WARFARE RESEARCH. HOWEVER, SPENDING ON BIOLOGICAL WARFARE RESEARCH HAS INCREASED FROM $63.5 MILLION IN FISCAL 1980 TO $348 MILLION IN FISCAL 1986. WE FEEL THAT THE JUSTIFICATION GIVEN FOR THIS MASSIVE INCREASE IS NOT VALID AND WE FEAR THAT OTHER NATION WHEN VIEWING OUR GREATLY INCREASED ACTIVITY, WILL RESPOND I TIME AND SET OFF A NEW ROUND OF ARMS ESCALATION.

WE FEEL THAT MUCH OF THE DEFENSIVE NATURE OF THE BDRP CAN BE CONTINUED BY TESTING DETECTION AND PROTECTION DEVICES USING LOW PATHOGENICITY, SIMULATE ORGANISMS. WE ALSO FEEL THAT THE VACCINATION PROGRAMS COULD BE MAINTAINED PERHAPS, UNDER THE GUISE OF OTHER RESEARCH INSTITUTES, BOTH OF THESE COULD CONTINUE WITHOUT THE INCREASED RISK OF INDUCING FEAR AND SUSPICION AMONG THE WORLD COMMUNITIES WHO LOOK TO US FOR GUIDANCE AND LEADERSHIP IN MORAL, AS WELL AS, MILITARY MANNERS.

WITH ALL OF THIS IN MIND, THEN, THE ENVIRONMENTAL HEALTH COMMITTEE OF THE UTAH MEDICAL ASSOCIATION WOULD LIKE TO GO ON RECORD WITH THE FOLLOWING RECOMMENDATIONS CONCERNING THE DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT OF THE

BIOLOGICAL DEFENSE RESEARCH PROGRAM AND CONCERNING THE BDRP ITSELF.

FIRST, A FINAL ENVIRONMENTAL IMPACT STATEMENT MUST INCLUDE A COMPROMISE ALTERNATIVE OR ALTERNATIVES TO CONTINUING THE PROGRAM AS IS VERSUS TERMINATION OF THE PROGRAM ENTIRELY. MANY QUALIFIED SCIENTISTS FEEL THAT THERE IS NO ADEQUATE JUSTIFICATION FOR THE USE OF ACTUAL BIOLOGICAL WARFARE AGENTS FOR CONDUCTING TESTS OF DETECTION AND PROTECTION DEVICES SINCE LOW PATHOGENICITY SIMULATE ORGANISMS CAN BE USED WITH EQUAL OR IMPROVED EFFICACY. THUS, THE USE OF SIMULANT ORGANISMS, PARTICULARLY FOR ANY AEROSOL TESTING, SHOULD BE VALID MEANS BY WHICH OUR CONCERNS FOR PUBLIC SAFETY CAN BE BALANCED WITH OUR CONCERNS FOR A STRONG NATIONAL DEFENSE.

SECOND, ALTHOUGH THE POTENTIAL FOR ACCIDENTAL RELEASE OR EXPOSURE TO SURROUNDING COMMUNITIES IS ADMITTEDLY VERY SMALL, THE CONSEQUENCES OF SUCH AN EVENT COULD BE DISASTROUS. BUT AS WE STATED IN OUR PRIOR RECOMMENDATIONS REGARDING THE PROPOSED BATF AT THE DUGWAY PROVING GROUND, THE BDRP MUST HAVE IMPROVED PLANS FOR MANAGING SUCH A RELEASE. IT MUST ALSO INCORPORATE A CIVILIAN SCIENTIFIC SURVEILLANCE COMMITTEE WHICH SHOULD INCLUDE NUMBERS OF THE ACADEMIC BIOLOGY RESEARCH COMMUNITY, THE NATIONAL ACADEMY OF SCIENCES, THE NATIONAL INSTITUTES OF HEALTH, THE CENTERS FOR DISEASE CONTROL, AND MEMBERS FROM THE LOCAL MEDICAL

ASSOCIATIONS AND STATE HEALTH DEPARTMENTS IN AREAS WHERE MAJOR BDRP ACTIVITIES ARE CARRIED OUT.

THIRD, ANY ALLEGATIONS OF NONADHERENCE TO THE 1972 BIOLOGICAL WEAPONS CONVENTION SHOULD BE TURNED OVER TO AN APPROPRIATE INTERNATIONAL AGENCY, THE UNITED NATIONS SECURITY COUNCIL, AS PROVIDED FOR IN ARTICLE 6 OF THAT TREATY FOR OPEN INVESTIGATION. IT IS UNFAIR AND UNJUST TO MAKE SUCH ALLEGATIONS AS JUSTIFICATION FOR INCREASED BIOLOGICAL WARFARE RESEARCH ACTIVITIES YET TO REFUSE TO BACK UP THOSE ALLEGATIONS BY CLAIMING THAT THE INFORMATION TO DO SO IS CLASSIFIED.

AND FINALLY, THE TERMS OF THE 1972 BIOLOGICAL WEAPONS CONVENTION SHOULD BE REVIEWED AND STRENGTHENED, PARTICULARLY IN LIGHT OF NEW CAPABILITIES FOR GENETICALLY ENGINEERING BIOLOGICAL WARFARE AGENTS AND ORGANISMS. WE MUST NOT LOSE THE VALUABLE START TOWARDS THE ELIMINATION OF AN ENTIRE MEANS OF WAGING WAR AGAINST OUR FELLOW MAN SIMPLY BECAUSE WE CONTINUE TO AMPLIFY MISTRUST OUT OF FEAR OR IGNORANCE.

THANK YOU VERY MUCH FOR THE OPPORTUNITY TO COMMENT ON THE ARMY'S BIOLOGICAL DEFENSE RESEARCH PROGRAM. WE APPRECIATE THE CHANCE TO WORK WITH YOU TOWARDS ENSURING THAT WE CAN MAINTAIN A STRONG NATIONAL DEFENSE, BUT NOT AT THE EXPENSE OF THE HEALTH AND SAFETY OF THOSE WHO LIVE AND WORK IN PROXIMITY TO THE DEFENSE PROGRAM. WE HAVE AN OBLIGA-

TION TO ENSURE THAT THE ENVIRONMENTAL AND PUBLIC HEALTH TO THE PEOPLE OF THE STATE OF UTAH IS OF FOREMOST CONSIDERATION IN ANY DISCUSSIONS AND MANAGEMENT OF THESE PROGRAMS AND WE WILL CONTINUE TO WORK WITH YOU TOWARDS THAT. THANK YOU.

MR. DASEY: THANK YOU, DR. BUCHI. THE NEXT SPEAKER WILL BE DR. WILLIAM SAYRES FROM THE PHYSICIANS FOR SOCIAL RESPONSIBILITY.

DR. SAYRES: I THINK DOCTORS HAVE A PUBLIG-SPEAKING PROBLEM WITH PREPARED COMMENTS. THERE ARE SOME GENERAL CONCERNS WHICH BECAME APPARENT TO ME UPON READING THE BDRP DEIS THE TONE OF THE REPORT IS NOTHING LESS THAN CONDESCENDING, ESPECIALLY IN THE DISCUSSION OF THE MORE CONTROVERSIAL ASPECT OF THE PROGRAM. WE ARE LED TO BELIEVE THAT PUBLIC PERCEPTION OF RISK IS FAR WORSE THAN REALTY WHEN, IN FACT, MANY OF THESE CONCERNS ARE BROUGHT FORWARD BY INFECTIOUS DISEASE AND GENETIC SPECIALISTS. WE ARE ALSO LED TO BELIEVE THAT RESISTANCE TO THE BDRP IS FOCUSED WITHIN, QUOTE, "CERTAIN SEGMENTS," UNQUOTE, OF THE POPULATION AS IF CONCERNED INDIVIDUALS WERE SOMEHOW DIFFERENT FROM OTHER AMERICANS.

I DOUBT THAT GOVERNOR BANGERTER, WHO EXPRESSED SEVERAL CONCERNS ABOUT THE BDRP, WOULD AGREE WITH THIS STATEMENT.

THROUGHOUT THE REPORT, RESEARCH WITH THESE DANGEROUS PATHOGENS IS DESCRIBED AS ROUTINE WHEN, IN FACT, THESE ORGANISMS ARE HIGHLY INFECTIOUS AND CAN CAUSE SERIOUS

DISEASE. IT IS MY VIEW THAT THIS TONE STIFLES THE FREE EXCHANGE OF IDEAS AND THEREFORE DEFEATS THE PURPOSE OF THE DEIS. FREE DISCUSSION OF ALTERNATIVES IS ALSO INHIBITED BY THE FACT THAT ONLY TWO ALTERNATIVES, THE TOTAL PROGRAM OR NOTHING, ARE DISCUSSED IN THE DEIS.

IT IS LAUDABLE THAT THE BDRP DEIS DELEGATES AS MUCH SPACE AS IT DOES TO THE DISCUSSION OF THE HISTORY OF ACCIDENTS WITHIN THE PROGRAM. IT IS INDEED SOBERING TO READ THAT THREE DEATHS RESULTED FROM EARLY RESEARCH IN THIS AREA AMONG LAB WORKERS. THE GREAT MAJORITY OF INCIDENTS OCCURRED DURING THE DEVELOPMENT AND EARLY OPERATIONAL STAGES OF THE PROGRAM AT FORT DETRICK. WITH THE DEVELOPMENT OF IMPROVED TECHNOLOGY AND THE RECENT SAFETY RECORD OF THE PROGRAM HAS BEEN GOOD. I AM NOT REASSURED, HOWEVER, THAT THIS GUARANTEES A CONTINUED SAFE RECORD. THE BDRP IS, AGAIN, IN THE DEVELOPMENTAL PHASE WITH THE INFUSION OF HUGE AMOUNTS OF MONEY INTO THE PROGRAM.

I WILL ADDRESS THE REMAINDER OF MY COMMENTS TO THE SPECIFIC TESTING PROCEDURES, AS DISCUSSED. A RECENT WASHINGTON POST ARTICLE DESCRIBED HOW THE ARMY WAS GOING TO, QUOTE, "TAKE AWAY THE MYSTERY," UNQUOTE, OF THE BDRP THROUGH MORE EFFECTIVE PUBLIC RELATIONS. LET ME ALSO DEMYSTIFY A LITTLE THE ORGANISMS WITH WHICH THE ARMY PROPOSES TO EXPERIMENT. THESE ORGANISMS ARE BAD NEWS. THEY'RE EASILY AEROSOLIZED AND ARE EXTRAORDINARILY ROBUST; ANTHRAX SPORES

HAVE BEEN SHOWN TO LAST OVER 20 YEARS, ESPECIALLY IN THE DRY DESERT SOIL CONDITIONS WHICH ARE FOUND AT DUGWAY. THEY ARE EXTREMELY INFECTIOUS WITH ONE ORGANISM, IN SOME CASES, ALL THAT IS NEEDED TO CAUSE DISEASE. THE DISEASES RANGE FROM MILD WITH SOME STRAINS OF TULAREMIA TO THE UNIFORMLY FATAL PULMONARY ANTHRAX, WITH ITS VICTIM DYING OF PULMONARY HEMORRHAGE.

THE THREE POTENTIAL AREAS OF CONCERN WHICH ARISE FROM READING THE DEIS ARE AEROSOL RELEASED INTO THE ATMOSPHERE, EXPOSURE OF AN ANIMAL VECTOR, AN EXPOSURE OF A LABORATORY WORKER TO AN ORGANISM. BEFORE DISCUSSING THESE POSSIBILITIES INDIVIDUALLY, IT IS APPROPRIATE TO MENTION THAT IN SPITE OF THE MOST ADVANCED CONTAINMENT TECHNOLOGY, QUOTE, "THERE IS NO SUBSTITUTE FOR GOOD TECHNIQUE," UNQUOTE. THIS IS A LETTER WRITTEN FOR THIS STATEMENT. THIS MEANS THAT EVERYTHING DISCUSSED IS SUBJECT TO HUMAN ERROR.

ALTHOUGH FAULT BY THE PREPARERS OF THE DEIS TO BE TOO SMALL TO WARRANT EVEN A CONTINGENCY PLAN, A REVIEW OF THE PRELIMINARY HAZARD ANALYSIS, IN APPENDIX 4 OF THE DUGWAY REPORT, AND I THINK IT APPLIES TO THIS BECAUSE IT DOES REFER TO THE TESTING, THE TESTING PROCEDURES THAT WERE DONE, REVEALS THAT PHYSICAL DAMAGE TO THE BUILDING, EXPANSION AND CONTRACTION OF THE BUILDING AND ITS ELECTRICAL SYSTEM WOULD CAUSE A, QUOTE, "CATASTROPHIC," UNQUOTE, RELEASE OF PATHOGENS, QUOTE, "SOMETIME IN THE LIFE OF THE SYSTEM,"

UNQUOTE.

WE ARE SURE THAT THERE IS NATURAL BARRIERS TO THE SPREAD OF THESE PATHOGENS. THIS IS, IN FACT, NOT THE CASE. THE WEATHER, IN SPITE OF AVERAGES, CAN BE ANYTHING BUT BENIGN. THE DRY DESERT SOIL IS IDEAL FOR THE SPORES OF ANTHRAX; IN FACT, THERE CONTINUES TO EXIST A SOURCE OF ANTHRAX SPORES NOT FAR FROM DUGWAY ORIGINATING FROM A CATTLE DRIVE IN THE LATE 1800'S. "Q" FEVER -- AND I WONDER IF WE ARE NOT GOING TO LOOK BACK IN 100 YEARS AND SAY, THERE'S THAT ANTHRAX COLLECTION LEFT OVER FROM THE DUGWAY EXPERIMENTS EARLIER ON. "Q" FEVER, IF MY READING IS CORRECT, WAS DISCOVERED IN UTAH AND NUMEROUS VECTORS EXIST FOR TULAREMIA AS WELL. THE EXECUTIVE SUMMARY OF THE DEIS DOES NOT EVEN MENTION THE HUGE POPULATIONS OF ARTHROPODS WHICH CONSERVE RESERVOIRS FOR DISEASE.

FOR SEVERAL REASONS, THE PRELIMINARY HAZARD ANALYSIS LISTS AS, QUOTE, "PROBABLY," UNQUOTE. THE POTENTIAL FOR THE ENTRANCE OF ENTOMOLOGICAL OR SMALL ANIMAL PENETRATION NOT ONLY INTO THE OUTER BUILDING, BUT ALSO INTO THE INNER BUILDING. THIS COMES AS NO SURPRISE TO THOSE OF US WHO SEE FLIES IN THE HOSPITAL INTENSIVE CARE UNIT. AS THE ANALYSIS SUGGESTS, THIS WOULD BE A CRITICAL EVENT. THERE IS, HOWEVER, NO CONTINGENCY PLAN FOR THIS EVENT IN THE DEIS.

THE MOST LIKELY VECTOR FOR THE ESCAPE OF ORGANISMS

FROM THE LAB WOULD BE MAN HIMSELF AND THIS IS GIVEN ELABORATE ATTENTION IN THE DEIS. EXPOSURE THROUGH A RIP IN THE SAFETY SUIT OR ACCIDENT IN THE BIOSAFETY CABINET ARE RATED AS, QUOTE, "CRITICAL EVENTS," WHOSE OCCURRENCE WOULD BE, QUOTE, "FREQUENT TO PROBABLE," UNQUOTE. ALTHOUGH VACCINATIONS AND TREATMENT PLANS ARE OUTLINED, LITTLE CONSIDERATION IS GIVEN TO THE CONCEPT OF LATENT INFECTION. AS OPPOSED TO THE IMMEDIATE ONSET OF SYMPTOMS WHEN ONE IS EXPOSED TO A TOXIN, SYMPTOMS FROM INFECTION MAY NOT OCCUR UNTIL DAYS OR WEEKS AFTER EXPOSURE. THIS CAN BE COMPARED TO INFECTION WITH HUMAN IMMUNODEFICIENCY VIRUS, AIDS TO MOST OF US, DURING WHICH ONE MAY HARBOR THE VIRUS FOR MONTHS BEFORE THE INFECTION MANIFESTS ITSELF. THIS CONCEPT IS IMPORTANT AS LAB WORKERS MAY EXPOSE OTHER INDIVIDUALS BEFORE THEY KNOW THEY HAVE BEEN INFECTED THEMSELVES. ALTHOUGH THE CONTINGENCY OF LAB WORKER INFECTION HAS BEEN ADDRESSED, THE PLANS DO NOT DEAL WITH THE POSSIBILITY OF LATENT INFECTION.

WITH THESE CONSIDERATIONS IN MIND, I FEEL THAT IT IS REASONABLE TO CONCLUDE THAT, ONE, THE EXPERIMENTAL ORGANISMS ARE EXTREMELY DANGEROUS, EVEN THOUGH ONE IS GIVEN THE IMPRESSION IN THE DEIS OF, QUOTE, "ROUTINE," UNQUOTE, BL3 EXPERIMENTS. TWO, THE NATURAL AND PHYSICAL ENVIRONMENT SURROUNDING DUGWAY PROVING GROUND IS NOT ONLY NOT HOSTILE TO THESE ORGANISMS, BUT ACTUALLY FAVORABLE TO THEIR SURVIVAL IN MANY CASES. THREE, VECTOR AND AEROSOL RELEASE OF THESE

ORGANISMS MAY BE MORE PROBABLE THAN IS IMPLIED IN THE DEIS. FOUR, EXPOSURE OF LAB WORKERS TO THESE ORGANISMS IS PROBABLE BUT THE CONCEPT OF LATENT INFECTION IS NOT ADDRESSED IN THE DEIS. FIVE, ALL SAFETY MECHANISMS ARE DEPENDENT ON HUMAN PERFORMANCE AND THAT HUMAN ERROR HAS BEEN AT THE ROOT OF MANY DISASTERS IN THE PAST.

FINALLY, VIS-À-VIS THE PROGRAM AS A WHOLE, IT IS MY VIEW THAT OVERSIGHT SHOULD BE THROUGH THE NIH OR ANOTHER INDEPENDENT AGENCY. JUST AS PHYSICIANS HAVE SHOWN THAT THE, CAN ONLY POORLY POLICE THEMSELVES, THE POSSIBILITY OF A CONFLICT OF INTEREST MAKES IT UNLIKELY THAT THE ARMY CAN MONITOR THIS PROGRAM IN AN UNBIASED FASHION. THE CAVALIER TONE OF THE DEIS'S, BOTH OF THEM, IN FACT, IN DISCUSSING EXPERIMENTS OF EXTRAORDINARY NATURE, ONLY SERVES TO REINFORCE THE CONCERN.

IT IS CERTAIN THAT MEDICAL KNOWLEDGE WILL BE ADVANCED BY THESE EXPERIMENTS, ALBEIT IN AN INDIRECT MANNER. I WOULD PROPOSE THAT THIS MONEY BE DEDICATED TO ELIMINATE FAR MORE CONCRETE PROBLEMS THAN POTENTIAL ENEMY ATTACK. FOR EXAMPLE, A VERY HIGH RATE OF SMALL BABIES IN THIS COUNTRY, RANKING ABOUT 15TH IN THE WORLD, OR THE CURRENT AIDS EPIDEMIC, TO TAKE AN EXAMPLE FROM THE INFECTIOUS DISEASE REALM.

THE BDRP AND, IN PARTICULAR, THE CONSTRUCTION OF THE BL3 LAB, IN PARTICULAR, HAS IMMENSE INTERNATIONAL

SIGNIFICANCE. PERHAPS THESE CONSIDERATIONS SHOULD PLAY A MORE ESSENTIAL ROLE IN THESE DISCUSSIONS, AS WELL. THANK YOU .

MR. DASEY: THANK YOU, DR. SAYRES. THE NEXT SPEAKER WILL BE DR. FRED GOTTLIEB.

DR. GOTTLIEB: UNFORTUNATELY I JUST RECEIVED THE STATEMENTS LAST NIGHT AND IN PLOWING THROUGH THEM IT GOT TO BE FAIRLY HEAVY READING AND I DIDN'T GET TIME TO PREPARE A STATEMENT AS I FELL ASLEEP WITH THE DATA.

ONE OF THE THINGS THAT I WANTED TO DO WAS, BRIEFLY TO MAKE SOME COMMENTS ABOUT THE DATA THAT WAS IN HERE REGARDING THE PROPOSED ORGANISMS TO BE TESTED. WHAT I FOUND IS -- I AM ALSO AN INSTRUCTOR IN INFECTIOUS DISEASES AND SO I FELT FAIRLY CONFIDENT IN READING SOME OF THIS. SOME OF THE ORGANISMS THEY WERE TALKING ABOUT WERE ANTHRAX AND IN THE ARMY STATEMENT THEY SAID THAT WHAT MADE IT SAFE WAS THE RELATIVE HUMIDITY IN THE DESERT, BUT IF IT'S LESS THAN 20 TO 40 PERCENT, IT BECOMES-- IT'S NO LONGER A PRODUCTIVE ORGANISM. THAT PRECISELY THE RELATIVE HUMIDITY BELOW 20 PERCENT WHEN IT BECOMES A SPORULATING ORGANISM WHICH MAKES IT MORE VIRULENT WHEN IT GETS TO PEOPLE. SO, PRECISELY IN THE DATA, WHAT MADE IT MORE SAFE IS WHAT I WOULD SUGGEST WHAT MADE IT MORE RISKY.

IN TERMS OF THE DATA REGARDING FRANCISCELLA TULAREMIA, THIS IS A DISEASE THAT IS MOST COMMONLY SPREAD

THROUGH RABBITS AND WE KNOW THERE ARE NO RABBITS IN UTAH.

THE NEXT THING IS DISCUSSION OF YERSINIA PESTIS, OR COMMONLY KNOW TO US AS THE PLAGUE. IN REVIEW OF THE ARMY'S LITERATURE, WHAT THEY TALKED ABOUT AS THE VECTORS WAS MAMMALS. THAT IS NOT THE CASE, THE VECTORS ARE TICKS AND LICE. AND IN THE ARMY'S -- IN THEIR REPORTS ON DATA, THEY HAVE SAID THAT IT WAS VERY PROBABLE THAT SOME LICE AND TICKS MAY GET INTO THE TESTING AREAS.

WHAT I FEEL AND UNDERSTAND IS IN TERMS OF AEROSOLIZED TESTING. IF SOME OF THE ORGANISMS, SUCH AS COXIELLA OR "Q" FEVER, IF ONE ORGANISM CAN BE INFECTIOUS AND THE FATALITY RATE CAN BE UP TO 100 PERCENT, HOW DO YOU CONTROL AN AEROSOLIZED TESTING. YOU CAN'T JUST TAKE THE AIR THAT THIS IS IN, REGARDLESS OF WHERE IT IS, AND SUCK IT UP IN A BOTTLE AND SEND IT AWAY SOMEWHERE. I JUST FAIL TO UNDERSTAND HOW ONE ORGANISM IN AN AEROSOLIZED TEST CAN BE CONTROLLED.

AND FINALLY, YOU KNOW, CERTAINLY IN TERMS OF SOME OF THE THINGS THAT DR. SAYRES MENTIONED, SOME OF THE LATENT INFECTIONS, AS THOSE OF US WHO HAVE TAKEN CARE OF AIDS PATIENTS ARE FULLY AWARE, IT'S NOT A NICE DISEASE TO HAVE, WE DIDN'T KNOW IT WAS BEING TRANSMITTED AT THE TIME IT WAS REACHING EPIDEMIC RATINGS. SOME OF THESE DISEASES, THE EQUINE ENCEPHALITIS VIRUS THAT ARE BEING TESTED WE JUST DON'T KNOW AND I THINK IN THOSE SETTINGS, ALTHOUGH I WOULD

HATE TO DISCOURAGE ANYTHING THAT MAY HAVE SOME MEDICAL BREAKTHROUGHS, CERTAINLY DISEASES LIKE AIDS, I FAIL TO UNDERSTAND HOW BIOLOGICAL TESTING CAN HAVE ANY DEFENSIVE CAPABILITIES. IT JUST DOESN'T SEEM TO ME THAT THIS SHOULD BE SOMETHING THAT IS IN ARMY OR MILITARY HANDS, IT SEEMS LIKE IT IS MORE NATIONAL INSTITUTE OF HEALTH OR MEDICAL CARE, AND AGAIN, HOPEFULLY, I CAN GIVE YOU SOME MORE ON THIS. MAYBE I CAN COME UP WITH SOME MORE INFORMATION LATER. THANKS.

MR. DASEY: THANK YOU. OUR NEXT SPEAKER IS MR. SIDWELL.

DR. SIDWELL: MY STATEMENT ISN'T SPECIFICALLY ON THIS EIS, BUT I FELT THAT IT COULD PERHAPS APPLY TO SOME OF THE COMMENTS THAT ARE ALREADY MADE.

WE ARE AN ARMY CONTRACTOR AND HAVE BEEN DOING RESEARCH AT UTAH STATE UNIVERSITY IN DEVELOPING NEW DRUGS TO CURE A VIRUS INFECTION WHEN IT OCCURS IN MAN. I SHOULD POINT OUT THAT IT'S MY UNDERSTANDING THAT IN MUCH OF THE RECENT INCREASE IN ARMY EXPENDITURES AND BDRP IS FOR DEVELOPMENT OF DRUGS, A MOST DEFENSIVE RESEARCH ATTITUDE.

NOW, SOME POINTS CONCERNING OUR RESEARCH. FIRST, THE DISEASE WE WISH TO CURE IS RIFT-VALLEY FEVER WHICH IS A VERY DANGEROUS PATHOGEN. IT'S OCCURRING AS AN EPIDEMIC IN NORTHERN AFRICA AT THIS TIME. NOW, WE ARE USING A LESS PATHOGENIC LOOK-ALIKE VIRUS AT THE ARMY'S RECOMMENDATION,

WHICH IS CLASSIFIED AS A BL2 VIRUS. NO ONE HERE WOULD EVEN KNOW THE VIRUS, I DIDN'T EVEN KNOW IT, AND IT IS BARELY PATHOGENIC FOR MAN. THAT VERY SUBSTITUTE-TYPE ORGANISM WAS AGAIN RECOMMENDED BY SEVERAL SPEAKERS EARLIER TODAY AND WAS RECOMMENDED TO US BY THE ARMY TO BE USED.

NUMBER TWO, BEFORE WE COULD EVEN WORK ON THIS ORGANISM, I WAS INVITED AT THE ARMY'S EXPENSE WITH OUR CAMPUS ARCHITECT TO GO TO FORT DETRICK AND MEET WITH DR. RALPH KUEHNE, THE CHIEF ARMY SAFETY ENGINEER AT DETRICK. WE WERE GIVEN AN EXPENSIVE TOUR AT THE FACILITY, INCLUDING MANY BEHIND-THE-SCENES AREAS IN ORDER TO DESIGN AN APPROPRIATE FACILITY FOR OUR RESEARCH THAT WOULD BE SAFE.

NUMBER THREE, SUCH A FACILITY WAS CONSTRUCTED ON OUR CAMPUS. IT IS A BL3 PLUS FACILITY. HAS NEGATIVE AIR; HAS HEPAT FILTERS; HAS PASS-THROUGH AUTOCLAVES; HAS TOTAL RESTRICTION OF ALL BUT COMPLETELY TRAINED INDIVIDUALS. AS OF TODAY, TWO AND A HALF YEARS AFTER WE BEGAN THIS WORK, WE ARE STILL WORKING WITH A BL2 AGENT IN THIS ARMY RECOMMENDED BL3 LABORATORY.

NUMBER FOUR, OUR FACILITY WAS INSPECTED DURING ITS CONSTRUCTION BY DR. GARY RESNICK OF DUGWAY AND LATER BY DETRICK SCIENTISTS.

IN SHORT, IN OUR GROUP WE WERE IMPRESSED WITH THE INTEREST AND CONCERN THAT THE ARMY MEDICAL RESEARCH INSTITUTE DEVELOPMENT COMMAND HAD FOR OUR SAFETY AND FOR THE PROPER

CONDUCT OF OUR RESEARCH PROGRAM. THANK YOU.

MR. DASEY: THANK YOU, DR. SIDWELL. OUR NEXT SPEAKER IS DR. SPENDLOVE.

DR. SPENDLOVE: WELL, FIRST I WOULD LIKE TO SPEAK TO THE SUBJECT AT HAND, THE EIS, AND GIVE YOU WHAT I CONSIDER A FEW SUGGESTIONS FOR ALTERING IT IN THE LIGHT OF WHAT I CONSIDER MISINFORMATION AND MISPERCEPTION, AND WHATEVER ELSE YOU WANT TO CALL IT.

FIRST OF ALL, I THINK THAT YOU NEED TO ESTABLISH THE NEED FOR-- FIRMLY FOR THIS TYPE OF RESEARCH. FOR EXAMPLE, VERY LITTLE IS SAID ABOUT THE RUSSIANS GOING IN OPPOSITION TO THE GENEVA ACCORD. NOTHING IS SAID ABOUT THE ACCIDENT AT SWEDLOCK IN APRIL OF 1979, WHEN SEVERAL HUNDRED RUSSIANS NEAR THAT COMMUNITY WERE KILLED BY A BIOLOGICAL BOMB THAT HAD BEEN PREPARED IN OPPOSITION TO THE GENEVA ACCORD.

THERE ARE SEVERAL OTHER THINGS THAT OUGHT TO BE STATED IN THERE TO MAKE THAT STRONGER. I THINK THAT YOU SHOULD STRENGTHEN YOUR MITIGATING CIRCUMSTANCES ON ACCIDENTS FOR EXAMPLE, I THINK YOU SHOULD SAY MORE ABOUT THE DECAY OF THESE FRAGILE ORGANISMS, PARTICULARLY THE DUGWAY ENVIRONMENT AND THE GOOD DOCTOR THAT JUST SPOKE ABOUT ANTHRAX BEING MORE VIRULENT AND THE SPORULATING FORM DOESN'T KNOW WHAT HE IS TALKING ABOUT. SPORES ARE NOT NEARLY AS INFECTED, IN FACT, THEY HAVE TO VEGETATE BEFORE

THEY CAN EVEN CAUSE AN INFECTION AND I THINK THAT THAT'S LARGELY WHAT WE ARE DEALING WITH HERE IS MOST OF THE PEOPLE THAT HAVE SPOKEN SO FAR, IN MY MIND, DON'T KNOW WHAT THEY ARE TALKING ABOUT.

I THINK YOU NEED A BETTER DESCRIPTION OF THE AFFECTED ENVIRONMENT, PARTICULARLY WIND DIRECTION AND SPEED. FOR EXAMPLE, WE ARE WORRYING ABOUT THE 70 MILES, THAT IS ALWAYS BROUGHT UP, THE 70 MILES FROM THAT LAB TO SALT LAKE THE WASATCH FRONT. WHAT PERCENTAGE OF THE TIME DOES THE WIND BLOW FROM THE LAB TO THE WASATCH FRONT IN THAT DIRECTION? VIRTUALLY NEVER. VIRTUALLY NEVER. THE TYPES OF WINDS THAT YOU HAVE AT DUGWAY ARE PREFRONTAL WINDS THAT BLOW UP INTO IDAHO, SEVERAL HUNDRED MILES BEFORE YOU GET TO ANYTHING OF ANY POPULATION. POSTFRONTAL WINDS WOULD BE FROM THE NORTHWEST THAT WOULD BLOW WAY DOWN INTO CENTRAL UTAH, A FEW FARMING COMMUNITIES MIGHT BE AFFECTED SOME 200 MILES AWAY. WHY ISN'T THIS BROUGHT OUT? YOU SEE, EVEN IF YOU HAVE A WORSE CASE SITUATION, THE CHANCES OF WIND TAKING THAT TO A POPULATED CENTER IS PRACTICALLY ZERO, NOT COUNTING THE LOW RELATIVE HUMIDITY THAT YOU HAVE AT DUGWAY. THAT IS BOUND TO MITIGATE ANY KIND OF ACCIDENT. I THINK THAT YOU SHOULD SAY MORE ABOUT THE DECAY RATE OF ALL OF THE ORGANISMS THAT YOU INTEND TO USE IN THE LABORATORY BECAUSE ALL OF THEM ARE EXTREMELY LOW. YOU MENTIONED WHAT YOU CONSIDER, I GUESS, A WORSE CASE SITUATION OF "Q" FEVER. YOU COULD HAVE

MENTIONED ANTHRAX, PROBABLY, AND EVEN WORSE ONES, BUT EVEN UNDER THAT CIRCUMSTANCE, THE CHANCES OF THEM GETTING OUTSIDE THE FENCE AROUND BAKER LAB IS PRACTICALLY NIL, LET ALONE GET TO THE FENCE OF DUGWAY AND GETTING TO SALT LAKE CITY IS JUST -- IT'S BEYOND THE REALM OF IMAGINATION, YOU SEE.

I WOULD LIKE TO REMIND THE GOOD MEMBER OF CONGRESS HERE THAT I AM ALSO A CITIZEN OF THE STATE OF UTAH -- I SHOULD SAY, BY THE WAY, I AM A PRIVATE CITIZEN. I HAVE NO CONNECTION WITH THE ARMY. THE ARMY DOESN'T TELL ME WHAT I CAN SAY AND I CAN'T SAY, THANK GOD, BECAUSE I SPENT 31 YEARS HAVING TO BE QUIET AND THANK THE LORD I CAN SAY SOMETHING NO BECAUSE I AM SORRY, REPRESENTATIVE OWENS, BUT WE ARE TALKING ABOUT A MILITARY PROBLEM HERE, AND IT IS BEING SOLVED BY CIVILIANS. PEOPLE THAT ARE IN THE LABS ARE CIVILIANS. VERY FEW PEOPLE THAT ACTUALLY WORK ARE MILITARY. THE REQUIREMENTS COME FROM MILITARY BECAUSE THEY ARE THE ONES THAT HAVE TO USE THEM, THAT HAVE TO -- THEY ARE THE ONES THAT HAVE PROBLEMS. THEY ARE THE ONES THAT WE ARE SPEAKING TO.

NOW, WE WANT REALISTIC REQUIREMENTS, BUT NOBODY EVER TOLD ME FOR THE EIGHT YEARS THAT I RAN THE LAB AT DUGWAY THAT I -- WHETHER OR NOT I COULD DO ONE THING OR ANOTHER. I ACTED IN A CIVILIAN CAPACITY JUST LIKE THE PEOPLE AT NIH, AND WHAT MAKES YOU THINK THAT THE MILITARY AREN'T AS PATRIOTIC AND CONCERNED ABOUT THE PEOPLE OF THIS

NATION AS CIVILIANS? REALLY -- WELL, I CAN'T UNDERSTAND IT.

NOW, I FEEL THAT I NEED TO SPEAK TO SOME OF THE OTHER STATEMENTS THAT HAVE BEEN MADE. I REALIZE THAT THIS DOESN'T HAVE ANYTHING TO DO WITH THE EIS, BUT I DON'T THINK ANY OF THOSE STATEMENTS HAD ANYTHING TO DO WITH THE EIS AND I THINK SOMEBODY NEEDS TO REBUT SOME OF THE RIDICULOUS STATEMENTS THAT HAVE BEEN MADE AND THAT'S ALL THEY ARE, AND THAT IN THE CATEGORY OF RIDICULOUS. I THINK, FOR EXAMPLE, BRIAN MOSS THINKS OF GOING TO WASHINGTON, HE BETTER GET HIS FACTS STRAIGHT BECAUSE HE DOESN'T KNOW WHAT HE IS TALKING ABOUT. HE IS GOING TO GET CUT TO RIBBONS BY THE WASHINGTON CROWD WHEN HE GETS BACK THERE. YOU KNOW, I WAS THINKING OF VOTING FOR HIM BECAUSE I DIDN'T LIKE HATCH'S IDEAS EITHER, NOW, I DON'T KNOW WHO TO VOTE FOR.

WELL, I HAVE TO AGREE WITH DR. GUBLER. I THINK THE ARMY ROLLED OVER AND PLAYED DEAD BY GIVING UP THE BL4 LAB. I DON'T THINK THAT YOU HAVE REDUCED THE SAFETY OF THE PEOPLE ALONG THE WASATCH FRONT ONE IOTA BECAUSE THERE WAS NO SAFETY PROBLEMS TO BEGIN WITH, WITH OR WITHOUT THE BL LAB I AM NOT TAKING ANY QUESTIONS.

MR. DASEY: SIR, IF YOU WANT TO SPEAK, GET YOUR NAME ON THE LIST.

DR. SPENDLOVE: OKAY. THE DOWNWINDERS. YOU KNOW, ALL OF THIS IS RABBLE-ROUSING AND HAS VERY LITTLE TO DO WITH THE LAB. I FEEL SORRY FOR THE PEOPLE DOWN IN

ST. GEORGE AND I ADMIT THAT THE GOVERNMENT, NOT THE ARMY OR DUGWAY, PROBABLY DID THEM A BAD TURN. SO WHY SHOULD WE WHY SHOULD WE LIMIT WHAT WE DO AT DUGWAY IN TERMS OF DEFENSE JUST BECAUSE SOMEBODY HAS GOT A BONE TO PICK? REALLY, IT JUST DOESN'T MAKE ANY SENSE. YOU KNOW, HE IMPUNED THE TRAINING OF THE PEOPLE AT DUGWAY. FOUR OF THOSE ARE YOUNG NATIVE SONS OF UTAH THAT WERE TRAINED AT UTAH STATE SPECIFICALLY AS AEROBIOLOGISTS AND I DON'T KNOW WHAT KIND OF TRAINING HE IS LOOKING FOR. FOR EXAMPLE, I HAVE OVER 50 PUBLICATIONS IN THIS AREA. I AM RECOGNIZED AS AN INTERNATIONAL AEROBIOLOGIST BY THE COMMUNITY OF AEROBIOLOGISTS AND THESE ARE THE PEOPLE WHO KNOW WHAT THEY ARE TALKING ABOUT, NOT YOU GUYS THAT ARE WORKING ON EMOTION AND RABBLEROUSING. SO, I DON'T KNOW WHAT INADEQUATE TRAINING YOU ARE TALKING ABOUT, HE TALKS ABOUT THE ANTHRAX ON THE SALT FLATS. DUGWAY PUT SHEEP ON THAT SALT FLAT. RIGHT ON THE SPOT, KEPT THEM THERE FOR HOW LONG I DON'T KNOW, SIX MONTHS. NOT A ONE OF THEM CAME DOWN WITH ANTHRAX. NOT A ONE OF THEM. I WOULD TAKE MY 19 GRANDCHILDREN AND HAVE A PICNIC ON THAT SPOT, THAT'S JUST HOW MUCH I THINK ITS -- HOW SAFE I THINK IT IS.

NOW, STEVE ERICKSON, YOU ALSO TALK ABOUT BIOLOGICAL ARMS RACE. WHAT BIOLOGICAL ARMS RACE? I DON'T KNOW OF ANY BIOLOGICAL ARMS THAT THE UNITED STATES IS PRODUCING AND YET YOU KEEP BRINGING THIS UP. WHAT IS BIOLOGICAL ARMS

RACE? YOU SEE, WHY DON'T SOMEBODY, INCLUDING YOU, WORRY ABOUT THE DOZENS OF CHLORINE-LATENT TRUCKS THAT COME THROUGH SALT LAKE CITY. THE 18-WHEELERS THAT ARE CARRYING CYANIDE YOU KNOW, THAT ONE THAT WENT OFF -- THAT WRECKED DOWN IN CENTRAL UTAH, THAT CAN JUST AS WELL HAVE BEEN IN SALT LAKE CITY. WHY DON'T YOU WORRY ABOUT THAT.

MR. DAISY: TIME, DR. SPENDLOVE.

DR. SPENDLOVE: I HAVE A FEW MORE THINGS.

MR. DASEY: 30 SECONDS.

DR. SPENDLOVE: I HAVE TWO OR THREE MORE THINGS, I'M SORRY.

DR. SAYRES TALKED ABOUT ONE ORGANISM OF ANTHRAX CAUSING A DISEASE. BOY, I WOULD LIKE TO HAVE THAT STRAIN. WOULDN'T THE ARMY LIKE TO HAVE IT? WE KNOW THAT IT TAKES 10 TO 15,000 ---

MR. DASEY: DR. SPENDLOVE, THAT'S IT. WILL YOU PLEASE SUBMIT THE REMAINDER OF YOUR COMMENTS TO THE REPORTER ONCE AGAIN, WE ARE NOT HERE TO DEBATE OR RESOLVE DIFFERENCES TONIGHT. THE ARMY IS ACCEPTING COMMENTS FROM THE PUBLIC ON THE DRAFT ENVIRONMENTAL IMPACT STATEMENT OF THE BIOLOGICAL DEFENSE RESEARCH PROGRAM. WE ASK YOU TO PLEASE LIMIT YOUR COMMENTS TO 10 MINUTES AND TRY AND FOCUS THEM ON THAT DOCUMENT.

THE NEXT SPEAKER IS MATTHEW HAUN.

MR. HAUN: GOOD EVENING. THE ARMY HAS ASSURED US

THAT THIS WHOLE MATTER, THE WHOLE BIOLOGICAL WARFARE RESEARCH PROGRAM, IS SAFE, SECURE AND UNDER CONTROL. PLEASE ALLOW ME TO EXPLAIN MY CRITERIA FOR EVALUATING THIS. MAINLY, THAT IF I WENT TO A BANK AND WANTED TO GET A LOAN FROM THEM AND I WOULD SAY TO THEM, HEY, I WILL PAY IT BACK, YOU CAN TRUST ME, BUT I AM SURE THEY WOULD CHECK MY CREDIT RECORDS. LIKEWISE, IF I BOUGHT A CAR OR SOME OTHER VALUABLE OBJECT, I WOULD WANT SOME KIND OF WARRANTY -- SOME KIND OF LEGAL GUARANTEE THAT IF IT TURNS OUT TO BE A LEMON THAT I HAVE SOME FORM OF LEGAL REDRESS.

NOW, THE ARMY HAS A TRACK RECORD THAT LOOKS LIKE CRAP AS FAR AS PUBLIC SAFETY AND AS FAR AS TELLING THE TRUTH. LIKEWISE, THE SUPREME COURT HAS ASSURED US THAT THE ARMY IS ENTIRELY IMMUNE FROM ANY FORM OF LEGAL REDRESS, REGARDLESS OF ANY KIND OF HIDEOUS CATASTROPHE THAT MAY TURN LOOSE. I ONLY WISH THE SUPREME COURT COULD GRANT THE REST OF US IMMUNITY FROM YOUR GERMS, BUT I DON'T THINK THAT IS IN THEIR POWER TO DO SO.

I WILL BE VERY BRIEF, YOU'RE LIARS, YOUR MURDERERS YOU HAVE COMPLETE IMMUNITY FROM ANY KIND OF LEGAL REDRESS, AND I DON'T TRUST YOU AS FAR AS I COULD INFECT YOU. SO, MY SUGGESTION FOR WHAT YOU DO WITH YOUR FACILITY, AND I KNOW YOU DON'T WANT TO TALK ABOUT DUGWAY HERE, YOU HAVE MADE THAT PLAIN, HOWEVER, GIVEN THAT, DUGWAY IS AN INTEGRAL PART OF YOUR PROGRAM. I AM NOT SURE WHERE TO DRAW THE LINE. I

WANT YOU, UNLIKE SOME OTHER PEOPLE HERE WHO HAVE SPOKEN AGAINST YOUR PROGRAM, I WANT YOU TO BRING THAT FACILITY HERE BECAUSE YOU WILL BE STOPPED HERE. I WANT YOU TO BRING THAT HERE -- BRING THAT TURKEY HERE BECAUSE I WILL BE HERE. ARE THERE ANY QUESTIONS FROM THE PANEL?

MR. DASEY: THANK YOU, MR. HAUN. THE NEXT SPEAKER IS PHYLLIS COLEY.

DR. COLEY: I WOULD LIKE TO THANK THE PANEL FOR THE OPPORTUNITY TO TALK. MY NAME IS DR. PHYLLIS COLEY AND I AM A PROFESSOR OF BIOLOGY AT THE UNIVERSITY OF UTAH AND NATURALLY AM VERY CONCERNED ABOUT BOTH THE PLANS HERE AT DUGWAY AS WELL AS THE BROADER QUESTION OF THE BIOLOGICAL RESEARCH PROGRAM.

CHANGING THE PLANS FOR HAVING A LEVEL 4 FACILITY IS CERTAINLY A STEP IN THE RIGHT DIRECTION IN MY OPINION, THOUGH IT'S A VERY SMALL STEP AND MANY OF OUR CHANGES NEED TO BE MADE BEFORE THERE IS ANY SIGNIFICANT PROGRESS. MANY OF THE ISSUES WHICH I HAD PLANNED ON RAISING HAVE ALREADY BEEN RAISED TONIGHT AND, OF COURSE, IN OTHER SESSIONS SUCH AS THIS. HOWEVER, THERE ARE A FEW THAT I WOULD LIKE TO EMPHASIZE AND A FEW NEW ONES THAT I WOULD LIKE TO BRING UP.

FIRST OF ALL, THE DANGERS OF USING EITHER NATURALLY OR GENETICALLY ENGINEERED ORGANISMS ARE ENORMOUS AND THIS IS NOT THE OPINION OF ESSENTIALLY THE UNEDUCATED PUBLIC. THAT MOST OF US HAVE BEEN SPEAKING SO FAR ARE EITHER SCIENTISTS

OR MEDICAL DOCTORS AND WE ARE VERY EDUCATED AND THAT'S PRECISELY WHY WE ARE NERVOUS ABOUT IT AND EVEN THOUGH, AS PEOPLE HAVE POINTED OUT, THE PROBABILITY OF ESCAPE FROM THESE FACILITIES IS VERY SMALL, IT IS NOT ZERO, IT IS A POSITIVE PROBABILITY AND IN ALL RISK ASSESSMENT YOU HAVE TO TAKE INTO ACCOUNT WHAT THE RISKS WOULD BE IF SOMEBODY WAS INFECTED AND SINCE THIS ISN'T A ZERO RISK, EVEN IN CENTRAL UTAH, I THINK THAT IT'S NOT SOMETHING THAT CAN BE TAKEN LIGHTLY AND IT HASN'T BEEN APPROPRIATELY ADDRESSED IN ANY OF THE ENVIRONMENTAL IMPACT STATEMENTS THAT I HAVE READ AND REEVALUATING THIS AFTER THE FACT, ONCE THERE HAS BEEN AN OUTBREAK AS THERE HAVE BEEN ACCIDENTS IN THE PAST, WILL NOT BE APPROPRIATE AND SINCE WE NOW HAVE THE POTENTIAL TO MAKE A MUCH BIGGER CATASTROPHE WITH THESE ENGINEERED OR OTHERWISE NATURALLY OCCURRING PATHOGENS, I THINK THE SAFETY LEVEL HAS TO BE MUCH GREATER THAN THEY APPEAR TO BE.

A SECOND EXTREMELY IMPORTANT POINT THAT HAS BEEN RAISED IS THE FACT THAT THE RESEARCH SHOULD BE REVIEWED BY A SCIENTIFIC BUT NON-ARMY COMMITTEE AND THIS IS DONE IN ALL SORTS OF OTHER GOVERNMENT AGENCIES SUCH AS THE NIH, AND THE NSF, AND THERE ARE TWO REASONS FOR THIS.

FIRST OF ALL, IT HELPS ASSURE A GREATER SCIENTIFIC VALIDITY AND PERHAPS EVEN A MORE APPROPRIATE METHODOLOGY AND SECOND OF ALL, BY HAVING OUTSIDE REVIEW IT DOES ALLOW A WATCHDOG-TYPE OF EVALUATION, AND AS HAS

BEEN BROUGHT UP QUITE A BIT TONIGHT, THE ARMY DOES HAVE A CREDIBILITY PROBLEM AND THIS WOULD BE ONE WAY TO SOLVE THAT AS WELL AS PERHAPS TO IMPROVE THE SCIENCE.

MY OWN RESEARCH SPECIALTY IS IN ECOLOGY AND POPULATION BIOLOGY AND I WAS A BIT SOMEWHAT DISTRESSED WITH THE EIS STATEMENT FROM LAST YEAR ABOUT THE LEVEL 3 FACILITY, WHICH IS STILL THE FACILITY WE HAVE AND ONE EXAMPLE IS THAT IN THAT EIS STATEMENT DUGWAY WAS NOTED AS BEING ISOLATED IN THE DESERT AND THEREFORE SAFE. WELL, IN FACT, IT'S ISOLATED IN A SEA OF VECTORS. ACTUALLY, A STUDY CARRIED OUT AT DUGWAY BY ARMY BIOLOGISTS SHOWED THAT THE RODENT POPULATIONS HAVE EXTREMELY HIGH DENSITIES HERE, THE 50 PERCENT CAPTURE RATE, WHICH IS AMONG THE HIGHEST YOU WILL FIND ANYWHERE IN THE COUNTRY. ALSO, THE DIVERSITY OF THE RODENTS IS ENORMOUS, MANY OF THEM BEING BATS, WHICH ARE CERTAINLY CAPABLE OF DISPERSING LONG DISTANCES AND THE OTHERS WHICH POPULATIONS ARE WIDESPREAD THROUGHOUT THE UTAH AND THE SOUTHWEST DESERT, MANY OF THESE ARE KNOWN RESERVOIRS FOR THE PATHOGENS THAT WE HAVE BEEN DISCUSSING AND THEY COULD EASILY BE PICKED UP BY THOSE LOCAL POPULATIONS OF RODENT AND WE WOULDN'T KNOW IT. EVEN UNDER A LOW PROBABILITY OF AN ACCIDENTAL RELEASE, EITHER HAVING RODENTS OR PEOPLE INFECTED, WE MAY NOT BE ABLE TO DETECT THIS UNTIL IT'S TOO LATE, PARTICULARLY IF IT'S A NON-HUMAN INFECTION. THIS IS A LESSON THAT WE SHOULD HAVE LEARNED FROM THE MANY STUDIES, BOTH OF HUMAN AND NONHUMAN

POPULATIONS, WHERE DISEASES HAVE BEEN FOLLOWED. IT'S ALSO A BASIC PRINCIPLE OF ECOLOGY, WHICH IS LOGISTIC POPULATION GROWTH IN WHICH POPULATIONS ARE KNOWN TO SHOW AN S-SHAPED GROWTH CURVE, SO AT VERY LOWPOPULATION DENSITIES POPULATION GROWTH IS ACTUALLY VERY LOW.

SO IF RODENT POPULATIONS WERE INFECTED, THAT WOULD BE VERY DIFFICULT TO DETECT FOR SOME PERIOD OF TIME FOLLOWING THIS LEG PHASE, AS IT'S CALLED IN THE POPULATION GROWTH. THERE IS AN EXPONENTIAL GROWTH RATE WHICH CAN BE VERY RAPID, ENORMOUS DOUBLING AND ONCE AN INFECTED POPULATION IS IN THIS PHASE, IT MAY BE OUT OF CONTROL BEFORE WE CAN DETECT IT AND DO SOMETHING ABOUT IT AND BY THEN IT WOULD PROBABLY BE TOO LATE. AND, IN SUMMARY, I WOULD LIKE T SAY THAT MUCH OF THE PAST RESEARCH THAT HAS BEEN DONE IN THE BIOLOGICAL WARFARE PROGRAM HAS GONE ON WITHOUT MUCH PUBLIC SCRUTINY OR MUCH PUBLIC KNOWLEDGE AND I THINK THIS IS BEGINNING TO CHANGE AND I AM SURE IT MUST SEEM LIKE A BIG NUISANCE TO YOU ALL, BUT I THINK IT'S DEFINITELY FOR THE GOOD AND BY HAVING PUBLIC INPUT FROM BOTH SCIENTISTS, AS WELL AS JUST CONCERNED CITIZENS, COULD HELP THE PROGRAM IN GENERAL AND CERTAINLY IMPROVE THE SAFETY OF LOCAL CITIZENS. THANK YOU.

MR. DASEY: THANK YOU, DR. COLEY. I HAVE 8:53, WE WILL BREAK FOR 10 MINUTES.

(RECESS TAKEN.)

MR. DASEY: THE NEXT SPEAKER IS PAGE WILDER.

MS. WILDER: I WOULD LIKE TO READ FROM SOME NOTES THAT I HAVE BEEN JOTTING DOWN WHILE LISTENING TO EVERYONE ELSE SPEAK. MY NAME IS PAGE WILDER AND I AM A BIOLOGIST AT THE UNIVERSITY OF UTAH.

FIRST I WOULD LIKE TO SAY AS A BIOLOGIST THAT I AM VERY SCARED BY WHAT THE ARMY IS PROPOSING. AS AN INDIVIDUAL I WORK FOR PEACE. I BELIEVE THE PROPOSED BIOLOGICAL WEAPONS DEFENSE PROGRAM WILL UNDOUBTEDLY ENTER US INTO ANOTHER ARMS RACE, AS OUR DEFENSIVE NUCLEAR WEAPONS RESEARCH HAS ALREADY DONE. THE DEIS DOES NOT ADDRESS THE FUNDAMENTAL ISSUE, BIOLOGICAL WARFARE IS IMMORAL.

I WOULD LIKE TO MAKE IT PERFECTLY CLEAR THAT WE ARE NO LONGER TALKING ABOUT WAGING WAR ON A BATTLEFIELD. BIOLOGICAL WEAPONS WILL BE TARGETED AGAINST EVERY SINGLE ONE OF US AND OUR CHILDREN. WE CANNOT OPEN THE DOOR TO ESCALATION OF BIOLOGICAL WAGONS WHICH IS WHAT THE OFFENSIVELY-DEFENSIVE PROGRAM WILL DO. I ASK THAT ALL OF US TONIGHT CONSIDER THE IMPLICATIONS OF THE DEFENSIVE PROGRAM WITH REGARDS TO THE FUTURE DIRECTIONS IT COULD TAKE. THANKS.

MR. DASEY: THANK YOU, MS. WILDER. THE NEXT SPEAKER IS PROFESSOR EDWIN FIERMAGE.

PROFESSOR FIERMAGE: I APPRECIATE THE CHANCE OF USING THE PODIUM. I HAVE NOT BEEN WELL FOR A LITTLE TIME AND I AM VERY SHAKY AND I WILL HAVE TO HOLD ON.

I HAVE HAD GOOD RELATIONS FOR MANY YEARS WITH THE MILITARY AND CIVILIAN LEADERSHIP HERE. I HAVE OPPOSED MOST OF WHAT THEY HAVE DONE AND STILL DO, BUT I AM GRATEFUL FOR THE COURTESY, FOR THE FRIENDSHIP, FOR THE QUICKNESS OF WHICH THEY HAVE RESPONDED TO MY FREEDOM OF INFORMATION ACT REQUESTS AND FOR GIVING ME TOURS AND INFORMATION AS I HAVE REQUESTED IT WITH COURTESY AND DISPATCH.

I WOULD SUGGEST ONE THING AND I WOULD OFFER IT TO WAYNE AS WELL AS OFFICIALS ON THE STAND IN TERMS OF FORMAT. I THINK IN A DEMOCRATIC SOCIETY IT WOULD BE APPROPRIATE, IT WOULD BE WELL IF THE GOVERNOR, CONGRESSMEN, IF THE OFFICE SPEAKER, AND IF THE MILITARY WAITED UNTIL WE HAD OUR SAY FIRST, AND THEN PRESENTED THEIR INFORMATION AT THE END. IT WOULD KEEP THE MEDIA HERE, MOST IMPORTANT. SYMBOLICALLY, IT SAYS WHAT SHOULD BE SAID IN A DEMOCRATIC STATE.

THE PROPOSAL THAT WE INCREASE OUR CAPACITY IN RESEARCH INTO BIOLOGICAL AGENTS TO BE USED AS WEAPONS FOR DEFENSES REVEAL THE INSANITY OF OUR SITUATION. SINCE THE DEVELOPMENT OF RECOMBINANT DNA, WE MUST KNOW THAT THERE IS NO DEFENSE POSSIBLE FOR THE USE OF BIOLOGICAL AGENTS. RECOMBINANT DNA CAN BE THE MANHATTAN PROJECT OF BIOLOGICAL WEAPONRY. WE MUST NOT ALLOW THAT TO HAPPEN. BY GENETIC ENGINEERING, GENE-SPLICING, WE CAN PRODUCE AN ENDLESS SPECTRUM OF BIOLOGICAL AGENTS FOR WHICH NO CONCEIVABLE

VACCINE OR ANTIDOTE WOULD BE POSSIBLE. MANY SIMPLE MEANS EXIST TO DISTRIBUTE OR DELIVER SUCH AGENTS BEING SO UTTERLY PERVASIVE TO MAKE DEFENSE POSSIBLE. AEROSOLS OF GREAT VARIETY CAN SPREAD DREAD PLAGUES ACROSS THE COUNTRY. NO AMOUNT OF EXOTIC CLOTHING, MASKS, OR VACCINE CAN REALLY BE EXPECTED TO PROTECT TROOPS IN THE FIELD. NO CONCEIVABLE MEANS EXIST OR COULD EVER BE DEVELOPED TO PROTECT CIVILIAN POPULATIONS THROUGHOUT THE NATION. NO CONTINENTAL ASTRODOME CAN PROTECT OUR AIR, OUR WATER, OUR PEOPLE. YET WORLD DEFENSES DO EXIST AGAINST THE USE OF BIOLOGICAL AGENTS AS WEAPONS. THESE DEFENSES, HOWEVER, ARE HURT, NOT HELPED, BY CONTINUING RESEARCH ON THE USE OF BIOLOGICAL AGENTS AS WEAPONS OR DEFENSES AGAINST SUCH AGENTS.

THE DISTINCTION BETWEEN SUCH AN OFFENSIVE AND DEFENSIVE USE BEING IMPOSSIBLE TO MAINTAIN. MOST IMMEDIATELY AND LEAST IMPORTANT THERE IS SIMPLY NOT A REALISTIC SITUATION IN WHICH AN ENEMY OF THE UNITED STATES WOULD USE BIOLOGICAL AGENTS AGAINST US WHEN OTHER AND BETTER WEAPONS ARE READILY AT HAND. BIOLOGICAL AGENTS WOULD NOT IMMEDIATELY IMMOBILIZE OUR FORCES. OUR REACTION, EVEN AFTER INFECTION, COULD BE SWIFT AND LETHAL WITH CONVENTIONAL OR NUCLEAR WEAPONS. AND SECOND, BIOLOGICAL AGENTS ARE NOT RELIABLE NOR CONTAINABLE. PERHAPS SUCH AGENTS WOULD BE RENDERED IMPOTENT BY ANY ONE OF ENVIRONMENTAL FACTORS, HEAT, COLD, RAIN, WIND. IF LETHAL AGAINST AN ENEMY WITHIN A SHORT TIME,

SUCH A PLAGUE WOULD INCAPACITATE FRIENDS OF THE AGGRESSOR STATE AND THEN THAT COUNTRY AS WELL. THE EFFECTS OF SUCH AGENTS CANNOT BE CONTROLLED OR CONTAINED.

THE POTENTIAL USERS OF SUCH PAINLESS WEAPONS WHO MIGHT NOT BE DETERRED BY SUCH PRACTICAL CONSIDERATION ARE TERRORIST GROUPS OR COMPLETELY IRRESPONSIBLE DANGEROUS STATES WITH LITTLE TO LOSE AT THE SPECTER OF MASS UNCONTROLLED CARNAGE.

OUR OWN RESEARCH WITH THAT OF THE SOVIET UNION AND OTHER NATIONS SIMPLY ADDS TO THE INFORMATION ULTIMATELY AVAILABLE TO OTHER STATES AND OTHER GROUPS. THE NOTORIETY OUR OWN ACTIONS GIVE BY THE CONTINUED DEVELOPMENT OF BIOLOGICAL AGENTS AS WEAPONS MAKE THEIR ACQUISITION OF EVENTUAL USE BY SOME TERRORIST GROUP OR TERRORIST STATE MORE LIKELY, NOT LESS SO.

MEANWHILE, THE IMMEDIATE COST OF THOSE OF US NEARBY, THE POSSIBILITY OF ACCIDENT, NATURAL DISASTER THROUGH EARTHQUAKES OR TARGETING BY FOREIGN ENEMY OR TERRORIST GROUP IS SUBSTANTIAL. IN OTHER WORDS, WE BEAR THE BURDEN OF POSSIBLE GREAT HARM, INTENTIONAL OR ACCIDENTAL WHILE THE RESULT OF THIS EFFORT PROVIDES OUR COUNTRY WITH LESS SECURITY, NOT MORE.

FAR MORE IMPORTANT, HOWEVER, IS THE HARM WE INFLICT UPON OURSELVES IN PARTICIPATING IN THIS PARTICULARLY SENSELESS SYSTEM OF MOST GRUESOME MASS DEATH.

OUR GREATEST HOPE AGAINST BIOLOGICAL AGENTS BEING USED AGAINST US IS THAT THE HUGE MASS OF HUMANITY RECOILS AT THE SUGGESTION THAT WE WOULD INFLICT SUCH HORROR UPON EACH OTHER, FELLOW HUMAN BEINGS. AS WE CONTINUE RESEARCH INTO SUCH MONSTROUS WEAPONS, WE MAKE OURSELVES AND EACH OTHER LESS HUMAN. WE LOSE THE SENSATE QUALITIES OF OUR OWN HUMANITY. WE ASSUME THAT OTHERS WILL LET LOOSE UPON US PLAGUES THAT MAY DESTROY MILLIONS OF HUMAN BEINGS. BY PROJECTING OUR FEARS ONTO OTHERS, WE THEN JUSTIFY OUR OWN ACTIONS THAT WOULD OTHERWISE BE INCONCEIVABLE TO OUR OWN HUMANITY. WE MUST OVERCOME OUR OWN FEARS. I FEAR OUR FEAR. I FEAR OUR FEAR MORE THAN I FEAR RUSSIANS, CHINESE, OR LIBYANS. WHAT I FEAR THE WORST, MY OWN CONSEQUENT ACTIONS, FULFILL THE WORST FEARS OF MY ENEMIES. THEN THEIR ACTIONS FILL MY OWN PERCEPTION AND SO ON.

THE ANSWER IS NOT IN DEVELOPING STILL MORE WEAPONS OF MASS DESTRUCTION, BIOLOGICAL PLAGUES TO TAKE THEIR PLACE IN A GHASTLY GALLERY ALONGSIDE MUSTARD GAS AND NUCLEAR WEAPONS. INSTEAD, SOMEHOW WE MUST LEARN HOW WE MIGHT DEFINE OURSELVES WITHOUT THE USE OF AN ENEMY. THE OTHER, WITHOUT HOME WE SEEM TO HAVE NO CONTENT AND NO PURPOSE.

AS INDIVIDUALS AND AS A NATION WE MUST DISCOVER AT OUR CORE, OUR CENTER, OUR IDENTITY. AN IDENTITY SO WONDERFULLY HUMAN THAT WE SEE PURPOSE AND DIRECTION WITHOUT FEARFUL PROJECTION ONTO ANOTHER.

WE BEG YOUR PARDON FOR ASKING THAT YOU SPEND PART OF YOUR LIVES IN DEVELOPING SUCH USE OF BIOLOGICAL AGENTS OR THE IMPOSSIBLE TASK OF INVENTING DEFENSES AGAINST SUCH AGENTS ON OUR BEHALF. FOR YOUR OWN HUMANITY AND OURS AS WELL, WE ASK THAT YOU STOP. THANK YOU.

MR. DASEY: THANK YOU, PROFESSOR FIERMAGE. THE NEXT SPEAKER IS HEIDI WALLENTINE.

MS. WALLENTINE: HELLO, MY NAME IS HEIDI WALLENTINE AND I AM HERE REPRESENTING THE PEOPLE OF THE STATE OF UTAH AS A PRIVATE CITIZEN, BUT ALSO THE PEOPLE OF THE PLANET AS A HUMAN BEING.

THERE ARE MANY THINGS THAT I DID NOT KNOW ABOUT THIS, OF COURSE, HERE I AM LIVING IN THE STATE AND YET I AM NOT AWARE OR THIS. SO TONIGHT, I HAD TO FORMULATE A LOT ABOUT WHAT I AM HEARING, ABOUT THE CONTROVERSY-- THE CONFLICTS OF INFORMATION THAT SHOCKS ME THAT I DON'T UNDERSTAND BUT ALSO THE FUTURE FOR ME AS A TEEN, FOR MY FRIENDS IN THE SOVIET UNION, AND IN THIS STATE, BECAUSE JUST AS I HAVE FRIENDS IN THE STATE OF UTAH THAT ARE AT RISK WITH THIS PARTICULAR PROGRAM, I HAVE FRIENDS IN OTHER COUNTRIES THAT ARE VIEWED BY THE GOVERNMENT AND BY THE MILITARY AS OPPONENTS AND ENEMIES THAT THESE PATHOGENIC ORGANISMS ARE PREPARED TO BE USED ON.

WE ALL UNDERSTAND THE CONSEQUENCES OF NUCLEAR WAR AND WE ALL DO NOT DESIRE NUCLEAR WAR. JUST AS NO ONE WANTS

A NUCLEAR WAR, NOBODY WANTS A BIOLOGICAL WAR AND I THINK WE ALL UNDERSTAND THAT FAMOUS QUOTE FROM A VERY INTELLIGENT MAN WHO ALSO HAD A GOOD HEART, EINSTEIN, "YOU CANNOT SIMULTANEOUSLY PREVENT AND PREPARE FOR WAR."

ALSO, I HAVE MANY QUESTIONS IN MY MIND ABOUT EXPENDABILITY. ABOUT PEOPLE WHO ARE CONSIDERED EXPENDABLE BECAUSE I CERTAINLY DO NOT CONSIDER MYSELF OR ANYBODY ON THIS EARTH EXPENDABLE. WHAT EXACTLY -- THIS IS A GREAT RESPONSIBILITY WE TAKE IN OUR HANDS. WHAT EXACTLY -- WHO EXACTLY DO YOU CONSIDER EXPENDABLE? THERE IS NO DOUBT THERE IS A RISK HERE WITH THE PEOPLE OF THIS STATE AND THIS IS A RESPONSIBILITY THAT YOU ARE TAKING IN YOUR HANDS.

ALSO, THE FACT THAT AS WE DEAL WITH NUCLEAR STRATEGY -- NOW, I UNDERSTAND THAT WE WERE ASKED TO ONLY TALK ABOUT THIS PARTICULAR PROGRAM, IT DEALS WITH ALL ASPECTS, IT DEALS WITH NUCLEAR WAR, IT DEALS WITH BIOLOGICAL WARFARE, IT DEALS WITH DEATH. WHAT GOOD ARE THESE NEGOTIATIONS THAT WE TALKED OF IN NUCLEAR WARFARE IF IT DOESN'T DEAL WITH THE TECHNOLOGICAL MOMENTUM THAT IS A CONSTANT BATTLE BETWEEN BOTH COUNTRIES. THE NEGOTIATIONS DO US NO GOOD IF WE CONTINUE TO KEEP BUILDING AND BUILDING AND BUILDING MORE WAYS TO KILL IN THE NAME OF-- FOR ME, IN THE YEAR 1988 HAS BECOME NOT NATIONAL, IT IS A PLANETARY CONCERN NOW, THIS IS A COMMON GROUND NOW FOR US BECAUSE WE ARE DEALING WITH MORE THAN JUST BIOLOGICAL WARFARE, WE ARE

DEALING WITH COMPLETE DEVASTATION. WE HAVE THE ABILITY AND WE ALL KNOW THAT.

AS I LOOK AT YOU MEN I SEE THAT YOU ALL KNOW THAT. WHY DO WE WANT TO PREPARE FOR THAT? I CAN' T ANSWER THAT. I TRY TO UNDERSTAND THE MENTALITY OF THE HUMAN SPECIE AS MUCH AS POSSIBLE, BUT THERE ARE STILL SO MANY THINGS THAT I DON'T UNDERSTAND. WE HAVE OUR FEARS AND THAT SEEMS TO BE WHAT WE BUILD ON, IS OUR FEARS. AS THIS MAN SAID, WE REACT OUT OF OUR EMOTIONS, HE IS RIGHT, WE REACT OUT OF OUR EMOTIONS.

SO, I AM NOT HERE TO TELL YOU THAT I ASK OF YOU, THAT I HOPE FOR YOU, WHAT I AM GOING TO TELL YOU IS THAT I REFUSE THE WORD CLASSIFIED INFORMATION OR EXPENDABLE IN THE NAME OF NATIONAL SECURITY. I WILL NOT LIVE IN THE FEAR OF IGNORANCE, THAT IS WHY I AM HERE.

AS I MAKE MYSELF MORE AWARE, I WILL NOT LIVE IN THE FEAR OF THE POLLUTED, DEADLY WORLD YOU PREPARE TO CREATE BECAUSE I AM A FUTURISTIC THINKER IN AN ASPECT THAT DEALS WITH NOT JUST MY NATIONAL STATUS AS AN AMERICAN, I AM A HUMANITARIAN AND I AM SURE THAT THIS IS A CONCERN THAT YOU ALL UNDERSTAND BECAUSE IT'S SOMETHING THAT AS WE LEARN TO OPEN OUR HEARTS MORE ALL?? COME ABOUT. AS WE CONSIDER OURSELVES MORE, THE CONCEPT OF HUMANITARIAN NOT JUST AMERICAN. THANK YOU.

MR. DASEY: THANK YOU, MS. WALLENTINE. THE NEXT

SPEAKER IS DR. DAVID THALER.

DR. THALER: WELL, I AM A MICROBIAL GENETICIST, MOLECULAR GENETICIST AT THE UNIVERSITY OF UTAH. I HAVE A STATEMENT ON THE IMPACT PROPOSED BIOLOGICAL WARFARE PROGRAM AND AFTER THIS SHORT STATEMENT I HAVE A FEW QUESTIONS THAT I WOULD LIKE TO ASK THE PANEL.

THIS STATEMENT IS, AND I AM GOING TO APPEAL TO YOUR INTELLIGENCE AND INTEGRITY, DO YOU THINK I HAVE A CHANCE? THE KEY ISSUE REGARDING BIOLOGICAL WARFARE IS THAT THE U.S. AND THE U.S.S.R. ARE ON THE VERGE OF A NEW ARMS RACE IN A DIFFERENT AREA. THIS NEW ARMS RACE THREATENS TO CORRUPT MOLECULAR AND MICROBIOLOGY DISCIPLINES WHICH SO FAR HAVE BEEN LINKED TO APPLICATIONS IN MEDICINE AND AGRICULTURE FOR BENEFICIAL ENDS. IT WOULD BE AN ACT OF INTEGRITY AND DECENCY FOR PRACTITIONERS OF MOLECULAR AND MICROBIOLOGY TO FOSTER A WORLD IN WHICH THE FRUITS OF OUR DISCIPLINE ARE NOT ABUSED BY BEING DRAGGED INTO THE ARMS RACE. IN FACT, WE WANT A WORLD IN WHICH OUR DISCIPLINE IS AN EXAMPLE OF OPENNESS AND THE SEARCH FOR TRUTH FOR ITS OWN SAKE AND FOR HUMAN BENEFIT IN ITS APPLICATIONS. BIOLOGY IS AT A CROSSROADS, A POINT AT WHICH IT IS VITAL TO SET THE DIRECTION FOR THE FUTURE. ON THE SURFACE, THE SITUATION REGARDING BIOLOGICAL WARFARE IS GOOD. BOTH THE U.S. AND THE U.S.S.R. HAVE SIGNED A TREATY PLEDGING, AMONGST OTHER THINGS, THAT THEY WILL NOT PURSUE OFFENSIVE BIOLOGICAL WARFARE.

UNFORTUNATELY, THE INTEGRITY OF THE TREATY IS BEING THREATENED BY THE NEW DEVELOPMENTS IN THE BIOLOGICAL WARFARE DEFENSIVE RESEARCH PROGRAM IN THE U.S. AND POSSIBLY WITHIN THE U.S.S.R. AS WELL.

THE U.S. MILITARY BIOLOGICAL WARFARE RESEARCH CONDUCTED UNDER THE RUBRIC OF THREAT ASSESSMENT CONTAINS MANY ELEMENTS THAT HAVE FORMED PARTS OF THE PROGRAM AIMED AT ESTABLISHING AN OFFENSIVE CAPACITY. THIS CONSTITUTES DE FACTO VIOLATION OF THE TREATY IRRESPECTIVE OF INTENT. ACTIONS THAT APPEAR TO VIOLATE THE TREATY COULD EASILY INSPIRE COUNTER ACTIONS AND SOON BE GENERATED INTO A NEW ARMS RACE.

THE NEW TEST FACILITY PROPOSED FOR DUGWAY AND THE WHOLE BIOLOGICAL WARFARE PROGRAM APPEAR TO BE DIRECTED TOWARD ACTIONS THAT ARE A VIOLATION OF THE TREATY. THE ARMY CLAIMS THAT ONLY WORK WITHIN THE CONFINES OF THE TREATY WILL BE CONDUCTED, BUT THE PROGRAM AS PROPOSED APPEARS MOST IDEALLY SUITED FOR WORK THAT IS NOT WITHIN THE CONFINES OF THE TREATY. EVEN IF THE ARMY IS HONEST IN ITS INTENT, THE PROGRAM COULD FRIGHTEN THE SOVIETS INTO NON-COMPLIANCE WHICH IN TURN WOULD ENGENDER U.S. RESPONSE AND SO ON.

THE INF TREATY, THE NUCLEAR TREATY IN EUROPE, HAS DEMONSTRATED THE POTENTIAL FOR NEW LEVELS OF COOPERATION BETWEEN THE SUPER POWERS TO ASSURE COMPLIANCE WITH ARMS CONTROL MEASURES. THE PHRASE "TRUST BY VERIFY," HAS BECOME

PART OF THE NATIONAL VOCABULARY. MOLECULAR BIOLOGICAL RESEARCH IS PARTICULARLY SUITED TO THIS KIND OF STRONG ENFORCEMENT BECAUSE AT THIS TIME THERE IS NO NEW DEVELOPED MILITARY APPLICATION, ONLY RESEARCH. BOTH THE U.S AND THE U.S.S.R. HAVE PLEDGED TO FOREGO OFFENSIVE BIOLOGICAL WARFARE, HOWEVER, THE INSTITUTIONAL MEASURES NECESSARY TO PREVENT THE DEVELOPMENT OF OFFENSIVE BIOLOGICAL WARFARE ARE INADEQUATE, BOTH INSIDE THE U.S. AND THE U.S.S.R. BECAUSE BIOLOGICAL WARFARE IS FORBIDDEN BY TREATY AND THERE IS AS YET NO NEWLY DEVELOPED APPLICATION AND BECAUSE THE FIELDS OF BIOLOGY, AGRICULTURE AND MEDICINE HAVE DEEP ROOTS IN AIDING THE HUMAN CONDITION, THE AREA IS RIPE FOR ACTION TO ENSURE THAT THE TREATY REMAINS IN FORCE IN BOTH COUNTRIES.

IN THE CASE OF BIOLOGICAL WARFARE, THE BEST DEFENSE IS NOT A GOOD OFFENSE. THE BEST DEFENSE WOULD BE FOR THE U.S. AND THE U.S.S.R. TO HONOR THEIR TREATY OBLIGATION AND TO BE WELL-ASSURED THAT THE OTHER SUPER POWER'S HONORING THE SAME OBLIGATIONS. TO ACCOMPLISH THIS GOAL, THE U.S. AND THE U.S.S.R. OUGHT TO FOREGO ANY CLASSIFIED WORK IN MOLECULAR BIOLOGY, INCLUDING EXOTIC TECHNOLOGIES, NOT ENVISIONED AT THE TIME THE TREATY WAS NEGOTIATED. THE JOINT PROGRAM, ON TRULY DEFENSIVE BIOLOGICAL WORK COULD BE INSTIGATED. THE COMMITMENT TO OPEN RESEARCH AS AN ALTERNATIVE TO AN ARMS RACE MIGHT BE UNDERSTANDABLE TO THE SOVIET POLITICAL ESTABLISHMENT AND MIGHT HELP OPEN UP

THE SOVIET SCIENTIFIC COMMUNITY, BOTH INTERNALLY AND TO INTERNATIONAL CORROBORATION.

OKAY, THAT'S MY STATEMENT. NOW, I HAVE A FEW QUESTIONS FOR THE PANEL.

MR. DASEY: YOU WILL DO IT IN THE FIVE MINUTES YOU HAVE LEFT. .

DR. THALER: YES, WITH SHORT ANSWERS, I BELIEVE I CAN.

WELL, FOR EACH MEMBER OF THE PANEL, I WOULD ASK YOU TO ANSWER YES OR NO. WOULD YOU AGREE -MR. DASEY: THE QUESTIONS ARE SUPPOSED TO HELP YOU CLARIFY ABOUT THE DOCUMENT AND THE PROGRAM.

DR. THALER: WOULD YOU AGREE THAT THE OPTIMUM OUTCOME WOULD BE AN ASSURED PROHIBITION OF BIOLOGICAL WARFARE BY ALL COUNTRIES OF THE WORLD, YES OR NO, FOR EACH PANEL MEMBER? -MR. DASEY: I'M NOT SURE THAT'S RELEVANT TO THE DOCUMENT. YOU ASK FOR OPINIONS.

DR. THALER: I AM ASKING FOR A YES OR NO ANSWER FOR ANY ONE OF YOU WHO IS BRAVE ENOUGH TO ANSWER IT. YES OR NO, I HAVE FEW MINUTES LEFT.

DR. OSTERMAN: DOCTOR, PERHAPS I COULD ASSUAGE YOUR CONCERN IN A DIFFERENT MANNER. YOU MAY NOT BE AWARE OF THIS -

MR. THALER: I WANT EXTRA TIME.

DR. OSTERMAN: YOU MAY NOT BE AWARE OF THIS, BUT WITHIN THE PAST 90 DAYS, I BELIEVE THAT'S A CORRECT VALUE, THERE HAS BEEN A CONTINGENT OF 10 SOVIET SCIENTISTS THAT HAVE VISITED THE UNITED STATES ARMY MEDICAL RESEARCH; INSTITUTE OF INFECTIOUS DISEASES FOR A GOOD PART OF OUR BIOLOGICAL RESEARCH DEFENSE PROGRAM AS CONDUCTED. THOSE FOLKS CAME UNDER THE AUSPICES OF THE NATIONAL ACADEMY OF SCIENCES, NOT ONLY HAD A TOUR OF THE FACILITY, BUT HAD A ONE HOUR NO-HOLDS BAR QUESTION AND ANSWER PERIOD WITH INVESTIGATOR FROM THE ASSIGNMENT AS WELL AS THEIR COMMANDING OFFICERS.

DR. THALER: WOULD YOU SAY THAT THE ULTIMATE GOAL WOULD BE A STOPPING OF THE BIOLOGICAL ARMS RACE?

DR. OSTERMAN: OF COURSE.

DR. THALER: OKAY, NOW, SINCE YOU ARE IN EFFECT ON THE GROUND FLOOR OF THIS BOOMING ARMS RACE, SHOULD IT OCCUR, I WOULD LIKE EACH ONE OF YOU TO TELL ME, WHAT IF THE BIOLOGICAL ARMS RACE DOES TAKE OFF AND THE BUDGET IS INCREASED BY A FACTOR OF 10, I WOULD LIKE TO ASK VERY QUICKLY WHAT THAT WOULD DO TO EACH OF THE COLONELS CHANCES OF BECOMING GENERALS DURING THEIR CAREER? THIS IS A VERY IMPORTANT ISSUE BECAUSE THERE IS INSTITUTIONAL PRESSURE.

COLONEL ROBINSON: IT DOESN'T MATTER. WE JUST MISSED IT ABOUT FOUR MONTHS AGO. WE ARE DONE. WE ARE MASKED. WE'LL NEVER BE GENERALS.

DR. OSTERMAN: THAT IS REALLY NOT A PERTINENT

QUESTION. YOU SEEM TO BE ANNOYED IN ADDRESSING SOME MEANINGFUL ISSUE AND THAT REALLY DOESN'T APPLY.

DR. THALER: WELL, IT'S A MEANINGFUL ISSUE, OF COURSE, BECAUSE IN EACH ARMS RACE THEY BECOME PEOPLE WHOSE INSTITUTIONAL OR PERSONAL COMMITMENT, WHOSE CAREER COMMITMENTS, BECOME INVOLVED IN CREATING NEW WEAPON SYSTEMS. IT IS VERY CLEARLY A PART OF NUCLEAR WEAPONS PROGRAM, DEVELOPED IN THE SOCIOLOGY END AS THE BIOLOGICAL WEAPON PROGRAM, PARTICULARLY IF IT RETAINS MILITARY CONTROL RATHER THAN A PERIOD OF CIVILIAN CONTROL WILL BECOME MORE AND MORE SUSCEPTIBLE TO THAT TENDENCY. SO IF YOU BELIEVE YOUR INTEGRITY IS ABOVE IT, LOOK AT YOUR LIEUTENANTS.

DR. WARD: I THINK IT WOULD BE APPROPRIATE TO ADDRESS YOUR SOCIOLOGICAL CONCERN IN THE FINAL DOCUMENT.

DR. THALER: AND THE DOCUMENT IS THAT YOU WOULD PREFER NOT TO OR THERE IS AN ENVIRONMENTAL DANGER IN CREATING A COTERIE?

DR. WARD: NO, YOU WILL SEE A RESPONSE TO YOUR CONCERN.

MR. DASEY: WE ARE REQUIRED TO ADDRESS EVERY COMMENT MADE TONIGHT.

DR. THALER: OKAY. MY CONCERN IS THE CREATION OF A MILITARY COTERIE OF BIOLOGICAL WARRIORS, MILITARY AND CIVILIAN, WHOSE CAREER-FINANCIAL PRESTIGE INTERESTS ARE MOTIVATED OR REWARDED BY FOSTERING A NEW ARMS RACE. IT IS

YOUR CAREER INTEREST. YES, I WILL ASK AN HONESTY QUESTION. NOW, THIS IS A QUIZ QUESTION. THE STATE DEPARTMENT OF THE U.S. STILL MAINTAINS THAT THE YELLOW RAIN OF THE SOVIET UNION THAT OCCURRED IN SOUTHEAST ASIA WAS A BIOLOGICAL WARFARE EFFORT BY THE SOVIET UNION. A GREAT DEAL OF INDEPENDENT SCIENTIFIC INVESTIGATION HAS APPEARED IN LITERATURE. I ASSUME THAT SINCE IT'S SO CLOSE TO EACH OF YOUR INTERESTS THAT YOU HAVE STUDIED THIS INDEPENDENT SCIENTIFIC LITERATURE AND I WOULD LIKE QUICKLY EACH OF YOU TO SAY, EACH OF YOU WHO ARE WILLING TO SAY, WHETHER YOU BELIEVE THE INDEPENDENT SCIENTIFIC LITERATURE WHICH WAS VERY CAREFULLY DONE AND HAS NEVER BEEN REFUTED OR ARE AFRAID TO SAY SOMETHING AGAINST THE GOVERNMENT BECAUSE AS GOVERNMENT EMPLOYEES IT IS VERY DIFFICULT FOR YOU TO HAVE INTEGRITY AS SCIENTISTS OR EVEN BE IN A CONFLICT. SO I WOULD LIKE EACH OF YOU TO STATE A POSITION ON THE YELLOW RAIN. IS THE YELLOW RAIN SOVIET BIOLOGICAL WARFARE OR IS THE INDEPENDENT INVESTIGATION CONDUCTED BY-- THE QUESTION IS, TO ASK EACH, WHO IS WILLING TO SPEAK ON THEIR SCIENTIFIC EVALUATION OF YELLOW RAIN, AND TO SPEAK TO THEIR CONFLICT BETWEEN THE MESELSON'S REVIEW AND THE GOVERNMENT'S POSITION. ARE THEY WILLING TO SAY THAT THE GOVERNMENT WAS WRONG?

DR. OSTERMAN: WELL, I WILL CERTAINLY SPEAK ON BEHALF OF MYSELF AND I WILL-- SIR, THAT I HAVE NOT HAD AN OPPORTUNITY TO REVIEW ALL THE LITERATURE, PERHAPS YOU

HAVE TO MAKE A JUDGMENT.

DR. THALER: THAT'S YOUR JOB.

DR. OSTERMAN: NO, IT IS NOT MY JOB TO BE AWARE OF EVERYTHING THAT TRANSPIRES IN THE SCIENTIFIC WORLD. I HAVE GREAT CONFIDENCE IN DR. MESELSON WHO I AM SURE YOU ARE AWARE WAS AN EARLY PIONEER IN MOLECULAR BIOLOGY. HE IS NOT A MAN TO BE TAKEN LIGHTLY AND CERTAINLY HIS VIEWS NEED TO BE TAKEN INTO CONSIDERATION, BUT I HAVE NOT HAD AN OPPORTUNITY TO REVIEW ALL OF THAT LITERATURE WHICH IS VOLUMINOUS. SO I CAN'T RESPOND TO YOUR QUESTION.

DR. THALER: ANYBODY WITH MORE COURAGE?

DR. OSTERMAN: IT'S NOT A QUESTION OF COURAGE, IT'! A QUESTION OF KNOWLEDGE. YOU'RE PRESENTING YOURSELF AS A SCIENTIST.

DR. THALER: INDEED, AND ARE YOU PRESENTING YOURSELF AS A SCIENTIST?

DR. OSTERMAN: YES.

DR. THALER: ARE YOU WILLING TO BE A SCIENTIST ABOVE BEING A GOVERNMENT SPOKESMAN?

DR. OSTERMAN: OF COURSE.

DR. THALER: CONGRATULATIONS.

MR. DASEY: THANK YOU, DR. THALER. THE NEXT SPEAKER IS DIANA HIRSCHI.

MS. HIRSCHI: WE HAVE BEEN ASKED TO KEEP OUR COMMENTS LIMITED TO THE DEIS AND I THINK THAT'S ALMOST

IMPOSSIBLE BECAUSE THE DEIS HAS SAID THAT THIS IS SAFE AND I THINK THE QUESTIONS WE HAVE TO ASK OURSELVES ARE A LITTLE DIFFERENT THAN JUST IS IT SAFE. I THINK WE HAVE TO THINK A LITTLE BIT ABOUT NUREMBERG AND THE RESPONSIBILITY WE HAVE TO ADDRESS OUR GOVERNMENT WHEN WE FEEL IT'S IN ERROR AND WE FEEL IT IS DOING SOMETHING THAT IS HORRIBLY AND TERRIBLY WRONG.

I WOULD LIKE TO ASK ALL OF US IN THIS ROOM TO LOOK INTO OUR HEARTS. JUST TURN OFF OUR MINDS JUST A LITTLE BIT AND LOOK INTO OUR HEARTS FOR A MOMENT AND SAY, ISN'T IT TIME WE STOPPED. COULD WE PLEASE JUST STOP. FOR YEARS AND YEARS AND YEARS THE MEN HAVE BEEN OUT ON THE BATTLE FIELD TRYING OUT THEIR NEW TOYS, HANDTO-HAND COMBAT WITH EACH OTHER AND NOW WE HAVE MOVED INTO AN ERA WHERE WE ARE TALKING ABOUT ANNIHILATING WHOLE SEGMENTS OF THE POPULATION ON PURPOSE, WHETHER ITS DEFENSIVE OR OFFENSIVE, AND THE DEFENSIVE SOON BECOMES OFFENSIVE. WE HAVE ALREADY SEEN THAT HAPPEN IN THE NUCLEAR ARMS RACE. ISN'T IT TIME FOR US JUST TO SAY, NO. LET'S NOT DO IT ANY MORE. LET'S NOT TRY OUT THIS TOY, LET'S NOT SEE IF IT WORKS. LET'S JUST LEAVE IT ALONE AND IN PLACE. WE'VE ALREADY -- YOU KNOW, WE TRIED OUT A NEW TOY 43 YEARS AGO AND WE DON'T WANT TO TALK ABOUT THAT TONIGHT BECAUSE IT'S NOT IN THE DEIS, BUT WE TRIED OUT A NEW TOY 4) YEARS AGO AND WE ARE THE ONLY COUNTRY ON THIS PLANET THAT HAS EVER KILLED CIVILIAN

POPULATION WITH A NUCLEAR WEAPON. WE HAVE DONE THAT. THAT'S OUR HOLOCAUST. THAT'S OUR RESPONSIBILITY AND UNDER NUREMBERG I BELIEVE I AM REQUIRED AS A CITIZEN TO STAND UP IN ANY FORUM, THIS FORUM OR ANY OTHER FORUM AND SAY, NO. WE WILL NOT DO IT WITH MY APPROVAL AND I ASK YOU TO LOOK INTO YOUR OWN HEARTS. DO YOU REALLY WANT TO CONTINUE? DO YOU REALLY WANT TO KEEP PLAYING THESE DANGEROUS GAMES? COULDN'T WE JUST STOP. THANK YOU VERY MUCH.

MR. DASEY: THANK YOU, MS. HIRSCHI. THE NEXT SPEAKER IS DR. NAOMI FRANKLIN. MARY KOBLER FOLLOWS DR. FRANKLIN.

MS. KOBLER: I AM MARY ALICE KOBLER, A CONCERNED LOCAL CITIZEN WITH A VERY LONG MEMORY. I AM UNCONVINCED OF THE ARMY'S RELIABILITY IN SEVERAL AREAS. CONSIDERING WHAT IT HAS TAKEN TO GET YOU GUYS HERE TONIGHT TO HAVE THIS HEARING HELD HERE TONIGHT, I AM UNCONVINCED THAT YOU ARE TRULY HERE TO LISTEN TO MY CONCERNS. I AM, HOWEVER, VERY, VERY GRATEFUL FOR OUR SYSTEM OF GOVERNMENT THAT ASSURES RESPONSIBLE PATRIOTIC CITIZENS TO EXPRESS OUR CONCERNS. SINCE THE ARMY IS LEGALLY UNTOUCHABLE AND OUR ONLY DEFENSE AS CONCERNED CITIZENS IS TO DEMAND AN ENVIRONMENTAL IMPACT STATEMENT THAT ADEQUATELY ADDRESSES WHAT YOU ARE CAPABLE OF DOING, NOT WHAT YOU SAY YOU ARE GOING TO DO, BUT WHAT YOU ARE CAPABLE TO DO. I THINK THE ARMY SHOULD HAVE TO PREPARE AN ENVIRONMENTAL IMPACT STATEMENT FOR EVERYTHING

YOU DO. IF YOU WOULD HAVE HAD TO PREPARE AN ENVIRONMENTAL IMPACT STATEMENT WHEN YOU MOVED FROM THE UNIVERSITY TO DUGWAY YOU WOULD NOT HAVE BEEN ABLE TO LEAVE ANTHRAX AND TULAREMIA IN GLASS VIALS ON SHELVES. WHEN ASKED TO TAKE RESPONSIBILITY AND TO CORRECT THE SITUATION, THE ARMY TOLD US THAT IT WAS OUR PROBLEM. ENVIRONMENTAL IMPACT STATEMENTS ARE THE ONLY ASSURANCE WE HAVE FOR DEMANDING RESPONSIBLE SCIENTIFIC STUDIES AND ACTION. ALL OTHER PROPOSED SCIENTIFIC WORK MUST INVOLVE RIGOROUS PURE REVIEW. I CALL UPON YOU TO DO RESPONSIBLE SCIENCE. I ALSO CALL UPON YOU TO EXAMINE YOUR EXTREME LACK OF CREDIBILITY WITH THE PATRIOTIC CITIZENS OF THIS STATE. PLEASE DON'T DISMISS US AS BEING EMOTIONAL, RADICAL, UNEDUCATED FOOLS. WHAT WE ARE DEMANDING OF YOU IS A BROAD BASED LONG-TERM PERSPECTIVE. THANK YOU.

MR. DASEY: THANK YOU. THANK YOU, MS. KOBLER. IF DR. FRANKLIN IS NO LONGER HERE, OUR FINAL SPEAKER IS MR. ROBERT MCBRIDE.

MR. MCBRIDE: THE CITIZENS OF THE STATE OF UTAH ARE SCARED. THEY ARE SCARED OF THIS NEW BIOLOGICAL WEAPON OUT HERE AT DUGWAY AND THEY ARE WANTING ANSWERS. THE BASIC QUESTION SHOULD BE, DO WE NEED THIS? IT SAYS IN THIS ENVIRONMENTAL IMPACT STATEMENT THAT BASICALLY THAT ONE OF THE REASONS FOR IT IS BASIC SCIENTIFIC RESEARCH. SURELY THIS CAN BE DONE BY CIVILIANS AND DONE ON DISEASES THAT ALREADY EXIST, SUCH AS DIABETES, AIDS, ETC., THAT HAVE NO

KNOWN CURE. SECOND REASON FOR THIS IS A DEVELOPMENT FOR MEDICAL DEFENSE. OBVIOUSLY, THIS IS LUDICROUS. THERE IS NO DEFENSE POSSIBLE AGAINST A BIOLOGICAL ATTACK. ANY SCIENTIST WITH ANY CREDIBILITY CAN MAKE A BIOLOGICAL WEAPON THAT COULD DEVASTATE THE COUNTRY. THERE IS NO WAY THAT WE COULD IMMUNIZE EVERYBODY AGAINST EVERY POSSIBLE CONCOCTION THAT SCIENCE CAN DREAM UP AND GERMS TEND TO MUTATE, THEY CHANGE. SO ONE DEFENSE THAT IS ADEQUATE ONE DAY, THE NEXT DAY IS NOT. THE THIRD REASON STATED IN HERE FOR BUILDING THIS IS TO BUILD A DEFENSIVE SYSTEM, OBVIOUSLY THIS CAN'T BE DONE WITHOUT A MEDICAL DEFENSE. SO THEREFORE, THERE ARE NO REASONS TO BUILD THIS LAB AND THIS PROPOSED LAB IS NOT SAFE. IF IT IS PERFECTLY SAFE, WHY BUILD IT OUT IN THE MIDDLE OF THE DESERT, WHY NOT IN NEW YORK CITY? LIVES IN IDAHO AND CENTRAL UTAH ARE JUST AS IMPORTANT AND VALUABLE AS ANY OTHER LIVES AND TO SAY THAT THE WINDS ARE JUST GOING TO BLOW DOWN THE CENTRAL UTAH AND NO BIG DEAL, I DON'T THINK CARRIES MUCH WEIGHT.

200 OPEN AIR TESTS HAVE ALREADY BEEN CONDUCTED OUT AT DUGWAY PROVING GROUND, MAYBE WITH DEADLY GERMS. WE ARE LUCKY SO FAR THAT AN EPIDEMIC HAS NOT OCCURRED BECAUSE OF THIS AND IT IS UNKNOWN WHAT FUTURE EFFECT THIS WOULD HAVE. LABORATORIES ACROSS THE NATION REGULARLY SEND SPECIMENS, MEANING GERMS, THROUGH THE U.S. MAIL DEPARTMENT. I FIND THIS TOTALLY REPREHENSIBLE. IF WE ARE CONCERNED

ABOUT NATIONAL SECURITY, SENDING IT THROUGH THE MAIL DEPARTMENT, WHERE TERRORISTS CAN GET A HOLD OF IT AND USE IT AGAINST US, IS OBVIOUSLY NOT THE WAY TO GO. THIS TOTAL LACK OF SECURITY IS JUST ANOTHER EXAMPLE OF HOW UNSECURE THIS BASE COULD BE. I AM A LABORATORY ASSISTANT AND I KNOW HOW ACCIDENTS CAN HAPPEN, EVEN UNDER THE BEST CONDITIONS. THEY DO OCCUR. I THINK THE ARMY'S MENTALITY ON THIS WAS, IF WE WANT BL3 OUT HERE AT DUGWAY, WE WILL ASK FOR A BL4 AND COMPROMISE AND GET WHAT WE WANTED IN THE FIRST PLACE.

NOW, FOR THE COMMENT ON WHAT SHOULD BE -- WHAT I WOULD LIKE ADDRESSED IN THE FINAL ENVIRONMENTAL IMPACT STATEMENT, A COMPLETE EVACUATION PLAN FOR A CHERNOBYL-TYPE DISASTER, OCCURRING OUT HERE. I KNOW IT'S NOT A NUCLEAR POWER PLANT, BUT IF IT ALL WENT UP INTO THE AIR, WENT UP AND DOWN CENTRAL UTAH OVER IN IDAHO, OVER IN SALT LAKE CITY, HOW ARE WE GOING TO GET RID OF ALL OF THESE PEOPLE OUT OF THE INFECTED AREA IN THE AMOUNT OF TIME THAT WE HAVE? THESE LIVES AREN'T EXPENDABLE.

I WOULD LIKE TO SEE A NONMILITARY OVERSEE OF THE PLANT. I THINK THAT THIS IS NECESSARY IN ORDER TO PREVENT OVERZEALOUS MILITARY PEOPLE, SUCH AS COLONEL NORTH AND ALSO JUST -- IT'S JUST COMMON SENSE. THE USE OF BL2 GERMS, NONTOXIC GERMS, THAT WOULDN'T KILL US RIGHT OFF, IS OBVIOUSLY A GOOD IDEA AND NOT TO USE THESE HIGHLY CONTAGIOUS

GERMS.

I AM SORRY FOR THE NONTECHNICAL USE OF IT, BUT THAT'S THE WAY THE PEOPLE OF THIS STATE REFER TO IT. IT'S NOT SOME EXOTIC THING, IT'S GERMS THAT CAN KILL THEM AND THAT'S WHAT THEY KNOW ABOUT AND IT'S DEADLY. NONAEROSOL TESTING, THROWING GERMS UP IN THE AIR AND LETTING THEM FLY AROUND AND SEE WHAT KIND OF AFFECT IT HAS, WHY I AM SURE YOU GUYS, BEING FROM BACK EAST, YOU WOULDN'T KNOW ABOUT THIS, IT'S NOT A VERY GOOD IDEA. WE DON'T APPRECIATE IT.

SINCE THE ARMY SAYS THAT SAFETY IS THE NUMBER ONE SAFETY OF THE UNITED STATES IS THE NUMBER ONE FACTOR, IT'S BETTER TO BUILD A SPACE TESTING FACILITY, THAT WAY WE KNOW IT WOULD BE SAFE OUT IN SPACE. WE COULD MONITOR IT A LOT BETTER AND IT WOULDN'T BE ABLE TO SPREAD. THIS IS A DEMOCRACY, THE UNITED STATES, AND I THINK THAT PEOPLE IN THE STATE OF UTAH HAVE THE INTELLIGENCE AND HAVE THE WISDOM TO MAKE GOOD CHOICES. I SAY, LET THE PEOPLE OF UTAH VOTE ON WHETHER THEY WANT THIS OUT HERE.

MR. DASEY: THANK YOU, MR. MCBRIDE AND I THANK EVERYONE WHO PROVIDED COMMENTS TONIGHT. ALL COMMENTS RECEIVED ARE PART OF THE RECORD AND WILL BE ADDRESSED IN PREPARATION OF THE FINAL ENVIRONMENTAL IMPACT STATEMENT, THE PUBLIC FACILITY COMMENT PERIOD ON THIS STATEMENT CLOSES 4 OCTOBER,
1988 AND THE FINAL ENVIRONMENTAL IMPACT STATEMENT IS DUE OUT IN APRIL, 1989. THANK YOU AND GOOD NIGHT

(THE PUBLIC HEARING WAS CONCLUDED.)

left blank intentionally

STATE OF UTAH) : SS.
COUNTY OF SALT LAKE)

I, JANE MARY FARLEY, SHORTHAND REPORTER AND NOTARY PUBLIC WITHIN AND FOR THE COUNTY OF SALT LAKE, STATE OF UTAH, DO HEREBY CERTIFY:

THAT THE FOREGOING PUBLIC HEARING WAS TAKEN BEFORE ME AT THE TIME AND PLACE SET FORTH HEREIN AND WAS TAKEN DOWN BY ME IN SHORTHAND AND THEREAFTER TRANSCRIBED INTO TYPEWRITING UNDER MY DIRECTION AND SUPERVISION;

THAT THE FOREGOING PAGES CONTAIN A TRUE AND CORRECT TRANSCRIPTION OF MY SAID SHORTHAND NOTES SO TAKEN.

IN WITNESS WHEREOF, I HAVE SUBSCRIBED MY NAME AND AFFIXED MY SEAL THIS 30 DAY OF SEPTEMBER, 1988.

JANE MARY FARLEY, SHORTHAND REPORTER AND NOTARY PUBLIC

UNITED STATES DEPARTMENT OF DEFENSE
DEPARTMENT OF THE ARMY
BIOLOGICAL DEFENSE RESEARCH PROGRAM
+ + + +
PUBLIC MEETING
ON THE
DRAFT ENVIRONMENTAL IMPACT STATEMENT
+ + + +

Monday, July 25, 1988

Rosslyn Westpark Hotel
Rosslyn, Virginia

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A14-140a

DR. ROSENBERG: I am Barbara Rosenberg of Sloan-Kettering Institute, a molecular biologist, who has been following the biological weapons issue for some years I have occasionally written on the subject, and I'd like to thank you for the opportunity to

speak today.

We're fortunate to have several lines of defense against biological weapons. The first line is drawn by the international treaties that outlawed the development, production, possession, and use of biological weapons: the Geneva Protocol and the Biological Weapons Convention.

Our second line of defense is deterrence, provided by a strong U.S. military position with regard to other types of weapons.

And the third line is the biological defense provided by the Biological Defense Research Program for the soldier in the field. Because of the Biological Weapons Convention and our strong military position, biological weapons do not pose a significant strategic threat to the United States.

Rather, the mayor threat arises from the possible use of biological weapons by terrorists or psychopaths or from accidental escape of biological weapons from the containment facilities in which they are studied.

The latter is one of the topics addressed in the draft Environmental Impact Statement. What is not addressed is the greatly increased danger of accidental escape that would result if there were a proliferation

of military facilities studying biological weapons, agents around the world.

Once a biological weapons race got started, it would not be constrained by cost or technological accessibility. Nor would it be likely to exclude efforts to develop novel agents using genetic engineering.

Proliferation is a very grave danger, not just because it could lead to biological warfare, but also because shoestring operations carried out with varying degrees of technical competence and responsibility in multiple locations and sometimes inadequate facilities are almost certain to result in breakdown of containment.

Against the resulting possibility of global epidemic for the establishment of new diseases, military defenses would be largely useless. The DEIS does not consider the relationship of Biological Defense Research Program to such a multiplied threat to the global environment.

It's important to recall that biological weapons have not been considered militarily useful because of their massive, unpredictable, and potentially uncontrollable consequences that could produce Global epidemics and impair the health of future

A14-141b

generations, as President Nixon said.

The new biotechnologies do not alter this situation. Consequently, it is the population that is at risk and more at risk than truce because along the way, before microbiological weapons agents can take effect, makes their battlefield use unlikely.

Military defenses cannot protect the public. Therefore, it is of primary importance that the military defense program should not undermine our primary lines of defense, the Biological Weapons Convention and deterrence by other weapons.

However, international confidence in the Biological Weapons Convention is being eroded by suspicion that alternative research, possibly involving the use of genetic engineering techniques to create novel pathogens with weapons potential, that such research is being carried on under the guise of defensive activities.

It behooves the United States and other nations as well to make every effort to dispel such suspicions. Otherwise, smaller nations may decide that they, too, must acquire the before -announced nuclear arms.

We are now at a critical point in the history of biological arms control. Biotechnology is new;

nothing happened yet. And there is strong international concern and desire to strengthen the treaty regime.

The reasons we've undertaken confidence-building measures involving the exchange of information are a prelude to the establishment of measures to verify compliance and resolve complaints. The stringent provisions already agreed to in the chemical weapons negotiations provide a model.

But the Department of Defense in recent years has been generating, rather than allaying, suspicions by its imprudent and unjustified rhetoric on the military utility Or biological weapons and by certain aspects of the BDRP. Various changes in the BDRP could solve this problem.

But because the problem is not acknowledged in the DEIS, all of the possibilities of change have been passed off. The moat controversial aspects of the BDRP are threat assessment, the possible development of novel organisms and toxins for that purpose, large-scale aerosol testing, and field testing.

These items, the major sources of suspicion, are scarcely mentioned in the DEIS. This vast document is anything but comprehensive. It appears to be intended as a therapeutic dose of highly repetitive

thin rule.

The big questions are avoided or obscured, questions such as: In what situations simulants are not adequate and why? When is aerosol testing necessary? with what agents and of what scale? What kind of evaluation and documentation is to be prepared before field testing or novel agent development? Is public input guaranteed? Who will decide?

One thing that the DEIS does not slight is the benefits of the medical program to science and public health. But these real benefits could better be provided in the civilian sector. They are not acceptable as rationales for a program whose purpose is national defense.

The medical work, of course, does provide defense benefits. But a medical defense can also be viewed as necessary for offensive use of biological weapons.

In addition, suspicions inevitably arise as to whether the medical work produces offensive information as a by -product or provides a cover for potentially offensive activities, such as the development of novel agents.

In this light, it is clear that the transfer of all medical activities to a civilian agency could

provide a reassuring and significant alternative to the present program.

Turning from the medical program to passive defenses: that is, protective devices, decontamination procedures, and detectors which are developed and operationally tested according to the DEIS at the BL1 and BL2 containment level, the question arises whether any testing of these items at higher containment against actual BE agents is necessary, and if so, whether it must be done with aerosols or on a large scale.

The DEIS merely states that limited use of high -hazard organisms is necessary, implying that small -scale non-aerosol testing is adequate. It's hard to see why defenses that meat work against all possible threats should require specific testing at all.

With a little ingenuity, it should be possible to devise teats with a series of innocuous agents, possessing a range Or relevant properties that would suffice.

Detectors, too, must have a wide range. It would not be sate to rely on specific detectors. There are too many potential BW agents. But, even for detectors based on specific recognition principles, it appears from the DEIS that development is carried out

with simulants.

Verification that specific adaptations actually do work could be accomplished on a very small scale. The need for field testing is not obvious and is never discussed in the DEIS.

Since all medical testing, which, unquestionably, does require the use of pathogens, is done at U.S. Armory, or so the DEIS suggests, there is no clear case for any testing at the Dugway Proving Ground, except with innocuous agents and indoors.

There is, however, one brief mention of a function requiring pathogens, listed among other functions, that may be the major BDRP activity at Dugway. And that is the laboratory assessment of biological threat agents.

If this is an important function, why is it not discussed? Is it really necessary? In the trade -off between public safety and confidence in the Biological Weapons Convention, on the one hand, and the ultra -complete testing of materiel and the study of potentially offensive agents on the other hand, where should the line be drawn? The Army has not come to grips with this question.

Perhaps it is more Dangerous to conduct secret threat assessment studies than not to do so.

A14-144a

And camouflaging threat assessment as materiel testing is no help.

Although the DEIS states repeatedly that all work under the BDRP is unclassified, the DOD Director of Environmental and Life Sciences, Thomas Dashiels, says, quote, abnormally our threat assessment and equipment vulnerability work is classified.

Furthermore, secret clearance is required for the members of the Dugway Institutional Biosafety Committee. But the DEIS does admit that those results which impinge on the national security may be classified.

I'd like to see a statement of how the work and the results are separated. It is important to recognize that secrecy or uncertainty about activities with offensive potential is provocative, regardless of the actual intentions and actions of the Army.

The DEIS-does not disavow the use of genetic engineering to create novel organisms with w eapons potential. It merely confines its discussion of genetically engineered materials to their use in medical research, thereby creating uncertainty.

It does say that no work with genetically engineered microorganisms is performed or planned at Dugway, while acknowledging that the program is ongoing

and changes can be expected.

A changed policy at Dugway can be anticipated if the proposed BL IV aerosol testing facility is built. Or perhaps not. But so it appears to interested observers around the world.

Clearly the option remains open to develop genetically engineered novel organisms for ambiguous defensive purposes such as threat assessment. And their development may be even now underway.

In such a situation, as Lieutenant Colonel Wyatt Colclasure has said, quote, "You do get information and like a lot of information, you can put it to different uses, n unquote. Thus the suspicion Or offensive activity.

DOD's interest in threat assessment with novel organisms, including work to be carried out at Dugway, is unequivocal. It is set forth in some detail in the DOD report to the House Committee on Appropriations dated May, 1986, which says in part, and I quote, "The threat posed by new biological agents must be established with the greatest degree of certainty possible.

"This high degree of certainty must also be established for information on the ramifications of new production and processing technologies as they apply to

conventional and novel threat biological agents. The proposed biological agent test facility is required to generate basic laboratory data to meet these threat assessment needs," unquote.

This policy is likely to provoke the very threat that is feared, without actually providing any defense against it. For, as the DEIS suggests, the number of novel biological weapons agents that could in theory be developed is so vast that the development of specific defenses is impossible.

Generic approaches are being explored. Indeed, truly generic defenses which could be developed, if they can be developed at all, without the creation of novel organisms would be the only logical ones. But again, the only real defense is a good treaty, good intelligence, and military strength from other weapons.

The possibility that exploratory research may already be going on at Fort Detrick to determine the military potential for genetic engineering is one that needs to be addressed in the EIS. Either it must be explicitly disavowed, or its environmental impact must be considered.

An accident with a novel agent could be far more serious than with a known agent, because of the

lack of medical experience with the agent, uncertainty about its effects in humans, lack of tested vaccines, possible built-in insensitivity to treatment, and so f orth.

Such experimental agents might be designed to persist under adverse conditions, making them difficult or impossible to eradicate.

The possibility of starting an epidemic, more devastating than AIDS, cannot be ruled out. The DEIS indicates that all perceived environmental threats are in fact so thoroughly controlled by the BDRP that the only true problem is psychological. But the recent preliminary report of Senator Levin's Government Management Oversight Investigation of safety in the BDRP finds otherwise.

More will be heard from that subcommittee on the safety issue. Suffice it to say here that the DEIS does not have a tenable basis for ruling out all changes in the existing BDRP.

In the scoping process, it was suggested that the simulants and the innocuous agents be used in place of hazardous agents, and that genetic engineering work be discontinued. Obviously, the medical program could not be carried on under those circumstances.

But what about the rest of the program? I've

already suggested that the medical program be transferred out of DOD to allay suspicions. If that were done, it would be a simple matter to apply general restrictions to the BDRP.

But if not, it is still possible to restrict certain facilities and projects. The large -scale aerosol testing at Dugway and elsewhere is non-medical. Why could this not be restricted to non-pathogens?

Or could testing with pathogens and hazardous materials be restricted to a small, specified scale? I would like to see unbiased expert input on these questions, with real scientific discussion, taking up the need for pathogen testing or not for each of the various purposes under the BDRP.

Since the BDRP is said to be unclassified, it should not be difficult to find means for making its activities more open, testing in particular. It is widely assumed that the main incentives for secret testing are to obtain offensive information and to keep secret the defensive capabilities needed for offensive use of biological weapons.

Increased openness would be an important step in preventing the erosion of the Biological weapons Convention. If tests with pathogens continue, advance notice of each test, including the names of the

organisms to be used, in the Federal Register would be a safety and confidence -building nature.

Outside review by experts of each intended use of pathogens or hazardous material, to verify the need would be reassuring, a way to solve the psychological problem. The public has a right to know about every organism that is handled in its facility.

At a minimum, an annual publication of an exhaustive list is a must. Another must is resolution of the question: What is a novel agent? DOD should renounce absolutely any work to develop or use novel agents except for cloning purposes in unclassified medical projects.

In sum, the DEIS shows that the BDRP is narrowly focuses on a small part of biological weapons problem, and there is no recognition of the need to ensure that the program fits constructively into the larger picture with regard to safeguarding the global environment.

A large number of scientists and members Of the public are seriously concerned about this. We want to see the BDRP reviewed with an open mind and modified appropriately, so that it can make an unambiguous contribution to real national security. Thank you.

MODERATOR DASEY: Thank you, Dr. Rosenberg.

Your comments will be considered in the preparation of the final Environmental Impact Statement.

I neglected to point out that the floor mikes are intended for use by presenters.

The next presenter is Mr. Andrew Kimbrell from the Foundation on Economic Trends.

MR. KIMBRELL: Thank you for the opportunity of speaking this afternoon. The comments from the Foundation on Economic Trends will be submitted in written form.

But I'm taking the opportunity today to provide a summary discussion of the problems we see in the Environmental Impact statement. I'm sure you all know that the Environmental Impact Statement wee prepared as a result of a lawsuit filed by our organization September '86.

In 1987, the Department felt, in essence, that it needed to make the final act of a policy action. And we have the Environmental Impact Statement now before us. Obviously, the policy act was not intended for such non -compliance.

The entire effort at passage, indeed the essence of it, wee that it be available prior to Agency decision -making, in order to inform both the Agency, other government agencies, and the public in general,

of the environmental potential for the particular program and to allow firm and judicious decision-making, given that record.

So we already have a problem with the Biological Defense Research Program, that compliance wee post hoc many, many years after it should have been accomplished. Therefore, the legal burden on this document is very, very heavy.

That burden is not only to make up for a fire non-compliance, but also to provide an adequate record of the environmental hazardous program so decision-making in the future may be based on this record.

And the lynch-pin Or the above, that the public know the Agency is going to be fully informed Or what this program entails and the hazards it entails.

Many of these concerns were carefully spelled out in the complaint that we filed in September, 1986 on this program. It's plain to see what our first l major problem with this draft Environmental Impact l Statement, which is a woeful act of information about BDRP. What we have is a Roman miracle edification, with over 100 contracts out, sites, facilities, where this research is ongoing.

But no big detailed description of what pathogens are being worked at those sites, exactly

what kind of work is being done with those pathogens, who precisely has access to those pathogens, what is being done as far as security, what is being done as far as inventory, what is being done as far as emergency measures while in that facility and the community surrounding that facility? What beyond the normal regulations are there in terms of transportation? And with laboratory surety?

What would be required, I think, for an adequate Environmental Impact Statement would be just such information about each and every national and international site currently involved in BDRP.

Without such discussion, it is very difficult to see how we can have a serious discussion of alternative sites, the rationale Of having a particular experiment done at a particular site, and any decision -making as regards the environmental hazards of any project and where that project is going to take place.

So the first major problem we have is with identification. I repeat, not only with sites, but exactly what pathogens are being worked at the sites, and what is being done with them, and the various work loads at each particular facility and location in their BDRPs.

The group does select certain sites, but the

decision on which sites to choose were obviously not part of the scope of the meeting of August 12th, and I cannot reason why each one was chosen, and, of course, I think we should see an entire review of all the facilities.

The second major problem I think that we have is that the discussion of alternatives, which is a substantial part of the things we need to discuss, is inadequate, and apparently a greater feeling of discussion of shifting much of the focus of civilian agencies.

There's many reasons, I think, for doing this, the major one being accountability, which is, for certainly all experiments which, and this is a nonclassified program, after all, they're dealing with pathogens, with NIH guidelines, which according to June comment would be far better than having them in NIH or some agency which is required to have guidelines rather than complying with them voluntarily.

Obviously, it would be good to set up required reporting of accidents, required reporting of violations, rather than the volunteer approach currently being taken.

The second major concern, I think, is in combining certain alternatives. That is, the draft

Environmental Impact statement deals separately with shifting research and civilian sites and a moratorium, for instance, on GEM.

It would seem one good possible alternative is shifting genetic engineering work, at least to civilian agencies, particularly those that require obeying of NIH guidelines.

It would be better for the Department of Defense to declare a moratorium in any genetic engineered work currently ongoing, allow that work to be taken at more accountable agencies.

This is important for another reason, which is, as the Appendix A of the Environmental Impact Statement carefully states, there is no real difference between offense and defense it work is being done at Department of Defense facilities.

Certainly when, as they did in Fiscal Year '87, the Department of Defense starts phoning, analyzing snake venom from sea snakes.

This is research at the cutting edge of possible passage into military significance and those of us in the public sector, of course, do feel distrustful that this work is solely being done for defense purposes without a showing that there is some offensive intent by some other nation to develop sea

snake venom as a meaningful weapon.

There's another reason for this besides the l distrust that offensive may become defensive, and that l is the use of substantial numbers of volunteers, not l only nationally but also internationally.

Fiscal year '87 report of the BDRP establishes that hundreds of volunteers have been used nationally and in the near future, thousands are to be used internationally.

Recently they've had an experiment in Wistar in Argentina where pseudo -rabies vaccine was being tested in Argentina. This caused an international incident as many of the workers became infected as part of the reaction to the vaccine.

This was done with voluntary compliance with NIH guidelines. We now have an international circumstance where NIH guidelines are still being clarified as to how one complies with them on an international basis.

We're not talking about pseudo-rabies In animals; we're ta lking about thousands of individuals being tested with BDRP vaccines internationally.

This is a very serious issue, both nationally and internationally, even with NIH guidelines. It seems quite appropriate that any such experimentation

be given to domestic agencies.

Third, it is impossible at this point to make any kind of analysis of the environmental hazards to the program until we have some certain navigation of the number of viruses, the types of pathogens, the types of bacteria that are constantly being investigated.

It is clear that one of the purposes of the program is to investigate just such unknown pathogens for military significance. This research, it seems to me, should have been taking place at Yale University and other places.

Additionally, the attempt of the Department of Defense to analyze novel pathogens, both by changing or rearranging the traditional pathogens, as well as the investigation of possible new pathogens for military significance, should be carefully circumscribed.

Should be allowed full public knowledge of exactly what new viruses and what new techniques are being used.

Without such full public information, the environmental hazards of this program cannot be known to the public and other agencies and therefore the need for the process cannot work.

And finally, I think that one of the

alternatives not mentioned is one that their belief is that much of the current genetic engineering technology doesn't fit in the 1972 Convention. This has been stated by Douglas Fyffe and even former Secretary Weinberger.

As such, this is again another reason to declare a moratorium on the genetic engineering experiments currently going on in the Department of Defense.

If there is some doubt, as the Administration has expressed, that there can be significant control in the use of genetic engineering as an offensive biological weapon, surely we should be in the forefront, because we are in the forefront of this research.

The forefront of the international community not even giving the appearance of creating such novel agents or using genetic engineering to create this novel agent, particularly when the Department of Defense admits itself that in the early stages of research that it is impossible to distinguish between and offensive and defensive work.

Indeed, it is only the quantitative and not the qualitative amount of such viruses that distinguishes offensive versus defensive. Given that very gray area, there seems to be another important alternative which is to declare that certain research is

unclear in terms of the 1972 convention and until that is clarified, a moratorium on any such work until that can be clarified.

So those major areas, full information provided on every facility, full discussion of analyzing the possible parts of the program going through an agency, particularly those agencies that are not voluntary but are required to submit to NIH guidelines.

Third, a mixing of those possible alternatives, and by the way, creating essentialized environmental concern for those agencies as well would be a big cooperation. And finally, a full examination of how the current program goes beyond the possible scope and restraining ourselves from any such research until that has been obtained. Thank you very much.

MODERATOR DASEY: Thank you; Mr. Kimbrell. A file of your comments will be considered in preparation of the final Environmental Impact Statement. The next speaker is Mr. Peter sticker, a resident of Frederick County, Maryland.

MR. STICKEL: Good afternoon. With all due respect to the technical knowledge and expertise of the distinguished panel up front, I would appreciate your indulgence for about three to five minutes to express my views as a private citizen in regards to this DEIS

thing. And I will read the statement from my notes.

Thank you for giving me the opportunity to respond to the statements made in the local Frederick County newspaper concerning the situation ongoing at Fort Detrick, Maryland.

I will only take approximately three to five minutes of your time to develop my opinion on the perspective and from the perspective of a typical average citizen of the United States.

Since I am a resident of Frederick City and also reside in a direct line geographically with the USAMRIID Laboratory. I'm in a position of knowledge as to the effect, environmentally speaking, of the conditions that presently exist there.

But, more importantly, I have a continuous awareness of its history and its total effect on the immediate Army community and its effect on surrounding neighbors such as myself.

As a public citizen, I am obliged to seek the necessary knowledge, to be an informed member of society concerning the laws, rules, and regulations governing civil order as duly constituted in the laws of our elected representatives who enact them, and these laws are binding on all the subjects of the state.

In relation to the observance of all our laws, whether just or whether unjust, a restatement of the virtue of patriotism is essential in this particular hearing conducted today, namely that patriotism is simply the love of one's country, and a good citizen will not hesitate to face death in the defense of his country.

Now, I regard with mixed feelings the press' view of the situation that exists at the Laboratory. One the one hand, I as a member of the public am being informed of a condition that's viewed by the local press as worthy of being looked into, whereas on the other hand, the press wants to give the impression that a, quote, "problem exists," or has been existing for some time in the past.

My reaction to the press' view is that the press should exercise extreme care in the reporting of the truth of the matter so that the reading public can balance it with sincere concern for the U.S. Army and USAMRIID Laboratory interest and not be so quick to point out a picture of a real or imagined problem that may or may not exist.

Freedom of the press carries with it a supreme obligation to carry out its responsibilities in a totally truthful manner, regardless of a particular

writer's or publisher's views or personal opinions on any given subject under discussion.

Especially careful should the press be when it reports on such topics on such paramount importance as the health and welfare of its citizenry. I am a reasoning member of the public and have a and have a duty to inform myself of the situation as regards to whatever risks that I feel that I can live with and inform my family of the situation and take the necessary action to protect my family from those risks that exist at the Laboratory.

A concurrent view of the press is to not look at the magnitude of the situation at the Laboratory, so that the public at large becomes unnecessarily alarmed and gives expression to its alarm by means of civil protest and disobedience to the civil laws governing society.

Because I am not connected in any way with Fort Detrick, and because I represent myself and my family's health and welfare, and their best interests, I personally feel that there is no greater risk to me and my family's health and welfare with the present setup at the Laboratory and it appears to me as a member of the public, that the USAMRIID Laboratory poses no threat or risk to the public at large

The constant idea that exists in the minds of the public concerning looking for fault and all that with the U.S. Government, and in particular looking for fault in the four branches of the military establishment is totally irresponsible and should be discouraged by all citizens of this great country and form of government that we all enjoy in fellowship and its privileges of citizenship.

The press should take a look at itself before it reports on its, quote, "alleged condition" that may or may not exist at Fort Detrick, Maryland and be more responsible to its own conditions of fairness and its responsibilities to the public at large, and its fairness to all sides of a given topic under scrutiny.

Let the people of Fort Detrick go on about their business of protecting the citizenry of the U.S. and participating in a very positive contribution so that all the citizens benefit from the research and scientific discoveries without any unnecessary interference from anyone, including all branches of Government, namely the Legislative, Executive, and Judicial branches.

In its basic and simplest terms, the Legislative branch of Government is unnecessarily interfering with the activities of another branch of

Government, namely the Executive branch, and exacerbating a situation with its present views on the merits or demerits of the USAMRIID Laboratory situation.

Thank you very much for allowing me this time to speak as a private citizen from the perspective of a typical citizen of the United States of America. Thank you very much.

MODERATOR DASEY: Thank you, Mr. Stickel. It's 2:00 now. We'll take a five -minute break.

(Whereupon, the foregoing hearing went off the record at 2:00 p.m. and went back on the record at 2:11 p.m.)

MODERATOR DASEY: We'll reconvene now; We have three more speakers. The first speaker is Mr. William Patrick, a resident of Frederick county.

MR. PATRICK: Thank you, Mr. Dasey. I am William C. Patrick, Continuing President of Frederick County, and have been since 1950. If you come from Frederick County, it's always important that you define how long you've been there.

In the 1967 and 1968 period, a small but vocal group of people began a campaign to bring about the abolishment of the offensive biological warfare program.

Their approach to this objective was to flood

the media with a steady stream of charges regarding program safety and security and safety of the community which surrounds Fort Detrick. By 1969, and environment of hysteria had been created, which prevented reasoned discussions with these people.

I was one of many employees in this program. who felt that our research and development were making an essential contribution to the defense of our country. I soon came to realize, however, that these people were not interested in biological safety, or any other aspects of the programs.

President Nixon succumbed to these and other political pressures and abolished the offensive biological warfare program in November of 1969. Thus, the United States unilaterally surrendered an entire weapons system.

I'd like to depart from my prepared text just momentarily to comment on Dr. Rosenberg's statement regarding the unpredictability of biological warfare. My wish, at some point in the future, is that the Department would declassify some Of the large-scale tests that were conducted which showed beyond any measure of a doubt that biological warfare was preplanned and under divine meteorological conditions, confirmed -- all those table, mathematical models, what

have you -- and that on these conditions, biological warfare was the weapons system that could be predicted.

Today, some 20 years later, another small but highly vocal group of protectors seemed to be targeting the defensive biological warfare programs, particularly the medical defensive program. Once again, safety seemed to be the principal buzzword. But let me tell you, ladies and gentlemen, they can't make it stick. Like one of the speakers at he recent Democratic convention stated, "That dog won't fly." It won't hunt, either.

During the offensive BE program at Fort Detrick, a small group of dedicated scientists established the principles on which modern-day safety technology and laboratory design were founded. Scientists such as Dr. Arnold G. Wedum, Riley D. Housewright, Charlie Phillips, and Everett Hanel, to name just a few, were truly heroic pioneers.

And every person who works on infectious disease laboratory today owes these gentlemen a tremendous debt of gratitude. Their contributions are described in somewhat greater detail in Appendix 9 of the Environmental Impact Statement.

During these 26 years of offensive BW studies at Fort Detrick, not a single person in the community

became infected or intoxicated. This demonstrates quite clearly that even 20 years ago, Fort Detrick did not pose a safety problem to the surrounding community.

Yes, there were infections among the at-risk laboratory workers -- 423 of them and three deaths occurred from 1943 to 1970. The important factor here is that these were at-risk people, people who worked in the hot areas of the laboratory.

By contrast, administrative people, like the secretaries, budget analysts and supply clerks who worked in clean areas, did not become sick. This is important because in most instances, the clean area wee separated from the hot area by a wall in the same laboratory building.

The medical defensive program for the entire Department of Defense was under the general direction of the Med Army Command, with USAMRIID as the principal leader.

USAMRIID has been able to take full advantage of the safety technologies and the laboratory building designs of the old offensive program, and to extend these technologies and laboratory designs to a high order of safety.

The safety record of USAMRIID is outstanding and is indicative of the safety measures being used in

the study of some very fancy organisms. It's true USAMRIID has had a few infections. But I submit to you that no work is risk-free.

The safety record at USAMRIID is significantly better than most industrial concerns. There have been no deaths and no disabilities or injuries.

USAMRIID employees work in the most unique and best safety-engineered laboratories in the Free World. These laboratories were designed with sufficient safety and redundancy to prevent the escape of infections and toxic parts in the surrounding community.

If old Fort Detrick labs did not cause infections in the community, you can bet your bottom dollar that the environmental laboratories at USAMRIID will not also.

I would like to believe that those of you who oppose the programs of medical defense against biological warfare do so on the basis of safety and our concern for the surrounding community. There's a body of logic which can be used to alleviate your fears.

I grant you have other motives such as stopping all defensive studies against BW. I have no sympathy with you or your cause. In the Iraq-Iran War, chemical warfare agents were used when it was in the

Iraqis' self-interest to do so, in spite of international treaties and international public opinion. BW agents could very well have been employed as subchemical agents.

The big difference between BW and CW is that the number of chemical casualties would have to be multiplied by a factor of 100 to 1,000 if BW agents were employed.

Biological defense remains our country's only deterrent. If it's stopped or even reduced, then the United States falls in a highly vulnerable position in an extremely hostile and non -Democratic world.

MODERATOR DASEY: Thank you, Mr. Patrick. Your comments will be considered in preparation of the final Environmental Impact Statement. our next presenter is Ms. Nachema Wilker from the Committee for Responsible Genetics.

MS. WILDER: Good afternoon. My name is Nachema Wilker. I am Executive Director Of the Committee for Responsible Genetics. The Committee for Responsible Genetics is a national organization with offices in Boston that represents a group of scientists, public health and public policy professionals, trade unions, environmentalists, and other concerned citizens committed to seeing the positive benefits of

the life sciences used safely and responsibly in our society.

The comment of the Committee for Responsible Genetics today will be presenting today in their abbreviated form and will be elaborated further in written comments to be presented at a later date. Our comments today will focus primarily on the discussion of alternatives within the draft Environmental Impact Statement.

The draft Environmental Impact Statement claims to address the implications of a wide range of policy options in the biological defense program. However, it quickly reduces the options in this program to two.

It concludes that continuation of the current program is the most reasonable alternative. CRG -that's the Committee for Responsible Genetics -- finds this assessment faulty for two reasons.

First, the EIS, in our opinion, has failed to address the full implications of continuation with the present policy, and second, the EIS has failed to address the full range of possible alternatives.

The goal of the biological defense program as described by the Army in the EIS is to define methods of detection for and protective measures against agents

of biological origin that could be used as weapons against the United States forces by hostile states or individuals.

These general goals may be implemented in a number of ways, depending on how the U.S. sees the threat posed by hostile states or individuals. As the Committee for Responsible Genetics has often noted, the U.S. Government in the 1980s developed a position on the nature of the biological weapons threat. As the EIS states, two factors have been important for the expansion of the biological defense program.

First, declaimed maintenance of an offensive Soviet biological weapons capability and, second, the realization that new weapons in molecular biology and genetic engineering potentially could be applied to the creation of novel BW agents or to the production of specific agents in quantities that far exceed their natural levels of biological ability.

In other words, the Department of Defense acknowledges that the specific form assumed by the biological defense program in the 1980s has been the emphasis of the threat posed by the Soviet use of new biogenetic technologies in the development of bioweapons agencies.

Implicit in this statement is that the

exploration of the threat posed by the use of new technologies for offensive purposes will continue. The Committee for Responsible Genetics finds the recommended option of Environmental Impact Statements to be inaccurate based on the following arguments.

First, it is impossible to develop effective prophylactic measures and detected defenses for genetically engineered agents. The Department of Defense would need to construct these very agents.

However, the Department of Defense interest in exploring properties of genetically modified pathogens is not addressed in the Environmental Impact Statement.

Such exploration is implicit in the results of the program and in the proposal to build an aerosol test facility at the Dugway Proving Ground. Since this is probably both the most novel and the most hazardous aspect of the program, it is essential that this be addressed more fully in the Environmental Impact Statement.

And third, the only scientifically persuasive rationale for exploring prophylactic measures and protective devices, particularly for genetically modified organisms is to protect personnel and defense laboratories and troops in combat.

A14-158a

For these reasons, the emphasis of the biological defense program of the 1980s is provocative and destabilizing. It is likely to be construed by other nations and is indicative of U.S. interest in developing novel biological weapons agents.

Based on the previous comments of the Committee for Responsible Genetics and recent concerns raised by more than 500 scientists on Friday announced their pledge not to engage in research that would lead to the development of biological weapons agents.

The Committee for Responsible Genetics proposes the following alternatives for the EIS to seriously consider. First, transfer medical research on infectious agents and toxins to civilian agencies. And let none of this work or its results remain classified.

Second, there should be no construction of novel agents in the biological defense program for any purpose.

Third, there should be no military testing or open air testing using biological agents. If there is a need for open air testing, it should be conducted with non-pathogenic simulants, unclassified, confined to unpopulated areas, and conducted in accordance with the Human Subjects guidelines.

A14-158b

And our fourth recommendation, while falling outside of the traditional scope of an Environmental Impact Statement, would be to strengthen the Biological weapons convention.

The strength of the treaty itself relies on the confidence of all signatory nations that no research is being conducted that could be reasonably perceived to violate the treaty.

Therefore, contracts in the Biological Defense Program and the results from all research development testing, including threat assessments, should be publicly disclosed and results should be publicly defended.

Thank you for this opportunity to make our comments.

MODERATOR DASEY: Thank you, Ms. Wilker, and I just wanted to remind you of the 12 August deadline for giving us the whole version of your input.

Our final speaker is Mr. Royd Smith, a delegate to the Maryland's General Assembly, who represents Frederick county.

MR. SMITH: Thank you. I am a member of the General Assembly and the Environmental Matters Committee, so it's real important to me to hear the decision, especially when it came down from Frederick

here.

And, as Mr. Patrick said, it's important to say how long you've been at Frederick, and I've been there since 1941. That's third grade. Anybody who's been there since the third grade qualifies to be called "home town boy."

So I've been there a long time and decided years ago to be a farmer. And, as such, our farm operation is only three or four miles from Detrick. In those years, it was called the "Biological Warfare Center."

And in those days, too, as a Boy Scout growing up in the community, we were introduced to Detrick Center. And all of us were back in that War World II period, I think you very graciously provide sound effects today to back that up.

But we all have the highest respect for what's been going on and the admittedly necessary strategies and investigations, as far as national defense protection.

So I think the majority of our community is convinced of the necessity. However, we do hear of a lot of problems. Now, when I was growing up back there in Frederick on the farm and J.C. was one of my best friends, whom I just saw here again today, and was in

the high echelon of Detrick echelon in the safety field.

And we always admired his courage in working with these highly infectious diseases. And we followed this all the way through. And having a close friend like that made it more prominent, as far as we were concerned, so it was first person then. And we agree. There was a lack of accidents, I think. It made the use imminent.

However, in those early years, there was also a storekeeper up on 6th Street, named Howard Dinterman, and he worked at Detrick part-time. And I could stand corrected, but I think 24 years ago, almost to the day, he was infected with staphylococcal enterotoxin B.

And it took 20 years to have the admission that this was an infection that did take place at Detrick. 20 years to admit that it had been committed and there have been settlements.

As a matter of fact, the settlement was to say, "Okay. $60,000. $7,000 a month and a van." That's what the settlement was. And this has -- Lena Dinterman is completely satisfied.

As far as Mrs. Dinterman is concerned, it is catastrophic to her life. She's been taking care of her comatose husband for 24 years.

And the point I'm making is the importance we have in Detrick. The importance we hear is not to be omitted, but there's also an importance for one person that falls through the cracks, just one person, this one widow. And she did get a settlement.

But now, now, three weeks ago, she gets a letter from the Claims Division of Workmen's Compensation that says, "When your husband dies, you have to return the van.

Now, here's an 30,000-dollar van that -- our government to her is Detrick, the President of the United States, the Workmen's Claim Division, and me. We're the government. We're all lumped in. "We have done" her "dirty," she says.

And so that one van, for them to say, "Okay. You take back my van," she's going to sue us for 15 million dollars. Now, what I'm asking is -- these meetings, I think, are very important .

And have them anywhere you want. Have them in places like this that it takes a farmer like me two hours to find. That's okay.

It's necessary for national defense. But for the sake of P.R. of Detrick and the United States government and cracking down on the miscarriage of justice, use your influence, please.

A14-160b

Use your influence to allow Lena Dinterman to keep her van, to keep her lusting 15 million dollars which she'll probably win.

MODERATOR DASEY: Thank you, Mr. Smith. We appreciate your concerns. Your comments will be considered in preparation of the final Environmental Impact Statement.

That concludes our public meeting today. Thank you very much.

(Whereupon, the foregoing hearing was concluded at 2:30 p.m.)

CERTIFICATE

This is to certify that the foregoing transcript
In the matter of: DOD, DOA, BDRP, PUBLIC MEETING ON THE DRAFT ENVIRONMENTAL IMPACT STATEMENT

Before: JOSEPH OSTERMAN

Date: JULY 25, 1988

Place: ROSSLYN, VIRGINIA

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.

STEVE FELDMAN

A14-161b

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APPENDIX 15

Responses to Comments Received on the DEIS

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B. Agreement with the comment A15-178

The Final Programmatic EIS has been modified, as appropriate, to provide further documentation and explanation on issues and concerns expressed by the commentors. Minor corrections and amplifications were also incorporated in the Final EIS. All of the questions raised by one commentor are not necessarily addressed in one place in Appendix 15, especially if they concern diverse areas of inquiry.

An individual response is given to each question or comment. In certain cases, where it is believed that the question is substantively similar to a question already answered at length, the response may be a reference to a previous response. In many cases, an individual response is given and supplemented by a reference to another relevant response. The commentor's original question is reproduced here to assist the reader in understanding the context of the response. In a few cases, especially where the original comment was complex and contained several distinct thoughts in one sentence, the reader may wish to refer to the full text of the comment as reproduced in Appendix 14.

SUBJECT AREA 1: ALTERNATIVES

Sub-Category: A - Eliminate Aerosol Testing

31-8 Comment: DEIS inadequately explains DOA rejection of elimination of aerosol testing of BW agents (pathogens) as an alternative

31-8 Response: As explained in the DEIS, Section 4.2.2, total elimination of aerosol testing of pathogens is not a viable option. Aerosol testing of equipment, detectors, vaccines, etc. with organisms/toxins was considered in the development and application of the IAMs (Appendix 6) including the analysis of the risk/issue categories and the specific sites where such studies might be conducted, Appendices 5 and 6. Conduct of studies with high hazard organisms/toxins under the appropriate biosafety conditions do not constitute a significant risk to the health and well being of the work force nor to the environment, see Sections 5 and 6, Appendix 4, pages A4-2 to A4-6 and A4-8 to A4-11 and Appendix 6, pages A6-59 to A6-62 and A6-67 to A6-70. There appears to be a misperception as to the frequency and magnitude of studies in which aerosol exposure is required. Studies in which aerosol exposure of equipment or animals is required are relatively infrequent, and on a very small scale, including those studies proposed to be conducted in the BATF. Further elaboration has been added to the FEIS to clarify this issue (see Section 4.2.2). Also, see response to comment 24-5c.

27-18a Comment: The three most important alternatives which are not adequately addressed are (1) the consideration of options to replace aerosol testing...

27-18a Response: See response to comment 31-8 above.

24-5a Comment: The most controversial aspects of the BDRP are large-scale aerosol testing.

24-5a Response: BDRP testing with aerosols of pathogens is and always has been small scale, and is conducted only in small sealed chambers inside closed containment rooms. Aerosol testing was recognized as one of the controversial aspects of the BDRP in Sections 1.6.2 and 3.5 of the DEIS. Also, see responses to comments 24-5b and 24-5c. The need for aerosol testing has been further clarified in Sections 2.4.1 and 4.2.2 of the FEIS. Also, see response to comment 31-8.

24-5b Comment When is aerosol testing necessary, with what agents and on what scale; could expert consultation perhaps

provide new answers?

24-5b Response: As explained in Section 4.2.2 of the DEIS, occasional, limited aerosol testing is a necessary aspect of both the medical and non-medical components of the BDRP Also, see response to comment 24-5c. Further explanation of this necessity has been added to Section 4.2.2 of the FEIS. It is not clear what additional value further expert consultation might provide since conduct of studies (including testing of animals and/or equipment by aerosol exposure) with high hazard organisms/toxins under the appropriate biosafety conditions does not constitute a significant risk to the health and well being of the work force, community health or the environment, (see Sections 5 and 6, Appendix 4, pages A4-2 to A4-6 and A4-8 to A4- and Appendix 6, pages A6-59 to A6-62 and A6-67 to A6-70). Also, see response to comment 31-8.

24-5c Comment: Passive defenses (protective devices and decontamination procedures) and detectors, which are developed and operationally tested, according to the DEIS, at the BL1 or BL2 level, the question arises whether any testing of these items against actual BW agents is necessary, and if so whether it must be done with aerosols or on a large scale. The DEIS merely states that limited use of high hazard organisms is necessary (A4-3), implying that small-scale, non-aerosol testing is adequate.

24-5c Response: Comment is based on an incorrect premise. No implication "that small-scale, non aerosol testing is adequate" for all needs was intended. Section 2.4.3 stated that "Because the most realistic biological warfare threat is the delivery of hazardous agents by aerosol, the testing procedures performed at DPG focus on the delivery of test materials by this route....Aerosol testing with pathogenic or toxic challenge materials is performed in biological containment facilities. Outdoor field tests with simulates (non-pathogenic and/or nontoxic materials) are performed on an as-required basis after preparation of appropriate NEPA documentation" and as stated in Section 4.2.2..."airborne particles (aerosols) are considered the most likely manner in which a biological attack would be initiated. Therefore, the design and testing of defensive materiel, such as protective devices and detectors, must address this factor. This preeminent consideration, together with the fact that a vaccine that is effective against disease transmitted by inoculation might not be effective against the same disease when transmitted by aerosol challenge (83), <u>makes aerosol testing a necessary element of the BDRP"</u> (emphasis added). The FEIS further explains that "The potential risks associated with aerosol testing are mitigated by the use of special procedures, specially designed equipment, and appropriate levels of containment, which effectively reduce the risks and protect the work force and the external environment." For example, aerosol

testing is conducted only in small sealed chambers inside closed containment rooms. Because the risk to human health and the environment are minimal, after consideration of alternative measures, the alternative to eliminate aerosol testing was not considered to be reasonable. See Section 4.2.2 of FEIS.

24-5d Comment: Large-scale aerosol testing at Dugway and elsewhere is non-medical. Why could this not be restricted to non-pathogens? Or could testing with pathogens and hazardous materials be restricted to a small, and specified, scale? Is any aerosol testing with pathogens necessary? I would like to see unbiased expert input on these questions, with real scientific discussion, taking up the need for pathogen testing, or not, for each of the various purposes under the BDRP.

24-5d Response: There is no large-scale aerosol testing at Dugway pathogens. Open air testing is conducted only with simulates (see Section 2.4.3). Such tests are not conducted elsewhere. See responses to comments 31-8 and 24-5c.

26-9a Comment: Indeed, DEIS Executive Summary Section ES.7 dismissed three options for the BDRP out of hand without even bothering to comment upon them: the elimination of aerosol testing;...

26-9a Response: See response to comment 31-8 above. The Executive Summary represents an abbreviated discussion of material covered in more detail in the body and appendices of the FEIS. The commentor is referred to Section 4.2.2, for more explanation as to why aerosol testing cannot be reasonably eliminated from the BDRP. This discussion has been expanded in the FEIS to provide additional clarification. As stated in Section 4.2.2 ".... airborne particles (aerosols) are considered the most likely manner in which a biological attack would be initiated. Therefore, the design and testing of defensive materiel, such as protective devices and detectors, must address this factor." See also response to comment 24-5c.

<u>Sub-category B - Use only Simulates</u>

30-7 Comment: We feel that much of the defensive nature of the BDRP can be continued by testing detection and protection devices using low pathogenicity, simulate organisms. We also feel that the vaccination programs could be maintained. Both of these could continue without the increased risk of inducing fear and suspicion among the world communities who look to us for guidance and leadership in moral as well as military matters.

30-7 Response: See response to comment 30-8a. As stated in Section 4.2.2, "It is standard practice to use lower hazard organisms or simulates, to the extent practicable, in the conduct of research and testing. Research design considers the objectives to be sought and seeks to accomplish these objectives in a manner which is both safe and cost effective (emphasis added). If lower hazard organisms or simulates will meet the objectives, they are normally selected." Thus, the use of simulates wherever feasible was and is already an integral part of the preferred alternative. As stated in Section 4.2.2 and Appendix 4, page A4-3, some studies can not be accomplished with simulates alone and thus the exclusive use of simulates would render the program ineffective. While on the surface it might appear that testing of detection and protection devices can be accomplished with low hazard (simulate) organisms, individual components of the detection system are sometimes based on very specific responses to an organism/toxin, thus as stated in Section 4.2.2, "actual pathogens must be used in the testing of detectors and diagnostics to assure their reliability." Conduct of studies with high hazard organisms/toxins under the appropriate biosafety conditions do not constitute a significant risk to the health and well being of the work force nor to the environment, see Sections 5 and 6, Appendix 4, pages A4-2 to A4-6 and A4-8 to A4-11 and Appendix 6, pages A6-59 to A6-62 and A6-67 to A6-70. Thus, the exclusive use of simulates would not materially improve the program or reduce impacts.

30-3 Comment: An entire appendix (Appendix 6) is devoted to explaining the means by which most of the relevant safety concerns were able to be categorized as not significant so that they did not need to be addressed, while only one paragraph (paragraph 1, page 4-4) was required to discuss the option of continuing the defensive studies of the BDRP using simulate, or low pathogenicity, organisms.

30-3 Response: See response to comment 30-7 above. Amplification and further clarification on the use of simulates and organisms of lower pathogenicity has been incorporated in Sections 3.5.4 and 4.2.2 of the FEIS. Also see responses to comments 30-8a and 27-2.

30-8a Comment: A final environmental impact statement must include a compromise alternative or alternatives to continuing the program as is versus termination of the program. Many qualified scientists feel that there is no adequate justification for the use of actual biological warfare agents for conducting tests of detection and protection devices, since low pathogenicity simulate organisms can be used with equal or improved efficacy.

30-8a Response: We agree that almost all tests of detection and protection devices may be done with low hazard organisms or simulates, and this is what is done in the BDRP. In many projects, only the final tests require the use of the high-hazard strains. This issue is addressed further in the revised discussion of Analysis of Scoring and Public Comment Recommendations in Section 4.2.2. As explained in Section 4.3 of the FEIS, the creation of a subset of alternatives which would merely reflect differing levels of emphasis or special attention to selected elements of the overall program would not serve any useful purpose in the NEPA context. See also responses to comments 30-7 and 30-3.

30-8b Comment: Thus the use of simulate organisms, particularly for any aerosol testing, should be a valid means by which our concerns for public safety can be balanced with our concerns for a strong national defense.

30-8b Response: It is agreed that the use of simulates, where practicable, is appropriate and this is an integral concept of the BDRP. As explained in Section 3.5.4 of the FEIS, simulates are utilized to the maximum extent practicable. See also responses to comments 30-7 and 30-8a.

14-4a Comment: The need to aerosolize high level (BL3) pathogens, as opposed to simulate organisms of very low pathogenicity, has not been explained satisfactorily either in the BATF DEIS or in the BDRP DPEIS.

14-4a Response: The commentor is referred to the EIS on the BATF for issues related to the proposed test facility at DPG (See Section 1.6.4). The exclusive use of simulates is not scientifically feasible, nor would it materially improve the program or reduce impacts. See responses to comments 30-7 and 30-8a. AS stated in Section 4.2.2 and Appendix 4, page A4-3, some studies can not be accomplished with simulates alone and thus the exclusive use of simulates would render the program ineffective. See also response to comment 24-5c on aerosolization of pathogens.

14-4b Comment: Human errors inevitably occur, and not all errors are promptly recognized. The risks vary with each organism, each individual worker, and each experiment. These risks cannot be dismissed entirely. Again, consideration should be given to the use of simulate organisms alone in BATF aerosolization experiments.

14-4b Response: The possibility of human errors was certainly

recognized in the DEIS (see Section 6.3.1 and Appendices 4 and 9). See response to comment 14-4a above on BATF issues. See also responses to comments 30-7 and 30-8a.

14-4c Comment: Given the hazards of both BL3 and BL4 research noted above, the exclusive use of simulates or agents of low pathogenicity in all experiments involving aerosolization would appear to merit more serious consideration than that provided by the DEIS.

14-4c Response: As explained in Section 3.5.1, Appendix 4, part 1, Appendix 6, pages A6-59 to A6-62, and Appendices 11 and 12 of the FEIS, the serious nature of BL3 and BL4 research is recognized. Appendices 11 and 12 describe the special equipment utilized to guard against injury or infection. The exclusive use of simulates or organisms of low pathogenicity in all aerosol tests is neither scientifically feasible (see Section 4.2.2 of the FEIS and responses to comments 30-7 and 30-8a) nor would such exclusive use materially improve the program or reduce impacts.

26-14 Comment: DEIS Appendix 4, Section 1.3 at page A4-3 provides no rationale whatsoever for the rejection of simulates as an alternative to the use of highly dangerous organisms for various aspects of the BURP. The use of simulates for a variety of purposes is simply dismissed out of hand. This section of the DEIS is completely inadequate and slipshod. Your Staff needs to produce a revised DEIS that contains a comprehensive analysis of the potential use of simulates throughout all aspects of the BDRP.

26-14 Response: The intent of Appendix 4, part 1.3 page A4-3, was not to provide rationale for where simulates could or could not be used but rather to illustrate why, in certain cases, high hazard organisms have to be used. The rationale for inclusion of low hazard organisms/simulates in the existing program is provided in Appendix 4 parts 4.2 and 4.3. The reason the use of simulates was not considered as a distinct alternative is that simulates are used whenever and wherever feasible and this is already an integral part of the preferred alternative, see response to comment 30-7 and Section 4.2.2 of the FEIS.

24-7a meet: The big questions are avoided or obscured: in what situations simulates are or are not adequate, and why; ... It is hard to see why defenses that must work against all possible threats should require specific testing at all. With a little ingenuity it should be possible to devise tests with a series of innocuous agents, possessing a range of relevant properties, that would suffice. (For further discussion of

simulates, see my comments on the BATF, DEIS, page 5).

24-7a Response: There are many cases where simulates are totally adequate. Typically, they involve testing where the only protection required is against droplet or particle size or testing the functioning of equipment, but not the specificity of the equipment. Similarly, in antiviral drug development, most of the studies are done with low pathogenicity relatives of the pathogen, but again, definitive testing for efficacy must be done with the pathogen. The use of simulates (low hazard organisms) is discussed in Sections 4.2.2 and 4.3 and Appendix 4, part 4.3. Conduct of studies with high hazard organisms/toxins, under the appropriate biosafety conditions, does not constitute a significant risk to the health and well being of the work force nor to the environment, see Sections 5 and 6, Appendix 4, pages A4-2 to A4-6 and A4-8 to A4-11 and Appendix 6, pages A6-59 to A6- and A6-67 to A6-70. Thus, the exclusive use of simulates would not materially improve the program or reduce impacts. Also see responses to comments 30-7, 24-7b, 30-8a and 26-14.

24-7b Comment: Detectors, too, must have a wide range. It would not be safe to rely on specific detectors - there are too many potential BW agents.

24-7b Response: Comment noted. Section 1.4 of the DEIS recognized the wide range of potential BW threats as well as the fact that it would not be practicable to develop unique defenses against all such potential threats. However, as described in Section 2.4.2 of the DEIS, the development of detection systems and technologies considers various approaches such as biological receptors, antibody binding reactions and analytical techniques in pursuit of adequate defensive measures.

24-7c Comment: But even for detectors based on specific recognition principles (e.g., antigen-antibody reactions) it appears that development is carried out with simulates; verification that specific adaptations actually do work could be accomplished on a very small scale.

24-7c Response: The concept of utilizing the smallest scale practicable in tests involving hazardous organisms represents a very practical suggestion that is already integral to the BDRP. As explained in Section 4.2.2 of the FEIS when more hazardous materials must be used, test protocols are designed to use only small quantities of infectious organisms or toxins, and to incorporate appropriate procedures and containment to protect adequately the workforce and external environment. Also, see response to comment 30-8a.

24-7d Comment: In the scooping process it was suggested that

simulates and innocuous agents be used in place of hazardous agents.

24-7d Response: We agree that simulates and innocuous agents should be used whenever and wherever feasible and that is what is done; see also responses to comments 24-5c and 24-7a. However, the exclusive use of simulates would not materially improve the program or reduce impacts, see Section 4.2.2 of the FEIS and responses to comments 30-7 and 30-8a above.

27-18d Comment: Additionally, the BDRP EIS does not adequately address the need for the use of simulates to replace the use of dangerous pathogens.

27-18d Response: See responses to comments 30-7, 30-8a, 24-7b and 26-14.

27-21 Comment: The simulate alternative has been much discussed for several years, yet the DOD continues to avoid any real discussion of its actions in this area. Any "hard look" analysis of the use of simulates should include, inter alia: 1) a listing by the Army of how many simulates have been approved by the Army for use and for what uses; 2) an explanation by the Army of its procedures for developing simulates or surrogates for testing, including a description of its program, if any, for developing such simulates, including facilities, personnel and funds dedicated to such purposes and what priority the Army has given to their development; 3) a precise description of which tests, and for which pathogenic organisms, simulates are ineffective; 4) an explanation and description of what specific characteristics in each of the pathogenic microorganisms will be useful for tests to be performed in the facility and to what extent those characteristics may be developed (or retained) in such simulates; 5) an explanation of why simulates in the form of attenuated strains, vaccine strains or related non-pathogenic species are not suitable for various contamination and decontamination tests, including specific characteristics of each specific simulate which do not make them useful in such tests.

27-21 Response: The views of the commentor are noted. The detailed information suggested for inclusion in the FEIS is not considered to be necessary or appropriate for a programmatic document. Discussion of the use of simulates can be found in Sections 3.5.4 and 4.2.2 and Appendix 4. Also see response to comment 30-7 and responses on similar comments on the use of simulates in this section.

27-28 Comment: Finally, changes in BDRP activities should include a total commitment to the use of simulates rather than

the toxic materials currently in use.

27-28 Response: The exclusive use of simulates would not materially improve the program or reduce impacts. The conduct of studies with high hazard organisms/toxins under the appropriate biosafety conditions does not constitute a significant risk to the health and well being of the work force nor to the environment, see Sections 5 and 6, Appendix 4, pages A4-2 to A4-6 and A4-8 to A4-11 and Appendix 6, pages A6-59 to A6-62 and A6-67 to A6-70. As stated in Section 4.2.2 and Appendix 4, page A4-3, some studies can not be accomplished with simulates alone and thus the exclusive use of simulates does not represent a scientifically valid option. See also responses to comments 24- and 24-7c.

38-2 Comment Given that there are problems in anticipating what pathogen with what surface properties will be used by enemies, any defensive research should focus on more general properties of organisms. The Army has never satisfactorily answered why simulates could not be used in this type of defensive research.

38-2 Response: In certain instances, simulates can be and are used when physical properties, such as surface characteristics or particle size are important. "Surface properties" of pathogens are of far lesser importance in medical defensive studies. However, exclusive use of simulates would not materially improve the program or reduce impacts. See also responses to comments 30-7, 30-8a and 24-7b.

36-2 Comment: We believe that the production of real disease germs in the research is inappropriate given that credible members of the scientific community claim that simulates would serve defensive purposes.

36-2 Response: The views of the commentor are noted. See Sections 3.5.4, 4.2.2 and Appendix 4 of the FEIS for a discussion on the need to utilize actual organisms in the BDRP See also, responses to comments 30-7 and 30-8a.

45-7 Comment: I have never heard a good argument out of the Army of why you can't use attenuated viruses, why you can't use simulates, and all we hear back is it is necessary that -- it's for national security.

45-7 Response: See responses to comments 30-7 and 30-8a.

32-1d Comment: On both counts DOD's need to provide detection, protection and decontamination will best be served by testing with harmless simulate organisms.

32-1d Response: See responses to comments 30-7, 24-7a, 7b, 7c and 27-21.

39-3 Comment: There is no need to aerosolize pathogens if the program is trying to develop "gas mask" type filters or protective clothing. There are many microorganisms that are just as small and easy to detect as any pathogens. Such "simulates" are completely adequate to test penetration.
39-3 Response: If the only considerations were particle size or electrical charge, this comment would be true and in fact under those circumstances, low hazard/simulate organisms are currently used. However, in some cases more specific application may be required in which, as stated in Appendix 4 page A4-3, "Laboratory testing of personal protective materiel, decontamination systems, detector methodologies, and rapid identification and diagnosis methodologies requires the limited use of high hazard organisms to verify specificity." (Emphasis added)

55-9 Comment: The use of BL2 germs, nontoxic germs, that wouldn't kill us right off, is obviously a good idea and not to use these highly contagious germs.

55-9 Response: Organisms studied in the BDRP are not highly contagious. See Appendix 9, part 6.1. Also, see responses to comments 36-2, 30-7 and 30-8a.

29-10a Comment: The CRG also contends that the Draft EIS fails to consider the following elements of an alternative biological defense policy that provides for generic defense against biological warfare agents while avoiding activities that are environmentally hazardous as well as politically provocative: Open-air tests should be conducted only with biological warfare simulates. All other open-air testing should be terminated.

29-10a Response: Open air tests are conducted only with simulate organisms, as stated in Sections 2.4.3, 4.2.2 and 5.3.3.2.3 and Appendix 6, pages A6-25 to A6-30.

29-10b Comment: The CRG also contends that the Draft EIS fails to consider the following elements of an alternative biological defense policy that provides for generic defense against

biological warfare agents while avoiding activities that are environmentally hazardous as well as politically provocative: Open-air tests should be conducted only with biological warfare simulates. All other testing of aerosols should be terminated.

29-10b Response: Aerosol testing with organisms/toxins was considered in the development and application of the IAMs (Appendix 6) including the analysis of the risk/issue categories (Appendices 4 and 6) and the specific sites where such studies might be conducted (Appendices 5 and 6). Studies in which aerosol exposure of equipment or animals are required as part of the BDRP are conducted within biocontainment laboratories using special equipment and are small scale. Aerosolization conducted under the appropriate conditions of safety does not pose a significant risk to the health and welfare of the work force or the environment. Also, see responses to comments 29-10a, 30-7 and 30-8a.

33-3 Comment: First, there is a good possibility that tests could be done with less-dangerous simulates rather than genetically-engineered germs for which we may never have a cure. That approach to "defense" has not been adequately explored by the Army.

33-3 Response: This comment may be based at least partially on a misinterpretation of the BDRP activities. If by tests with "genetically-engineered germs" the commentor envisions the enhancement of virulent properties by genetic engineering and the subsequent use of such "engineered organisms" in aerosol **studies,** etc. - no such studies are being conducted. As stated in Appendix 10, the deliberate creation and testing of such organisms is prohibited by the recombinant DNA guidelines. The DOD is in full compliance with these guidelines. As explained in Section 4.2.2 of the FEIS, simulates are used to the maximum extent practicable. Also, see responses to comments 30-7 and 308a.

Sub-category C - Transfer the medical program to a civilian agency

22-1a Comment: DOD argues that shifting the greater part of the program to civilian agencies would result in a loss of efficiency. We find their analysis wanting. The DEIS does not provide a shred of evidence that shifting BDRP to civilian agencies would actually increase costs, add an additional management layer, or weaken our defense posture. In the FEIS, DOD should either abandon these arguments, or support them with greater specificity and care. But the DEIS lacks a credible analysis for shifting all or a substantial part of BDRP management to civilian agencies. In these comments, the DEIS fails to fully analyze the possibility of shifting BDRP to one or more civilian agencies.

22-1a Response: The commentor does not suggest how shifting management of the program to a non-DOD agency would lessen any adverse environmental effects. The alternative of transferring a part or all of the BDRP to another Federal agency such as NIH was examined. This alternative would not alter significantly any impacts on health or the environment, nor would it eliminate controversies associated with genetic engineering, use of high hazard infectious organisms or toxins or laboratory aerosol testing, (see Section 4.2.2). Such an alternative would not significantly affect any resource utilization. Thus, this approach did not merit identification as an alternative to the proposed action. Determining DOD needs/requirements for the BDRP and directing these needs/requirements to another Federal agency to assure adequate allocation of resources to meet these needs, would indeed add another layer of management, undoubtedly with some decrease in efficiency as stated in the DEIS.

22-1b Comment: By placing responsibility for BDRP in civilian agencies, DOD can defuse the nagging suspicion that crucial parts of the program are withheld from view.

22-1b Response: This is not a relevant NEPA consideration. Also see response to comment 22-1a.

22-1c Comment: The CDC and NIH are responsible for developing defense against normally occurring diseases, and thus there is no reason why they should not protect us from anthropogenic epidemics. In addition, CDC and NIH are responsible for getting the vaccines to people who need them, and they have the information and institutional structure required to accomplish the task efficiently.

22-1c Response: Comment noted. See response to comment 34-1.

22-1d Comment: Unlike DOD research facilities, the CDC and NIH operate under a competitive grant system. It is generally agreed that a rigorous system of competitive grants assures the highest quality research. As a result, papers which are produced from such research tend to be published by prominent journals in the field rather than being relegated to obscure or secondary publications. Although DOD D extols BDRP's contribution to scientific knowledge, it is far from clear that its work measures up to the research generated by CDC and NIH grants. If BDRP's publication record is used to judge the program, the results are mediocre at best. Thus, the benefits of shifting to a civilian agency are threefold: Fellow scientists will have greater confidence in the work, the results of the research will tend to receive greater exposure in prestigious journals, and citizens will be more confident in DOD's openness.

22-1d Response: This comment is not relevant to environmental issues and cannot be addressed in the NEPA context.

29-11 Comment: Where there is a recognized medical need for activities involving the construction of novel biological agents, these activities should be transferred to civilian agencies. Non-medical activities involving construction of novel biological agents should be terminated.

29-11 Response: Assuming the commentor intends to imply that novel biological agents are being created for offensive purposes, this is not being done and is not a part of the BDRP. Such activities are prohibited by the Biological Weapons Convention and DOD policy. Also see responses to comments 22-1a and 43-8a.

24-8 Comment: One thing that the DEIS does <u>not</u> slight is the benefit of the medical program to science and public health. But these real benefits could better be provided in the civilian sector; they are not acceptable as rationales for a program whose purpose is national defense.

24-8 Response: The public benefits of the program, which are not the rationale for the program, were provided only as background information and not as factor in the BDRP-EIS analysis. Medical contributions to society as a whole were not intended as justification for the BDRP. Also, see response to comment 22-1a.

24-17 Comment: I have already suggested that the medical program be transferred out of DOD, to allay suspicions. If that were done it would be a simple matter to apply general

restrictions to the BDRP; but if not, it is still possible to restrict certain facilities and projects.

24-17 Response: See responses to comments 22-1a and 24-8.

34-1 Comment: I understand that there is valuable research being conducted by the Army in development of vaccines. These vaccines are valuable in protecting the health of our personnel in different parts of the world. I would think that such a program would more appropriately be conducted by the National Institutes of Health, whose mission, after all, is health. The very presence of this program under DOD raises concerns.

34-1 Response: DOD has the responsibility to preserve the fighting force, which includes providing protection from hazards that may be encountered in a theater of operations, and that is the focus of the BDRP. The HHS (CDC) has responsibility for the health hazards faced by the civilian populace within the U.S. All information and products are openly shared and made available to the CDC. Also, see response to comment 22-1c.

34-3 Comment: As a consequence of the Dugway track record, the Army's need for secrecy and the nature of the Army's mission, I do not feel secure when this research with deadly biological agents is in Army hands. Would it not be reasonable to let this research be conducted under auspices of NIH, in an open fashion, with review by free scientists? Vaccines could be developed for DOD upon request. Simulate pathogens could be provided to DOD for testing. My suspicions, and those of our adversaries would not then become exercised, causing escalatory measures to be undertaken.

34-3 Response: The alternative of transferring a part or all of the BDRP to another Federal agency such as NIH was examined, see response to 22-1a. The BDRP is an open unclassified program. See Section 2.1. Also see responses to comments 30-7 and 1410.

43-3b Comment: ...and apparently a greater feeling of discussion of shifting much of the focus to civilian agencies.

43-3b Response: See response to comment 22-1a.

43-3c Comment: There's many reasons, I think, for doing this, the major one being accountability, which is, for certainly all experiments which, and this is a nonclassified program, after

all, they're dealing with pathogens, with NIH guidelines, which according to June comment would be far better than having them in NIH or some agency which is required to have guidelines rather then complying with them voluntarily.

43-3c Response: See responses to comments 22-1a, 27-20, 34-3, 30-7 and 14-10. The DOD voluntarily opted to adopt the NIH guidelines over 10 years ago and thus compliance with those guidelines became a requirement on all research with the same impact as within HHS. DOD researchers and NIH/CDC researchers are thus under the same level of compliance requirements.

7-3a Comment: There is a question here about whether the Army should control this entire program, and I read with interest the material faxed to me out here from my Washington office this afternoon, and then listened as the good Doctor presented his remarks tonight, that you consider the possibility of moving some of the biological defense research program through nonmilitary controls. I assume the panel is aware that I have introduced just such legislation several months ago. I believe that we should place into civilian hands the National Institutes of Health, the control for the research and development under the biological defense research program, the testing. I think properly done by the Army and I think, however, in its research and development, give way to military-nonmilitary control, so I take direct issue with that decision which you have made and which you have just announced.

7-3a Response: See response to comment 22-1a.

26-8 Comment: DEIS Section 4.2.2 states that it "would not be appropriate, even if it could be done institutionally, to transfer defense responsibility to another agency or organization." (page 4-6). Yet that is precisely what has historically been done with respect to nuclear weapons. Originally, the Truman administration decided to establish civilian control, as opposed to military control, over nuclear weapons by means of creating the Atomic Energy Commission. Such government supervision over nuclear weapons now resides in the civilian Department of Energy, which is exclusively responsible for the research, design, development and testing of nuclear weapons systems themselves, not the Department of Defense. The same type of civilian function could certainly be performed with respect to the BDRP by the National Institutes of Health, for example. In any event, the DEIS dismissed this alternative out of hand without even bothering to discuss or analyze it. A revised DEIS must contain a detailed analysis of the utility of this civilian alternative by your staff.

26-8 Response: See response to comment 22-1a. The DOE is not

exclusively responsible for nuclear weapons systems as the commentor states, and the DOE is not responsible for determining research needs. The Defense Nuclear Agency determines needs and directs production schedules, etc. The DOD provides the requirement specifications, performance characteristics, etc., the DOE then oversees and directs the RDT&E aspects.

26-9c Consent: DEIS Executive Summary Section ES.7 dismissed three options for the BDRP out of hand without even bothering to comment upon them:...transferring the management responsibility for the BDRP to a non-military agency. (page ES-4)

26-9c Response: See response to comment 22-1a.

27-18c Comment: The three most important alternatives which are not adequately addressed are...3) the transfer of the management of the BDRP to a non-military agency.

27-18c Response: See response to comment 22-1a.

27-20 Comment: *The* EIS also fails to look at these alternatives in conjunction with each other. For example, the DOD could declare a moratorium on genetic engineering research and transfer any truly necessary recombinant research to the National Institutes of Health or other agency which, unlike DOD, are required to follow the NIH Guidelines for such research.

27-20 Response: Several commentors have noted that DOD is in voluntary compliance with the CDC/NIH Guidelines. This appears to have been interpreted to mean that DOD researchers may choose to comply or not to comply. The belief is also often expressed that researchers under HHS (e.g. CDC and NIH) are more firmly obligated to follow the guidelines. Both implications are untrue. Employees of HHS are required to follow the guidelines because of a directive of the Secretary of the Department. Employees of DOD D are required to follow the guidelines because of a directive of the Secretary of Defense. The source of the requirement is exactly equivalent. We know of no substantive suggestion that any employee of either Department has knowingly violated the guidelines. There is no basis for the suggestion that employees of HHS are more likely to follow the CDC-NIH Guidelines than the employees of DOD. In fact, as described in the response to comment 22-9, Army personnel are subject to significantly more severe penalties in case of such a violation. Also, see responses to comments 27-2 and 43-3c.

27-23 Comment: In review, the first step in improving the conduct of BDRP activities would be to shift the recombinant research currently ongoing at the BDRP to civilian agencies. The DOD should declare a moratorium on the use of recombinant DNA research and shift research which has public value to the civilian agencies such as the NIH or CDC.

27-23 Response: See responses to comments 24-4c and 27-2.

7-3b Comment: I think that the decisions -- the decision to give this research and development aspect to the National Institute of Health would be supported by two primary factors, two primary reasons. The first being a much greater record of safety as I gather from reading the reports on the Army's program.

7-3b Response: See responses to comments 22-1a, 7-3c and 27-2.

Sub-category D - Eliminate recombinant DNA work

43-4b Comment: It would be better for the Department of Defense to declare a moratorium in any genetic engineered work currently ongoing, allow that work to be taken at more accountable agencies.

43-4b Response: The consideration of not employing genetic engineering in part or all of the program was discussed in Section 4.2.2. Genetic engineering, appropriately conducted, does not pose a significant risk to the workforce, nor does it threaten mankind. A detailed analysis of genetic engineering and its safeguards is included in Appendix 10. While a moratorium on the use of genetic engineering as a research tool would probably alleviate at least a portion of the opposition to the BDRP and might well also reduce some of the controversy, it would not significantly alter the impact of the BDRP on the environment. It would, however, render a substantial portion of the BDRP scientifically ineffective, and thus constitute a waste of resources. A moratorium on genetic engineering to alleviate distrust of the DOD by some elements of the public, does not constitute a reasonable alternative. Also, see responses to comments 24-4a and 27-2.

24-4a Comment: The most controversial aspects of the BDRP are...the possible development of novel organisms and toxins for that use (threat assessment).

24-4a Response: If by "novel organisms and toxins" is meant the deliberate creation of altered organisms or toxins that are more pathogenic or more toxic than organisms/toxins already found in nature - this is not being done and is prohibited by the BWC. The laboratories of the DOD and its contractors performing research in the BDRP effectively use all of the state-of-the-art biotechnologies in the performance of studies targeted at the development of protective vaccines, prophylactic compounds, diagnostic kits, micro-organism and toxin detectors, and protective clothing and equipment. Novel pathogens are not created. However, both virulence factors and protective epitopes are studied through genetic engineering techniques in order to provide these measures of protection for the troops. For instance, if the toxic domain of a toxin can be identified along with the domains responsible for the elicitation of protective antibodies, then, through site-specific mutagenesis techniques, the toxic domain can be inactivated while retaining the antibody specific regions. Production of this mutated protein results in a safer, more efficacious vaccine to protect against the native toxin. Such research is reviewed routinely by the NIH Recombinant Advisory Committee (RAC) working group on toxins. Approval by the RAC is a pre-requisite to approval by the local IBC of these types of experiments. The DOD does not use genetic engineering in its laboratories to create novel organisms with

weapons potential. However, declaring a moratorium on research involving genetic or engineering biotechnology would seriously inhibit the rapid search for more effective medical defenses and detector methodologies. GEMs are not developed for field testing and weaponization; they are developed only for the study of protective mechanisms. See Sections 3.5, 4.2.2 and Appendices 4, 6 and 10.

24-4b Comment: The big questions are avoided or obscured: ... What kind of evaluation and documentation is to be prepared before ... novel agent development?

24-4b Response: If by "novel agent development" is meant the deliberate creation of an altered organism or toxin that is more pathogenic or more toxic than the organisms/toxins already found in nature - this is not being done and is prohibited by the BWC. Since such novel agents are not being created - evaluation and preparation of documentation is not required. The applications of genetically engineered microorganisms in the BDRP are defined in Sections 2.4.1, 3.5.2, 4.2.2, 6.1.1 and Appendix 4 pages A4-5 to A4-8.

24-4c Comment: In the scooping process it was suggested ... that genetic engineering work be discontinued. Obviously the medical program could not be carried on under those circumstances, but what about the rest of the program?

24-4c Response: Genetic engineering within the BDRP was given separate consideration because of its controversial aspect (Sections 1.6.2, 3.5.2) and thus was specifically considered in the development/application of the TAM, see Appendix 4, pages A4- to A4-8 and Appendix 6, pages A6-71 and A6-72. Genetic engineering, conducted in compliance with appropriate control measures, does not pose a significant risk to the workforce, nor does it threaten mankind (see Appendix 4, pages A4-5 to A4-8, Appendix 6, pages A6-71 and A6-72 and Appendix 10). Thus, the implementation of this suggestion would deny to DOD scientists a significant research tool, thereby degrading the quality of the science and indirectly wasting resources. Although the "medical program" constitutes over 90% of the BDRP and encompasses the bulk of the genetic engineering work conducted in the program, genetic engineering techniques are also used productively in the physical protection portion of the BDRP in the development of detector methodologies. Thus, both the medical and non-medical aspects of the program would be impaired seriously by discontinuation of genetic engineering work.

32-3 Comment: By renouncing military research on genetically

engineered organisms, while conducting defensive research in full view, DOD will contribute to reducing rather than escalating the risk of biological warfare.

32-3 Response: If by military research on genetically engineered organisms is meant an offensive biological warfare program, we agree. There is no need to "renounce" offensive military research on GEMs, because there is not and has never been any. The U.S. is conducting the BDRP in full compliance with the BWC, (see Section 1.6.2). Also, see response to comment 24-4c.

27-18b Comment: The three most important alternatives which are not adequately addressed are... 2) a moratorium on research involving genetic engineering...

27-18b Response: See response to comment 24-4c above.

26-9b Comment: DEIS Executive Summary Section ES.7 dismissed three options for the BDRP out of hand without even bothering to comment upon them:...placing a moratorium on research involving genetic-engineered micro-organisms (GEMs);...

26-9b Response: See response to 24-4c above.

Sub-category E - Preferred alternative

27-2 Comment: The BDRP EIS fails in both these purposes. It does not adequately address the environmental consequences of the proposed action nor does it provide a full and fair description of possible alternatives to the current BDRP scope and implementation. Moreover, the findings in the BDRP on environmental impact are conclusory and unsupported.

27-2 Response: As explained in Section 1.2 of the DEIS, the proposed action is the continuation of the BDRP. The consequences of continuing the program were discussed in Section 6.3.1 of the DEIS. The Programmatic DEIS addressed the environmental consequences of the BDRP from the perspective of risk/issue categories under normal operating conditions (see Sections 1.6.4, 3.5, 5, 5.1, 5.2, 6.1.1 and Appendices 4 and 6), and under abnormal conditions (see Maximum Credible Events, Appendix 9). Site-specific considerations of environmental consequences were analyzed for the three primary sites of program execution and for selected secondary sites (see Sections 2.4, 2.5, 5.3, 5.4, 6.1.2, 6.1.3 and Appendixes 5 and 6). A full discussion of the alternatives considered, including those suggested in the public scoring and public comment processes, is presented in Section 4 of the EIS. Additional information or clarifications have been provided where appropriate in the final Programmatic EIS.

27-22 Comment: As described the EIS should have adequately examined the need for alterations in the BDRP to avoid risk to human health and the environment. As noted these alterations would have to involve change in the conduct, type and scale of BDP activities.

27-22 Response: The DOD has adequately examined the BDRP in terms of risk/issue categories in Appendix 4. Program matrix analyses and site-specific matrix analyses are provided in Appendix 6. The safety record of the BDRP has been outstanding; see Appendix 8. Also, note the categories under the "Biophysical Environment" and the Human Health category along with a discussion for areas of relevant concern in each category (Appendix 6). Also, see responses to comments 27-31a and 27-2.

27-31a Comment: Finally, the environmental impacts of the BDRP program could be minimized through a change in the location of BDRP operations. Such research should not be dispersed through the several dozen laboratories currently in use. Instead any BDRP research found absolutely necessary should be located at remote sites away from populations.

27-31a Response: The contracts to conduct research under the BDRP are awarded to those institutions which are already engaged in the type of research they propose to perform. These institutions have demonstrated experience and possess appropriate facilities for the type of work proposed. Other requirements for awarding contracts include knowledge and experience of the principal investigator as well as of the research group that would be performing the research. Research at these institutions and universities is conducted in compliance with appropriate guidelines and safety considerations for each risk/issue category. Examination of the ongoing program found that all significant issues relate to the program and not to specific sites (see Sections 1.6.4, 4.2 and 5.2) and did not identify any site-specific significant areas of concern. (See Sections 2.5, 4.4, and 5.4). Also, as noted in Section 4.4, site-specific considerations will be addressed for future actions for which there is the potential for such impacts. Representative secondary sites were selected from those risk/issue categories that theoretically might have the greatest environmental concern or be the most contentious (Categories I, II, III). Consideration was also given to diversity of geography, type of institution and environmental setting, e.g., rural, urban or suburban. Environmental, health and safety considerations, waste stream management, security and accidents and incidents were analyzed by risk/issue category and examined at all the primary sites and the secondary sites that were site-visited (see Appendices 4 and 5). All secondary site research efforts were evaluated "as appropriate to determine if: 1) any unique circumstances or extraordinary conditions exist; 2) adequate facilities are available; 3) there is evidence of implementation of the appropriate controls that mitigate any areas of concern identified in the risk/issue IAM and 4) appropriate environmental compliance measures are in place. No non-compliance problems were identified and no significant environmental impacts associated with the BDRP were identified." (Appendix 3).

27-31b Comment: Environmental and safety consideration should, and legally must, be included in the decision as to which facilities will conduct which parts of the BDRP.

27-31b Response: Environmental and safety considerations are, and have always been, a part of the decision-making process concerning the awarding of research contracts under the BDRP (see Sections 3.3.2, 4.4 and Appendix 3). Also, see responses to comments 27-10 and 43-1.

12-2 Comment: Another primary concern is that the DEIS presents only two possible alternatives, i.e., terminate the BDRP or the preferred alternative of continuing the BDRP <u>unchanged</u>. The discussion of these two alternatives is confusing. A No-Action

alternative, as the DEIS indicates, means to maintain the status quo. The status quo is the ongoing BDRP and is the same as the proposed action. The other alternative of terminating the BDRP is questionable as a viable alternative because of the Congressional mandate to conduct the BDRP.

12-2 Response: We agree that the term "no action" may be confusing as applied to an activity which has been in place for many years. We have used "no action" to mean "no activities." The "No Action" alternative as indicated in the EIS means to terminate the BDRP (see Section 4.1), and the "Preferred" alternative is to continue the BDRP, essentially unchanged. The proposed action, continuation of the BDRP, was identified as the preferred alternative. Also, see responses to comments 27-2 and 27-31a above.

43-3a Comment: The second major problem I think that we have is that the discussion of alternatives, which is a substantial part of the things we need to discuss, is inadequate.

43-3a Response: See response to comment 27-2 above.

19-4 Comment: This brings me to another, more general criticism of the draft statement; viz., it does not distinguish between BDRP work at sites in or near highly populated areas from similar work in remote rural areas. Surely, vastly different impact considerations apply to those different areas. The more hazardous programs of other government agencies (e.g., the Department of Energy) are carried out in very remote sites for this reason. We are aware of your recent unsuccessful efforts to build such a site in a Western State. By not speaking to this population density issue, you infer that the most hazardous materials and experiments can be used and carried out at remote and urban sites with equal impunity and equivalent impact. Is this inference correct? If so, it should be stated.

19-4 Response: See response to comment 27-31a above.

32-1b Comment: In the first place, any use of actual pathogens, particularly in aerosols, will present a hazard to workers, their families and the community at large; even endemic agents of such diseases as anthrax, tularemia and plague, normally poorly transmissible, will become highly dangerous when aerosolized.

32-1b Response: Aerosol testing with pathogenic or toxic materials is performed in biological containment facilities, and no open-air testing with dangerous biological is performed (see

Sections 2.4.3, 3.2.1.6, and 5.3.3.2.3). Aerosol testing of equipment, detectors, vaccines, etc., with organisms/toxins was considered in the development and application of the IAMs (Appendix 6) including the analysis of these risk/issue categories and the specific sites where such studies might be conducted (see Appendices 5 and 6). Conduct of studies with high hazard organisms/toxins under the appropriate biosafety conditions does not constitute a significant risk to the health and well being of the work force nor to the environment, see Sections 5 and 6, Appendix 4, pages A4-2 to A4-6 and A4-8 to A4- and 6, pages A6-59 to A6-62 and A6-67 to A6-70. There appears to be a misperception as to frequency and magnitude of studies in which aerosol exposure is required. Studies in which aerosol exposure of equipment or animals are required are small scale, including those studies proposed to be conducted in the BATF. Exposure risk to the workforce from working with high hazard organisms and toxins was recognized in applying the IAM as a minor risk to the workforce see Appendix 6, pages A6-62 and A6- Transmission from exposed laboratory workers to close contacts has never occurred from organisms studied within the laboratories conducting BDRP research (see Appendix 4, parts 1.7, 2.7, 3.7 and 4.7).

32-1c Comment: In the second place, an infinite variety of potentially lethal agents already exist or could be produced by genetic engineering; engineered organisms raise the specter of epidemics that can be neither diagnosed nor treated. In view of the variety of agents possible it is essential that defense be general rather than specific, if it is to provide protection of wide scope that will not soon become obsolete.

32-1c Response: Genetic engineering within the BDRP was given separate consideration because of its controversial aspect, see Sections 1.6.2, 3.5.2 and thus was specifically considered in the development/application of the IAM, (see Appendix 4, pages A4-5 to A4-8 and Appendix 6, pages A6-71 and A6-72). Genetic engineering, appropriately conducted, does not pose a significant risk to the workforce, nor does it threaten mankind, (see Appendix 4, pages A4-5 to A4-8, Appendix 6, pages A6-71 and A6-72 and Appendix 10). For a detailed response to the comment "that defense be general rather than specific," see responses to comments 36-1b and 29-2a. It should also be noted that in the phrase "lethal agents...could be produced by genetic engineering..." the commentor refers to the potential biological threat, and not to any efforts within the BDRP.

29-5a Comment: The environmental impact statement fails to address the full range of possible alternative policies.

29-5a Response: See response to comment 27-2.

29-5f Comment: These activities pose hazards to the environment and surrounding communities in the areas where they are conducted that have not been satisfactorily addressed by the Draft Environmental Impact Statement.

29-5f Response: The nature of the hazards has not been described by the commentor in either qualitative or quantitative terms. Pertinent activities posing potential hazards to the environment, including analyses of accidents, were defined and addressed in the DEIS. See response to comment 27-2. In addition, refer to the Impact Analysis Matrices for representative primary and secondary sites for any potential environmental effects (Sections 5, 6, and Appendix 6).

31-6 Comment: DEIS fails to justify DOA rejection of suggested controls and procedures suggested by independent scientists and other government agencies.

31-6 Response: The DEIS does not reject appropriate controls, regulations, guidelines, etc. Indeed, many of the controls and precautions are integral components of the BDRP as proposed, see Section 3.3. As stated in Section 4.3, however, changes or improvements in controls, regulations, guidelines, etc. do not in and of themselves constitute reasonable alternatives for the BDRP.

38-3a Comment: The safety features in the BDRP are impressive, but not good enough for work with incurable pathogens, and certainly not with aerosols. The problem of human error has not been addressed in the EISs. As we are learning in the nuclear power industry, human error and machine malfunction are unavoidable.

38-3a Response: It was recognized in the DEIS that all accidents are not avoidable, see Sections 5.2.2.1 and 5.2.2.3. Also, see Appendix 9 for a discussion on the Maximum Credible Events, and Appendix 8, which describes the safety record of the BDRP. The safety record of all laboratories working with all levels of pathogens is summarized in the CDC-NIH Guide to Biosafety in Biomedical and Microbiological Laboratories, and that safety record is in fact quite good. The safety features used in the BDRP are based on the recommendations of the CDC-NIH Guide, and are the same features as those used in all U.S. laboratories that conduct studies with high hazard pathogens. As discussed in Section 2.4 of the FEIS, aerosol studies with pathogens are conducted only in sealed chambers in indoor biocontainment laboratories using specially designed equipment

which mitigates any hazard to the workforce or environment that could otherwise arise from such studies.

39-4 Comment: The main use of an aerosol test involving pathogens could be to assay the efficacy of novel organisms as biowarfare agents.

39-4 Response: Aerosol testing that may be conducted with pathogenic organisms or toxic materials is performed in biological containment facilities to study disease pathogenesis, vaccine or drug efficacy, or the sensitivity and specificity of a detector component, and is not used to "assay the efficacy of novel organisms as biowarfare agents", (Section 4.2.2). See also response to comment 20-2. The BDRP does not create novel biowarfare agents for any purpose.

31-11 Comment: DEIS fails to address plans and alternatives for clean-up of contaminated facilities used for BW research and testing.

31-11 Response: There are no contaminated facilities where research activities under the BDRP are or were performed (see Section 1.6.4). Decontamination technologies are discussed in Appendix 13.

31-4a Comment: We consider the Army's contention that the preferred alternative means maintaining the status quo to be a distortion of the truth. In reality, the BDRP is experiencing rapid expansion - it is nowhere near a static or stable program.

31-4a Response: The BDRP is an ongoing program which supports RDT&E efforts necessary for the maintenance and development of defensive measures with respect to potential biological warfare threats. Increased interest in and funding of BDRP activities is recognized in Section 2.1 of the EIS. An expanded program is not necessarily a different program. (See Section 4.4 on "Future Changes in Scope, Content, or Location" concerning this program). Also, see response to comment 27-15.

29-1a Comment: Since 1980, the Biological Defense Research Program has expanded greatly. As a result of this expansion, the Army has initiated extensive research and development activities that involve investigation of the properties of lethal biological agents, open-air testing, and testing of large aerosols of biological agents.

29-1a Response: The BDRP conducts tests on defensive equipment

materiel, vaccines, etc. by aerosol exposure to high and low hazard organisms and toxins. Open air testing with pathogenic and toxins is not done, nor is "testing of large aerosols of biological agents." Also, see responses to comments 27-15, 32-1b and 29-5b.

29-1b Comment: Future plans include exploration of the properties of genetically modified pathogens. As the Army's Draft EIS for the Biological Aerosol Facility at Dugway Proving Ground stated, there is a "need for the development of test methods to match new features of biological defense that are under development to meet newly perceived types of threats."

29-1b Response: There are absolutely no genetically modified pathogens being constructed or tested in the BDRP. The commentor has apparently misinterpreted the quoted material. See response to comment 43-7.

29-2a Comment: Since 1980s, the Department of Defense has moved toward development of specific (as opposed to generic) defense against "conventional" (that is, naturally occurring) biological warfare agents; it has also strongly implied a need to move in the future towards development of specific defenses against genetically modified organisms and novel toxins.

29-2a Response: To the contrary, the DEIS specifically stated: "With the recognition that the new techniques in "biotechnology" could be applied, by hostile entities, to the development of novel or "unconventional" biological warfare agents, efforts have been directed toward the development of drugs and vaccines that will provide therapy for, or immunity to, broad groups of potential threat agents rather than to only a single agent" (See Sections 2.1 and 2.4). Also see responses to comments 36-1b and 24-3b.

29-2b Comment: However, the range of conventional biological warfare agents is large; moreover, the possibility of use of genetically engineered organisms multiplies the uncertainties almost infinitely. Thus, the concept of a specific defense is untenable and misleading since such defense can always be circumvented by the use of a different biological warfare agent.

29-2b Response: Section 1.4 addresses the need for the BDRP. See responses to comment 29-2a above and comment 20-2.

9-2 Comment: Section 2.4.3, paragraph three, states: "Outdoor

field tests with simulates (non-pathogenic and/or non-toxic materials) are performed on an as-required basis after preparation of appropriate NEPA documentation."... The document is not site specific as to the locations of the proposed tests; therefore, it can be assumed that the tests could occur where wind drift might impact public lands and public land users. The BLM Salt Lake District requests that copies of the NEPA documents relating to these tests be forwarded for review by the District.

9-2 Response: The DEIS on the BDRP is a programmatic document and not a site-specific one. Therefore, in this context, a tiered approach to environmental analysis is applied. Thus, as stated in Section 2.4.3 of the DEIS, appropriate NEPA documentation is prepared on an as-required basis for outdoor field tests conducted with simulates. This documentation is available upon request from the organization conducting such tests. In any case, by definition, any outdoor test sponsored by the BDRP involves only simulates or harmless, inert materials (see Appendix 5).

9-1 Comment: The document is unusually vague as to the type of activities and where these activities will occur on the Dugway Proving Ground facility. Based on the general statements and descriptions in the draft EIS, the BLM is unable to determine the extent to which there may be a likelihood that neither biological agents (pathogens, viruses, toxins, GEMs, etc.) nor simulates will be deposited on adjacent public lands or come in contact with the flora, fauna, and human users of public lands. Since the possibility of such exposure exists, we must conclude that the proposal is not consistent with proper management of the public lands under BLM management.

9-1 Response: Open-air testing with dangerous biologicals is not performed at DPG or any other location as part of the BDRP (See Sections 2.4.3, and 3.2.1.6, and 5.3.3.2.3). Outdoor testing in the BDRP is required very infrequently and only simulates or inert materials are used in such tests (see Appendix 5, part 2.3.5). Laboratory work performed at DPG is conducted under contained conditions and no recombinant DNA studies or work with GEMs is performed under the BDRP at this site (see Appendix 6, page A6-25). In addition, investigations conducted on selected aspects of the flora and fauna of the DPG environs have supported the conclusions that there have been no measurable effects (see Appendix 5, part 2.3.2). Also, refer to the IAM on DPG in Appendix 6, which shows no impacts on land-use and plant and animal ecology from BDRP-related activities at DPG. See also response to comment 9-2.

29-9 Comment: It is clear that there is great public anxiety in certain communities concerning the possible impact of the use and testing of agents of biological warfare. Plans for the

construction and use of the Aerosol Test Facility at Dugway Proving Ground, Utah, have aroused widespread public concern. Yet the question of the psychological impact of use and testing of biological warfare agents is not addressed in the Draft EIS.

29-9 Response: While some amount of "public anxiety" may exist concerning research activities conducted under the BDRP, the DEIS did not identify any "real" threats or significant risks to the environment or the general populace, (see Section 1.6.2; and part 3 of Appendix 10 on public controversy).

14-7 Comment: Brief mention is made (p. 5-21) of outdoor testing at Dugway Proving Ground using simulate organisms in aerosol form. This program needs further explanation regarding its purposes, the biological species involved, amounts released, sites and conditions of release, and precautions taken to avoid any possible adverse environmental or community health effects. It should be noted that under some conditions in susceptible individuals, even normally non-pathogenic microorganisms can cause infection.

14-7 Response: DPG's principal mission, as related to the BDRP, is outlined in Section 2.4.3 of the DEIS. Outdoor field tests with simulates are performed on an as-required basis after a test-specific environmental evaluation has been performed and appropriate NEPA documentation prepared, (see Sections 3.2.1.6 and 5.3.3.2.3). Also, see Appendix 5, part 2.3.14 for an explanation of any effects of BDRP-related activities at DPG on human health. Also, see responses to comments 29-9 and 9-2.

55-6b Comment: This total lack of security is just another example of how unsecure this base could be.

55-6b Response: As discussed in the DEIS, security is an important aspect of the BDRP (see Section 3.3.3). The comment refers to person(s) getting onto grounds of DPG. This is not the same thing as getting into a specific laboratory of a specific building at a time when a specific organism/toxin would be available. Appendix 9 considered a terrorist/sabotage scenario in assessing maximum credible events. Also see responses to comments 11-1 and 27-9e.

42-4b Comment: I am not a scientist, I do not know all the magic words to say, but we are not sure you can protect us and we are not sure that we will be able to survive if this plant has some sort of catastrophic escape, and that escape can move over the Oakridge and can affect all of the Wasatch front and all of the areas.

42-4b Response: Refer to Appendix 9 for potential effects of accidents within the laboratory (part 2), aerosol release from DPG (part 3.1), and other "catastrophic" escapes. Also, see response to comment 9-3.

27-19 Comment: The BDRP EIS rejects all these alternatives in just over two pages (4-4,6). The DOD admits that "no detailed study" has been made of these proposals despite the fact that they would significantly eliminate the environmental impacts of the BDRP program.

27-19 Response: A full discussion of the alternatives considered, including those suggested in the public scoring and public comment processes, is presented in Section 4 of the EIS. Additional information or clarifications have been provided where appropriate in the FEIS. The proposed alternatives were all accorded a thorough analysis in order to determine which alternatives might reasonably resolve any conflicts in utilization of resources, minimize adverse environmental impacts, or otherwise improve the BDRP. Those alternatives that failed to offer any environmental or programmatic improvements were not given further detailed study as reasonable alternatives to the proposed action. Many other "alternatives" consisted of suggestions which were found to already be a part of the ongoing BDRP, and thus incorporated in the "preferred alternative."

26-9d Comment: Whoever was responsible for preparing the DEIS was grossly negligent in not producing a comprehensive analysis as to why either one if not all three of these alternatives should have been seriously considered with respect to all or significant parts of the BDRP. I would respectfully request that you go back to your Staff and demand that they produce a revised DEIS that seriously addresses these three aspects of the problem.

26-9d Response: Respectfully disagree with commentor's conclusion. Further clarification on the feasible alternatives has been provided in the FEIS. Additional detail is provided under Section 4.2.1 and 4.2.2 as to the alternatives that were recommended by scoring and alternatives that were eliminated from consideration as viable options. Also, see responses to comments 27-2 and 27-19.

27-16 Comment: The BDRP is also expanding its vaccine program to include large numbers of national and international volunteers. The 1987 Annual Report states that the BDRP has "established protocols for field testing efficacy of Argentine hemorrhagic fever vaccine in 3,000 volunteers residing in endemic

disease areas." The increase in the number and type of pathogens being investigated by the BDRP and the expanded use of international volunteers in BDRP programs causes a growing potential for health and safety risks. The expansion of the international research in the BDRP comes at a time when the NIH is still undecided as to how its research Guidelines apply to research done aboard.

27-16 Response: All development and testing of drugs and vaccines are conducted in accordance with existing U.S. law governing such development and testing regardless of the location, foreign or domestic, of such activities. In addition to U.S. laws and regulations, when such studies are conducted at a foreign location they are done in compliance with the laws of that country as well, as stated in Section 3.5.6 of the EIS. Because such studies are conducted only where and when a target disease occurs naturally; there is no introduction of a non- agent into the environment (see Sections 5.2 and 6.1.4). Thus, it provides no additional risk to the human environment or to health and safety than that which would be present due to the natural occurrence of the endemic disease.

43-5a Comment: There's another reason for this besides the distrust that offensive may become defensive, and that is the use of substantial numbers of volunteers, not only nationally but also internationally. Fiscal year '87 report of the BDRP establishes that hundreds of volunteers have been used nationally and in the near future, thousands are to be used internationally.

43-5a Response: See response to comment 27-16 above.

24-16b Comment: More will be heard from that Subcommittee on the safety issue. Suffice it to say here that the DEIS does not have a tenable basis for ruling out all changes in the existing BDRP.

24-16b Response: The EIS has not ruled out all changes. Adjustments are made regularly , as new or additional information is forthcoming. However, these adjustments/changes are not of such a nature as to warrant separate consideration as a distinct alternative, e.g., the recently undertaken preparation of a centralized safety regulation that consolidates existing safety practices, local safety regulations and Standing Operating Procedures. Also see response to comment 27-2.

31-3 Comment: As for the DEIS document itself, we object to the

narrowing of program options to the no action alternative (eliminate BDRP) or the preferred alternative (business as usual). The rationale offered to reduce alternatives to this all or nothing choice is thin and specious. In light of recent Senate OGM reports and hearings and GAO investigations pointing our numerous, serious deficiencies in the Army's CBW programs and making more than a dozen serious, intelligent recommendations for improvements in those programs, we find the Army's posture on alternatives absurd and condescending. There are other alternatives: the Army simply refuses to seriously examine them. This is a fatal flaw in this DEIS.

31-3 Response: The identification of two alternatives resulted only after extensive examination of the multiple options that were proposed during public scoring, or were gleaned from other sources (see Section 4). No other "reasonable" alternatives in the NEPA context were identified. The reference in this comment to the Senate OGM report is an apparent misunderstanding of what the report says. This preliminary report does not examine the current safety practices of particular facilities conducting CBW research. Nor does it reach final conclusions as to whether, currently, CBW research is being conducted in a safe manner. Rather, the report was only preliminary in nature and addressed only the management of safety issues, e.g., centralization of a safety office, regulation, etc. The DEIS considered safety in terms of risk/issue category of the type of research performed (Section 3.5) in the development and application of the IAM (Appendix 6 page A6-62 to A6-82 and Appendix 4). Environmental, health and safety considerations, waste stream management, security, accidents and incidents were analyzed by risk/issue category and examined at all the primary sites and the secondary sites that were site-visited (See Appendices 4 and 5). All secondary site research efforts were evaluated "as appropriate to determine if: 1) any unique circumstances or extraordinary conditions exist; 2) adequate facilities are available; 3) there is evidence of implementation of the appropriate controls that mitigate any areas of concern identified in the risk/issue IAM and 4) appropriate environmental compliance measures are in place. No non-compliance problems were identified and no significant environmental impacts associated with the BDRP were identified" (see Appendix 3). The GAO report was somewhat more extensive and looked at safety practices at two contractor sites conducting BDRP research. The following text is reproduced from that report:

> DOD risk assessment and safeguards management activities for contractors are structurally different from those developed and implemented in the chemical program. DOD has not developed its own safeguard standards or regulatory assessment and inspection system but instead relies on an existing safeguard system largely established by the biomedical research community.
> ...
>
> DOD has not perceived a need for developing its own

systematic, centralized regulatory approach because DOD officials do not see a distinction between the type of research and development taking place in the biological warfare defense program and non-DOD biomedical research on pathogenic microorganisms. ...

DOD's management and oversight of the biological defense contractors focuses principally on the scientific aspects of the contract work. DOD officials, with input from an external peer review committee of scientists, evaluate contract proposals for their scientific feasibility and merit and for their relevance to program objectives. Laboratory safeguards are addressed as part of this review, according to DOD officials. The type of agents and procedures proposed are reviewed as well as the qualifications of the research contractors and their experience in working with pathogenic microorganisms. DOD officials reported that pre-award site visits to survey safety and security measures have been conducted at selected contractor facilities, particularly those where contractors had limited experience with high-risk agents. DOD does not conduct regular inspections or evaluations to ensure that contractor facilities have adequate safeguards, but during site visits it does informally review them, according to DOD contract officers. Officials at the two facilities we visited confirmed that the DOD contract officers had conducted periodic site visits in which laboratory safeguards were discussed. ... At these two sites, we found that contractors had organized and implemented a risk management process. We did not find that they had conducted any formal risk assessments, however the site officials we interviewed were knowledgeable about the risks associated with the agents and procedures they were using. At the university research center we visited, the principal investigators were in fact leading experts in the fields of virology and epidemiology and had made significant scientific contributions to what is currently known about several of the viral agents under study. ...

Officials at the vaccine and drug development site had completed and recently updated an environmental assessment that discussed mitigation measures for the handling and disposal of infectious material. ...

We found that each of the contractor sites had established a process for setting safeguard policies, developing safety, security, and emergency preparedness procedures, and conducting oversight activities. The structure of the process was somewhat different at each of the sites, largely reflecting differences in the type of institution and the nature of their research and development efforts. At the university research center, contractors were required to obtain approval on contract proposals from a

biosafety committee that met regularly to review contract work and other research safeguard issues. In addition, a separate biosafety office was set up to conduct employee training and periodic inspections of all laboratory facilities. At the laboratory institute, where vaccine and drug development work was underway, certain staff were assigned responsibilities for developing the written standard operating procedures for safety and for reviewing laboratory procedures and any accidents or incidents' that occurred. These staff also had conducted some audits to check on compliance with safety procedures and the FDA "good manufacturing practices" requirements. ...

DOD is relying on a system of safeguards that was largely developed by the biomedical and microbiological research establishment that is implemented individually by research investigators and institutions. DOD has not developed its own safeguard requirements or conducted regular, formal evaluations of contractor facilities. ...

The lack of a formal DOD risk assessment and safeguards management process in the biological area makes it difficult to determine whether contractors are using the CDC/NIH or other recommended guidelines; whether safeguards are being used properly; and whether the existing safeguards are, in fact, effective. ...

We recommend that DOD take a more active role in the risk assessment and safeguards management of contractor facilities by developing and establishing a process to evaluate safeguards. A more systematic, centralized evaluation process for contractor facilities would provide useful information to address concerns about risks. The evaluations conducted may well demonstrate that existing safeguards at contractor facilities are adequate. However, until such evaluations are completed, there is no way to determine this empirically, and uncertainties will persist about the adequacy of existing safeguards governing biological research and development.

As we were preparing testimony for these hearings, DOD informed us that several new policy initiatives have recently been implemented since we began our review with respect to safeguards management in the biological defense program. One policy is a requirement now that research contractors follow the CDC/NIH biosafety guidelines. Research contractors will also be required to submit a safety and security plan to DOD, and those conducting work with particularly hazardous biological agents or procedures will be regularly inspected by a DOD biosafety officer. As we have already stated, we believe that these initiatives are important steps toward establishing more effective safeguards management and evaluation process.

43-3e Comment: ...full discussion of analyzing the possible parts of the program going through an agency, particularly those agencies that are not voluntary but are required to submit to NIH guidelines. Third, a mixing of those possible alternatives, and by the way, creating essentialized environmental concern for those agencies as well would be a big cooperation.

43-3e Response: DOD compliance on the part of research programs is not voluntary but is mandated by the Secretary of Defense. This is the same level of requirement as is placed on employees of the CDC and NIH. Also, see responses to comments 27-2 and 24-.

30-1 Comment: Our major concern regarding the programmatic DEIS relates to the proposed and discussed alternatives which are limited to 1. continue the BDRP unchanged (the preferred alternative)' or 2. terminate the BDRP (page ES-5, 4.2 to 4.8). The DEIS rightfully points out many of the benefits which accrue from the continuation of the BDRP, not the least of which is that "the DOD cannot ignore completely the possibility that biological warfare threats exist and fail to provide any deterrents to their potential application"...(page 1-1). This alone is a strong argument, with which we completely agree. However, if the only other possible option is to completely eliminate the BDRP, thus losing all capability to maintain an adequate defense program, the Department of the Army has unjustifiably eliminated the opportunity for public input and discussion of the overall safety of the program, and means by which the program can still continue but with adequate safeguards for the public health.

30-1 Response: The narrowing of the program options to two occurred only after extensive examination of the possible options that were proposed during public scoring, or were gleaned from other sources (see Section 4). Also see responses to comments 31-3, 30-7, 24-5b and 24-4c. The EIS has not ruled out all changes. Minor adjustments are made regularly, as new or additional information is forthcoming. However, these adjustments/changes are not of a magnitude to warrant separate consideration as an alternative, see Sections 4.3 and 4.4. The concern for, and attention paid to, the safety, health, and welfare of the work force, as well as for protection of the external environment, are illustrative of the commitment on the part of the proponent to manage the BDRP responsibly. Thus, it was not considered necessary, nor appropriate, to develop a subset of alternatives which would merely reflect differing levels of emphasis or special attention to selected elements of the overall program. Continued ongoing public input is provided through their elected representatives. The U.S. Congress specifically approves funding for and authorization of the BDRP, see Section 2.3 and a report on the BDRP is presented to Congress

annually in accordance with PL 91-121 as amended by PL 91-441. Future changes to the BDRP will be examined in the NEPA context and public input, as appropriate, on those changes will occur. Also, see responses to related comments 27-19 and 27-2.

1-2 Comment: We were somewhat surprised that the DEIS considered only the two extreme alternatives in detail, having eliminated intermediate alternatives as being unreasonable.

1-2 Response: Many of the suggestions were quite reasonable, and are part of the preferred alternative already. The suggestions were not, however, considered to be viable alternatives. See response to comment 30-1 above.

43-2 Comment: The group does select certain sites, but the decision of which sites to choose were obviously not part of the scope of the meeting of August 12th, and I cannot reason why each one was chosen, and, of course, I think we should see an entire review of all the facilities.

43-2 Response: Reports, records, statements of work and proposals of each secondary site were examined to identify the nature of the work performed by risk/issue category. Representative secondary sites were selected from those risk/issue categories that theoretically might have the greatest environmental concern or be the most contentious (Categories I, II, III). Consideration was also given to diversity of geography, type of institution and environmental setting, e.g., rural, urban or suburban. The incorporation of a specific review of all facilities in a programmatic EIS would be inappropriate.

24-6a Comment: The most controversial aspects of the BDRP are field testing. What kind of evaluation and documentation is to be prepared before field testing.

24-6a Response: No field testing at all is done with pathogenic organisms or active toxins. Open air tests with only non- and/or non toxic materials, as stated in Section 2.4.3, are performed very infrequently on an as-required basis and only after preparation of appropriate NEPA documentation. Phase III (human clinical testing) of drugs and vaccines is conducted only where and when a target disease occurs naturally, see Section 3.5.6.

24-3a Comment: The most controversial aspects of the BDRP are threat assessment. There is however, one brief mention of a function requiring pathogens, listed among other functions (2-7),

that may be the major BDRP activity at Dugway: "the laboratory assessment of biological threat agents." If this is an important function, why is it not discussed? Is it really necessary?

24-3a Response: This function was considered in the application of the IAM to DPG primary site as well as considerations of the various risk/issue categories. No special or unusual methodologies are involved in these studies and no significant risks/impacts on the health or environment were identified. Therefore, specific detailed description of studies to be performed were considered inappropriate.

24-3b Comment: In the trade-off between public safety and confidence in the BWC, on the one hand, and the ultra-complete testing of materiel and the study of potentially offensive agents, on the other, where should the line be drawn? The Army has not come to grips with this question.

Perhaps it is more dangerous to conduct secret threat assessment studies than not to do so. And camouflaging threat assessment as materiel testing is no help. DOD's interest in threat assessment with novel organisms, including work to be carried out at Dugway, is unequivocal. It is set forth in some detail in the DOD Report to the House Committee on Appropriations, dated May, 1986, which says (in part): "The threat posed by new biological agents must be established with the greatest degree of certainty possible. This high degree of certainty must also be established for information of the ramifications of new production and processing technologies as they apply to conventional and novel threat biological agents. The [proposed] biological agent test facility is required to generate basic laboratory data to meet these threat assessment needs."

This policy is likely to provoke any defense against it -for, as the DEIS suggests, the number of novel BW agents that could in theory be developed is so vast that the development of specific defenses is impossible.

24-3b Response: The U.S. is not creating novel agents for doing laboratory assessment of threat agents. Use of recombinant DNA procedures with pathogenic organisms and toxins is closely controlled at all locations, both within and outside the government. Development of a more virulent strain of a pathogen is specifically prohibited under any circumstance, and is not the goal of any BDRP effort. The laboratory assessment of any suspect threat organism/toxin obtained by overt or covert means from a potential adversary might be required. The BDRP-DEIS does not suggest that the number of novel BW agents that could in theory be developed is so vast that the development of specific defenses is impossible as stated in Section 2.4.1." The rationale for these "generic" approaches is that, while there are numerous different individual infectious organisms and toxins,

many of these agents act through common mechanisms of action at the cellular level. Thus, for the large number of viruses and toxins that pose potential threats, there are a finite number of cellular sites at which these viruses or toxins exert their effects. See Section 2.4.2. Thus, receptor responses are the basis of the concept of "generic" detection of biological threat agents.

24-3c Comment: DOD's interest in threat assessment with novel organisms, including work to be carried out at Dugway, is unequivocal. It is set forth in some detail in the DOD report to the House Committee on Appropriations, dated May, 1986, which says (in part): "The threat posed by new biological agents must be established with the greatest degree of certainty possible. This high degree of certainty must also be established for information on the ramifications of new production and processing technologies as they apply to conventional and novel threat biological agents. The [proposed] biological agent test facility is required to generate basic laboratory data to meet these threat assessment needs." This policy is likely to provoke the very threat that is feared, without actually providing any defense against it - for, as the DEIS suggests, the number of novel BW agents that could in theory be developed is so vast that the development of specific defenses is impossible.

24-3c Response: See responses to comments 24-3a and 24-3b.

27-9e Comment: The environmental concerns about this research include ... Laboratory security.

27-9e Response: Laboratory security was considered in the analysis of environmental health and safety of activities within the BDRP, see Section 3.3.3. Terrorist or disgruntled employee action to cause deliberate release of organisms or toxins was considered in Appendix 9.

27-9f Comments: The environmental concerns about this research include ... Risks involved in decontaminating facilities.

27-9f Response: Decontamination, including safety of procedures employed was considered and discussed in Appendix 13. Decontamination of effluents was an integral part of IAM analysis, see Section 3.2.2.2.

27-9h Comment: The environmental concerns about this research include ... Economic and social impacts to areas adjoining BDP

sites .

27-9h Response: Economic and social impacts were an integral part of development and application of the IAM, see Appendices 5 and 6. We note that economic impacts, through employment, are positive.

12-4 Comment: Based on these few observations, I must conclude that the DEIS is not only too general in its content, but represents an inadequate presentation of the potential impacts of the BDRP.

12-4 Response: The BDRP programmatic EIS considered all aspects of conducting a biodefense program from a risk issue category under normal operations, see Sections 1.6.4, 3.5, 5, 5.1, 5.2, 6.1.1 and Appendices 4 and 6 and abnormal operations (maximum credible events Appendix 9. Site specific considerations were analyzed for the three primary sites of execution and selected secondary sites, see Sections 2.4, 2.5, 5.3, 5.4, 6.1.2, 6.1.3 and Appendices 5 and 6.

31-4b Comment: The proposed Dugway aerosol testing lab is just the most obvious example of program expansion.

31-4b Response: The BDRP grew in funding from 1980 to 1984; but has remained consistent since that time in terms of constant dollars. The program has not changed in terms of type of studies conducted, nor in the nature and biohazard of organism/toxin under consideration. The proposed utilization of the Dugway BATF would not alter program direction, content or magnitude.

27-15 Comment: The recently released Department of Defense Annual Report on the BDRP (October 1986 through September 1987) demonstrates that the BDRP is expanding in many important areas. The Annual Report demonstrates that the BDRP is continuing to aggressively investigate, purify, propagate, clone and alter traditional and new pathogens.

27-15 Response: The implications of this statement are not true. There has been an approximately 5 fold increase in appropriated dollars for the BDRP between FY 81 and FY 87 as reported in the Army Science Board report. This recent infusion of money into the program did not change to any significant degree the nature and type of studies conducted, nor quantities of organisms or toxins under study. Indeed, the Department of Defense Annual Report to Congress on the BDRP for October 1979 to September 1980 stated:

Research is conducted to select and appraise the potential of new concepts for rapid detection identification and decontamination of biological threat agents in the field. Potential threats to present and future material or systems are also considered.

These fundamental studies are designed to generate a broad base of knowledge concerning toxin actions in order to improve treatment and to change toxins into safe toxoids which can be used to immunize soldiers. Therefore, current and future studies will concentrate on: (a) identification of toxigenic and antigenic sites; (b) the means by which bacterial toxins get into, and are processed by mammalian cells; (c) definition of how toxins and toxoids protect the soldier; (d) purification and chemical characterization of the amino acid sequence of those toxins that are militarily important; (e) the testing of drugs that will protect body cells against toxins; and (f) application of principles and techniques developed to study other important toxins as quickly as possible.

Important questions concerning medical defense against BW attacks are not presently contained in official guidance. New threats may be opened up by various technological and scientific advances. As examples, recombinant DNA technology could make it possible for a potential enemy to implant virulence factors or toxin-producing genetic information into common, easily transmitted bacteria such as E. coli. Within this context, the objective of this work is to provide an essential base of scientific information to counteract these possibilities and to provide a better understanding of the disease mechanisms of bacterial and rickettsial organisms that pose a potential BW threat, with or without genetic manipulation.

Not all defense-related requirements defined in official guidance are being funded at an adequate level. Newly discovered groups of extremely dangerous viruses must now be evaluated for their potential threat to U.S. forces either as BW weapons or as natural threats in certain geographic area. These include viruses of the Marburg-Ebola varieties from Africa and additional hemorrhagic fever viruses.

Continuing emphasis will be devoted to the disease progression of Rift Valley fever virus, Ebola virus, Korean hemorrhagic fever and other viral diseases.

The anthrax program is currently being expanded by redirection of programmed resources with the development of improved techniques for producing, purifying and characterizing anthrax toxins.

The development of new vaccines constitutes a major

requirement of USAMRIID and this program will continue to attempt to create new vaccines against important viruses, with emphasis on viruses that produce highly lethal hemorrhagic fevers such as Argentine and Bolivian hemorrhagic fever, Korean hemorrhagic fever, Congo-Crimean hemorrhagic fever, and Lassa fever.

Those studies included botulinum toxin A, the most potent naturally produced neurotoxin known, Ebola and CCHF viruses (classified as BL-4 organisms) and applied recombinant DNA technology to addressing some of the research needs. No infectious organism of a higher biosafety level than those cited in that report or more potent toxin than botulinum toxin type A has been added to the BDRP and the quantities employed in these studies has not been increased.

If the comment is meant to imply the DOD is propagating, cloning or altering natural organisms by genetic engineering to create more virulent organisms, this is not being done. The description of the potential threat is different from the description of techniques being used in biomedical treatment and diagnosis.

High hazard (BL 3/4) infectious organisms, toxins, GEMs and other lesser risk/issue categories were considered in the development and application of the IAMB, see Sections 3.5.1, 3.5.2, 3.5.3 and Appendices 4 and 6.

27-5a Comment: Traditional biological agents include *Yersinia pestis* (the plague), anthrax, botulism, snake venom, tularemia, Rift Valley fever, *Coxiella burnetii* (Q fever), eastern equine encephalitis, and smallpox.

27-5a Response: Smallpox is not part of the BDRP. By international agreement under the auspices of the World Health Organization, all smallpox virus strains in the U.S. are permitted to be retained and stored only at the CDC. Vaccinia virus, derived from cowpox and used universally as an vaccine to protect against smallpox infection, is used within the BDRP for consideration as a vaccine vector for antigens of other viruses for immunization purposes.

29-4a Comment: The environmental impact statement fails to address the full implications of continuation of the present policy.

29-4a Response: The preferred alternative - continuation of the BDRP (essentially as presently constituted) was analyzed thoroughly, see Sections 1, 2, 3, 4, 5 and 6. The environmental implications of conducting studies by risk/issue category was

integral to the development of the impact analysis matrix (see Appendix 5) and the analysis of each of these categories is contained in Appendix 4. The IAM analysis of the conduct of BDRP activities at the primary sites and selected secondary sites and site visits to these sites are presented in Appendix 5. Risk assessment is presented in Appendix 8 and intentional or incidental release of organisms/toxins was considered in Appendix 9. Also, see response to comment 27-2.

43-4a Comment: The second major concern, I think, is in combining certain alternatives. That is, the draft Environmental Impact Statement deals separately with shifting research and civilian sites and a moratorium, for instance, on GEM.

It would seem one good possible alternative is shifting genetic engineering work, at least to civilian agencies, particularly those that require obeying of NIH guidelines.

43-4a Response: See responses to comments 27-2, 27-19, 31-3 and 30-1.

14-3 Comment: The statement in the PDEIS (p. 5-20) that there are no unique areas of significant concern at Dugway Proving Ground appears false. The operation of the proposed Biological Aerosol Test Facility (BATF), designed to aerosolize pathogens, must be considered an unusual potential hazard.

14-3 Response: The types of studies to be conducted at DPG were considered in the BDRP-EIS, see Sections 2.4.3, 3.4.1, 5.3.3 and Appendix 5, part 2.3 and Appendix 6, pages A6-25 to A6-30. Aerosol testing of equipment, detectors, vaccines, etc. with organisms/toxins in a small, sealed chamber within a biocontainment laboratory was considered in the development and application of the IAMs (Appendix 6) including the analysis of the risk/issue categories and the specific sites where such studies might be conducted, Appendices 5 and 6. The potential risks associated with aerosol testing are mitigated by the use of special procedures, specially designed equipment, and appropriate levels of containment, which effectively, reduce the risks and protect the work force and the external environment. Potential impacts unique to the proposed BATF are addressed in the BATF

SUBJECT AREA 2 - SAFETY

Sub-category A - General

22-2b Comment: The Environmental Defense Fund is concerned by the lack of a comprehensive plan for maintaining safety within the program. As it stands now, the unclassified elements of BDRP are governed by a web of regulations, the enforcement of which is the responsibility of numerous agencies.

22-2b Response: The laboratories of the Department of Defense (DoD) performing research in the BDRP currently operate effective safety programs to assure compliance with the myriad of regulatory requirements promulgated by Federal and state agencies mentioned in this comment. The DoD pursues an aggressive safety program at its own laboratories through written safety SOP's and policy statements administered by the local safety offices and the principal investigators. The DoD pursues an aggressive safety program at its contractors' laboratories through contracting requirements for safety programs at each of the extramural research laboratories and monitoring of the contract execution by the Contracting Officer's Representative (COR), a scientist working in the same research area (see DEIS Section 3). These written DoD and subordinate laboratory policies reflect the requirements of the regulatory agencies and serve to minimize the environmental and health effects of the BDRP. There is no classified research and development in the BDRP; therefore, there is no review conflict involving regulatory agencies. Illustrative of the sensitivity to compliance is the fact that the Secretary of Defense mandated compliance with NIH Guidelines for Research Involving Recombinant DNA Molecules for all research laboratories of the DoD, including its contractors (see reference 32 in Section 7 of the DEIS and Appendix 10). See also responses to comments 29-6a and 22-9.

22-2c Comment: These include the Department of Transportation (Packaging standards, 49 C.F.R. sec 173), Environmental Protection Agency (Toxic Substances Control Act, 5 U.S.C. sees 2601-2929; Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. sees. 136-136y), US Department of Agriculture Virus-SerumToxin Act: 21 U.S.C. sees. 151-158), Food and Drug Administration (Food, Drug and Cosmetic Act: 21 U.S. C. sees. 301 et seq.) and the Nuclear Regulatory Commission (use of radioactive isotopes, 10 C.F.R. sec. 1).

22-2c Response: See response to comment 22-2b.

22-2d Comment: In addition, DoD voluntarily follows the NIH guidelines governing recombinant DNA (rDNA) work (49 Fed. Reg. 40659 (1984)).

22-2d Response: The Secretary of Defense mandated compliance with NIH Guidelines for Research Involving Recombinant DNA Molecules for all research laboratories of the DoD. See responses to comments 22-2b, 29-6a and 22-9. This is equivalent to the level of compliance applicable to the employees of the CDC and NIH themselves, i.e., a directive by the Secretary of the department.

22-2e Comment: Wielding a $90-million budget in 1986, BDRP is a large program. BDRP research is conducted in three US Army facilities and in 100 independent laboratories. The burden of this research does not fall on all these facilities equally, nor do they all work with materials and organisms which pose the same degree of risk. Nevertheless, the size of the program does call for a clearly articulated programmatic safety policy. It is not sufficient for DoD to rely on the present tangle of regulations and guidelines to insure environmental protection, health and safety. In general, these agencies have strained budgets and are understaffed; DoD cannot assume they will aggressively enforce safety requirements for BDRP.

22-2e Response: External enforcement is not a prerequisite to adherence to safety provisions. Section 3 of the FEIS has been updated to provide further clarification on safety issues and responsibilities. See also responses to comments 22-2b, 30-4 and 24-16b.

22-2f Comment: Moreover, we do not see how these agencies could regulate parts of BDRP which may be classified.

22-2f Response: There is no classified research and development in the BDRP; therefore, there is no review conflict involving regulatory agencies. See Executive Summary ES.2 and Section 4.2.2 of the FEIS.

22-2g Comment: While DoD claims adherence to state of the art biohazard containment protocols, these safety mechanisms can be circumvented. If there is only a slight chance that a dangerous event will occur, people tend not to guard diligently against such an event. Personal risk assessment is highly idiosyncratic; while it seems perfectly rational for someone to protect their health to the fullest extent possible, people often, for a variety of reasons, reject safety devices. Seat belt and motorcycle helmet laws provide a good example; in the absence of an active enforcement program, compliance with these laws drops dramatically. A similar situation can exist in a lab. Without diligent enforcement, lapses in safety protocols can become

endemic within the facility.

22-2g Response: See responses to comments 22-2b, 22-2e and 30-5.

27-17 Comment: This lack of integration and coordination is particularly evident in the DOD's apparent inability to assess and minimize the environmental and health impacts of the BDRP. The DoD is content to allow the BDRP's impacts to be governed and monitored by a series of regulations, the enforcement of which is the responsibility of numerous agencies. These include the Department of Transportation (Packaging standards, 49 C.F.R. sec 173), Environmental Protection Agency (Toxic Substances Control Act, 5 U.S.C. sees. 2601-2929; Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. sees. 136-136y), US Department of Agriculture Virus-Serum-Toxin Act: 21 U.S.C. sees. 151-158), Food and Drug Administration (Food, Drug and Cosmetic Act: 21 U.S.C. sees. 301 et seq.) and the Nuclear Regulatory Commission (use or radioactive isotopes, 10 C.F.R. sec. 1). In addition, DOD voluntarily follows the NIH guidelines governing recombinant DNA (rDNA) work (49 Fed. Reg. 40659 (1984)).

The BDRP makes no analysis of the Army Science Board finding nor how such an uncoordinated research program can rely for its safety on the enforcement of the regulatory tangle cited above.

27-17 Response: See responses to comments 22-2b and 22-2d. The specific comment to "lack of integration and coordination" is a misinterpretation of the Army Science Board report (see page 5 of Army Science Board report). "There does not presently exist within the Army an adequate mechanism for assuring the systems integration of the total BD program and the authority to control the programs' collective directions and outputs to assure this integration does not exist below DA level." This "integration and control" does not affect the health and safety aspects of the environment.

27-11 Comment: The EIS also makes it clear that the BDRP has never instituted a comprehensive study on accidental exposures and other hazards of the BDRP. The DOD has admitted that there have been approximately 20 "potential accidental exposures" at Fort Detrick since 1983, but the DOD has not provided information on the rest of the BDRP.

27-11 Response: A safety problem occurring at any laboratory of the BDRP is reported to the Safety Office of the primary research facility of the DoD. The USAMRIID safety record was described (see Appendix 8) because its 20 potential exposures was indicative of all of the accidental exposures in the BDRP. This tabulation also serves as a useful example of the types of

hazards encountered by laboratory workers. Also, it should be noted that there have been no occurrences of infection or illness in non-laboratory workers or in the general community arising from organisms or toxins handled in the facilities associated with the BDRP (see Appendix 4, parts 1.7, 2.7, 3.7, 4.7, 5.7, 6.7, and 7.7).

22-8 Comment: Furthermore, the DEIS should have had a far more comprehensive section on accidental exposures. Table A8-3 of the DEIS covers 20 "potential accidental exposures" at Fort Detrick since 1983, but there is no information presented for the whole BDRP.

22-8 Response: Coverage on accidental exposures presented in the DEIS is considered appropriate, especially since the BDRP has an outstanding safety record. See response to comment 27-11.

28-1 Comment: I find the document to be vague and inconclusive in assessment of potential hazards to the public from the accidental release of the toxins and biological agents stored and tested at Dugway Proving Grounds.

28-1 Response: Conduct of studies (including testing of animals and/or equipment by aerosol exposure) with high hazard organisms/toxins under the appropriate biosafety conditions, which include use only in a sealed chamber, does not constitute a significant risk to the health and well being of the work force, community health or the environment, see Sections 5 and 6, Appendix 4, pages A4-2 to A4-6 and A4-8 to A4-11 and Appendix 6, pages A6-59 to A6-62 and A6-67 to A6-70. See also response to comment 31-8. The specific consideration for DPG and the application of the IAM to the activities at that site is found in Appendix 5, parts 2.3 through 2.3.14 and Appendix 6, pages A6-25 through A6-30. Storage of organisms, toxins, reagents, etc. was analyzed under the category of storage in the IAM, (see Section 3.2.1.2).

14-13 Comment: No mention is made of an explosive potential when paraformaldehyde is heated to produce formaldehyde vapor, to be used for laboratory decontamination. In general, the explosion and fire risks, with the potential of pathogen release, deserve more serious consideration.

14-13 Response: Paraformaldehyde (EPA/OPP Chemical Code 043002) is not identified as explosive in the EPA Pesticide Fact Sheet Registration Standard for Formaldehyde and Paraformaldehyde, nor in the CRC Handbook of Chemistry and Physics. Small quantities of paraformaldehyde are boiled in an electric skillet in

biocontainment laboratories to generate formaldehyde vapors for decontamination of laboratory and equipment surfaces. The risk of an explosion, and subsequent release of organisms, due to the paraformaldehyde decontamination procedure is exceedingly small. Accidental releases of organisms as a result of explosion and other maximum credible events is discussed in Appendix 9, parts 5 and 6. While there is a report of the explosion of a biosafety cabinet, after paraformaldehyde decontamination and during the subsequent heating of ammonium carbonate to neutralize residual formaldehyde vapors, it is postulated that the cause of the accident related to the a combination of factors, including possibly the use of larger quantities of paraformaldehyde than recommended plus sparking of an exposed circuit. (The laboratory in which the accident occurred was not part of the BDRP.) Electric skillets with sealed circuitry are normally used for heating paraformaldehyde, and the levels used in laboratory decontamination are 10 fold less (0.8%) than those required to produce a potentially explosive formaldehyde vapor (8%) (Laboratory Safety: Principles and Practices, B.M. Miller, ed. (1986) American Society for Microbiology, Washington, D.C.). Thus, there is a significant margin of safety allowed for in the use of paraformaldehyde to decontaminate biocontainment laboratories within the BDRP.

14-17 Comment: It should be noted that the term "Biosafety Level" refers not simply to a building or laboratory design, but to a concept of pathogenic organisms. Thus, a laboratory designed to aerosolize pathogens intrinsically violates these biosafety principles.

14-17 Response: This is not an accurate interpretation of the CDC/NIH guidelines, nor the term "Biosafety Level." It is recognized by the Guidelines that any activities that might create an aerosol require special attention and in particular, BL-2 and BL-3 organisms need to be considered for handling at a higher biosafety level (see Section 3.5.1 of the DEIS). This more intense protection level is a precautionary measure to afford greater protection for the work force and the environment. However, the guidelines do not prohibit or specifically recommend against testing by aerosol exposure. They merely note the increased care required when aerosols may be present.

39-2 Comment: One component of the proposed program involves aerosol testing under so called BL3 and BL4 conditions. BL3 and 4 are said to correspond, respectively, to P3 and P4 under the N.I.H. guidelines for recombinant DNA research. However one of the key points in the N.I.H. guidelines is that pathogens should not be aerosolized. Thus the proposed BL3 and BL4 facilities do not correspond to P3 and P4. Work with aerosolization must be

considered more hazardous than work in which aerosolization is prohibited.

39-2 Response: The NIH Guidelines caution against inadvertent generation of aerosols in the conduct of research manipulations involving GEMs. Intentional aerosolization in equipment specially designed for safe generation and containment of the aerosol is not prohibited by the NIH Guidelines. See also response to comment 14-17.

22-7a Comment: A serious accident would likely trigger the convening of a formal board of inquiry.

22-7a Response: Comment is speculative as to how a hypothetical accident might be investigated. The assumption of a serious accident is not consistent with the analysis of the BDRP (see Sections 3, 4, 5 and 6 and Appendices 4, 5, 6 and 9) nor with the history of the BDRP (see Appendix 4 parts 1.7, 2.7, 3.7, 4.7, 5.7, 6.7, and 7.7 and Appendix 8).

22-7d Comment: Moreover, as the DEIS repeatedly stresses, the greater part of the program is devoted to non-recombinant microbial work and, as a result, is beyond the oversight of the IBC's. At any rate, the IBC's work entirely at the local level, so they have no impact upon the program as a whole.

22-7d Response: See response to comment 22-2b. In addition, IBCs do not operate in a vacuum, but coordinate with the institutional safety office and with the NIH Recombinant Advisory Committee (RAC) as specified in the NIH guidelines. Overall institutional safety is the responsibility of the safety office, and is not attributed to an IBC that is specifically constituted to evaluate work with recombinant DNA. Section 3 of the FEIS has been expanded to clarify safety issues.

30-4 Comment: Although the Department of the Army's group of expert professionals are confident that little or no safety hazards and that adequate safety and regulatory controls exist to assure that no accidents will happen (page 3-5 to 3-9), the Senate subcommittee on Oversight of Government Management apparently does not agree: "With respect to research involving BW agents, DOD's safety protections appear to be fragmented and, particularly for BDP contractors, completely inadequate. There is no comprehensive set of safety regulations for research with BW agents and toxins, no emphasis on safety in the contractor program, and no office that monitors contractor safety." (page 8 Senate Subcommittee Report).

30-4 Response: The Senate subcommittee did not consider the BDRP DEIS in its preliminary report (see page 10 of report) "The extent to which the EIS addresses safety issues is not yet known." Furthermore, page 1 of report states: "This preliminary report does not examine the current safety practices of particular facilities conducting CBW research. Nor does it reach final conclusions as to whether, currently, CBW research is being conducted in a safe manner." Rather, the report was only preliminary in nature and addressed only the management of safety issues, e.g., centralization of a safety office, regulation, etc. The BDRP EIS considered safety in terms of risk/issue category of the type of research performed (see Section 3.5 on the development and application of the IAM, and Appendix 6 pages A6-62 to A6-82 and Appendix 4). Environmental, health and safety considerations, waste steam management, security and accidents and incidents were analyzed by risk/issue category and examined at all the primary sites and the secondary sites that were site- see Appendices 4 and 5. All secondary site research efforts were evaluated "as appropriate to determine if: 1) any unique circumstances or extraordinary conditions exist; 2) adequate facilities are available; 3) there is evidence of implementation of the appropriate controls that mitigate any areas of concern identified in the risk/issue IAM and 4) appropriate environmental compliance measures are in place." (See Appendix 3, page A3-1.) No problems of noncompliance and no significant environmental impacts associated with the BDRP were identified.

24-16a Comment: The DEIS indicates that all perceived environmental threats are in fact so thoroughly controlled by the BDRP that the only true problem is psychological. The recent preliminary report of Senator Levin's Government Management Oversight investigation of safety in the BDRP finds otherwise.

24-16a Response: See response to comment 30-4.

6-2b Comment: Although, as described in the Draft EIS, the proposed program would be conducted in a safe manner and has no planned releases of biological materials, we do have the concerns discussed above. According to EPA's procedures we have rated this Draft EIS EC-2. This means that we have environmental concerns regarding the program and additional information is requested for the Final EIS.

6-2b Response: The concerns mentioned in this comment involve a request for further description of the controls in place to monitor research conducted at the secondary sites. As described in the DEIS, Section 3.3.2.2, no research contract is ever awarded to an institution which does not have adequate facilities for the research. Each proposal must include a statement from

the appropriate institutional officials verifying the adequacy of the research facilities. In addition, all locations at which BL- or BL-4 research is required are inspected by safety personnel from the primary site laboratory awarding the funding prior to the initiation of research. Within the past year, additional policies have been instituted which require annual (BL-3) or semiannual (BL-4) inspections to assure the Army that the facilities meet all Army safety requirements and are following all required procedures. Finally, all institutions which participate in BDRP-funded research are required, by Army policy and contractual obligation, to adhere to the CDC-NIH guidelines for biosafety The DOD policy of adherence to the NIH Guidelines for Research Involving Recombinant DNA applies to contractors as well as the DOD laboratories (see Section 3.3.2).

6-2a Comment: We also requested that the Draft EIS present the administrative mechanisms by which environmental protection is assured at non-Army facilities. This issue is not discussed sufficiently in either Section 2.5 or Section 5.4. Section 2.5 explains how the Army seeks and funds participation of non-DOD organizations in the program, but with no explanation of environmental requirements being part of this process. Section 5.4 provides the environmental procedures and settings at representative non-DOD sites. However, the Draft EIS does not present the steps the Army will follow to make certain that outside facilities are environmentally satisfactory before initiating Army funded research. We recommend that the Army present a discussion of the mechanisms in the Final EIS.

6-2a Response: See response to comment 6-2b above. In addition, Section 2.5 of the FEIS describes the administrative review process for non-Army facilities. An Army Regulation and Technical Pamphlet on biosafety in the BDRP are in preparation; when finalized, both will apply to Army and non-Army laboratories that participate in the program.

48-1 Comment: It is laudable that the BDRP DEIS delegates as much space as it does to the discussion of the history of accidents within the program. It is indeed sobering to read that three deaths resulted from early research in this area among lab workers. The great majority of incidents occurred during the development and early operational stages of the program at Fort Detrick. With the development of improved technology and the recent safety record of the program has been good. I am not reassured, however, that this guarantees a continued safe record. The BDRP is, again, in the developmental phase with the infusion of huge amounts of money into the program.

48-1 Response: As noted by the commentor, the great majority of incidents occurred during the development and early operational

stages of the weapons program at Fort Detrick. During this time period, safety improvements in facility, cabinetry and equipment design were evolving based on the knowledge gained at Ft. Detrick, see Appendix 8, page A8-6. Also, the types of studies conducted and quantities of organisms under study were vastly different, see Appendix 8, pages A8-2 through A8-5. The studies currently conducted in the BDRP employ the latest in safe facility and cabinetry design, see Appendices 11 and 12, and quantities of virulent or highly toxic material are minimized. The "recent infusion" of money into the program did not change to any significant degree the nature and type of defensive studies conducted, nor quantities, nor types, of organisms or toxins under study.

27-9b Comment: The environmental concerns about this research include ... Effects on DOD personnel from potential exposure to biological warfare agent being researched.

27-9b Response: Consideration of effects on the work force was an integral part of the impact analysis matrix, see IAMs in Appendix 6, Potential area impacted, item 14, human health, subgroup work force, and Section 5.2.1.5 in the body of the DEIS.

27-9c Comment: The environmental concerns about this research include ... Impacts on the thousands of national and international volunteers being used in BDRP projects.

27-9c Response: Consideration of impacts on medical research volunteers was considered under the risk/issue category, vaccine and drug therapy development. A small, but identifiable, risk to the medical research volunteer subjects who participate in BDRP activities was recognized, see Appendix 6, page A6-75 and Figure A6-18. See also response to comment 27-16.

7-2a Comment: The GAO, for example, warned of the uncertainties that surround the adequacies of the safeguards to the program.

7-2a Response: This comment, apparently based upon the commentor's interpretation of the Summary of the GAO report, refers to a lack (at the time of the report) of a centralized procedure to look at the safety of contractors - it did not state that safety was inadequate. Indeed, the GAO comments on the two contractor sites visited support the DEIS finding of adequacy of safety (see pages 23-25 of the GAO report).

7-2b Comment: More alarmingly, really, the senate report

ominously warns that DOD's safety protection appear to be fragmented and completely inadequate.

7-2b Response: The Senate subcommittee did not consider the BDRP DEIS in its preliminary report; see response to comment 30-4.

7-2c Comment: The report goes on to discuss examples of fires.

7-2c Response: The occurrence of fires is not an unlikely event. Concern for fires is inherent in the management of all facilities, e.g., department stores, laboratories, etc. as well as those of the BDRP Such possibility was considered (See Appendix 9, part 5).

7-2d Comment: The report goes on to discuss examples of ... misplaced vials of BW agents

7-2d Response: This alleged incident involving missing virus occurred in 1981 and has been the subject of several intensive investigations and occasioned a visit to the laboratory by a concerned member of Congress - all investigations and inquiries concluded that the vials were not lost, but had been destroyed inadvertently, perhaps by the research team itself. Further, the allegedly misplaced vials contained an attenuated candidate vaccine virus and not a virulent organism.

7-2e Comment: The report goes on to discuss examples of ... laboratory spills...

7-2e Response: Laboratory spills do occur - and SOPs exist for dealing with such spills. Such events were considered in the DEIS; see Section 6.3.1 and Appendix 9, parts 5 and 6.

7-2f Comment: The report goes on to discuss examples of ... employee exposures to BW agents...

7-2f Response: Employee exposure to organisms and/or toxins of low to high biological safety hazard were considered in the development and application of the IAM. See matrices in Appendix 6; potential areas impacted item 14, Human health-Workforce. Also, see Appendix 9, part 4.3.1.3.

27-12 Comment: There have also been widely reported cases of

fires and other accidents at Fort Detrick including missing quantities of viruses.

27-12 Response: See responses to comments 7-2c and 7-2d.

27-13a Comment: One of the most recent incidents is the loss of a sample of Crimea Congo hemorrhagic fever en route from the Center for Disease Control to the BDRP lab at Fort Detrick, Md. According to the National Institutes of Allergy and Infectious Diseases the Congo fever virus is so "highly infectious" that "most labs won't work on it."

27-13a Response: This alleged incident involved the shipping of CCHF virus from the CDC to USAMRIID. The sample was not "lost"; the package arrived at USAMRIID undamaged and unopened, but contained diagnostic reagents instead of CCHF virus. An intensive investigation by the CDC determined that the CCHF virus was never shipped. Crimean-Congo hemorrhagic fever virus is classified in the CDC NIH Guide as an agent requiring BL-4 facilities, equipment and procedures.

27-13b Comment: With this virus, and many others being worked on in the BDRP labs even small amounts of the pathogen if dropped from a plane or truck or dumped into the water supply, could have devastating effects.

27-13b Response: This statement is not true. Survivability of the organism and its ability to infect an appropriate host and to develop an appropriate biological transmission cycle for its self-perpetuation into an epidemic under these circumstances does not represent a valid assumption. Such possible scenarios were considered and discussed in the DEIS. See Appendix 9, parts 6, 6.1, and 6.2.

7-1 Comment: I note that there are at least two very serious studies done which question the adequacy of the draft programmatic environmental statement. The GAO and the Senate subcommittee on the oversight of Government Management have recently investigated the biological chemical defense program and neither supports the optimistic scenario....in your statement.

7-1 Response: Neither report questions the adequacy or inadequacy of the draft programmatic EIS. The GAO investigation was conducted from March to May 1988, and looked at the DEIS near the end of this investigation. The following is excerpted from page 26 of the GAO report: "DOD published a draft environmental impact statement on the biological warfare defense program on May 12, 1988, which provides the first reasonably comprehensive

assessment of possible environmental impacts and health and safety risks. In developing the statement, DOD reviewed safeguards at a sample of contractor facilities and also looked at likely maximum credible events that might occur. These included possible infections of laboratory personnel and the unintentional release of agents into the environment. DOD concluded from its assessment that there is a very low probability of such incidents occurring, and if they were to occur, existing control measures would provide adequate containment. We found, however, that the available information and data in the report itself were not sufficient to allow us to assess DOD'S review of contractor facilities." The Senate subcommittee preliminary report was released 11 May 1988, the day before the release of BDRP DEIS for public comment. Neither report cited safety problems with the programs, rather noted a lack of a central mechanism for safety management. Also see responses to comments 30-4 and 7-2a.

43-5c Comment: We now have an international circumstance where NIH guidelines are still being clarified as to how one complies with them on an international basis.

We're not talking about pseudo-rabies in animals; we're talking about thousands of individuals being tested with BDRP vaccines internationally.

This is a very serious issue, both nationally and internationally, even with NIH guidelines. It seems quite appropriate that any such experimentation be given to domestic agencies.

43-5c Response: Within the BDRP, all development and testing of drugs and vaccines are conducted in accordance with existing U.S. law governing such development and testing regardless of the location, foreign or domestic, of such activities. All international BDRP studies are conducted with host country scientists as collaborators. In addition to U.S. laws and regulations, when such studies are conducted at a foreign location they are done in compliance with the laws of that country as well, as stated in Section 3.5.6 of the DEIS. Clinical studies are conducted only where and when a target disease occurs naturally; there is no introduction of a nonorganisms into the environment (see Sections 5.2 and 6.1.4). Thus BDRP activities produce no additional risks to human health or environmental health and safety over that which is a result of the occurrence of natural, endemic disease. Also see responses to comments 22-2b, 27-9c and 27-16.

Sub-category B - External Oversight

14-9a Comment: The formation of a national committee for BDRP oversight to review all of the BDRP research projects and report to the United States Congress. This committee should be comprised of nationally recognized biological and medical scientists who are neither appointed by, nor otherwise associated with, the Department of Defense....The Utah Department of Health recommends a national committee of oversight for the BDRP composed of independent scientists reporting to the U.S. Congress.

14-9a Response: Recommendation is noted. As stated in the DEIS, the BDRP has exhibited an excellent safety record. Even so, additional measures are continually being incorporated into the program. Section 3 of the FEIS has been updated to reflect such additional measures. The need for additional external oversight is not apparent.

14-9b Comment: Local safety and review committees composed of civilian lay persons as well as biological and medical scientists. These committees would be responsible for monitoring the conduct and safety of research conducted at Fort Detrick, Aberdeen Proving Ground, and Dugway Proving Ground....We also recommend independent local review committees to oversee the safety and operation of programs at the primary research centers.

14-9b Response: Comment noted. Oversight of the safety and operation of programs at the primary BDRP research centers is the responsibility of the individual laboratory Commanders, the installation Commanders, and, through Army Staff channels, the Army Safety Office. See also response to comment 14-9a.

14-9c Comment: The pressures of meeting research deadlines are known to compromise strict adherence to safety principles in some laboratories. Without outside oversight, the BATF may be especially vulnerable to such pressures. This points to the need for independent civilian and state government representation on the laboratory safety committee.

14-9c Response: This comment refers specifically to the BATF EIS and is not appropriate in the context of the BDRP-EIS. If the comment in any way relates to the overall BDRP, see responses to comments 14-9a and 14-9b.

43-3d Comment: Obviously, it would be good to set up required reporting of accidents, required reporting of violations, rather than the volunteer approach currently being taken.

43-3d Response: This comment is based upon an incorrect assumption. The reporting of accidents and violations is required by several existing Army regulations and is mandatory rather than voluntary.

27-24 Comment: Other changes should include the establishment of an independent (non-DOD) review committee to assess the environmental and health implications of BDRP research.

27-24 Response: Environmental and health implications of BDRP research are addressed in this EIS, prepared under the auspices of the Council on Environmental Quality NEPA regulations and Army Regulation 200-2, "Environmental Effects of Army Actions."

27-25 Comment: Additionally, there should be mandatory reporting of all BDRP accidents with full investigation of any such accident by independent (non-DOD) investigators.

27-25 Response: Reporting of BDRP accidents falls under the provisions of several existing Army regulations as well as under provisions of a new Army safety regulation (in preparation) that will pertain specifically to the BDRP. See responses to comments 14-9a, 14-9b and 43-3d.

30-9b Comment: It must also incorporate a civilian scientific surveillance committee, which should include members of the academic biology research community, the National Academy of Sciences, the National Institutes of Health, the Centers for Disease Control, and members from the local medical associations and state health departments in areas where major BDRP activities are carried out.

30-9b Response: The BDRP is an open, unclassified program which is subject to frequent formal and informal review by the Army, DOD, Congress, and the scientific community (See Sections 1.5, 3.3.4.2, 4.2, 5.2.1.3 and 6.1 of the DEIS).

14-18 Comment: It would be desirable,...to commission an overall review of biological warfare defense issues by a panel of independent civilian scientists. This panel could evaluate the need for such research as well as its risks and limitations, and could address in detail the safety concerns raised.

14-18 Response: Such an overall review was undertaken by a group of interested scientists, who sponsored a roundtable

discussion on "Defense Related Biological Research" at the 1988 Annual Meeting of the American Society for Microbiology. In addition, safety in the BDRP was recently the subject of Congressional examination (see responses to comments 30-4 and 7-1).

22-7b Comment: However, incidents of lesser significance, which often presage serious events, need some measure of formal review by scientists and safety technicians.

22-7b Response: Every accident and incident relating to potential exposure of the workforce or any other safety breaches is investigated by safety professionals and other scientists as the situation might indicate. This is reflected in institutional safety regulations and SOPs. See Section 3 of the FEIS.

Sub-Category C - DOD/DA Oversight

22-2a Comment: The Department of Defense has neglected other reasonable policy alternatives, particularly the strengthening of centralized safety and environmental oversight. Moreover, even in its analysis of the current program, the DEIS is inadequate. The development of organization-wide environmental and health safeguards is neglected. The latter was a major concern of those individuals and organizations which participated in the "scoring" meeting. Given the size and nature of BDRP, we find it puzzling that the DEIS does not mention a central office which sets and, just as importantly, enforces safety and environmental regulations within BDRP. A central office could also investigate problems within DOD labs, and those of its contractors.

Another reasonable course of action is to restructure the current program, addressing the safety and environmental concerns expressed in the "scoring" meeting. This option was not considered in the DEIS. We feel that it should appear in the final programmatic environmental impact statement (FEIS) as a viable policy alternative. The following comments address this omission.

22-2a Response: There are no changes identified in the comment which would result in the formulation of a distinct alternative course of action for the BDRP. Absence of a single centralized office for safety and environmental oversight for all BDRP activities did not appear to be the cause of any deficits in the safety within the program, nor was it seen that the existence of such an office would improve or provide significant additional protection to the human environment. However, as stated in Section 4.3, the ongoing BDRP has areas which can be improved and efforts are continually being made in this regard. For example, safety and security measures are the subject of intense oversight. Appropriate adjustments are implemented as needed or as opportunities to upgrade or improve are recognized. Subsequent to the publication of the DEIS, the Army Safety Office announced plans to issue an Army regulation and implementing technical pamphlet that pertain specifically to the BDRP. This regulation will describe program safety responsibilities at all managerial levels, and identify the Army Safety Office as the focal point for setting and enforcing safety and environmental regulations within the BDRP. It was not considered necessary, nor appropriate, to develop a subset of alternatives which would merely reflect differing levels of emphasis or special attention to selected elements of the overall program. See Section 3 of the FEIS for an update and clarification of safety issues and Section 4 for a discussion of alternatives.

22-7e Comment: DOD may have a formal programmatic environmental and safety system, complete with outside reviewers which we view as crucial to a credible system. If one exists, a description of

it should be included in the final programmatic environmental impact statement (FEIS), together with an examination of the structure and effectiveness of the various IBC's at both BDRP's primary sites and its contractors. If none exists, we feel restructuring of the program's health and environmental safeguards on an organizational level should be evaluated as a reasonable alternative course of action. Organizational charts and reporting procedures should be included in the evaluation.

22-7e Response: The Army Safety Office is preparing an Army regulation with an implementing technical pamphlet pertaining specifically to the BDRP. This regulation will describe program safety responsibilities at all managerial levels, and identify the Army Safety Office as the focal point for setting and enforcing safety and environmental regulations within the BDRP. Until the issuance of this new regulation, existing safety and environmental regulations continue to be fully implemented at the level of individual laboratories/Commands.

Institutional Biosafety Committees (IBC's) constituted under the NIH Guidelines for Research Involving Recombinant DNA Molecules are responsible primarily, but not necessarily solely, for reviewing proposed work that would involve genetic engineering. The composition of such committees is described in section IV-B- of the Guidelines:

> The IBC shall comprise no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research experiments and any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the IBC) and shall represent the interest of the surrounding community with respect to health and protection of the environment. ....The [institutional Biological Safety Officer], mandatory when research is being conducted at the BL3 and BL4 levels, shall be a member.

All primary and secondary BDRP sites have a safety officer and one or more safety committee(s) that address both general laboratory safety as well as biosafety. Those organizations conducting work involving recombinant DNA molecules under the sponsorship of the NIH or the DOD have, in addition, IBC's as mandated by the NIH Guidelines and described above. By composition and definition, these IBCs provide external oversight to this component of the BDRP. As recognized in the DEIS the BDRP has demonstrated an excellent safety record and further emphasis on safety aspects can be expected to produce even better results (see Sections 3 and 6.3).

5-2 Comment: The final EIS should, however, contain more detail

on supervision of work practices of off-site contractors. The Army needs assurance that the institutional authorities at non- laboratories are, in fact, assuring safety.

5-2 Response: Contractor's proposal submissions to conduct BDRP studies are reviewed prior to award of any contract for program relevance, research objectives, qualifications of personnel, suitability of facilities and equipment, care and safety, budget, and environmental considerations. It is DOD policy, as established by the Director of Defense Research and Engineering, that all work conducted under the BDRP be conducted in compliance with the CDC-NIH Guide to Biosafety in Microbiological and Biomedical Laboratories. This requirement will also be reflected in the new Army safety regulation for the BDRP as well as in contract clauses. The USAMRDC, which is the only BDRP primary organization that currently sponsors contracts requiring BL-3 or BL-4 laboratories, requires pre-award site visits to such laboratories, with annual safety site visits after contract award for BL-3 laboratories and semiannual safety site visits after contract award for BL-4 laboratories. The Contracting Officer's Representative monitors contractor performance and progress and evaluates overall laboratory function as well as technical performance when conducting site visits, regardless of the biosafety level of a given contractor laboratory. Section 3 of the FEIS has been expanded and updated to more fully describe the elaborate safety provisions applicable to the BDRP.

Sub-category D - Contingency Plans

30-9a Comment: Although the potential for accidental release or exposure to surrounding communities is admittedly very small, the consequences of such an event could be disastrous. Thus, as stated in our prior recommendations regarding the proposed Biological Aerosol Test Facility at the Dugway Proving Grounds, the BDRP must have improved plans for managing such a release.

30-9a Response: The DEIS recognized the potential for accidental release or exposure to surrounding communities is very small. However, our analysis did not indicate that the consequences of such an event would be disastrous. Appendix 9 discusses maximum credible events, in which the consequences of just such events were analyzed, and found to present minimal, if any, risk of exposure beyond very limited distances from the locus of the event. The models used for the calculation of the potential results of such maximum credible events postulate total and simultaneous failure of multiple protective systems, including active, backup, and alarm systems. Facility engineering and equipment safety systems are continually improved and upgraded as technological improvements become available. Beyond the active and aggressive maintenance and improvement of facilities and equipment, coupled with conscientious application of the principles of laboratory biosafety, it is unclear what sort of improved plans could be proposed or implemented. It is also unclear what is meant by the term "managing such a release," especially when both the remote possibility, and the localized nature of the potential effects, are considered. See Appendix 9.

14-1b Comment: EMERGENCY RESPONSE: The DEIS does not clarify which civilian authorities the Army would contact in event of an emergency. It is critical to identify specific local and state agencies for notification. Included in the BATF proposal should be the definition of a relationship between officials of Dugway Proving Grounds and Officials of the Utah State Government and, specifically, the Utah Department of Health. It is essential that the Department of Health have some oversight of research conducted at Dugway. Specifically, the Utah Department of Health should be apprised of all microorganisms being tested, and should be notified immediately of any accidental pathogen or toxin exposures or releases. The Utah Department of Health, Utah Department of Public Safety, and local health departments should be involved in contingency planning in the event of such accidents.

14-1b Response: Comment was made in response to BATF-DEIS. Existing Army regulations and policies specify responsibilities and reporting channels for different types of accidents. Army installation commanders are responsible for establishing communication channels and agreements, as appropriate, with local communities, other regional bodies, and states. In the unlikely

event that there were to be an emergency situation at an Army BDRP site that had the potential to affect the surrounding community or environment, local commanders would be responsible for coordination with the appropriate local or state agencies (Health, Environment, etc.) as well as for reporting through appropriate Army channels. The portion of the comment related to the BATF at the Dugway Proving Grounds is more appropriately addressed to the DEIS for that proposed action.

14-1a Comment: The DPEIS does not adequately address the need for state and local health officials to be apprised regularly of research involving higher hazard microorganisms. These officials should have knowledge of specific pathogens being tested. The Army should assist state and local health officials to develop contingency plans for protection of the public, in the event of an accident wherein pathogens escape which have potential for causing infection in the community. These plans should be developed even though such accidents are deemed very unlikely. In particular, such plans should be developed for the areas surrounding Fort Detrick, Maryland and Dugway, Utah.

14-1a Response: There are no regulatory requirements, outside of the USDA regulation of restricted plant and animal pathogens, for notification to health officials of use of higher hazard microorganisms on the part of any organization, be it military, government or civilian. The U.S. Public Health Service (CDC) has requirements for reporting of the incidence of certain communicable diseases; these requirements do not address research or RDT&E using any class of microorganisms in the BDRP. Existing Army regulations and policies specify policies, responsibilities and reporting channels for different types of accidents. Army installation commanders are responsible for establishing communication channels and agreements, as appropriate, with their local communities and states. In the unlikely event that there were to be an emergency situation at an Army BDRP site that had the potential to affect the surrounding community or environment, local commanders would be responsible for coordination with the appropriate local or state agencies (Health, Environment, etc.) as well as for reporting through appropriate Army channels. As discussed in Appendices 7 and 9, the organisms studied in the BDRP are not considered communicable diseases, that is, those whose primary mode of transmission is from man to man. Thus, their potential for causing infection in the community, even in the event of an "accidental escape," is markedly limited. Consideration of site-specific plans such as those mentioned in this comment would be more appropriately addressed in site-environmental considerations rather than in a programmatic EIS.

31-10 Comment: DEIS makes no provisions for evacuation of

citizens near DOA facilities or BDRP contractors conducting BW research in the event of an accident, or for informing local health authorities in the event of an accident.

31-10 Response: As discussed in Appendix 9, Part 6.3, there are no mass evacuation plans formulated specifically with reference to the BDRP because there is no identified need for such special evacuation plans. The small quantities of infectious organisms or toxins on hand, their environmental liability and the limited scope of impact of even the largest potential "escapes" or "releases" do not warrant the development and implementation of such public policies. In the unlikely event that an emergency situation developed at an Army BDRP site, which had the potential to affect the surrounding community or environment, local commanders would be responsible for coordination with the appropriate local or state agencies (Health, Environment, etc.) as well as for reporting through appropriate Army channels.

55-7 Comment: Now, for the comment on what should be -- what I would like addressed in the final Environmental Impact Statement, a complete evacuation plan for a Chernobyl-type disaster, occurring out here. I know it's not a nuclear power plant, but if it all went up into the air, went and down central Utah over in Idaho, over in Salt Lake City, how are we going to get rid of all of these people out of the infected area in the amount of time that we have? These lives aren't expendable.

55-7 Response: Appendix 9 of the FEIS discusses Maximum Credible Events and their potential consequences to surrounding populations and the environment. Part 6.1 of Appendix 9 discusses biological pathways of disease transmission, and Part 6.3 discusses considerations of evacuation plans. The transmission of diseases of the type studied in the BDRP from person-to-person is a rare occurrence; the diseases studied are not communicable. Even in the extremely unlikely event that an infectious organism or toxin were "released" to the environment from a BDRP facility, the effects of such a release would be localized in time and place, and would in no way cause pervasive, catastrophic consequences to the human environment. Thus, there are no mass evacuation plans formulated specifically with reference to the BDRP because there is no identified need for such special evacuation plans. Also, see response to comment 30-9a.

30-5 Comment: As we pointed out in an earlier statement regarding the Biological Aerosol Test Facility proposed for the Dugway Proving Ground, we continue to be concerned with an apparent lack of advance planning for the management of a potential release of organisms or toxins into the environment. We are impressed with and commend the Army on an impressive

safety record in the testing and handling of these agents over many years of both offensive and defensive research (Appendix 8). However, as is clearly outlined in Table A8-3 (page A8-10), this safety record is not perfect, nor are all the accidents remote history.

30-5 Response: Accidents cannot be eliminated completely, however, they can be minimized and the consequences can be influenced to a significant degree. Table A8-3 referred to reports of incidents resulting in potential exposure of a laboratory worker. The consequences of those "accidents" was that no illness developed. The historical record of working with infectious agents within DOD and elsewhere in the U.S. does not warrant such a proposed management plan. While the possibility of laboratory-acquired infections is a known risk to the laboratory work force, no documentable evidence exists to indicate that these infections become a community health risk. The following excerpt from *Biosafety in Microbiological and Biomedical Laboratories CDC/NIH,* 1988 (cited as reference 5 in the FEIS) helps to put this issue into perspective - "In contrast to the documented occurrence of laboratory-acquired infections in laboratory personnel, laboratories working with infectious agents have not been shown to represent a threat to the community." In addition, as explained in Part 6.3 of Appendix 9, evacuation plans and other elaborate management plans are not warranted.

Sub-category E - Disease Transmission

47-1b Comment: First of all, the dangers of using natural organisms are enormous and this is not the opinion of essentially the uneducated public. And even though, as people have pointed out, the probability of escape from these facilities is very small, it is not zero, it is a positive probability and in all risk assessment you have to take into account what the risks would be if somebody was infected and since this isn't a zero risk, even in central Utah, I think that it's not something that can be taken lightly and it hasn't been appropriately addressed in any of the environmental impact statements that I have read and re-evaluating this after the fact, once there has been an outbreak as there have been accidents in the past, will not be appropriate and since we now have the potential to make a much bigger catastrophe with these engineered or otherwise naturally occurring pathogens, I think the safety level has to be much greater than they appear to be.

47-1b Response: The use of high hazard, low hazard and genetically engineered microorganisms (GEMs) was considered in the development/application of the IAM, (see Appendices 4 and 6). GEM's research, appropriately conducted, does not pose a significant risk to the workforce, nor does it threaten mankind (see Appendix 4, pages A4-5 to A4-8, Appendix 6, pages A6-71 and A6-72 and Appendix 10). Research involving high hazard and low hazard organisms in the BDRP conducted under the appropriate biosafety conditions, does not constitute a significant risk to the health and well-being of the environment. Consideration of risks of the non-normal situation is presented in Appendix 9, Maximum Credible Events. The safety record within the BDRP has been outstanding (see Appendix 4, parts 1.7, 2.7, 3.7, 4.7, 5.7, 6.7 and 7.7 and Appendix 8).

14-15 Comment: The [BATF, sic] DEIS describes laboratory risks with microorganisms requiring BL3 precautions, such as *Francisella tularensis, Bacillus anthracis, Coxiella burnetii,* and the Venezuelan equine encephalitis virus. Workers and their families are exposed to some risk with these specific organisms but, with proper precautions, the risk to the general public appears low. This assessment must be made with caution, however, because the full range of pathogens is not known and because the DEIS does not take into account the possibility of asymptomatic pathogen colonization of laboratory workers, especially immunized workers, who could pose a risk to the larger community. Effective means of regular surveillance of workers and their families to exclude a possible pathogen carrier state must be addressed.

14-15 Response: Workers may potentially be exposed to these microorganisms during the performance of their normal duties, and this is a risk which has been considered fully in applying the

IAMs. The postulate of asymptomatic carriers, and the presumption that family members are at risk, is not supported by any evidence of the presence of infections in the families of workers in these laboratories. This conclusion is based on thousands of person years of experience. Furthermore, epidemiological data in the medical literature does not support the transmission of these agents from man-to-man during an active infection nor is there credible evidence that a carrier state exists for any of the agents mentioned. See also response to comment 30-5.

14-5a Comment: Accidental contamination arising from the handling and aerosolization of BL3 pathogens can pose a risk to BATF workers and their close contacts.

14-5a Response: Immunizations and individual decontamination procedures, established for Class III biosafety cabinets, are designed to eliminate the risk of an individual becoming infected during the performance of his duties. Aerosol studies with BL3 agents are fully contained within Class III biosafety cabinets and the possible contamination of personnel working on the exterior of these lines is less than that potentially encountered during normal laboratory operations. Exposure risk to the workforce from working with high hazard organisms and toxins was recognized, in applying the IAM, as a minor risk to the workforce (see Appendix 6, pages A6-62 and A6-70). Transmission from exposed laboratory workers to close contacts has never occurred from organisms studied within the laboratories conducting BDRP research (see Appendix 4, parts 1.7, 2.7, 3.7 and 4.7). See also responses to comments 14-15 and 30-5.

14-5b Comment: It is also quite possible that a worker could be unknowingly contaminated with a pathogen, spreading this in the community before the contagion is recognized. The DEIS must address the possibility, if this occurs, that workers, their families, and perhaps members of the larger community may require treatment in nearby civilian hospitals. Should this happen, it must be understood that the attending physicians involved require full access to information regarding the nature of the exposure and the pathogen or toxin involved. Finally the possible need under some circumstances for community quarantine measures should be considered in the DEIS.

14-5b Response: The response to the first sentence is the same as response to comment 14-15. The pattern of disease transmission suggested by the commentor does not occur with the organisms used in the BDRP. All of the work is open and any information required for medical treatment of any BDRP employee is available upon request. The concept of quarantine is not operative in most infectious disease situations given the

knowledge available at this time. Appropriate isolation techniques in patient treatment facilities have replaced this approach to the containment of infected patients. The infectious organisms that are studied in the BDRP are not known for their man-to-man contagion as implied in the comment (see Appendices 7 and 9, part 6.1). The Army requires that laboratories conducting work with BL-4 organisms have established medical procedures and access to appropriate facilities for treatment of any personnel who might become exposed to a hazardous organism in the laboratory.

41-2 Comment: Animal vectors such as the highly diverse rodent population around the Dugway research facility make the spread of dangerous organisms potentially rapid, widespread, impossible to monitor, and unstoppable.

41-2 Response: This scenario does not represent a probable course of events. Refer to Appendix 9, Part 3.1 for Maximum Credible Events and Appendix 5, Part 2.3.2 for information relevant to DPG. In addition, refer to the Dugway Proving Ground DEIS on the Biological Aerosol Test Facility in relation to "worst-case" scenarios. Also, see responses to comments 47-1b, 14-15, 30-5 and 24-14.

38-7 Comment: In the evaluation of safety factors at Dugway, the abundance and diversity of rodents was not given sufficient consideration. Desert communities are well known for having large rodent populations, and Dugway is not an exception. Army surveys show high trap success (50%) and high diversity of flying and non-flying mammals. These are potential reservoirs for pathogens. Populations are not monitored, and the potential for infection from accidental releases may be very high.

38-7 Response: The premise expressed regarding animal populations serving as "reservoirs for pathogens" is not supported by the scientific evidence. Studies conducted at DPG do not indicate problems of this nature (see Part 2.3.2 of Appendix 5). See also responses to comments 41-2, 47-1b, 14-15, 30-5 and 24-14.

40-2 Comment: Furthermore, we oppose the construction of the biological warfare lab because the public could be exposed to numerous environmental health and safety risks. The facility will be used for testing highly contagious germs and possibly non-curable diseases. If the general public were exposed to these agents, there could be a massive epidemic. There is no certainty that this will not happen. In addition, the Army has not developed adequate preventative measures to assure the public

that workers, small animals, wind-drifts, and other materials will not transmit such deadly germs as anthrax, Q fever, tularemia, and Rift Valley fever to the general population.

40-2 Response: Conduct of studies (including testing of animals and/or equipment by aerosol exposure) with high hazard organisms/toxins under the appropriate biosafety conditions do not constitute a significant risk to the health and well being of the work force, community health or the environment, (see Sections 5 and 6, Appendix 4, pages A4-2 to A4-6 and A4-8 to A4- and Appendix 6, pages A6-59 to A6-62 and A6-67 to A6-70). Also, see responses to comments 31-8, 47-1b, 24-11 and 14-15. Refer to the IAM on DPG (Appendix 6) to examine effects on human health and safety from BDRP activities performed at Dugway. In addition, refer to the DEIS on the Biological Aerosol Test Facility (BATF) if the "biological warfare lab" refers to the proposed BATF at DPG.

22-3c Comment: The DEIS does not cover certain categories of pathogens which, at the present, are not studied in the BDRP. These include the highly contagious microbial diseases spread from human to human, either directly or via inanimate objects. Example of excluded organisms are Typhoid Fever and Lassa Fever. Pathogens of this sort are dangerous to the lab workers, and they are difficult to contain. Even though they are studied under the rigorous biosafety level 4 procedures, when such pathogens escape containment they are among the most difficult microorganisms to control. Therefore, we question the exclusion of any category of pathogenic organisms from the FEIS.

22-3c Response: It is not clear what "category of pathogenic organisms" the commentor considers as being excluded. In any event, typhoid fever bacillus is not part of the BDRP but also is not necessarily that difficult to control. Lassa fever virus is examined in the BDRP and was considered as an organism requiring BL-4 safety. See Section 1.5 of the DEIS. The possibilities of laboratory accidents and escape from containment involving hazardous organisms are addressed in Appendix 9 of the DEIS. Also, see responses to comments 14-16, 22-3b, 30-5 and 24-13a.

38-4 Comment: Ecological theory and epidemiological studies have shown that population growth, or the spread of a disease has an initial lag phase where abundance’s are low and difficult to detect. This is followed by an exponential growth phase where populations increase extremely rapidly. Once in this phase, latency period before symptoms are obvious, control becomes even more difficult.

38-4 Response: Comment presents a simplified view to disease control. See responses to comments 14-15, 14-5a 14-5b 31-3,

24-13a and 30-5.

48-2 Comment: Anthrax spores have been shown to last over 20 years, especially in the dry desert soil conditions which are found at Dugway. They are extremely infectious with one organism, in some cases, all that is needed to cause disease. The diseases range from mild with some strains of tularemia to the uniformly fatal pulmonary anthrax, with its victim dying of pulmonary hemorrhage.

48-2 Response: This comment is very difficult to interpret because it combines statements about anthrax and tularemia. The first sentence may be true since there are anthrax hot spots scattered around the U.S. that are dependent on soil composition, climatic conditions, and subsequent recontamination of the soil by animals that die of anthrax. This can occur due to natural circumstances in no way related to the BDRP. The second sentence may be true for tularemia but is not true for anthrax. Epidemiological studies indicate that the number of organisms required to initiate pulmonary infections in non-human primates is greater than 1000 organisms. Data from studies at Ft. Detrick would support the possibility that one tularemia organism can cause disease. The last sentence again has combined concepts for anthrax and tularemia. Tularemia can produce mild influenza like disease, and pulmonary anthrax is a serious life threatening infection. These statements are accurate. The BDRP does not require, allow or necessitate the release or dissemination of any pathogens.

24-13a Comment: The risks discussed all concern known, non-communicable (except through vectors) agents, for which vaccines and/or treatments are available. The latter play an important role in the risk determination. However, there is nowhere any disavowal of the use of other kinds of agents.

24-13a Response: The organisms/toxins used in the maximum credible event were chosen, not because a vaccine or therapy existed, but because they would potentially pose the greatest risk to unprotected populace vis-à-vis low infective dose (by aerosol exposure) and were used to assess risk under such circumstances. The non-communicability (except through vectors) was considered in that all infectious organisms studied under the BDRP have a very low (or zero) man-to-man transmission rate. Highly communicable infectious organisms (those whose primary mode of transmission is from man-to-man) are not currently part of the BDRP. However, in general, while the possibility of laboratory acquired infections is a known (though small) risk to the laboratory work force, no documentable evidence exists to indicate that these infections become a community health risk, see Appendix 11 and the CDC-NIH Guide, Biosafety in

Microbiological and Biomedical Laboratories CDC/NIH 1984, 1986, 1988.

24-13b Comment: The list of organisms given (A4-3) is not inclusive but merely "representative", and although it is stated that person-to-person spread of the organisms studied is "technically and epidemiologically impossible" (5-9), the list includes at least one virus, Ebola, that is highly infective from human to human, highly lethal, and for which there is no vaccine or treatment available.

23-13b Response: Ebola is not normally highly infective from human to human. As stated in Appendix 9, Part 6.1 such man-human transmission has occurred, e.g., non-social transmission but such episodes are rare and self limiting.

24-14 Comment: Furthermore, none of the scenarios consider the possibility of a host-vector system becoming established.

24-14 Response: Comment is incorrect. The establishment of a host-vector system was considered, see Appendix 9, Parts 2.1.6, 2.3, 4, 4.1, 4.2, 4.2.3, 4.3.1.1, 4.3.2.1, 4.3.1.3, 5, 6, 6.1, and 6.2.

27-9a Comment: The environmental concerns about this research include 1) effects on the general public from potential exposure to biological warfare agents during normal operations or due to advertent or inadvertent release of the hazardous organisms (i.e. human error, equipment failure, terrorism, or natural disasters.

27-9a Response: The organisms and toxins under study in the BDRP are infectious agents and toxins that occur naturally and are considered to be potential biological warfare threats to the U.S. They do not contain any unique characteristics not found in their natural occurrence. The advertent or inadvertent release of such organisms or toxins was considered in the multiple maximum credible events presented in Appendix 9.

27-5b Comment: These pathogens are selected for research because they have potential use as warfare agents due to, inter alia, their pathogenicity, quick infectivity, and ability to rapidly disseminate.

27-5b Response: DOD is not conducting offensive BW research. Inclusion of infectious organisms within BDRP is based on multiple factors, including their probability as potential

threats and their occurrence as endemic disease hazards throughout the world. No infectious organisms studied in the BDRP have the ability to rapidly disseminate from man-to-man or man-to-animal, i.e., they are not contagious see Appendix 9 part, 6.1).

27-14 Comment: Additionally, the danger of experimentation with pathogens is highlighted by the reporting of several NIH research experiments, not related to the BDRP, which have led to the infection of workers with the pathogens ranging from pertussis to AIDS. One internal NIH report on such accidents pointed to the need for upgraded standards when dealing with large scale research activities with pathogens because of, *inter* alia, "the potential for introducing infective agents into the community outside the laboratory." The BDRP EIS makes no analysis of how these NIH accidents relate to the hazards in BDRP research.

27-14 Response: Pertussis and AIDS are both diseases that can be readily spread directly from man to man; such is not the case for organisms studied within the BDRP, see Appendix 9, Part 6.1. The circumstances for which the NIH recommended upgraded standards was the large scale, pilot plant production of *Bordetella pertussis* in 100 liter quantities for vaccine production, an activity that was at the time being conducted under BL-2 conditions. Such an activity conducted at only the BL-2 level with an organism as infectious for man as B. *pertussis* could indeed pose a risk warranting a higher biocontainment level. The context of the quotation from the NIH report is actually: "The occurrence of the pertussis infection in a spouse of an employee [with a laboratory-acquired infection] identifies the potential for introducing infective agents into the community outside the laboratory." (phrase in brackets added). As stated in the CDC-NIH Guide to Biosafety in Microbiological and Biomedical Laboratories, "In contrast to the documented occurrence of laboratory-acquired infections in laboratory personnel, laboratories working with infectious agents have NOT been shown to represent a threat to the community" (emphasis See also response to 24-13a.

Sub-category F - Recombinant DNA Work

29-6b Comment: Second, the NIH Guidelines were assessed for their environmental impacts in 1976 and in 1978. Since 1978, however, two fundamental changes in the guidelines have occurred. First, the NIH Guidelines have been undergone several major revisions. Second, the NIH Guidelines have been expanded to encompass large-scale uses of genetically engineered organisms. Yet no further Environmental Impact Statement or Assessment has been developed. Therefore, it has not been demonstrated that the 1986 NIH Guidelines now in effect provide adequate protection of the environment and human communities.

29-6b Response: Recombinant DNA research practices and historical experience since the assessment of the Guidelines in 1976 and 1978 have established the adequacy of safety and protection for the environment and human communities. Revisions to the Guidelines only occurred after careful and considered deliberations by the NIH Recombinant Advisory Committee, (see Appendix 10).

29-6c Comment: Third, the containment of deliberately generated aerosols has never been addressed by the NIH Recombinant DNA Advisory Committee since the operating assumption of this committee was that generation of aerosols should be avoided as much as possible.

29-6c Response: We agree that exceptional care is required when generating aerosols. However, there are no recombinant pathogens generated in the BDRP and no BDRP activities which generate aerosols of recombinant pathogens. The NIH Guidelines caution against inadvertent generation of aerosols in the conduct of studies with GEMs. Intentional aerosolization in equipment specially designed for safe generation and containment of the aerosol is not prohibited by the NIH Guidelines. See also response to comment 14-17.

29-6d Comment: Therefore, the fact that the U.S. Army may follow the 1986 NIH Guidelines is not a sufficient guarantee that its activities involving genetically engineered pathogens and toxins can be performed safely.

29-6d Response: See response to comment 29-6b.

22-9 Comment: Finally, we challenge the oft repeated statement that using rDNA techniques to engineer a more virulent strain of a pathogen is forbidden. Such work is barred by the NIH guidelines. These guidelines have no force of law and have been adopted voluntarily by DOD. But the only enforcement mechanism

behind the guidelines is the withdrawal of research funding if they are not followed, hardly a problem for the BDRP. There is nothing to stop DOD from relaxing or retreating totally from compliance with the guidelines, either selectively for certain elements of the program or in its entirety. If BDRP were under the authority of a civilian agency, the prohibition would be more credible.

22-9 Response: Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules is mandatory for all research laboratories of the DoD (see response to comment 22-2d). The civilian head of the DoD, the Secretary of Defense, established this mandatory policy in 1981 and it was reiterated in 1984. Any laboratory commander ignoring this policy would be in violation of the Uniform Code of Military Justice. Therefore, for military personnel, the potential penalties for not adhering to the NIH Guidelines are much greater than the loss of funding a civilian scientist might suffer at a university or private research institute. The NIH Guidelines require the establishment of local IBC's to review and approve rDNA research at each individual institution. Program review of compliance with NIH Guidelines by extramural contractors is the responsibility of the primary BDRP laboratory. Coordination with the Chairman of the IBC of the primary BDRP laboratory is accomplished by the Chief, CMO during contract proposal review. In addition, COR review of compliance is performed annually, with specific reporting requirements to the IBC of the primary BDRP laboratory. The Assistant Surgeon General of the Army for Biotechnology, located at the USAMRDC, maintains files on all research involving r DNA in the DoD and by the contractors for the DoD.

29-6a Comment: First, the Department of Defense is not legally required to use the NIH Guidelines. It does so on a voluntary basis. It is conceivable that it could invoke national security interests for not revealing details of its procedures to the NIH Recombinant DNA Advisory Committee.

29-6a Response: Compliance with NIH Guidelines for Research Involving Recombinant DNA Molecules is mandatory for all research laboratories of the DoD (see response to comment 22-2d). This is the same level of compliance required of employees of CDC and NIH, who conduct such work under policy established by the Secretary of Health and Human Services. See also responses to comments 22-9 and 27-20.

43-7 Comment: Additionally, the attempt of the Department of Defense to analyze novel pathogens, both by changing or rearranging the traditional pathogens, as well as the investigation of possible new pathogens for military significance, should be carefully circumscribed. Should be

allowed full public knowledge of exactly what new viruses and what new techniques are being used. Without such full public information, the environmental hazards of this program cannot be known to the public and other agencies and therefore the need for the process cannot work.

43-7 Response: The research laboratories of the DoD and its contractors use all of the state-of-the-art biotechnologies in the performance of studies directed at the development of protective vaccines, prophylactic compounds, diagnostic kits, micro-organism and toxin detectors, and protective clothing and equipment. Novel pathogens are not created. However, both virulence factors and protective epitopes are studied through genetic engineering techniques in order to provide the measures of protection for the troops described above. For instance, if the toxic domain of a toxin can be identified along with the domains responsible for the elicitation of antibodies, then through site-specific mutagenesis techniques the toxic domain can be inactivated while retaining the antibody-specific regions. Production of this mutated protein results in a safer, more efficacious vaccine to protect against the native toxin. Similarly, genetic engineering is used in efforts to develop more efficacious vaccines. Such research is reviewed routinely by the NIH RAC Working Group on Toxins. Approval by the RAC is a prerequisite to approval by the local IBC of these types *of* experiments. The DoD does not use genetic engineering to create novel organisms with weapons potential. Genetic engineering within the BDRP was given separate consideration because of its controversial aspect, see Sections 1.6.2, 3.5.2 and thus was specifically considered in the development and application of the IAM, (see Appendix 4, pages A4-5 to A4-8 and Appendix 6, pages A6-71 and A6-72). Genetic engineering, appropriately conducted, does not pose a significant risk to the workforce, nor does it threaten mankind, (see Appendix 4, pages A4-5 to A4-8, Appendix 6, pages A6-71 and A6-72 and Appendix 10).

20-1 Comment: The Army's draft statement is a disturbing mixture of contradictory reassurances. On the one hand it says: Genetically engineered microorganisms do not constitute a programmatically defined category per se because genetic engineering is not a discrete object of study but rather is considered a state of the art tool to be applied to attaining specific research objectives (3.5.2, p. 3-14).

This denial that genetic engineering raises any special issues is as fallacious as to say genetically engineered organisms are no different since they are still made of atoms and molecules. The point -- as it concerns environmental impact -- is the rate and degree of difference. Here genetic engineering crosses a watershed. The environmental and military issues it raises are on a different scale from previous technologies. The Statement's cavalier dismissal of this calls into question the good faith and

seriousness of the Army's reassurances that it will use biotechnology circumspectly.

20-1 Response: The thrust of the statement contained in the DEIS has apparently been misconstrued. The statement was intended to explain that the BDRP is not specifically studying the techniques of genetic engineering, and that genetic engineering is not a goal or targeted product of the BDRP. Rather, genetic engineering is a technological tool used in the BDRP as in any quality biomedical program. See also responses to comments 24-4c and 43-7.

42-4a Comment: That leads to a very serious concern of genetic tinkering that creates viruses and germs that may, in fact, escape and get out into the atmosphere and that's the group problem I think you have with the people of Utah.

42-4a Response: See responses to comments 24-4c, 38-1c and 27-2.

26-5 Comment: DEIS Section 2.4.1 states with respect to gene cloning of protein toxins: "The general approach is to identify the portions of the protein toxin responsible for eliciting immunity, as opposed to that portion of the molecule responsible for toxicity." (Emphasis added.) (page 2-5). The use of the words "general approach" implies that there are also "other approaches" undertaken by the DOD with respect to this particular type of research. More concretely, there is nothing to prevent researchers from cloning the portion of the molecule responsible for toxicity, which they have already implicitly identified when distinguishing it from the immunogenic portion. The DEIS provides absolutely no assurance or mechanism to guarantee that this is not occurring under the aegis of the BDRP even though the DEIS makes it quite clear that such prohibited research can in fact occur.

26-5 Response: See responses to comments 43-7, 22-9 and 27-20. In addition, it is not true that identification of an immunogenic portion of a protein "implicity identifies" the portion of the protein responsible for toxicity. Both immunogenicity and toxicity can be dependent on many factors in addition to the amino acid sequence of a particular region of the protein. Once an immunogenic and non-toxic region is identified, that region can reasonably be excluded as a "toxic" region. The toxic region of a protein is not automatically identified by the subtractive process of identification of another region that is immunogenic. The term "general approach" was used as a simplified expression of the research techniques. No subtleties in wording were intended, and no "other approaches" were obscured.

24-l0b Comment: It merely confines its discussion of genetically-engineered materials to their use in medical research, thereby creating uncertainty.

24-l0b Response: Comment is correct, but there is no uncertainty. At the present time, GEMs are identified only as a part of the medical research portion of the BDRP. See Appendix 3 for classification of sites by risk/issue category. Therefore, discussion of genetically engineered materials was appropriately confined to their use in medical research.

22-7c Comment: While the DEIS does state that, in accordance with the NIH guidelines, BDRP has Institutional Biosafety Committees (IBC's) wherever rDNA work is performed there is doubt as to the veracity of this claim.

22-7c Response: The existence, composition, and curricula vitae of all members of the IBC's supporting the BDRP are recorded in the Office of Recombinant DNA Activities at the NIH (12441 Parklawn Drive, Suite 58, Rockville, Maryland 20852). They are extant, active, and useful.

47-1a Comment: First of all, the dangers of using...genetically engineered organisms are enormous and this is not the opinion of essentially the uneducated public.

47-1a Response: Genetic engineering within the BDRP was given separate consideration because of its controversial aspect, (see Sections 1.6.2, 3.5.2) and thus was specifically considered in the development and application of the IAM, (see Appendix 4, pages A4-5 to A4-8 and Appendix 6, pages A6-71 and A6-72). Genetic engineering, appropriately conducted, does not pose a significant risk to the workforce, nor does it threaten mankind, (see Appendix 4, pages A4-5 to A4-8, Appendix 6, pages A6-71 and A6-72, and Appendix 10).

24-11 Comment: An accident with a novel agent could be far more serious than with a known agent, because of the lack of medical experience with the agent, uncertainty about its effects in humans, lack of tested vaccines, possible built-in insensitivity to treatment, and so forth. Such experimental agents might be designed to persist under adverse conditions, making them difficult or impossible to eradicate. The possibility of starting an epidemic more devastating than AIDS cannot be ruled out.

24-11 Response: If this comment concerns the deliberate creation of a novel agent that is more pathogenic or more toxic than those already found in nature - this is not being done. The accidental creation of a more hazardous organism was considered by the NIH in the development of the guidelines for recombinant research and the current guidelines are designed to prevent the deliberate or accidental creation and environmental release of hazardous GEMs (see Appendix 10, Part 2).

27-6c Comment: The DOD report states that: potent toxins which until now were available only in minute quantities, and only upon isolation from immense amounts of biological materials, can now be prepared in industrial quantities after a relatively short developmental period. This process consists of identifying genes, encoding for the desired molecule and transferring the sequence to a receptive micro-organism which then becomes capable of producing the substance. The recombinant organisms may then be cultured and grown at any desired scale...Large quantities of compounds, previously available only in minute amounts, thus become available at relatively low costs.

27-6c Response: While this statement might be theoretically true, the U.S. is not producing such quantities of these materials. The report was citing the theoretical risk to the U.S. of such an action by an adversary. Such large quantities, if more than justifiable for defensive research, would be in violation of the BWC. The U.S. is in full compliance with the BWC. Use of recombinant DNA procedures with pathogenic organisms and toxins is closely controlled at all locations, both within and outside the government. Development of a more virulent strain of a pathogen is specifically prohibited under any circumstance, and is not the goal of any BDRP effort. In fact, BDRP uses of recombinant techniques are with the goal of producing a less virulent strain of an organism which may be more safely used in the laboratory or for vaccine development. Section 3.3 and Appendix 10 discuss the many safeguards which preclude the development, let alone the release, of "deadly" recombinant organisms.

Sub-category G - Transportation of etiologic agents

14-14 Comment: Transportation of hazardous biological agents
carries some risk; this is discussed only briefly (page D-27). Alternatives to the use of the U.S. Postal Service should be considered.

14-14 Response: Comment requests that transportation methods for shipment of etiologic agents other than the U.S. Mails be examined. The Draft EIS (Appendix 2, page A2-6) notes that the mail has not been used for several years for such shipments. Commonly, private express services are used for these shipments. The number of such shipments is, in any case, often over-stated. On the average, less than one shipment per week is made from USAMRIID, which is by far the most active
location. Many research locations send or receive no more than one or two shipments per year in support of the BDRP. The risks associated with transportation of hazardous biological agents are minimized by compliance with multiple regulations (USPHS, DOT, IATA) on
the part of BDRP laboratories.

55-6a Comment: Laboratories across the nation regularly send specimens, meaning germs, through the U.S. Mail Department. I find this totally reprehensible. If we are concerned about national security, sending it through the mail department, where terrorists can get a hold of it and use it against us, is obviously not the way to go.

55-6a Response: This comment is correct in that virtually all types of laboratories across the nation regularly send organisms, diagnostic specimens, and cultures through the U.S. mail. The USPS, USPHS and DOT regulate such shipments and have specific packaging and labeling requirements. There have been no identified infections in postal service personnel arising from the many thousands of these shipments per year. The concerns of the commentor regarding potential terrorist interception of a mail shipment containing a hazardous organisms are addressed in Appendix 9. Also see response to comment 14-14 above.

10-1 Comment: The Department of Health and Mental Hygiene recognizes that there are significant dangers involved in the research of biological agents which take place at Fort Detrick. The safety of citizens of Frederick and Maryland must be assured. Messenger service with deadly potential to those who come in contact with their packages, must be fail-safe; the immediate locale must be assured that any possible leakage into the community has fail-safe protection.

Although the Department is expressing no philosophical viewpoint to the federal government's experimentation, we do reserve the

right to express this concern for the safety of our citizens, and as such respectfully request the United States Army to address these issues prior to their continuation of the program.

10-1 Response: The Draft EIS (Appendix 2) discussed the safety of packaging in some detail. The size of the average shipment is extremely small, less than a teaspoon in volume, and the packaging is specifically designed to contain the total volume even if the innermost container should break. No case of infection relating to a leaking package is known to the Postal Service or to any other shipping company from the hundreds of daily routine shipments of etiologic agents to and from any medical laboratories. See also the responses to comments 14-14 and 11-1.

11-1 Comment: We wish to reiterate our concern that alternative means of transportation be considered, such as the use of specially trained couriers or Army personnel. We believe consideration of such alternatives is necessary to ensure adequate protection to the people and environment of California should materials be shipped through our state.....

Indeed, because the warning labels will be placed on the hermetically sealed can, inside the shipping box, where the warnings can only be seen if the package has been partially opened, Postal Service employees will not even know that they ought to be taking any extra precautions. Certainly they will not have the training or equipment to deal with a release of toxins that may cause anaphylactic shock, or a release of VEE virus or other viruses or bacteria. Further, the temperature, time of day and humidity prevailing at the time of any accidental release in shipping may be those that favor survival of the agents released, allowing them to live and possibly infect people exposed to them.

We believe that the accidental release of biological agents during shipments is a reasonably foreseeable event, and that therefore the EIS should analyze the possible environmental effects of such a release and reveal them to the public.
Certainly, such a possibility is within the "rule of reason" cited in 40 CFR 1502.22. An automobile accident involving a Postal Service vehicle, a fire at a Postal Service facility, carelessness on the part of mail handlers, misdirection of mail and other mishaps are a part of everyday life, and are not only reasonably but easily foreseeable. We therefore believe that the National Environmental Policy Act requires the Army to address these possibilities, and to discuss fully the possible effects of a release during shipping, where containment, specialized personnel training, and other safeguards are absent.

The DEIS states that federal regulations governing shipment of biological agents will be complied with and necessary permits

obtained. While we commend the Army for following the applicable rules and regulations, nevertheless, this is not a substitute for compliance with NEPA. Case law clearly and repeatedly has held that compliance with the regulations of other federal agencies does not substitute for or excuse compliance with the NEPA full disclosure requirements. See The Steamboaters v. FERC, 795 E. 2d 1382 (9th Cir. 1985); Oregon Environmental Council v. Kunzman, 714 F.2d 901 (9th Cir. 1983). Similarly, in this case, even though the Army has complied with appropriate regulations and obtained required permits, it must still analyze and reveal the possible environmental consequences of utilizing a shipping method that may result in accidental releases.

In addition, the EIS must address the alternatives to use of the Postal Service to ship these materials. No discussion of alternatives to this facet of the project occurs in the DEIS, even though this may well be the one area of the project most likely to cause an unintentional release of biological agents. The consideration of alternatives is the heart of the EIS process, and certainly here the Army is legally required to consider alternatives to this non-secure method of shipping. See 42 USC 4332(E); Environmental Defense Fund, Inc. v. Corps of Engineers 492 F.2d 1123 (5th Cir. 1974); Natural Resources Defense Council v. Calloway, 524 F.2d 79 (2d Cir. 1975). For example, the use of Army personnel, appropriately trained, using military transport that is appropriately equipped, could be considered. Special courier services who are aware of what they are carrying and are prepared to deal with an accident might also be considered. We are confident that the Army can devise and evaluate alternative shipping methods. We believe they are required to do so.

We are aware that the possibility of a release that actually infects people or animals is probably a small one. Nevertheless, the danger posed if such a release does occur is a substantial one.

11-1 Response: See response to comment 14-14. The comment further suggests that the release of infectious materials as a result of an accident while being transported is "reasonably foreseeable" and must thus be examined under the regulations of 40 CFR 1502.22 (NEPA). We disagree that accidental release of shipments made under present conditions and regulations may reasonably be anticipated. In remarks prepared for hearings held October 5, 1988 before the Subcommittee on Postal Personnel and Modernization, House Committee on Post Office and Civil Service, Assistant Postmaster General Frank R. Heselton reported on the results of their request for comments on a proposed ban on shipment of etiologic agents through the mails. His statement relates "... There has been no prior record of anyone being accidentally infected in the handling of at least 100,000 shipments a year in the mails in over 25 years. ..." The statement in the Draft EIS (Appendix 2, part 3) that any BDRP shipments are only a very small portion of the national

total of such shipments is thus in agreement with this independent estimate. Please note also that the question of U.S. Postal Service shipments has been moot for many years insofar as shipments out of USAMRIID are concerned.

27-9i Comment: The environmental concerns about this research include ... Transportation and shipping of BDP pathogens.

27-9i Response: Transportation and shipping was considered in Appendix 2. Also see Section 3.2.1.3 and responses to comments 10-1, 11-1 and 14-14.

SUBJECT AREA 3: VALIDITY OF EIS PROCESS

Sub-category A - All Inclusiveness

43-1 Comment: Many of these concerns were carefully spelled out in the complaint that we filed in September 1986 on this program. It's plain to see what our first major problem with this draft Environmental Statement, which is a woeful lack of information about BDRP. What we have is a Roman miracle edification, with over 100 contracts out, sites, facilities, where this research is ongoing.

But no big detailed description of what pathogens are being worked at those sites, exactly what kind of work is being done with those pathogens, who precisely has access to those pathogens, what is being done as far as security, what is being done as far as inventory, what is being done as far as emergency measures while in that facility and the community surrounding that facility? What beyond the normal regulations are there in terms of transportation? And what with laboratory safety?

What would be required, I think, for an adequate Environmental Impact Statement would be just such information about each and every national and international site currently involved in BDRP.

Without such discussion, it is very difficult to see how we can have a serious discussion of alternative sites, the rationale of having a particular experiment done at a particular site, and any decision-making as regards the environmental hazards of any project and where that project is going to take place.

So the first major problem we have is with identification. I repeat, not only with sites, but exactly what pathogens are being worked at the sites, and what is being done with them, and the various work loads at each particular facility and location in their BDRPs. So those major areas, full information provided on every facility.

43-1 Response: Commentor's characterization and views on the DEIS are noted. As discussed in Section 1.6.2, the amended complaint in the above referenced litigation was utilized as one of the source documents for identification of issues in the preparation of the DEIS. The approach utilized in addressing the identified issues was developed to conform with the CEQ regulations, thus providing adequate levels of detail, while also being responsive to 40 CFR part 1500.4, regarding "Reducing paperwork." For the BDRP programmatic EIS, the utilization of risk/issue categories along with identification of primary and secondary locations of execution was determined to best accomplish the spirit and intent of the CEQ regulations. See Sections 3.5, 5.4, and Appendices 3, 4 and 6. Specific details on various aspects of the program, such as which pathogens are used, just how they are used, and where, are considered less relevant than the category of risk/issue involved, what controls

are employed for this category and the requirements for having the appropriate control measures in place. It is not clear what the function of a catalog of information, such as that suggested, or the specificity implied, might be in the NEPA context. Sections 2 and 3 of the EIS provide considerable detail on the BDRP, the control mechanisms, the sites of execution, and the activities that constitute the program. As noted in Section 3.5.1, the CDC-NIH guidelines are utilized to determine what activities, for each organism, require a particular level of biosafety containment. These guidelines are recognized and utilized by the medical research profession in the public and private sector. As further noted in Section 3.3.2.5, "As a rule of thumb, where there is uncertainty as to the appropriate level of protection measures for a given situation, the highest available level of primary protective barrier is employed." Section 3.3.4 discusses regulatory controls. Because the BDRP is an ongoing program, actual performance can be used to assess the potential for adverse effects as opposed to speculation about effects. Appendix 8 illustrates the outstanding safety record of the BDRP. Also, see response to comments 27-11, 43-2 and 31-3.

43-6 Comment: Third, it is impossible at this point to make any kind of analysis of the environmental hazards to the program until we have some certain navigation of the number of viruses, the types of pathogens, the types of bacteria that are constantly being investigated. It is clear that one of the purposes of the program is to investigate just such unknown pathogens for military significance. This research, it seems to me, should have been taking place at Yale University and other places.

43-6 Response: It is not considered impossible to assess the environmental hazards of the program in the absence of publication of an exhaustive list of organisms or sites. The potential hazards of the organisms studied in the BDRP were considered in the discussion of the program by Risk/Issue Category (see Section 3.5 and Appendix 4), and in the development of the Impact Analysis Matrices (see Section 1.6.2 and Appendix 6) used to assess the potential impacts of the program from the standpoint of Risk/Issue Area as well as from a site-specific perspective. In addition, Appendix 9 presents an analysis of maximum credible events in which a number of scenarios, representing the potentially most severe circumstances, including the nature of the biological material involved in the "event", are considered. It is not clear what is meant by "unknown pathogens." However, the BDRP does involve research with hazardous organisms and the DEIS contained considerable information and detail on this topic. Appendix 4 provides an overview of typical hazardous organisms on which research is conducted. Appendix 3 contains a list of the sites of program execution by risk/issue category. See response to comment 431. As described in Section 2.5 and Appendix 3, precautionary measures, containment facilities and the experience and expertise

of the investigators all influence where, how and by whom particular research activities are conducted.

27-10 Comment: The BDRP EIS fails to adequately address these concerns. The EIS does not even provide full relevant data on all facilities involved in BDRP research. To be adequate, the EIS should describe what pathogens are being researched at each facility and what type of research is being conducted. Additionally, safety and security measures, inventory, emergency medical procedures and other similar protocols should be described for each site. The EIS in selecting only a few sites for any extensive review leaves the impression that those preparing the EIS did not have full information as to all facilities or even full access to the legal pleadings which led to the preparation of the EIS.

27-10 Response: See responses to comments 43-1 and 43-6 above. The rationale for providing information on primary sites and on secondary sites representative of the various risk/issue categories is presented in Appendix 3 and Appendix 5, part 3. The salient information required for an evaluation of the risk of working with hazardous organisms is the identification of the biosafety level required for the conduct of the work rather than a listing of each organism, see response to comment 14-16. Further explanation of the safety provisions associated with research activities requiring BL 3 and BL 4 containment levels has been provided in Section 3.3.2.2 2 of the FEIS. Also see response to comment 6-2b.

27-26 Comment: Moreover, the BDRP should make available to the public an updated list of all pathogens being researched, the location of such research, and the safety and security measures, including emergency protocols, for all such locations.

27-26 Response: The programmatic analysis of the BDRP presented in the DEIS considered the potential hazards of the biological materials studied in the BDRP on the basis of Risk/Issue category (see Section 3.5 and Appendix 4) and in the development of the Impact Analysis Matrices (see Section 1.6.2 and Appendix 6) used to assess the potential impacts of the program from the standpoint of risk/issue category as well as from a site-specific perspective. In addition, Appendix 9 presents an analysis of maximum credible events in which a number of scenarios, representing the potentially most severe circumstances, including the nature of the biological material involved in the "event", are considered. A conclusion of this analysis is that program-emergency protocols for "catastrophic events" are unwarranted. The development of safety procedures and measures for dealing with incidents such as spills within a laboratory are included in the consideration of laboratory procedures. Safety

and security measures, applicable on a program-wide basis, are discussed in Section 3. As discussed in Section 2.5, the secondary sites performing BDRP work change over time, but are all subject to the same review and evaluation process prior to the award of support and during the performance of the work. Appendix 3 lists institutions performing BDRP work and identifies the associated risk/issue category. Appendix 4 contains an analysis of the programmatic risk/issue categories as well as a discussion of examples of the organisms and toxins studied. As noted in Section 2.1, all work conducted under the BDRP is UNCLASSIFIED, published openly in the scientific literature, and subject to inquiry under the Freedom of Information Act. Because the programmatic DEIS considered the impacts of the various types of potential hazards associated with BDRP work as well as the actual and potential impacts on the basis of representative site situations, a more explicit listing of pathogens and/or locations would change neither the conclusions derived from the analyses nor the actual impacts. As stated in Section 4.4, the tiering approach developed in the programmatic DEIS, based on programmatic risk/issue categories, provides a framework for future environmental review and documentation of any proposed major change in the scope of the BDRP or of any significant site specific considerations. Also see responses to comments 43-1 and 6-2b.

14-16 Comment: BL4 research carries substantially greater risk, both to the workers and to the general public. BL4 research might include the study of virulent exotic microorganisms or novel microorganisms created through recombinant DNA manipulations. Such organisms might not be well characterized, but could potentially be contagious, highly pathogenic, and without effective treatment. With scrupulous adherence to BL4 precautions, the probability of an accidental contamination or release of such an organism may be relatively low, but certainly cannot be ignored. A precise risk assessment is not possible without specific knowledge of each organism to be studied at the BATF. If an accidental release of BL4 pathogens occurred, the possibility exists of disastrous consequences to the larger community. Thus, the potential public health risk of BL4 research must be viewed as serious, and such research cannot be recommended by the Department of Health. Should BL4 level research ever be conducted, a cooperative program with the State of Utah involving epidemiological surveillance of unusual diseases in human and animal populations in regions surrounding Dugway would be advisable.

14-16 Response: The DEIS certainly recognized the sensitivity and potential risks associated with BL 4 category research as well as the extraordinary measures for containment and worker safety (see Sections 3.5.1, 5.3.1.2.5 and Appendices 11 and 12). If by "novel organisms" is meant the deliberate creation of an altered organism that is more pathogenic than the natural

organisms already found in nature, this is not being done, see response to comment 24-4a. Adherence to established biosafety protocols certainly represents an integral component of the BDRP. The statement that "a precise risk assessment is not possible without specific knowledge of each organism (to be studied at the BATF)," is not correct. It is precisely because organisms can be grouped into categories of hazard based on pathogenicity, transmissibility, availability of protective vaccines, and laboratory experience that the CDC and the Subcommittee on Arbovirus Laboratory Safety of the American Society of Tropical Medicine and Hygiene have assigned organisms to four biosafety level categories. This classification scheme in essence constitutes an assessment of the potential risk to laboratory workers in handling organisms classified at each biosafety level. Thus, the salient information required for an evaluation of the risk of working with hazardous organisms is not necessarily a listing of each organism, but rather the identification of the biosafety level required for the conduct of the work. Also, see responses to comments 30-9a, 14-1a and 14-. Insofar as this comment refers to any future activities related to the proposed BATF, or otherwise, at DPG, these would be addressed through appropriate NEPA documentation (see Section 2.4.3 of the DEIS).

22-3a Comment: Also, DOD improperly limits the scope of organisms covered by the DEIS. These are serious oversights which must be remedied in the final environmental impact statement. The DEIS also inappropriately limits the scope of organisms that will be studied in the BDRP. As a result, the DEIS is flawed and inadequate.

22-3a Response: See responses to comments 14-16, 27-11, 43-1, 43-6 and 27-26. The DEIS did not limit the scope of the organisms that may be investigated in the BDRP. Procedures, protocols and control measures were described which assure that RDT&E activities of the BDRP have been and will be conducted in aresponsible manner with appropriate safeguards. It appears inappropriate to assess the possible effects of the use of organisms which either do not exist or are not part of the BDRP. The outstanding safety record of the ongoing BDRP illustrates that the RDT&E activities of the program can be conducted in a responsible manner.

22-3b Comment: The direction of BDRP's research is influenced by reports from the various intelligence agencies. The renewal of interest in biological warfare was in response to intelligence reports alleging the use of mycotoxins, "Yellow Rain," in Laos and the possibility that the USSR is experimenting with *Bacillus anthracis* in Sverdlovsk. We will not deal with the controversy surrounding these allegations; we only invoke them to illustrate

the strong influence such reports can have on the direction of research within BDRP. If, for example, a series of intelligence reports alleged that a hostile group or state was culturing a highly contagious hemorrhagic virus as a biological weapon, the DOD would most likely respond quickly and secretly to the perceived threat. DOD must acknowledge the possibility that it may have to change the scope of its research sometime in the future. We can think of no pathogen category which should be excluded from analysis in the FEIS.

22-3b Response: By its very nature as a defensive program, the purpose of the BDRP is to maintain a solid national defense posture with respect to potential biological warfare threats, (see ES.2). Military or diplomatic responses to such a hypothetical threat situation, other than research efforts aimed at defensive measures, are not within the purview of this EIS. The BDRP studies are unclassified, see response to comment 1410. While it is recognized that organisms which are not currently in the program may need to be included at some future time, it would not be productive, practical nor appropriate to attempt to address hypothetical situations or research. This programmatic EIS provides the basis for analyzing proposed future BDRP activities as the need evolves, (see ES-1 and Section 4.4). The need for additional NEPA documentation is acknowledged if new research programs are not adequately covered by the Programmatic EIS. The addition of an organism or toxin not now under study is not considered to be a "new" program per se if the characteristics of the organism or toxin are such that laboratory studies with that organism or toxin do not constitute an environmental risk/impact significantly different from those identified in this EIS. Also, see responses to comments, 14-16, 24-16b, 30-1, 24-13a and 27-26.

27-27 Comment: All new and/or controversial research should be published in the Federal Register for full notice and comment.

27-27 Response: This BDRP-EIS is programmatic in nature and is intended to serve as a document from which environmental consideration of future actions can be tiered when the nature of the action requires new NEPA documentation. The tiering approach developed in this programmatic EIS, based on programmatic risk/issue categories, provides a framework for future environmental review and documentation in compliance with NEPA, CEO and Army requirements. Publication in the *Federal Register* is not considered a specific requirement for all future actions in the BDRP. In conformance with current NEPA guidance, a Notice of Intent for any proposed action requiring publication of additional NEPA documentation would be issued and published in the *Federal Register.* See Sections 1.6.1 and 4.4.

Sub-category B - Quantification of Risk

19-3 Comment: The draft statement does not quantify the impact of potential accidents which may result in catastrophic release of hazardous BDRP biological agents. The DEIS should state the statistical degree of risk of such an accidental catastrophic release to the environment and what would be the consequent risk to nearby residents and environment if such a release did occur. The DEIS indicates that there are, indeed, various possible combinations of human error and mechanical failure which, with some degree of probability, albeit "immeasurably low," could result in a catastrophic release of some hazardous biological agent. What is the quantitated statistical risk value that is being dismissed here as "immeasurably low?" Is it immeasurably lower, for example, than the risk of meltdown that is now effectively halting the whole nuclear power industry in the U.S.? The DOE has quantified this nuclear risk. Surely the possible BDRP catastrophic release scenarios referred to in the DEIS can be similarly quantified so that reasonable person can judge if the risk is acceptably low as well as "immeasurably low."

19-3 Response: The terms "immeasurably low" and "immeasurably small" were used in the Draft EIS (Section 6.3.1 and elsewhere) in sections which summarized and evaluated the overall consequences. A reference is usually provided to the places "Appendices 8 and 9) where all such risks are discussed in detail and quantitative assumptions are made. Any omissions are regretted and the reference has been inserted in Section 6.3.1 of the FEIS. In this context, Appendix 9, part 3.2 describes a "catastrophic release" of an infectious organism. In this analysis, it may be shown that the total quantity of infectious material used in any one experiment, if discharged into the atmosphere with no precautions, is insufficient to cause, on average, any infections beyond a downwind distance of (approximately) 80 feet. The specific analysis of risk to the Ft. Detrick community of an accidental infection is examined in Appendix 8, part 3.4 and Table A8-10. The overall risk assessment developed for the EIS and presented in Table A8-10 concludes that the chance of a member of the off-post civilian community being exposed is less than 1 in 10 billion in any one year, and the possibility that an infection resulted was less than 1 in 10 trillion. The likelihood that even one death might result is somewhat less than this. This is the risk described in the summary text as "immeasurably low." We believe the use of the term is fully justified.

24-12 Comment: The DEIS is full of complex quantitative calculations, involving many assumptions, to show that the risk is minute. More relevant is the fact that events of very low calculated probability do occur. This is important when the consequences are grave. I have discussed this more fully in my

comments on the BATF DEIS (pp3-4).

24-12 Response: Comment requests that we acknowledge that an improbable or unlikely accident may occur at any time. Statistically, this is undeniable. It is acknowledged that, perhaps once or twice a century, a member of the general public might be exposed to an infectious organism released by a laboratory accident. The possibility of an infection resulting is much lower than this, with the possibility of even one death lower still. The likelihood that this individual infection would become a fulminating epidemic, in turn, is even more unlikely. Consideration of such potential epidemic spread is discussed in Appendix 9. Any exposure whatsoever is undesirable, and additional safety procedures are continually being implemented to help reduce the possibility of infection from an accident even further. We believe that the risks from even "worst case" events are minimal. (See also response to comment 19-3 above.)

9-3 Comment: Page 2-7, section 2.4.3, paragraph four, states: "Biological stocks including sera, antigens, toxins, cultured cell lines and microorganisms are maintained at the Baker Laboratory area by Life Sciences Division personnel." Page A9-21 (part 3.1.6 Extent of Downwind Hazard) first paragraph states: "The estimates in this appendix are therefore not firm predictions; they are no better than very rough estimates."... While the risk of accidental exposure to the general public from these biological stocks may be low, it is believed that this risk should be analyzed further in the EIS with regard to the potential for exposure by users of the surrounding public lands.

9-3 Response: Comment requests an analysis of the risk to the general public using public lands (under the control of the Bureau of Land Management) in the vicinity of the Dugway Proving Ground. In Appendix 9 of the Draft EIS an independent estimate is made, using reasonable and conservative estimating factors and accepted dispersal models, of the effects of a massive (i.e. "catastrophic") release of *Coxiella burnetii,* the organism which causes Q fever (Section 3.1.6). (Note that this is NOT the result of any test procedure, but is a hypothetical example developed specifically for use in the EIS.) The results of this calculation were presented in Table A9-1 of the Draft EIS, from which it may be concluded that the maximum distance at which there is ANY hazard is approximately 5 miles. There are no inhabited areas within this distance, including other areas on Dugway Proving Ground. No "public lands" are located within this radius, as may be seen in Figure A9-2. The models used do include assumptions for some organisms decay with time, but also assume total aerosolization of the material (which is not physically possible), and total failure of all protective systems, involving a concatenation of 3 to 5 individually unlikely acts which would combine several "1 in a million" events in one sequence. Thus, the likelihood of this sequence taking

place and resulting in even this modest effect is literally less than one chance in several billion. In regard to the adequacy of the "rough estimates," the text of the cited sections makes clear that any errors are likely to be in the direction of OVER estimation of the hazard.

Sub-Category C - CEQ Considerations

27-1 Comment: We insisted that major concerns about the efficacy of the biological warfare program, its security, and its environmental effects be included in the court ordered environmental documentation.

27-1 Response: The U.S. does not have a biological warfare program. The efficacy of the BDRP is a judgmental, subjective analysis that is beyond the scope of this BDRP-EIS. Security and environmental effects were considered; see Sections 3, 5 and 6 and Appendices 4, 5 and 6.

19-1 Comment: The statement should be site specific rather than program specific; i.e., it should consider the impacts of all programs at each site involved rather than just those which derive from the Biological Defense Research Program (BDRP). The impact of the BDRP: could be synergistically affected by other unrelated site specific programs; e.g. an explosion at a nearby non-BDRP facility may cause release of hazardous BDRP biological agents.

19-1 Response: The views of the commentor are noted. As explained in ES.1 of the Executive Summary and Section 1.6.1, the programmatic EIS was selected as the appropriate approach, in conformance with 40 CFR Parts 1500-1508. A programmatic EIS examines broad issues, which may occur many times in many places. It is intended to be supplemented by more specific local NEPA documentation, as appropriate under current regulations implementing NEPA. Also, see responses to comments 43-1 and 436. While there is always the possibility of other activities or events affecting BDRP activities, this was not considered to be a significant risk. Advertent or inadvertent release of organisms/toxin, including the results of accidents and sabotage, was considered in Appendix 9.

8-1 Comment: No information has been provided on the impact to prime farm land or potential impacts to the soil in general. The Soil Conservation Service (SCS) has soil information available. Further information can be obtained from....State Soil Scientist, at the above address.

8-1 Response: Prime farmland was not addressed explicitly

because there were no proposed actions or activities which would impact these resources. Prime farmland was considered in applying the IAM'S (see Appendix 6). The offer of assistance is appreciated and may be utilized if proposed future activities could adversely affect these resources. See Sections 4.4 and 6.2 of the EIS.

27-3 Comment: The Council on Environmental Quality (CEQ) regulations stipulate that "Agencies shall insure the professional integrity of the discussions and analyses in environmental impact statements. They shall identify any methodologies used and shall make explicit reference by footnote to the scientific and other sources relied upon for conclusions in the statement." 40 C.F.R. 1502.24 Throughout, the BDRP EIS is in violation of this and other NEPA regulations.

27-3 Response: Comment is noted. The DEIS was prepared by a competent professional interdisciplinary staff, as described in Section 8. The methodologies utilized are described and the DEIS contained 75 references in the main text as well as others in the appendices to scientific and other sources where appropriate (see Sections 1.6, 5, 6, 7, 8, 9 and Appendices 4, 5, 6, 7, 8 and 9.) Additional references have been incorporated into the FEIS.

22-5 Comment: Additionally, they should identify and discuss the overlaps between DOD's vaccination research and that carried out under the aegis of the National Science Foundation, Centers for Disease Control and the National Institutes of Health. Duplication of effort wastes resources and increases the probability of an accident.

22-5 Response: As noted in Section 1.5, BDRP scientists and medical personnel work in concert with other government agencies to address special public health situations such as outbreaks of epizootic diseases. They also consult with scientists from these agencies and the academia, as well as with the literature, to minimize overlap of programs and to provide technology transfer from the BDRP activities. The interest of the BDRP is to protect the fighting force against possible exposure to an aerosol of organisms/toxins generated by an adversary. This route of exposure creates a need for a different set of protective efforts than does the natural routes of exposure which are the primary interests of the non-DOD agencies. Also, see response to comment 34-1.

31-4d Comment: Massive BW expansion, turns the entire document into a sham.

31-4d Response: The BDRP is not a BW program (see Section 1 of EIS). Also see responses to comments 27-1 and 27-15.

12-3 Comment: Lastly, in a discussion of the current BDRP program, the DEIS states that the IAM process identifies areas of potential concern or impact that are found not to be relevant. It identifies these as endangered species, cultural resources, wetlands and habitats, and concludes that they are not measurably affected by the "ongoing BDRP". However, an EIS process must assess the likely or possible impact associated with aspects of a proposed action and if a precise analysis of likely events cannot be documented, then a worse case scenario is constructed to allow assessment of potential impacts. The DEIS dismisses any possible worse case scenario as being unlikely. Therefore, so are the impacts. Thus, the impacts are all reduced to what has already been observed to exist. This does not represent a full analysis of potential impacts.

12-3 Response: Comment noted. The EIS addresses the relevant areas of concern and significant impacts. See Sections 1.6, 3.5, 5, 6 and Appendices 2 through 13. As stated in Section 4.4, the tiering approach developed in the programmatic DEIS, based on programmatic risk/issue categories, provides a framework for future environmental review and documentation of any proposed major change in the scope of the BDRP or of any significant site specific considerations. The distinction must be made between potential for effects and possibility of effects. The IAM determined that the potential that the possible consequences (mentioned by the commentor) would occur was extremely low. Maximum credible events (that have not been observed to exist) are considered in Appendix 9. In a revision to the NEPA regulations published in June, 1987, the CEQ stated that, a "worst case" analysis may be replaced with an analysis of the most severe credible accident.

58-1 Comment: The staff of the Utah State Historic Preservation Office has received for review the above referenced Environmental Impact Statement. It is unclear from the document whether there will be any new construction at the Dugway Proving Grounds in Utah. If there is to be new construction as a part of this program, our office hopes that the Defense Department identifies and evaluates any historic properties that might be affected by the project as specified in the National Historic Preservation Act of 1966, as amended.

58-1 Response: As stated in Sections 1.6 and 1.6.4, the BDRP as currently defined, is an ongoing program without proposed construction or expansion of facilities. (The construction of the BATF at DPG is evaluated for potential environmental impacts in a separate DEIS). Any future activities involving alteration

to the physical environment would require appropriate examination of potential impacts on these areas of consideration, followed by NEPA documentation as appropriate. This would include historical sites. The IAM (Potential area impacted item 7 "Cultural Resources") includes both historical and archeological resources (see Appendix 6). Also see Section 5.1.1.7.

59-1 Comment: The Health Interim Committee of the Utah State Legislature recently requested that the Department of the Army conduct public hearings in the State of Utah on the Draft Environmental Impact Statement for the Biological Defense Research Program (BDRP). I concur in that request.

I agree with the Committee that the people of Utah should be allowed ample and equal opportunity to review and comment on the BDRP DEIS and to participate in the decision-making process on the future of this program. This is especially important since the Dugway Proving Ground is one of the three main facilities in the U.S. for biological warfare research, and Dugway is the site selected for a proposed new aerosol test facility which has generated considerable controversy in our state.

T believe it is important that the general public have the benefit of seeing "the big picture" of the Army's biological weapons program before any decisions are made regarding the proposed Dugway aerosol testing lab.

I ask that the Army respond promptly and favorable to the Committee's request for hearings and if necessary, extend the August 12 comment deadline for the BDRP DEIS to accommodate Utah hearings.

59-1 Response: Comment noted. The public comment period for the BDRP-DEIS was extended to 4 October 1988 and a public meeting on the BDRP-DEIS was held at Tooele Army Depot, Tooele, Utah, on 19 September 1988. As a point of clarification, the Army does not conduct a biological weapons program.

31-1 Comment: We also note that the Army has thoroughly botched the environmental review process for the BDRP and the proposed BATF by conducting these analyses backwards. DOA should, according to NEPA regulations, proceed from the general to the specific in its analyses, not the other way around, as it has done with these two DEIS's. Downwinders pointed this out to DOA in a letter dated March 13, 1988. We received no reply and DOA failed to take any corrective action to comply with NEPA regs.

31-1 Response: Comment noted. It is desirable to proceed from the general to the specific, which is what the BDRP programmatic EIS is intended to do. However, circumstances of these actions

dictated near simultaneous consideration of both actions. A record of decision (ROD) on the BATF-EIS will not occur prior to the ROD on the BDRP-EIS. The time sequence of the development of the BATF-EIS and the BDRP-EIS, has been based, in part, on the sequence of legal actions over which the Army has no control, and did not alter any considerations and findings in the BDRP-EIS.

5-3 Comment: On pages 1-4 which begins "The programmatic EIS..., "The Department of the Army should describe exactly how future BDRP actions will be examined; that is, (1) what criteria are used for identifying "new" versus continuing BDRP actions, (2) who will be clearly responsible for identifying "new" BDRP actions for review, (3) what organization will actually conduct the review of identified actions, and (4) will there be an ongoing formal program review element that helps to identify new actions? We feel that this identification in the Final EIS of a formal structure would better demonstrate the intent of the Department of the Army.

On page 1-16, the paragraph that begins "For item 2)..."seems to say the BDRP has an excellent tract record for safety, particularly in recent years. Is the continuing BDRP using the same research techniques, quantities and types of organisms, safeguards, etc., as have been used in the past when this good track record was established or is the BDRP venturing into new areas of research involving new biohazards and new techniques? The implication throughout the DEIS is that the program is a continuation of activities of similar risk to those conducted in the past. In our review we could not find an explicit statement of how the work described in this DEIS is similar to or different from past BDRP activities. For the Final EIS, it would be reassuring to know that nothing really new is being proposed here, if indeed that is the case.

5-3 Response: We believe the definition of what is "new" or what may be termed "continuing" actions under the BDRP is adequately clear. A new action would, by definition, be one whose environmental effects or consequences are not covered in this Programmatic EIS. If, however, there were a need to propose such additions to the BDRP, funding (and approval) would be sought from Congress, and appropriate NEPA documentation would be prepared. Changes of research focus from one organism to another, so long as present containment and safety procedures are adequate, are not viewed as defining a new program. The Medical Research and Development Command is responsible for monitoring such proposed changes as well as for the preparation of NEPA documentation, should it be required. In response to the last sentence within this comment, the program described in the EIS is not identical to, but is a logical development of, the historic, ongoing BDRP. Each year there are some small changes and additions, thus no individual year has the exact same content, but the overall character does not change greatly in any one

year. This is similar to any dynamic, ongoing research program containing numerous individual projects.

7-29 Comment: We see many of the same charges from very responsible people made on the programmatic biological research program, nationwide program, national program, that were raised **on the** initial draft environmental impact statement for the new Dugway facility.

7-29 Response: Comment noted.

Sub-category D - Effluent Controls/Issues

19-2 Comment: The purpose of a NEPA impact statement is to inform the public of current and potential environmental damage. There is no way that I, as a neighbor of Ft. Detrick, for example, can come to understand the overall impact of that facility on my family and my environment if each program underway at that site prepares separate impact statements. By proceeding with separate programmatic statements like this, you are defeating the whole public information purpose of the NEPA provisions requiring such statements. It appears that you are employing the oldest of military tactics in order to diffuse public understanding and criticism, viz. "divide and conquer."

19-2 Response: Comment suggests that it is the intent of this Programmatic EIS to conceal the total picture of what is taking place at Ft. Detrick. We believe that an EIS covering all the broad issues of a nationwide program is not unreasonable. It is, in fact, what was requested by the original complainant and required by the court. A programmatic document describes the large issues which apply across an entire program, and gives only sufficient detail about any one site within the program to serve to exemplify an issue. It is recognized that BDRP activities do not constitute more than about one-sixth of the total activity on Ft. Detrick, less than 2 percent of that at Dugway Proving Ground, and less than one percent of the activity at Aberdeen Proving Ground. In the analysis of impacts under the IAM process, cumulative impacts were considered. See Sections 2.3.5 and 6 and Appendix 6.

19-5 Comment: Finally, the draft statement indicates that solid wastes from BDRP work at Ft. Detrick are buried in a sanitary landfill in accordance with applicable regulations. It acknowledges that "there is a potential for low impact to soils, topography and erosion from the contribution USAMRIID makes to the overall solid waste landfill requirements at Fort Detrick." This terse, unsupported conclusion leaves several questions

unanswered. For example, (1) What criteria were used to determine that the impact of the landfill is "low?" (2) What other responsible government agency (state, local, federal) have evaluated this landfill to verify that its impact is "low?" (3) The above quote from the draft statement does not mention any impact on ground water, yet it is well known that waste leachate entering ground water is the predominant impact of most landfills. Several monitoring wells are in place around the Ft. Detrick landfill. Surely there is data which reveals what, if any, leachate migration exists around the site. This matter should be discussed. (4) No mention is made of disposal procedures for radioisotopes. Are any long lived radioisotopes buried in the landfill? If so, have they leached into ground water? (5) Do insects, birds and/or burrowing animals disperse hazardous buried materials from the landfill, e.g., house flies or crows. This would seem to be a very likely and very fast mechanism for dispersal. Has it been investigated? Since I live very close to it, I would like it discussed in the Statement. I realize that the DEIS indicates that no hazardous materials are being buried there now; however, some of my neighbors helped bury them there in the past.

19-5 Response: The Ft. Detrick sanitary landfill is discussed in the Draft EIS in Section 5.3.1.2.9. This landfill is operated under a letter of permit from the State of Maryland, and is subject to inspection by the state. Monitoring wells have been in place for some years, and are subject to unannounced sampling by the state. Neither the unannounced sampling nor regular Army sampling has shown presence of any contaminant in the groundwater at a level in violation of state regulations. The landfill is not used for any hazardous materials, including radioactive isotopes. There is an active pest control program in the vicinity of the landfill whose purpose is to minimize the type of effects discussed by the commentor. All materials from the USAMRIID laboratories are incinerated prior to landfilling. All cultures and animal carcasses have been autoclaved prior to incineration. The ash from the incinerator is tested regularly, and has not been found to be hazardous in itself. The "...low impact to soils..." (Appendix 6, page A6-17) about which questions are raised refers solely to the question of excavation, surface disturbance and earthmoving, which are characteristic of the operation of any landfill. Additional information on the landfill has been incorporated into the FEIS (see Section 5.3.1.2.9)

25-1a Comment: The subject DEIS states that Ft. Detrick and the other BDRP program laboratories rely on filters which remove 99.95% of the particulate from the air exhausted from hoods. The filtration efficiency is entirely inadequate to protect the Frederick citizen neighbors of the facility. The 0.05% of the particulates which pass through these filters make up a huge number of particles being dumped into the environment by every

hood in the facility. It is well known that every cubic centimeter of air in our homes and environment and presumably in the Fort Detrick fume hoods contain from 3000 to 5000 particles. Assuming 4000 per cm cubed and 5 m cubed/min of exhaust from a hood, the 0.05% loss figure is translated to 200 million particles emitted every minute from every hood. Of course, this simple calculation does not speak to the proportion of biologically active particles interspersed among these escaping particles. This value would of course vary with each type of experiment. I suggest that any estimate of the impact of the program on the Ft. Detrick environment caused by routine airborne releases must start with this number. It should be stated in the EIS together with appropriate analysis for each number and type of biologically active particulate which escapes.

25-1a Response: Comment refers to various aspects of the filtration of air from the laboratories at USAMRIID. At the time when the Draft EIS was prepared, one laboratory air exhaust system relied on 99.95% efficient filters. This has now been changed to at least 99.97% efficient filtration through modification of the air handling system in that laboratory. The comment suggests that 99.95 or even 99.97% efficiency is much less than the state of the art. In an absolute sense this is a correct observation. The particles of interest in this biological research setting, however, are relatively large in the terms used by the commentor. The filters actually used are tested by the manufacturer prior to shipment to USAMRIID, and are marked as showing efficiencies of 99.992% to 99.997% in retaining particles larger than or equal to 0.3 microns. It should be noted that this exceeds the requirements of the CDC/NIH for BL-3 filtration (as described in Appendix 12). Any incidental dispersions of disease-causing microorganisms, including virus particles, are substantially larger than this size, so that removal of the viable particles is in accordance with the stated efficiencies. Filtration of the exhaust of critical areas is actually performed two to five times rather than once. The final removal of particles is thus much more than the single-pass percentages would indicate. In addition, most of the 3000 to 5000 particles per cubic centimeter referred to are inert and/or non-hazardous, and their passage cannot be considered a major hazard. The critical consideration in filtration of air effluents from biocontainment laboratories and equipment is the removal of potentially hazardous microdroplets that are in the size range that is retained by the lung. Particles above a critical size do not gain access to the alveolar areas, and particles smaller than a critical size are not retained. Also, see response to comment 25-lb.

25-1b Comment: The DEIS implies that the 99.95% particulate retention figure is superior state of the art containment. It is not so. High efficiency filters are now available which capture 99.99999% of the particles. They are routinely used to remove

particles from large volume air flows into clean rooms. The EIS must acknowledge this fact and state why this simple means of reducing the release of extremely toxic particles is not employed in the BDRP

The DEIS authors must acknowledge that Ft. Detrick lies within the corporate limits of a large and growing city and that the risk from these releases is much greater here than from more remote BDRP facilities. The DEIS overlooks this simple fact entirely.

25-1b Response: Comment refers to various aspects of the filtration of air from the laboratories at USAMRIID, and makes the comparison of high efficiency filters used in providing air to "clean rooms." Assuming that the commentor is referring to "clean rooms" such as those used for manufacturing processes in the microelectronics industry, the considerations of filter efficiency and range of particle size removal are entirely different from those appropriate for the control of biological materials in laboratory air effluents. The 99.99999% efficiency filters referred to are intended to remove even the most minute, inert particles from the air entering a "clean room" so that no particulate material contaminates, and thus renders useless, a microelectronic component. As described above in response to comment 25-1a, the relevant filtration considerations for biohazardous materials are different. It is recognized in the DEIS, Section 5, that Ft. Detrick lies within the limits of Frederick, MD, but the risks arising from the discharge of properly filtered, non-hazardous air effluents from the laboratory are extremely small, and no different than they would be were the laboratory located in a less populated area.

25-2 Comment: I served as the program manager for the airborne waste R&D program for the Dept. of Energy for several years prior to my retirement. All of the high efficiency filters used by that department at their nuclear facility are individually tested to assure they are at least 99.97% efficient. Moreover, all of the facilities involved are in very remote locations. Also, few radioactive particles which may escape cannot multiply in the environment as can biological materials. I make this comparison to convince you and the statement authors that the EIS must evaluate the impact of this particle release issue in much more detail. It is a most serious matter.

25-2 Response: See responses to comments 25-1a and 25-1b. As stated, the primary concern with respect to potentially biohazardous particles is the particle size and its pulmonary retention characteristics. In contrast to radioactive materials, which retain their radiologically hazardous characteristics regardless of physical form or size, biological materials in particulate or microdroplet aerosols only present a hazard in air effluents if they are in a narrow, optimum size range. In

addition, while it is true that organisms can multiply, there are numerous essential requirements to support such multiplication as described in Appendix 9, part 6.1, and Appendix 7. In the absence of the many factors required before multiplication can occur, organisms progressively lose viability and die. In this context, it is acknowledged that radioactive materials also undergo decay, but it is clear that the properties and risks associated with biologicals and radiologicals are substantively different. All filters used are tested to a minimum of 99.97% efficiency, with most rated above 99.992%. Also, air from hazardous areas is filtered two to five times, assuring even greater overall protection.

14-11 Comment: Because of the possibility that highly infectious pathogenic microorganisms will be tested in aerosol media in the Dugway facility, special attention must be given to air emissions control. The air must be fully treated before it is discharged, with adequate safeguards to ensure that no test material which is hazardous is emitted. The methods of accomplishing this must be explained in more detail than that provided by the sic [BATF] DEIS (C-8). Volumes of air exhausted during full operation periods in the laboratory need further detailed explanation. Sources of air, such as incinerators, design capacity of pumps, emission estimates, air pollution control devices, etc., also should be explained.

The measurements of air movement in the laboratory during down time are not addressed in the sic [BATF] DEIS. When tests are completed and aerosols have decayed prior to cleanup, chemicals will be used for sterilization, neutralization or heat treatments. During such time, it is not stated if the direction of air movement will change, nor is it clear if there will be periods when air movement reverses or when filters are inactivated, allowing non-treated air to escape the building. At all portals of air discharge from the building, monitoring for particulates should be carried out during the time when systems are partially or totally inactivated to assure that all discharges contain no infectious or toxic materials.

14-11 Response: This comment was submitted as a public comment to The BATF DEIS. The specific engineering parameters requested in this comment are more appropriately addressed in the site- BATF-EIS rather than in this programmatic EIS on the BDRP. The general subject of physical plant operational controls for waste stream management, air, liquid, and solid was addressed in the BDRP-EIS Sections 3.3.1.1 and 3.3.1.2. All tests by aerosol with high hazard (BL-3 or BL-4) organisms are conducted in sealed chambers equivalent to a Class III biosafety cabinet which in turn are inside an appropriate BL-3 or BL-4 laboratory. The degree of absolute treatment of air emissions is a function of hazard level of organism under study. Thus for an organism requiring BL-4 containment, the CDC/NIH guidelines

requires a double HEPA filter (99.97% efficiency) in series after the air leaves the Class III cabinetry system, whereas an organisms requiring BL-3 containment are not required by the CDC/NIH guidelines to have the facility exhaust air filtered. The BDRP facilities, as an extra safety measure, use HEPA filter(s) for exhaust air from BL-3 laboratories. Appendices 11 and 12 address design and safety features for conducting studies with hazardous organisms and toxins and Appendix 13 discusses decontamination/disinfection technologies/procedures. See also the responses to comments 25-1a, 25-1b and 25-2 above.

14-12 Comment: 1) The (BATF) DEIS vaguely refers to "hazardous chemical waste such as disinfectants, corrosives, acids, or rodenticides/pesticides" (page G-2) without further identification or description. Peracetic acid, used for decontamination, is the only chemical waste specifically named. Solid waste is described as "spent HEPA filters, animal waste, bedding and carcasses, and other disposable material." These descriptions should be more specific. 2) The DEIS is deficient in that it gives no estimate of the quantity of any waste generated. 3) The DEIS states that solid and liquid wastes will be "decontaminated/inactivated by...heat or chemical treatment" without specifying what chemicals may be used in such treatment, except to describe then as "disinfectants".

14-12 Response: Comment was submitted as a public comment to the BATF DEIS. In any event, a detailed description of technologies for decontamination/ disinfection is provided in Appendix 13 of the BDRP-DEIS. Site specific liquid/solid wastes disposal is discussed in Sections 5.3.1.2.5, 5.3.1.2.9, 5.3.2.2.2 and 5.3.3.2.2 and in Appendix 5.

27-9d Comment: The environmental concerns about this research include ... Impacts on air, and water quality and biota from BDP operations or accidents.

27-9d Response: Impacts on air, water quality and biota from BDRP operations were considered in development and application of the IAM to assess the impact of various activities in relation to organism or toxin under study, see Sections 3, 5, and 6 and Appendices 6 and 9. It was concluded that no significant effects on these resources exist in the present BDRP, even following accidents many times more severe than any actually observed.

27-9g Comment: The environmental concerns about this research include ... Treatment and disposal of BDP research wastes.

27-9g Response: Treatment and disposal of BDRP research wastes

was considered in the development and analysis of IAMB, see Sections 3.2.2.2, 3.3.1.2, 5.3.1.2.2, 5.3.1.2.9, 5.3.3.2.2, 5.4.1.1.2, 5.4.1.2.2, and Appendices 5, 6 and 13.

SUBJECT AREA 4: NOT SPECIFIC TO THE BDRP DEIS

Sub-Category A - Questions raised about non-BDRP

29-7a Comment: Open-air testing of dangerous biological agents is carried out at the U.S. Army Dugway Proving Ground.

29-7a Response: Open-air testing with dangerous biologicals is not performed at Dugway Proving Ground or at any other location. Open-air testing as part of the BDRP is conducted only with simulate organisms and currently only at Dugway Proving Ground. See Sections 2.4.3, 3.2.1.6, and 5.3.3.2.3. Separate NEPA documentation is prepared before each test or series of tests.

29-7b Comment: The Draft EIS acknowledges that this is a "significant area of concern to the locale because of the perceived high hazard associated with it." However, we have not been able to find any discussion of the environmental impacts of open-air testing of dangerous biological agents. Clearly this is a major omission since such organisms could be disseminated in the air or water or through animal vectors to surrounding communities.

29-7b Response: Open-air testing not open-air testing of dangerous biologicals, since this is not being done) was recognized in application of the IAM as a significant area of concern to the locale because of the perceived high hazard associated with it. See Appendix 6, matrix analysis summary, page A6-21, and also see page A6-27 public opinion: "Additional controversy and social concerns at Dugway Proving Ground arise from the open-air testing of biological simulates that takes place at this site. Much of the controversy and concern relate to other activities conducted at Dugway Proving Ground that are not related to the BDRP" or they are based on the belief that outdoor tests using toxins or pathogenic organisms are part of the BDRP; there are no such tests done for any purpose. Also see responses to comments 29-7a, 42-1, 45-1b, 45-6a, and 45-6b.

55-5 Comment: ...200 open air tests have already been conducted out at Dugway Proving Ground, maybe with deadly germs. We are lucky so far that an epidemic has not occurred because of this and it is unknown what future effect this would have.

55-5 Response: Open-air testing with dangerous biologicals is not performed at Dugway Proving Ground or at any other location. See response to comment 29-7a. The 1977 Army document (see reference 16 in Appendix 9), which was made available to Congress and other government officials, incorporated a summary

of activities conducted under the Biological Warfare program, which was terminated in 1969. The BDRP-EIS covers only what is currently being done or anticipated to be done as part of the BDRP in the reasonably foreseeable future. The possibility that an epidemic might result from BDRP activities was closely examined and determined to be so unlikely as to be, for all practical purposes, not possible.

45-la Comment: You know, I think that your environmental impact statement has some very serious problems, but I think in comparison to your credibility problem, the Commissioner here says that by and large the Army has done a pretty good job of being credible. I think that perhaps we ought to review a few documents before we proceed any further on the credibility issue.

According to recent reports from a freedom information request, recently released documents, in 1977 the Army presented a lengthy and supposedly very thorough documentation of all the tests that took place in the Dugway Proving Ground. Well, how thorough was it is the question. Not included in that analysis was the fact that the Army splattered 450 gallons worth of biological fog all over the west desert from an aircraft and this appeared to be only about a quarter of what was actually done and we are still trying to solve the problem of the new Glasnost of the Dugway Proving Ground. We are not impressed at this juncture.

45-la Response: All outdoor test activities under the BDRP utilize only simulates. See responses to comments 55-5, 42-1, 29-7a and 29-7b.

29-5c Comment: The open-air testing of biological warfare agents ... should be discontinued

29-5c Response: All outdoor testing which is a part of the BDRP utilizes only non-pathogenic, simulate organisms. Also, see responses to comments 14-7, 29-5b, and 29-7a.

22-6a Comment: DOD acknowledges that open air testing with bacteria and viruses is necessary in BDRP.

22-6a Response: Some open air testing is required, however, open-air testing is conducted only with simulate organisms and currently only at Dugway Proving Ground, (see Sections 2.4.3, 3.2.1.6, and 5.3.3.2.3). Separate NEPA documentation is prepared before each test or series of tests.

33-1b Comment: As a Utahn and as a citizen of the United States and the planet earth, I urge the Army to abandon its biological weapons testing program. I firmly believe that the health of our nation's people and the future of our human family depends on it.

33-1b Response: The United States is not conducting a biological weapons program. No weapons are being developed, and none are being tested. The U.S. is in full compliance with the 1972 Biological Weapons Convention and is conducting only a biological defense research program. See Section 1.6.2 of the EIS.

33-1a Comment: It is not enough to oppose germ warfare testing in Utah. That attitude contains a "contaminate the other guy" mentality which is immoral and politically dangerous. It also fails to recognize the inherent danger of biological weapons testing and, even worse, it fails to remember that we are a global family. When we contaminate any part of the world with disease or genetically engineered germs, we harm our entire planet and all of its people.

33-1a Response: See response to comment 33-1b.

33-2 Comment: The Army's biological weapons testing program is dangerous because the entire concept of germ warfare is dangerous. It opens up a Pandora's Box of new weapons proliferation that we may never be able to close.

33-2 Response: See response to comment 33-1b.

22-6b Comment: Professor Cole, in his comments prepared for the "scoping" meeting, reminds us that, even though it is required to notify Congress and local official prior to a test involving humans, DOD narrowly defines test subjects to include only people deliberately exposed to the agent. As a result, during viability or dispersant tests notification is not required, even though humans may be inadvertently exposed to viruses or bacteria.

22-6b Response: Testing viability and dispersibility of hazardous organisms and toxins is not part of the BDRP Also, see responses to comments 29-7a and 33-1b.

55-1 Comment: The citizens of the state of Utah are scared. They are scared of this new biological weapon out here at Dugway and they are wanting answers.

55-1 Response: There are no biological weapons at Dugway Proving Grounds or any other location. Presumably the commentor is referring to the BATF, which is a facility planned to be used to conduct tests of materiel and equipment as part of the biological defense research program. The BATF is a subject of a separate EIS, and any decisions related to the BATF will be based on that EIS (see Section 1.6.4).

38-3b Comment: For example, there are several fairly well documented examples of "mistakes" at Dugway which, among other things, have led to massive sheep kills. The potential risks, if this type of research continues, are of such magnitude as to warrant more serious consideration.

38-3b Response: The sheep kill incident was not part of the BDRP and is not related to the RDT&E examined in this EIS (see Section 1.6.4).

42-1 Comment: One of the very great concerns we all have, as I mentioned my memory, is the memory of 8,000 sheep mysteriously dying out in the desert. We have a memory of clouds of dust rolling across the southern parts of our state. We have a memory of wanting to be the nuclear dumping ground of the Nation. And quite frankly, that's a serious concern of the people of Utah. We feel like we have been dumped on, sprayed over, we have had clouds roll over us, and we have citizens who are dying in the southern parts of our state, and we have many other things that the government said, quite frankly, were not of concern and were not something we had to worry about.

42-1 Response: Items of concern in this comment were not and are not part of the BDRP. Also see responses to comments 22-6a, 38-3b, 29-7a, 29-7b and 55-5.

45-1b Comment: You know, a single organism of "Q" fever can cause significant health problems, possibly death. There are thousands and thousands of organisms within one single drop of "Q" fever. The Army saw fit, in a 1968 test, to drop 40 gallons worth of "Q" fever all over the place from an F-100A jet traveling at near supersonic speed. At least 69 field tests conducted over 18 years were left out of your congressional testimony in 1977, when you attempted to tell Congress how safe it all is.

We have recently found out that you didn't know whether it was endemic, when you first started splattering that around the

desert, of course. Now, it's too late to come up with any logical conclusion of whether it was there in the first place, of course, you have also said to the Congress that this never created any particular problem, despite the fact that your own documents show that there was an epidemic in the wildlife of "Q" fever in 1959 and 1960, that hasn't gone away.

45-1b Response: Q fever is endemic throughout much of the U.S., including the state of Utah. No open-air testing with Q fever or any other high hazard organism or toxin is a part of the BDRP. Also see responses to comments 29-7a and 55-5.

45-1c Comment: In your EIS, I recall on the biological aerosol test facility you said that there was something to the effect that you wouldn't test it if the winds were over six miles an hour, and I can remember commenting that it's rare that the winds are less than six miles per hour in this part of the state of Utah. While in the past you have conducted wind speed tests with biological agents when the wind was 30 to 60 miles an hour. It seems that you have dropped bombs containing agent US, which no one seems to know what that is, apparently it is one of your pathogens from a 25,000 foot elevation out of an airplane to detonate at 10,000 feet. So much for your meteorological control. I believe we could also go into the fact that you have leaked agents all over your runway before out here, that you have allowed anthrax spores to cross I-80 which at the time was That’s just a few things.

45-1c Response: Whether factual or not, the incidents referred to in this comment are not part of the BDRP. Specific comments related to text of the BATF DEIS are more properly addressed to and by the preparers of that document. Any BDRP related outdoor testing has used and will use only simulants. Also, see responses to comments 29-7a, 29-7b and 55-5.

45-6a Comment: I think another issue that is critical is what about the mess you have already got out there? Where are your anthrax spores. There's an island off Scotland that is off limits to human beings for the next 100 years and that's because there are anthrax spores spread all over by biological tests done by the British.

45-6a Response: Open-air testing with anthrax spores or any other pathogens is not part of the BDRP. Gruinard Island, referred to as "an island off Scotland," has been decontaminated. Its contamination occurred many years ago through testing of offensive weapons, not as a result of research for defensive purposes. Anthrax spores were released outdoors on one test grid at Dugway Proving Ground in the 1950's as part of

the biological warfare program. Environmental rate studies of anthrax spores in Dugway soils done at the time of the testing (the 1950s), as well as repeated soil samplings of the grid itself, indicate no residual anthrax hazard exists. The high alkalinity, high pH and limited vegetation are probably responsible for the rapid decrease in spore viability in DPG soils, relative to other soil types.

45-6b Comment: Is Dugway off limits? I don't think so. I have heard stories of people driving pickup trucks across there and never getting stopped. Stories of transients wandering from Wendover all the way to Salt Lake City and being stopped at the gate on the east end going out of the Dugway Proving Ground and our freedom of information request, all we wanted to know is where is your contamination?

Now, I understand that you have about $10 million to clean it up, you don't even know where to start. What kind of conclusions are the Utah public support to make from that kind of track record?

45-6b Response: Dugway Proving Ground is fenced and posted, with the exception of the west portion that is made up of salt flat terrain. This section has no improved roads and is inaccessible during wet years and during wet months of dry years. All test areas are routinely patrolled by ground security patrols and helicopter over-flights of the perimeter. Baker area, where the laboratory is located, is patrolled 24-hours a day.

All potential hazardous waste sites identified in the 1988 DPG Solid Waste Management Unit (SWMU) report are associated with the chemical mission of DPG and normal base operations. Soil samples from test areas previously used for biological testing, with pathogens, have shown no residual biological contamination exists in Dugway soils. There are no hazardous biological waste sites at DPG.

54-1 Comment: I am Mary Alice Kobler, a concerned local citizen with a very long memory. I am unconvinced of the Army's reliability in several areas. Considering what it has taken to get you guys here tonight to have this hearing held here tonight, I am unconvinced that you are truly here to listen to my concerns. I am, however, very grateful for our system of government that assures responsible patriotic citizens to express our concerns. Since the Army is legally untouchable and our only defense as concerned citizens is to demand an environmental impact statement that adequately addresses what you are capable of doing, not what you say you are going to do, but what you are

capable to do. I think the Army should have to prepare an environmental impact statement for everything they do. If you would have had to prepare an environmental impact statement when you moved from the University to Dugway, you would not have been able to leave Anthrax and tularemia in glass vials on shelves. When asked to take responsibility and to correct the situation, the Army told us that it was our problem. Environmental impact statements are the only assurance we have for demanding responsible scientific studies and action. All other proposed scientific work must involve rigorous peer review. I call upon you to do responsible science. I also call upon you to examine your extreme lack of credibility with the patriotic citizens of this state. Please don't dismiss us as being emotional, radical, uneducated fools. What we are demanding of you is a broad based long-term perspective. Thank you.

54-1 Response: Comment noted. Contrary to the opinions expressed, the EIS process is specifically intended to examine actions which are planned and within the authority of the agency to implement. We believe the BDRP Programmatic EIS does cover all aspects of the present and planned program. Other activities and incidents referred to in this comment are not part of the BDRP.

51-1 Comment: The Army has assured us that this whole matter, the whole biological warfare research program, is safe, secure and under control. Please allow me to explain my criteria for evaluating this. Mainly, that if I went to a bank and wanted to get a loan from them and I would say to them, hey, I will pay it back, you can trust me, but I am sure they would check my credit records. Likewise, if I bought a car or some other valuable object, I would want some kind of warranty -- some kind of legal guarantee that if it turns out to be a lemon that I have some form of legal redress.

Now, the Army has a track record that looks like crap as far as public safety and as far as telling the truth. Likewise, the Supreme Court has assured us that the Army is entirely immune from any form of legal redress, regardless of any kind of hideous catastrophe that may turn loose. I only wish the Supreme Court could grant the rest of us immunity from your germs, but I don't think that is in their power to do so.

I will be very brief, you're liars, you're murderers, you have complete immunity from any kind of legal redress, and I don't trust you as far as I could infect you. So, my suggestion for what you do with your facility, and I know you don't want to talk about Dugway here, you have made that plain, however, given that, Dugway is an integral part of your program. I am not sure where to draw the line. I want you, unlike some other people here who have spoken against your program, I want you to bring

that facility here because you will be stopped here. I want you to bring that here -- bring that turkey here because I will be here. Are there any questions from the panel?

51-1 Response: There is no biological warfare research program at any location. The remainder of the comment does not appear to be relevant to the BRDP-EIS.

52-1 Comment: Hello, My name is Heidi Wallentine and I am here representing the people of the state of Utah as a private citizen, but also the people of the planet and a human being.

There are many things that I did not know about this, of course, here I am living in the state and yet I am not aware of this. So tonight, I had to formulate a lot about what I am hearing, about the controversy -- the conflicts of information that shocks me that I don't understand, but also the future for me as a teen, for my friends in the Soviet Union, and in this State, because just as I have friends in the state of Utah that are at risk with this particular program, I have friends in other countries that are viewed by the government and by the military as opponents and enemies that these pathogenic organisms are prepared to be used on.

We all understand the consequences of nuclear war and we all do not desire nuclear war. Just as no one wants a nuclear war, nobody wants a biological war and I think we all understand that famous quote from a very intelligent man who also had a good heart, Einstein, "You cannot simultaneously prevent and prepare for war."

Also, I have many questions in my mind about expendability. About people who are considered expendable because I certainly do not consider myself or anybody on this earth expendable. What exactly -- this is a great responsibility we take in our hands. What exactly -- who exactly do you consider expendable? There is no doubt there is a risk here with the people of this State and this is a responsibility that you are taking in your hands.

Also, the fact that as we deal with nuclear strategy -now, I understand that we were asked to only talk about this particular program, it deals with all aspects, it deals with nuclear war, it deals with biological warfare, it deals with death. What good are these negotiations that we talked of in nuclear warfare if it doesn't deal with the technological momentum that is a constant battle between both countries. The negotiations do us no good if we continue to keep building and building and building more ways to kill in the name of -- for me, in the year 1988 has become not National, it is a planetary concern now, this is a common ground now for us because we are

dealing with more than just biological warfare, we are dealing with complete devastation. We have the ability and we all know that.

As I look at you men I see that you all know that. Why do we want to prepare for that? I can't answer that. I try to understand the mentality of the human species as much as possible, but there are still so many things that I don't understand. We have our fears and that seems to be what we build *on, is* our fears. As this man said, we react out of our emotions, he is right, we react out of our emotions.

So, I am not here to tell you that I ask of you, that I hope for you, what I am going to tell you is that I refuse the word classified information or expendable in the name of national security. I will not live in the fear of ignorance, that is why I am here.

As I make myself more aware, I will not live in the fear of the polluted, deadly world you prepare to create because I am a futuristic thinker in an aspect that deals with not just my national status as an American, I am a humanitarian and I am sure that this is a concern that you all understand because it's something that as we learn to open our hearts more will come about. As we consider ourselves more, the concept of humanitarian not just American. Thank you.

52-1 Response: We share many of the comment's concerns about the global consequences of biological warfare. This is one of the reasons why the BDRP research, following our country's (at that time) unilateral withdrawal from use of biological weapons of any type, has focused on two areas: 1. detection of enemy's use of biological weapons, and 2. prevention, diagnosis and treatment of casualties that may result from the use of such weapons.

26-12 Comment: In this regard, I have also noted in DEIS Appendix 3 that both the Wistar Institute of Philadelphia, Pennsylvania and the Pan-American Health Organization in Argentina are classified as sites for the BDRP. Since that is the case, I would like to know whether or not DOD funding under the aegis of BDRP research or otherwise was behind the controversial experiment developed by the Wistar Institute involving a genetically-engineered rabies vaccine that was injected into animals in Argentina without official sanction by the governmental authorities *of* that country. Argentinian officials have since charged that the virus spread beyond the animals that had been vaccinated. If DOD funding was behind that Wistar experiment, then it is obvious that DOD quality and safety controls have proven to be completely inadequate. In any event, because of the Argentinian affair, it appears that Wistar should

not under any circumstances be allowed to conduct BDRP research. What assurances can you provide to the American People that comprehensive controls will be instituted with respect to all BDRP research occurring at so-called secondary sites whether in the United States or aboard by irresponsible contractors such as Wistar?

26-12 Response: Rabies virus research is not a part of the BDRP. The Wistar studies referred to were not funded by and are not related to the BDRP. All development and testing of drugs and vaccines are conducted in accordance with existing U.S. law governing such development and testing regardless of the location, foreign or domestic, of such activities. In addition to U.S. laws and regulations, when such studies are conducted at a foreign location, they are done in compliance with the laws of that country as well, as stated in section 3.5.6 of the EIS. Such studies are conducted only where and when a disease of interest occurs naturally; there is no introduction of a non- agent into the environment (see Sections 5.2 and 6.1.4), and no additional risk to human or environmental health and safety over that which is a result of the occurrence of natural, endemic disease.

43-5b Comment: Recently they've had an experiment in Wistar in Argentina where pseudo-rabies vaccine was being tested in Argentina. This caused an international incident as many of the workers became infected as part of the reaction to the vaccine. This was done with voluntary compliance with NIH guidelines.

43-5b Response: Rabies virus research is not a part of the BDRP. The Wistar studies referred to were not funded by the BDRP. Also see response to comment 26-12.

24-15 Comment: Finally, there is no mention of plant or strictly animal pathogens. If they are not now in use, what about the future?

24-15 Response: While there are bacteria, viruses and toxins that can affect and presumably destroy crops, the study of such agents is not and never has been part of the DOD BDRP. Evaluation and development of defensive measures for crops is a mission of the U.S. Department of Agriculture. Many of the infectious organisms and toxins of concern to the BDRP mission can affect animals as well as people and many of the defensive countermeasures developed by the BDRP for protection of man can and have been used to protect animals, see Section 1.5. Any future changes in the BDRP would be evaluated for their potential environmental consequences as described in Section 4.4 of the EIS.

27-4 Comments: The BDRP is devoted to research in "militarily significant" bacteria, viruses and toxins. These pathogens can be used to destroy animals, crops, and people.

27-4 Response: Seeking to destroy animals, crops or people is not part of the BDRP. While there are bacteria, viruses and toxins that can affect and presumably destroy crops, the study of such agents is not part of the DOD BDRP. Also, see response to comment 24-15. The military significance of the biological materials studied in the BDRP relates to their potential for use as weapons by hostile parties and to the hazard they present as endemic diseases in various parts of the world.

18-1 Comment: Attached is a copy of an article from the Detroit News stating that the AIDS virus was created in a lab at Fort Detrick, Frederick, Maryland.

After much research, Dr. Robert Strecker, a Los Angeles physician, sent a 40 page report to President Reagan, the vice- all cabinet officials and governors, the F.B.I and the C.I.A.

I would like you to know firsthand what is in this article so I am asking the reader of my letter to please read it for you .

Being a resident of Frederick County all my life and knowing many employees of Fort Detrick, past and present, I must say the study done by Port Detrick does not do the truth justice, although what it does contain is enough to alert anyone to the dangers of such a facility.

I believe stating that the research being done at Fort Detrick only poses a negligible risk to employees and the general public is false and if an independent study were done, it would be proven so. The risk is far greater than what has been implied in the recent newspaper articles and the study itself, and with the extreme increase of development in Frederick County, the health of the public must be considered now.

Please be informed that I sent a letter, dated June 7, 1988' and a copy of the article from The Detroit News, to Dr. Everett Koop, of which I have not received a reply, so I am asking at this time that an investigation be done concerning the information given you today and if this information be true, then charges must be brought against those responsible for such an outrageous act.

18-l Response: AIDS virus (a retrovirus) is not now and never has been part of the BDRP. In a subsequent letter to the editor of the Frederick News-Post daily papers, dated 13 September 1988, the commentor retracted this allegation.

29-5d Comment: The construction of novel biological agents under the BDRP should be discontinued...

29-5d Response: If this comment concerns the deliberate creation of a novel agent that is more pathogenic or more toxic than those already found in nature, this is not being done. Also, see response to comment 43-7.

27-6a Comment: Moreover, the BDRP is involved in large scale genetic engineering of biological warfare agents. In a May 1986 report to the Committee on Appropriations of the United States House of Representatives, the Department of Defense pointed out that recombinant DNA and other genetic engineering technologies are finally making biological warfare an effective military option.

27-6a Response: The BDRP is not involved in large scale (or any scale) genetic engineering of biological warfare agents. The fact that recombinant DNA and other genetic engineering technologies are finally making biological warfare an effective military option does not mean the U.S. is pursuing this option. Use of recombinant DNA procedures with pathogenic organisms and toxins is closely controlled at all locations, both within and outside the government. Development of a more virulent strain of a pathogen is specifically prohibited under any circumstance, and is not the goal of any BDRP effort. In fact, BDRP uses of recombinant techniques are with the goal of producing a less virulent strain which may be more safely used in the laboratory or for vaccine development. Section 3.3 and Appendix 10 discusses the many safeguards which preclude the development, let alone the release, of "deadly" recombinant organisms.

27-6b Comment: Genetic engineers are cloning previously unattainable quantities of "traditional" pathogens.

27-6b Response: Comment is incorrect. The implication that genetic engineering is being used to enable the production of large quantities of pathogenic organisms by the U.S. is not true. See response to comment 27-6a. In the original reference from which the commentor took the thought, the use of these words referred to the danger that a hostile part might perform these actions.

27-7 Comment: Using recombinant DNA technology, it is now possible to develop a nearly infinite variety of "novel" designer biological warfare pathogens never before seen. The DOD report summarizes: [new advances in biotechnology]...permit the elaboration of a wide variety of 'novel' warfare materials...The novel agents represent the newly found ability to modify, improve or produce large amounts of natural materials or organisms previously considered to be militarily insignificant due to problems such as availability, stability, infectivity and producibility.

27-7 Response: While this statement might be theoretically true, the U.S. is not investigating such novel agents for offensive purposes. The report was citing the theoretical risk to the U.S. of such an action by an adversary. See response to comment 27-6a.

27-8 Comment: As noted, this research involves numerous bacteria strains such as *Salmonella marcescenes,* and *Yersina pestis,* numerous viruses including Rift Valley fever, Yellow fever, poliovirus, Ebola and Marburg viruses and human retroviruses.

27-8 Response: Comment noted. Presumably *Salmonella mascescenes is* either *Salmonella sp* or *Serratia marcescens,* neither of which is part of the BDRP Polioviruses and retroviruses are not now and never have been part of the BDRP.

29-5b Comment: The CRG contends that the testing of aerosols of biological warfare agents ... should be discontinued.

29-5b Response: The U.S. is not "testing of aerosols of biological warfare agents," but rather, as needed, is testing equipment, materiel, vaccines, etc., by exposure to aerosols of potential biological warfare organisms/toxins in small, sealed chambers inside enclosed laboratories under strict biocontainment conditions. Also see response to comment 32-1b.

Sub-category B - Issues not specific to NEPA

33-5 Comment: Finally, if you read the Salt Lake Tribune this morning, you understand that the Army--according to its own Science Board ad hoc subgroup--has not been able to demonstrate any threat from foreign germ warfare.

33-5 Response: This comment refers to a Salt Lake City Tribune article on an Army Science Board report on the BDRP. The comment is a misstatement/misinterpretation of that report. Adequacy of threat information is not a subject of this FEIS. This comment misinterprets the ASB report; the full quote should be:

"the definition and analyses of BW threats are more difficult than for the more tangible, visible, and unitary hardware weapons that typically have long development cycles. Therefore, somewhat different ground rules regarding the certainty of information might have to be adopted to avoid serious underestimates of BW capabilities. Conclusion: An adequate definition of the BW threat, to include an assessment of the vulnerability of the U.S. Armed Forces and civilian populations of the U.S. and its allies, does not presently exist."

The issue of whether there is or is not now an immediate biological warfare threat is a public policy or a national defense issue, and not an environmental issue.

45-3 Comment: I think we could also refer to the fact that no legitimate and adequate threat assessment has been conducted. So, so much for yellow rain and for anthrax outbreaks in the Soviet Union, it's clear that the Army with its own evaluation, doesn't understand just what the threat is. So what is it that we are doing this defense against?

45-3 Response: Adequacy of threat analysis is not a subject of this FEIS. Comment seems to be referring to an article which appeared in the Salt Lake City Tribune 19 September 1988, see comment and response 33-5.

42-2 Comment: Quite frankly, I'm not sure of the absolute need for the biological testing. As I read from the Tribune story this morning, the military has yet to prove an actual need for all of this defensive testing.

42-2 Response: See response to comment 33-5 above.

27-29 Comment: An important change in the scale of the BDRP would be the requirement that all BDRP researchers and research locations keep a careful inventory of all BDRP pathogens.

27-29 Response: Such an inventory would not change the scale of the research and would not affect any impacts on the environment. The development and maintenance of such an

inventory, therefore, was not considered to be a significant consideration in this document. BDRP cultures are not unique and do not differ in any way from cultures maintained or stored at dozens of university and private laboratories.

27-30 Comment: Additionally, no new pathogens should be investigated by the BDRP unless there is some intelligence that there is a real need for defensive research into such pathogens.

27-30 Response: The issue of whether there is or is not now an immediate threat with biological and toxins is not an appropriate issue for consideration in this BDRP-EIS. Furthermore, the mission for the BDRP includes the capability to respond to known and potential biowarfare threats and to prevent a technological surprise (see Section 1.4). Also see response to comment 24-15.

38-6 Comment: Why can the US and USSR not establish a mechanisms for mutual monitoring of biological warfare research? This appears to be working with nuclear arms research. Similarly, it would seem to be the best way to insure that biological agents were not developed or used for warfare purposes, a goal that should be universal.

38-6 Response: The goal of mutual trust and monitoring is an admirable one. It is however, an international relations and arms reductions issue, not a NEPA consideration, which is the focus of the EIS. It is not clear in any case that such an agreement would preclude defensive studies such as those conducted now in the BDRP by either the U.S. or other countries.

31-2 Comment: Since the proposed BATF at Dugway is a critical part of the BDRP, we suggest that all public comments, verbal and written, that were submitted in the DEIS process for the BATF be included as official comments on the BDRP DEIS as well.

31-2 Response: Such blanket inclusion is not an appropriate NEPA procedure. Numerous comments have, however been duplicated because their originator re-submitted them to the BDRP DEIS. Such comments which appeared to have BDRP relevance were incorporated in this Final EIS.

31-5 Comment: DEIS fails to address, except in the context of the BW Convention, the absence of a no first use policy for BW agents.

31-5 Response: The U.S. is in full compliance with the BWC. BW weapons and stockpiles were destroyed following the disestablishment of the Biological Warfare Laboratories 19691972. The destruction of all stockpiles of biological or toxin agents maintained in support of operational plans and their associated munitions was completed on October 18, 1972, and the destruction or conversion of all delivery systems designed to use biological agents or toxins was accomplished on January 21, 1974. See Appendix 1. Because the United States renounced the use of lethal methods of bacteriological/biological warfare in 1969, and possess no biological weapons in any case, the absence of a no first use policy is a moot point.

31-7 Comment: DEIS fails to explain the rationale for increased contracting of BW research.

31-7 Response: The rational for contracting BDRP research is discussed in Section 2.5 of the FEIS, and is independent of the magnitude of the extramural program. In most cases, the proposals which are funded are extensions of pre-existing research work carried out at the same location, by the same research teams utilizing the same organisms and techniques which were used before BDRP contracts were even considered. Also see responses to comments 27-15, 27-31a and 31-4b.

31-9 Comment: DEIS does not address provisions for release of information to the public about BDRP or provisions for scientific peer review of BW research activities.

31-9 Response: Such provisions do not affect the environmental considerations of the BDRP. As stated in Section 2.1, the BDRP is an open, unclassified program. Information regarding the BDRP is provided to Congress annually (see Section 2.3). BDRP researchers routinely publish results of their efforts in peer- scientific journals and present the work at national and international meetings.

24-19 Comment: In sum, the DEIS shows that the BDRP is narrowly focused on a small part of the BW problem, and there is no recognition of the need to ensure that the program fits constructively into the larger picture with regard to safeguarding the global environment. A large number of scientists and members of the public are seriously concerned about this. We want to see the BDRP reviewed with an open mind, and modified appropriately, so that it can make an unambiguous contribution to real national security.

24-19 Response: The BDRP is a research and development program

(see Section 2) designed to develop ways of protecting U.S. troops from an adversary's use of biological organisms or toxins. What other "parts of the BW problem" the commentor is referring to is not specified, but presumably could/would entail diplomatic/political initiatives and considerations. As such, these are outside the purview of the biological defense research program and therefore beyond the scope of the EIS.

39-9 Comment: A deep impact of the proposed program would be to create a group within the military whose career interests would be served by expanding the biowarfare horizons and whose personal interests would be ill served by restraint on this potential new sort of arms race. Such a development would not be in the national interest. The potential of such a development should not be overlooked. Analogous situations currently exist in nuclear weaponry and in the Star Wars (S.D.I.) program.

39-9 Response: This comment is not an appropriate NEPA issue. There are no biological weapons, nor plans to develop any. The research is in the hands of medically-trained personnel with no weapons orientation.

14-8 Comment: Among representatives of the civilian scientific and medical communities, a central area of concern about the BDRP pertains to the intent and the hazards of biosafety level 3 (BL3) and biosafety level 4 (BL4) research. The DPEIS describes the policy of the United States to continue observing the 1972 Biological Weapons Convention banning offensive research. The DPEIS states, "Development of a more virulent strain of a pathogen is specifically prohibited under any circumstance, and is not the goal of any BDRP effort." (DPEIS p. 5-9) This statement is somewhat reassuring, but does not entirely remove our concerns.

14-8 Response: Comment noted. DOD is not developing more virulent strains of organisms by genetic engineering or any other mechanism. See Appendix 10 for a discussion of safeguards on genetic engineering.

30-6 Comment: Finally, again in the spirit of public safety not just in Utah but throughout the United States, we are concerned about the entire scope and direction which the BDRP has taken over the past few years. The United States has formally renounced the use of biological warfare agents since 1969, and joined with more than 100 other nations in signing the 1972 Biological Weapons Convention, which prohibits any stockpiling of or offensive research on BW agents. We do believe that the Department of the Army has no plans for offensive BW research;

however, spending on BW research has increased from $14.9 million dollars in fiscal 1981 to $73.2 million dollars in fiscal 1987. We feel that the justification given for this massive increase is not valid, and we fear that other nations, when viewing our greatly increased activity, will respond in kind and set off a new round of arms escalation.

30-6 Response: Expansion of the research efforts merely means that more work is being performed in more areas, not that the character of the work is substantially changed. Also, see responses to comments 33-5, 26-2 and 27-15.

39-7 Comment: The program includes a large non-classified component which is to involve contracts administered by the Army and for which it has been argued that these contracts are essentially as benign as those administered by the National Institutes of Health or the National Academy of Science. Army contracts typically include a clause which requires the contractee to submit to the Army a summary or a copy of work before that work is to be published or presented at a meeting. The contracts specifically retain for the Army the right to classify or to otherwise prohibit public dissemination of the information.

Pre-publication notification is never a requirement for money awarded from the N.I.H. and N.S.F.

The ability to prohibit public dissemination of information (contained in each contract to be issued under the proposed program) gained in the biowarfare program would allow a defensive program to shift into weapons development at a moments notice, with no external control on that decision. External agencies, domestic or foreign, would have no way of knowing if information was being censored.

39-7 Response: The commentor makes an incorrect statement, and then builds a case based upon it. Classification of the program, if it occurred, would not be a NEPA issue since classification would not affect health and the environment and other NEPA issues. However, as stated in Sections 2.1 and 4.2.2, the BDRP is an open UNCLASSIFIED program and only results which impinge on National Security might be subject to classification. The clause in Army BDRP contracts related to presenting or publishing data is not for classification of data and the report, but for comment only. The pertinent section of the standard contract clause reads: "Manuscripts intended for publication in any media shall be submitted .... simultaneously with submission for publication. Review of such papers is for <u>comment</u> to the Principal Investigator not for <u>approval</u> or <u>disapproval</u>."

26-2 Comment: Next, DEIS section 2.1 cites the Sverdlovsk incident and allegations of the use of toxins in Southeast Asia and Afghanistan by the Soviet Union as evidence of a resurgence of interest in biological warfare agents by the supposed adversaries of the United States government. Yet all of the scholarly literature written on these subjects agrees on the points that "yellow rain" was nothing more than bee feces and that the Sverdlovsk incident was produced by contaminated cattle feed. Since these matters are discussed at greater length in my 1986 *Article* and in the recent book by Piller and Yamamoto entitled *Gene Wars* (1988), I will not bother to review that literature in detail here. Suffice it to say that the Department of Defense can not produce a realistic assessment of the alleged biological weapons threat to the United States of America when its only two unclassified pieces of evidence have been definitively proven to be erroneous. How can the American Public rely upon the integrity of the DEIS when it is Premised upon such faulty assumptions?

The entire DEIS itself has been seriously compromised by dredging up such unsubstantiated and spurious allegations that have now been completely discredited by the scientific community. Whoever on your Staff was responsible for drafting these sections of the DEIS did no good service to the Department of Defense in reproducing such disingenuous allegations here. The DEIS's reliance upon these thoroughly debunked allegations simply raises the question of whether the Department of Defense is purposefully creating the specter of a Soviet offensive BW threat in order to justify its own development of retaliatory/offensive BW "deterrents" (to use the DOD's own term) under the guise of the BDRP.

26-2 Response: The Sverdlovsk incident and "yellow rain" were presented as background information and as examples of incidents responsible for renewed interest in an adequate biological defense research program. Multiple factors enter into determining the needs of the BDRP. See Sections 1.1, 1.4 and 2.1. In the final analysis, the U.S. Congress specifically approves funding for and authorization of the BDRP (see Section 2.3) and a report on the biological defense research program is presented to congress annually in accordance with PL 91-121, as amended by PL 91-441. We again note that this is the only U.S. military program in which the term "defensive" does not mean a weapon to be used in a defensive mode. As used in the BDRP, "defense" is restricted to detection, protection and medical response to enemy weapons use.

39-13 Comment: The State Department of the U.S. still maintains that the yellow rain of the Soviet Union that occurred in southeast Asia was a biological warfare effort by the Soviet Union. A great deal of independent scientific investigation has appeared in literature. I assume that since it's so close to

each of your interests that you have studied this independent scientific literature and I would like quickly each of you to say, each of you who are willing to say, whether you believe the independent scientific literature which was very carefully done and has never been refuted or are you afraid to say something against the government because as government employees it is very difficult for you to have integrity as scientists or even be in a conflict. So I would like each of you to state a position on the yellow rain. Is the yellow rain Soviet biological warfare or is the independent investigation conducted by -- the question is, to ask each, who is willing to speak on their scientific evaluation of yellow rain, and to speak to their conflict between the Meselson's review and the government's position. Are they willing to say that the government was wrong?

39-13 Response: Commentor's questions and ideas are noted. They raise questions not within the scope of the EIS. We must note that the BDRP is not directed against the actions of any single group or nation, including the U.S.S.R. See response to comment 26-2 above.

29-1c Comment: As the Draft EIS notes, the rationale for this expansion is based on claims that I) the Soviet Union maintains an offensive biological warfare capability; ii) the Soviet Union has produced toxin weapons for use in Afghanistan and Southeast Asia; iii) that new biogenetic technologies such as genetic engineering could be used to construct novel biological agents and toxins.

The Draft EIS makes no mention of the fact that claims I) and ii) are both highly controversial and are not presently supported by any other nation. The Soviet Union has recently provided medical evidence against the U.S. claim that the outbreak of anthrax in Sverdlovsk was caused by a release of the organism from a biological warfare facility. Many experts see the second claim as entirely discredited at this point as a result, in part, of new evidence generated by the United States and other governments. The Draft EIS exhibits considerable bias in using sources that support claims I) and ii) while ignoring entirely the body of evidence against those claims.

29-1c Response: See responses to comments 26-2 and 39-13.

41-1b Comment: Need. If dangerous research is to be justified, some need must be shown. There has never been any verifiable and believable evidence suggesting offensive biological weapons are being developed by other countries. Phenomena cited as evidence of biological weapons testing have been repeatedly shown to be bogus. An example is "yellow rain". I was appalled to find the "scientists" at the Tooele hearings had not heard of Meselson's

review which showed irrefutably that yellow rain is/was a natural phenomenon and not the result of biological weapons testing. The treaty of 1972 banning the development of biological weapons has so far been honored by both sides. We need to continue to strictly adhere to the treaty in order to avoid sparking a new arms race.

41-1b Response: We agree that the U.S. and other *nations* need to continue to adhere strictly to the BWC. The U.S. is in full compliance with the BWC. Also, see responses to comments 26-1, 26-2 and 22-4a. While some of the organisms and toxins studied in the BDRP are classified as high hazard organisms, this classification is for purposes of ascertaining the appropriate safety level (BL1 thru BL4) for the conduct of the studies, not, as implied in this comment, that the research is dangerous.

53-1 Comment: We have been asked to keep our comments limited to the DEIS and I think that's almost impossible because the DEIS has said that this is safe and I think the questions we have to ask ourselves are a little different than just is it safe. I think we have to think a little bit about Nuremberg and the responsibility we have to address our government when we feel it's in error and we feel it is doing something that is horribly and terribly wrong.

I would like to ask all of us in this room to look into our hearts. Just turn off our minds just a little bit and look into our hearts for a moment and say, isn't it time we stopped. Could we please just stop. For years and years and years the men have been out on the battle field trying out their new toys, hand-to- combat with each other and now we have moved into an era where we are talking about annihilating whole segments of the population on purpose, whether its defensive or offensive, and the defensive soon becomes offensive. We have already seen that happen in the nuclear arms race. Isn't it time for us just to say, no. Let's not do it any more. Let's not try out this toy, let's not see if it works. Let's just leave it alone and in place. We've already -- you know, we tried out a new toy 43 years ago and we don't want to talk about that tonight because it's not in the DEIS, but we tried out a new toy 43 years ago and we are the only country on this planet that has ever killed civilian population with a nuclear weapon. We have done that. That's our holocaust. That's our responsibility and under Nuremburg I believe I am required as a citizen to stand up in any forum, this forum or any other forum and say, no. We will not do it with my approval and I ask you to look into your own hearts. Do you really want to continue? Do you really want to keep playing these dangerous games? Couldn't we just stop. Thank you very much.

53-1 Response: Comment noted. The statement appears to be a condemnation of biological warfare, with which the DOD agrees completely. The remainder of the statements are beyond the scope of the BRDP-EIS.

55-2 Comment: The basic question should be, do we need this? It says in this environmental impact statement that basically that one of the reasons for it is basic scientific research. Surely this can be done by civilians and done on diseases that already exist, such as diabetes, AIDS, etc., that have no known cure.

55-2 Response: The need for the BDRP is determined by multiple factors, followed by authorization and funding by Congress. See Sections 1.3 and 1.4.

32-1e Comment: In any case it is unconscionable that DOD be allowed the capacity to develop new pathogens in order to test our defenses against them.

32-1e Response: Comment noted. The DoD does not develop new pathogens in order to test our defenses against them, or for any other reason.

45-2 Comment: Then there is a science, an Army science report, which I would love to hear an explanation from our distinguished guests up on the podium about the qualifications of personnel, the inadequate number of doctorate level personnel, to conduct this program, and the inadequate training of the rest of the personnel involved.

45-2 Response: This comment utilizes fragmentary ideas and selected words out of context from the Army Science Board Report. The implied "qualification of personnel, the inadequate numbers of doctorate level personnel to conduct this program" referred to recognized deficiencies in doctorate level personnel at CRDEC in terms of modern biotechnology - a deficiency that was being corrected at the time of the ASB's report (page 7 of report). "The inadequate training of the rest of the personnel involved" referred to comments on training and doctrine given to troops at large, which is not BDRP activity.

12-1 Comment: However, there are some disturbing aspects to it with respect to its tone and purpose. The tone of the document suggests that anyone who questions the safety of the program are

misinformed, ignorant or basing their position on emotion rather than fact.

The DEIS reads as public relations document rather than an assessment of impacts from continuing the BDRP. Since the BDRP is a Congressionally mandated program, the DEIS does not need to present a defense of its purpose nor does it need to be condescending toward critics and reviewers. Yet it does both.

12-1 Response: Comment noted.

30-2 Comment: We are particularly concerned with the attitude expressed throughout the DEIS that opposition to the BDRP as currently operative is based more on public perception of risk than on true risk, when in fact the problem seems to be more one of how do we assess and quantify these potential risks in order to compare them to the more easily quantified benefits. The attitude appears throughout the statement that those who question the safety of the program are operating on misinformation, emotion, ignorance, or other less than admirable motives. ("An evaluation complexity arose, however, because virtually all of the significant adverse impacts were either perceived, rather than actual, or were associated with a potential accident or incident. Professional scientific scrutiny by the interdisciplinary team did not lend credence to the expressed fears or hypothetical risks", (page 1-15 to 1-16; see also pages ES-5, 42, 4-3, 6-8, A6-6, among others).

30-2 Response: Comment noted. Perceived risks versus actual risks were presented to attempt to put the analysis in perspective. Evaluation complexity arose because no substantive impacts could be identified.

39-10 Comment: The proposed program is likely to have adverse economic effects and adverse effects on the public health via the redistribution of resources and research talent in the biological sciences. Biotechnology is currently a very bright spot in the U.S. economy and has great potential. Military involvement is likely to distort the competitive market, i.e. to condition what types of projects are worked on and thereby channel resources away from projects which would otherwise receive more attention. The Biowarfare program's advocates will doubtless mention the possibility of spin-offs. The military is not however the most competent agency to direct Biotechnology in this country, far more expertise exists in the N.I.H. and the N.S.F.

39-10 Response: Comment noted. There is no U.S. "biowarfare program." Comment is highly speculative and no response is required.

39-11 Comment: The proposed program would be highly divisive in the community of molecular biologists. Many would refuse to cooperate with the proposed program and even with fellow academics or industrial microbiologists who take part in it. The effects of this loss of synergy on the research community would be hard to quantify, but they would be large. The result would be a less productive scientific community as a whole, a relative loss of economic advantage and quite possibly a lessened ability for the accomplishment of those goals of the proposed program that are benign and within the confines of the treaty prohibiting Biowarfare.

39-11 Response: The BDRP is an ongoing program. Such speculative divisiveness is not apparent.

45-4 Comment: It's also interesting to note that we are throwing money at an unprecedented rate at the Biological Defense Program. In fact, we have seen an increase of 500 percent since Ronald Reagan took office and the analysis of the internal document, Army document, says, "We cannot assess with confidence whether the Army assigned adequate priorities to biological defense compared to other needs."

Well, it seems that the money trail that it indicates that you have thrown an awful lot of emphasis on this program without really knowing where it is going.

45-4 Response: Presumably, the documents referred to in the commentor's first remark are those referred to in the local media just prior to the public meeting at Tooele, 19 September 1988. These documents purportedly report prior open-air tests during the biological warfare program (prior to 1969) with pathogens, as well as with simulants for the BDRP up to the present. If by quoting the following from the Army Science Board is meant to imply a waste of resources ("We cannot assess with confidence whether the Army assigned adequate priorities to biological defense compared to other needs"), it is a misinterpretation of the report. The quote (page 5 of report) was meant to imply a need for more emphasis on training and detection, not that resources were being wasted. The report continues "However, based on what we have learned during this study, it is our collective judgment that in the past and at present inadequate priority and resources have been assigned to the total BD program, particularly to training and to R&D aspects of the detection of BW agents and other non-medical issues." The gist of the report was the reverse of that implied by the commentor.

24-6b Comment: The need for field testing is not obvious and is never discussed in the DEIS. Since all medical testing, which unquestionably requires the use of pathogens, is done at USAMRIID (or so the DEIS suggests), there is no clear case for any testing at the Dugway Proving Grounds except with innocuous agents, and indoors.

24-6b Response: Comment is incorrect. See responses to comments 30-7 and 24-6a, Sections 2.4.3, 3.2.1.6, 4.2.2, and Appendix 4 parts 1.2 and 1.3.

16-1 Comment: Thank you. I am a member of the General Assembly and the Environmental Matters Committee, so it's real important to me to hear the decision, especially when it came down from Frederick here.

And, as Mr. Patrick said, it's important to say how long you've been at Frederick, and I've been there since 1941. That's third grade. Anybody who's been there since the third grade qualifies to be called "home town boy."

So, I've been there a long time and decided years ago to be a farmer. And, as such, our farm operation is only three or four miles from Detrick. In those years, it was called the "Biological Warfare Center."

And in those days, too, as a Boy Scout growing up in the community, we were introduced to Detrick center. And all of us were back in that World War II period, I think you very graciously provide sound effects today to back that up.

But we all have the highest respect for what's been going on and the admittedly necessary strategies and investigations, as far as national defense protection.

So, I think the majority of our community is convinced of the necessity. However, we do hear of a lot of problems. Now, when I was growing up back there in Frederick on the farm and J.C. was one of my best friends, whom I just saw here again today, and was in the high echelon of Detrick echelon in the safety field.

And we always admired his courage in working with these highly infectious diseases. And we followed this all the way through. And having a close friend like that made it more prominent, as far as we were concerned, so it was first person then. It made the use imminent.

However, in those early years, there was also a storekeeper up on 6th Street, named Howard Dinterman, and he worked at Detrick part-time. And I could stand corrected, but I think 24 years ago, almost to the day, he was infected with staphylococcus, enterotoxin B.

And it took 20 years to have the admission that this was an infection that did take place at Detrick. 20 years to admit that it had been committed and there have been settlements.

As a matter of fact, the settlement was to say, "Okay. $60,000. $7,000 a month and a van." That's what the settlement was. And this has -- Lena Dinterman is completely satisfied.

As far as Mrs. Dinterman is concerned, it is catastrophic to her life. She's been taking care of her comatose husband for 24 years.

And the point I'm making is the importance we have in Detrick. The importance we hear is not to be omitted, but there's also an importance for one person that falls through the cracks, just one person, this one widow. And she did get a settlement.

But now, now, three weeks ago, she get a letter from the Claims Division of Workmen's Compensation that says, "When your husband dies, you have to return the van."

Now, here's an 30,000-dollar van that -- our government to her is Detrick, the President of the United States, the Workmen's Claim Division, and me. We're the government. We're all lumped in. "We have done" her "dirty," she says.

And so that one van, for them to say, "Okay. You take back my van," she's going to sue us for 15 million dollars. Now, what I'm asking is -- these meetings, I think, are very important.

And have them anywhere you want. Have them in places like this that it takes a farmer like me two hours to find. That's okay.

It's necessary for national defense. But for the sake of P.R. of Detrick and the United States government and cracking down on the miscarriage of justice, use your influence, please.

Use your influence to allow Lena Dinterman to keep her van, to keep her lusting 15 million dollars which she'll probably win.

16-1 Response: Comment noted. This is not a BDRP EIS issue. The Howard Dinterman case involves the U.S. Department of Labor and not the U.S. Army. Mr. Dinterman was medically retired in 1970, as a result of slipping on wet floor and re-injuring a hip, which was somewhat crippled from a childhood polio attack. Subsequent claims to the Department of Labor citing this hip injury and an earlier exposure to staphylococcal enterotoxin B resulted in the initial U.S. Department of Labor award to Mr. Dinterman. As reported in October 7, 1988, Frederick News-Post, the U.S. Department of Labor and Mrs. Dinterman have resolved their differences.

30-10a Comment: Any allegations of non-adherence to the 1972 Biological Weapons Convention should be turned over to an appropriate agency, the United Nations Security Council, as provided for in Article VI of that treaty, for open investigation. It is unfair and unjust to make such allegations as justification for increased BW research activities, yet to refuse to back-up the allegations by claiming that the information to do so is classified.

30-10a Response: United States concerns regarding Soviet compliance with Articles I, II and III of the Biological Weapons Convention (BWC) have been expressed to the U.S.S.R. under the provisions of Article V of the Convention, which requires that "States Parties to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention." The "Sverdlovsk incident" and use of toxins mentioned in the DEIS were presented as background information in the context of renewed interest in an adequate BDRP (see Sections 1.1, 1.4 and 2.1) and represent only two of the unclassified reports of increased offensive biological warfare activity among both signatories and nonsignatories to the BWC. The decision to continue a biological defense program is not based solely on the two incidents referenced. The U.S. Congress specifically approves funding for and authorization of the BDRP, (see Section 2.3) and a report on the BDRP is presented to Congress annually in accordance with PL91-121 and PL91-441. The BDRP grew in funding from 1980 to 1984 but has remained consistent since that time in terms of constant dollars. The program has not changed in terms of the types of studies conducted nor the nature and biohazard of organisms/toxins under consideration. Also, see response to comment 26-2.

Sub-category C - Biological Weapons Convention Issues

41-1d Comment: Political consequences. Any secret research into biological weapons will enhance tensions between competing nations, increasing the likelihood of a biological arms race. As long as all research is absolutely shared among countries, and as long as there is no perception that offensive biological weapons are being researched, then perhaps we can avoid such an arms race. Offensive and defensive research can not be distinguished in most cases, thus any research can be perceived as potentially offensive. Lets take a stand and renounce <u>all</u> biological weapons research. We should take every opportunity to prevent the development of weapons which every sane person agrees have no place on this earth. The DEIS refers to the BDRP as a research <u>and</u> development program. As such it must be stopped.

41-1d Response: It is agreed that secret research into biological weapons would enhance tensions between nations. DoD does not conduct research into biological weapons (secret or

otherwise). See Sections 2.1 and 4.2.2. The BDRP is a research and development program of defensive countermeasures to potential biological warfare threats. Countermeasures do not include an offensive capability. See response to comment 22-4a for a discussion of the distinction between offensive and defensive research. Also, see response to comment 26-1.

26-1 Comment: For example, right at the very outset of the DEIS, Section 1.1 directly raises the issue of BDRP compliance with the BWC in the following words: "The Department of Defense (DoD) cannot ignore completely the possibility that BW threats exist and fail to provide any deterrents to their potential application, much less fail to provide a reasonable level of protection to U.S. forces." (Emphasis added.) (page 1.1). Section 1-1 clearly raises the question of whether or not the BDRP has for its purpose the development of offensive BW threats to serve as "deterrents" to an alleged or supposed threat by an adversary of the United States. Moreover, section 1.1 makes it quite clear that the development of such "deterrents" is a DoD objective that is quite different from providing "a reasonable level of protection to U.S. forces." Clearly, "protection" is permissible under the terms of the Biological Weapons Convention. But since the DEIS distinguishes "protection" from "deterrents," then obviously the DoD intends to mean that such "deterrents" are something beyond mere "protection." If so, then there exists a distinct possibility that DOD research, development and testing of such "deterrents" would violate the BWC.

For example, in the areas of chemical weapons, nuclear weapons, and conventional weapons, whenever the Department of Defense has talked about developing "deterrents" to their respective uses, it has always meant the research, development, testing and deployment of chemical, nuclear, and conventional weapons that will be used in retaliation in the event an adversary should resort to the first use of such weapons. Likewise, the entirety of the DEIS produces the strong implication that the Department of Defense is seriously contemplating the development of biological weapons in order to serve as "deterrents" to their expected use by an adversary of the United States government. In any event, a reasonable person reading the DEIS could certainly conclude that the Department of Defense is moving toward the development of BW "deterrents" that would be illegal under the terms of the BWC. At the very least, I suspect that is how the Soviet Union will read the DEIS. What concrete assurances can the DOD provide to the American people and to the Soviet government that this is not the case?

26-1 Response: The BDRP is an open UNCLASSIFIED program, (see Sections 2.1 and 4.2.2). The BDRP is a research and development program of defensive countermeasures to potential biological warfare threats. Countermeasures do not include an offensive

capability and as stated in Section 5.2.1.4, "Because BW is the only threat for which the U.S. possesses no capability for retaliation in kind, the existence of an active defensive research program serves as the only deter NT (emphasis added) to potential adversaries in planning for indiscriminate use of bioweapons in operational war plans." The comment suggests that the BDRP somehow involves defensive weapons. There are no weapons. We agree that there is no logic in suggesting that a biological WEAPON could be used in a defensive mode only. The defense utilized is of two types, the detection of weapons usage, and the development of medical diagnosis and treatment, including immunizations. It could not be less threatening to a prospective enemy, while still providing some minimal protection to U.S. forces.

26-6 Comment: In this regard, the various federal laws, statutes and regulations mentioned in the DEIS are completely inadequate to implement the strict terms of the Biological Weapons Convention for the reasons explained in my 1988 Testimony and in my 1987 Memorandum that I prepared on behalf of the Committee for Responsible Genetics, copies of which are attached to this letter. Nowhere in the DEIS has your Staff indicated that qualified and independent legal experts have vetted the BDRP in accordance with the strict terms of the BWC, or that such oversight and examination would be conscientious, continuous and comprehensive. What assurances do the American people have that the Department of Defense is scrupulously adhering to the terms of the Biological Weapons Convention other than the self- DEIS statements to that effect?

26-6 Response: As stated in the BDRP-DEIS Section 1.6.2, "The BDRP is conducted in strict adherence and compliance ... with the provisions of the BWC." The U.S. Congress specifically approves funding for and authorization of the BDRP (see Section 2.3) and a report on the BDRP is presented annually to Congress in accordance with PL91-121, as amended by PL91-441, (see Section 3.3.4.2).

26-7 Comment: I would submit that if the Department of Defense wants to obtain public acceptance and support for the BDRP, then it must establish both external and internal procedures whereby independent lawyers, in addition to independent scientific experts, can guarantee and assure to the American people that the BWC is being strictly adhered to throughout all aspects of the BDRP. Since the BDRP is generally not classified, such procedures should not be too difficult to set up, assuming the DOD really wants to. I would be happy to meet with you and your Staff in order to establish such procedures that might provide some degree of credibility with respect to BDRP/BWC compliance in the eyes of the American scientific and legal communities.

26-7 Response: An oversight group established to win public support for the BDRP is not considered to be necessary nor appropriate.

26-10 Comment: Proceeding sequentially through the DEIS, I next have serious concerns with respect to BDRP research going on at secondary sites outside the territorial jurisdiction of the United States. I would like to know whether or not and how the Department of Defense is making sure that such research is being conducted in accordance with the strict terms of the Biological Weapons Convention irrespective of whether the host country is a party to the BWC. There is a potential for the Department of Defense to take the position that it is not responsible for absolutely guaranteeing that BDRP research conducted in countries not parties to the BWC is consistent with the terms of the Convention. Is this the case or not?

26-10 Response: All research funded by the BDRP is conducted in full compliance with the laws of the U.S., as well as the laws of the country in which the studies are conducted. The BDRP is not circumventing the BWC or any U.S. or international law through the use of contractors or by any other means.

26-11 Comment: For example, I am especially concerned that BDRP research is currently taking place in Liberia, which is not a party to the BWC, as indicated in Appendix 3, page A3-4. As you undoubtedly know, Liberia is ruled by a ruthless dictator named Samuel K. Doe, who is kept in power by the Central Intelligence Agency and the DOD Army's Special Forces. What assurances can you provide to the American people that BDRP research currently being conducted in Liberia is in full compliance with the terms of the BWC when Liberia is not a party to the BWC? Such questionable foreign BDRP research contracts create the strong suspicion that the Department of Defense has been purposely letting out BDRP contracts to sources in Liberia and other non-states for the express purpose of circumventing or undermining the stringent controls of the BWC.

26-11 Response: The studies in Liberia are conducted under contract to Columbia University, a U.S. organization, and not under contract to the nation of Liberia nor a Liberian organization. The studies consist of collection of serum from patients who have recovered from Lassa fever and from which gamma globulin has been recovered and used in the treatment of Lassa fever patients elsewhere in Africa in joint studies with the CDC. The studies conducted in Liberia and in any other foreign country are conducted solely for the purposes of developing defensive measures.

26-15a Comment: DEIS Appendix 4, section 3.2 states that with respect to toxins, research, development and testing activities include: "structural analyses to identify the parts of a toxin responsible for immunity." Yet, since that is the case, then the same "structural analyses" can also be used to "identify the parts of a toxin responsible for" pathogenicity. Once again, such dual-use studies and activities raise serious questions of BDRP compliance with the BWC. What assurances can the DOD provide to the American people that these "structural analyses" are not being put to prohibited purposes?

26-15a Response: The EIS and the BDRP must, by law and regulation, examine proposed actions or activities, not knowledge or possibilities. The activities proposed do not contain any that would violate the BWC, nor has any BDRP activity ever done so. At the basic research level, the techniques and approaches needed for offensive versus defensive research are similar, but as the work progresses toward more applied aspects, defensive versus offensive is readily separable. As stated in the BDRP- Section 1.6.2, "The BDRP is conducted in strict adherence and compliance ... with the provisions of the BWC." The U.S. Congress specifically approves funding for and authorization of the BDRP (see Section 2.3) and a report on the BDRP is presented annually to Congress in accordance with PL91-121, as amended by PL91-441, (see Section 3.3.4.2). This annual congressional report summaries studies such as those described, and the future plans for such projects are presented to Congress in additional presentations and reports. See also response to comment 22-4a for a discussion of some of the many differences between defensive and offensive research.

26-15b Comment: A similar criticism applies to a DOD contract here at the University of Illinois for *The Development of a Toxic Knowledge System (viz.,* DAMD 17-87-C-7114).

26-15b Response: The implied suspicion (of DOD motives) in this comment is not an appropriate NEPA issue. Contract DAMD 17-87-C- involves the development of relevant information extracted from the literature in a readily retrievable format to be of practical use to medical department patient care personnel. The correct title is *The Development of a Toxin Knowledge System.*

57-1a Comment: As are most citizens in America, I am opposed to the development and use of biological weapons.

57-1a Response: We share in the opposition to the development and use of biological weapons. The U.S. considered biological warfare to be repugnant to the conscience of mankind and

therefore unilaterally renounced such development and use of biological weapons in 1969 and were prime signatories to the BWC, see Appendix 1. The United States is not conducting a biological weapons program. The U.S. is in full compliance with the 1972 Biological Weapons Convention and is conducting only a biological defense research program, (see Section 1.6.2).

57-1b Comment: I realize, as Ollie North stated in the Iran/Contra hearings, that "we live in a dangerous world" and that, as a result, we must maintain a constant state of readiness to defend ourselves against any act of aggression. But I can't think of one such act that would require retaliation with biological weapons.

57-1b Response: See response to comment 57-1a.

57-1c Comment: There is no such thing as defensive war, but only retaliation, since first strikes are called retaliations for some great injustice, and since all actions in war are offensive. We are therefore in violation of the treaty governing offensive biological weapons when we create arguments in favor of the proliferation of defensive biological weapons. War may be a game to play, but we should not trifle with the treaty-making process, since trust, above all, is the basis for all world peace.

Due to their very nature, biological weapons are immoral; aggression against civilian population, especially in the case of genetically involved biological weapons is not war, but genocide. There may be no proud soldiers in acts of violence with biological warfare. And quite glibly, may I add, what is war without pride. What good is world domination if we can't feel glad about having it. What fun was it for Oppenheimer when, after being heralded for his advancement of nuclear technology and after the bombing of Hiroshima and Nagasaki he repented of his involvement in nuclear research.

57-1c Response: On the whole, this comment is not appropriate for consideration in this BDRP-EIS. Defensive biological weapons are not being developed in the implied sense of retaliation, and as stated in Section 5.2.1.4, "Because BW is the only threat for which the U.S. possesses no capability for retaliation in kind, the existence of an active defensive research program serves as the <u>only deterrent</u> (emphasis added) to potential adversaries in planning for indiscriminate use of bioweapons in operational war plans." See also response to comment 26-1.

57-1d Comment: Being less than an idealist, and knowing that governments are lastly concerned with wisdom, I understand that Utah will long be the home *of* the production and development of biological weapons. This being the case, I see it as essential that we maintain a thorough and constant state of readiness against local contamination from all strains stored in the state. We must be made aware or the risk to public safety should a leak of any level occur; our doctors must be made prepared to deal with all catastrophes.

However, this does not mean I will use any less of my power to defeat the proponents of biological weapons.

57-1d Response: No biological weapons are being developed or produced or stored in Utah or at any other location by the United States. The United States is not conducting a biological weapons program. The U.S. is in full compliance with the 1972 Biological Weapons Convention and is conducting only a biological defense research program, (see Section 1.6.2).

29-3 Comment: The only scientifically persuasive rationale for developing specific prophylactic measures is to protect personnel in defense laboratories and troops in combat in preparation for development and use of biological warfare agents. For this reason, this emphasis of the BDRP is provocative and destabilizing since it is likely to be construed by other nations as evidence for offensive intentions.

29-3 Response: This is a matter of opinion and not a substantial comment. See responses to comments 57-1c and 57-1d.

20-3 Comment: There is only one way to prevent a biological arms race: to halt biological warfare programs, particularly ones using genetic engineering, not only at Dugway but anywhere they are being carried out. There is no military defense against biological weapons. Our current program thus undermines the only restraint available: the Biological Weapons Convention.

20-3 Response: This comment is a matter of opinion. The long term prospects for biological arms proliferation must be considered in light of the pervasiveness of commercial biotechnology and the possibility that belligerents can apply it to warfare purposes. The United States has pledged not to do so as a matter of unilateral national policy and as a States Party to the Convention. As described in Section 2.2, the military defense against biological weapons involve development of methods of detection, protection and decontamination of potential biowarfare materials.

32-1a Comment: Although we recognize DOD's responsibility to provide defense against possible biological attack, we find their program to be flawed, hazardous and likely to break the constraints of the 1972 Convention.

32-1a Response: No data have been presented to support allegation of a flawed and hazardous program. As stated in the BDRP-EIS Section 1.6.2, "The BDRP is conducted in strict adherence and compliance ... with the provisions of the BWC." The U.S. Congress specifically approves authorization and funding for the BDRP (see Section 2.3) and a report on the BDRP is presented annually to Congress in accordance with PL91-121, as amended by PL91-441, (see Section 3.3.4.2).

22-4a Comment: We continue to harbor serious reservations about the wisdom of DOD pursuing the biological defense program. An aggressive strategy will strain compliance with the 1972 Convention on Prohibition of the Development, Production and Stockpiling of Bacteriological "Biological) and Toxin weapons and on their Destruction. As DOD admits, offensive and defensive biological warfare programs are indistinguishable at the research phase. We believe the United States should maintain a leadership position by avoiding any appearance of noncompliance with the Convention's provisions. The nation's defense posture is not served by weakening-the treaty.

Furthermore, nothing in the DEIS allays our concern that BDRP will metamorphose into an offensive program.

22-4a Response: At the basic research level, the techniques and approaches needed for offensive versus defensive research are similar, but as the work progresses toward more applied aspects, defensive versus offensive is readily separable. The implication that there is only a fine line between defensive and offensive research and that defensive findings may "easily" be converted to offensive use is patently untrue. During the former existence of a United States offensive biological weapons program, one of the first lessons learned was that a bacterial culture is not, of itself, a weapon. Thousands of person-years of effort went into the problem of converting cultures into weapons, and, while much was learned, hundreds of problems were also identified. To prepare weapons quantities of offensive agents requires massive facilities which DOD does not now have, delivery systems which no longer exist, and deployment and employment which ceased 20 years ago. Military training is now conducted in a fishbowl. Even if, as the allegation is stated, research of an offensive nature could be concealed in the U.S., then production surely could not, and neither could the integration of such weapons into military training and doctrine. This would appear to be an area in which the dispersal of research to many public entities subject to

their own public scrutiny makes it even less likely that any offensive program is being concealed. As stated in the BDRP-EIS Section 1.6.2, "The BDRP is conducted in strict adherence and compliance ... with the provisions of the BWC." The U.S. Congress specifically approves funding for and authorization of the BDRP (see Section 2.3) and a report on the BDRP is presented annually to Congress in accordance with PL91-121, as amended by PL91-441, (see Section 3.3.4.2).

22-4b Comment: DOD repeatedly stresses that the BDRP is only defensive. Yet no definitive barrier stands between defensive and offensive weapons. DOD defines the differences in terms of quantities. With microorganisms, large quantities can be grown very rapidly. We provide the following example.

For the bacterium which causes tularemia, *Franciscella tularensis,* DoD reports that a research program requires approximately 5 liters of cultured bacteria per week, while an offensive program would require 3634 liters per week. At first glance, it looks like a massive difference, more 726.8 fold to be exact. However, this increase in volume represents less than 14 doubling times. If the doubling time for the bacterium is a day, DoD could be up to offensive capacity in two weeks. In reality, doubling times are much shorter, often on the order of minutes or hours. With modern incubation techniques, culturing large volumes of bacteria can be accomplished with ease.

22-4b Response: Biological weapons development is not being done. There is a quantum leap in capability and accomplishment from producing large quantities of organisms or toxins to incorporating such quantities into an effective weapons delivery system. Such quantities are not being produced and weaponization is not being done. See also response to comment 22-4a.

39-8 Comment: The argument has been made by Army spokesmen that the proposed program will not involve weapons development "or anything like that" because the quantities of pathogens involved is anticipated to be "guise small." This argument is specious because microorganisms grow rapidly.

In the correct facility, a single organism could be grown into several tons in a matter of days. Such facilities are common in the context of pharmaceutical production.

39-8 Response: Biological Weapons development is not being done. There is a quantum leap in capability and accomplishment from producing large quantities of organisms or toxins to incorporating such quantities into an effective weapons delivery system. Such quantities are not being produced and weaponization is not being done. Size of cultures is only one - though

important - difference between offensive and defensive research. It should be noted that a culture is not a "weapon," no matter what its size. See responses to comments 26-2, 22-4a and 22-4b.

22-4c Comment: Therefore, we find it impossible to be sanguine about DOD's "defensive" plans.

22-4c Response: See responses to comments 22-4a and 22-4b.

22-4d Comment: The rapidity with which offensive quantities of bacterial and viral agents can be generated requires that close attention be paid to the provisions of the Biological Warfare Convention (BWC). Indeed, DoD professes to recognize the importance of complying with BWC. There is no evidence, however, that in preparing the DEIS the issue of compliance was studied. DoD merely states that it will continue to abide by the BWC's provisions, but does not offer any supporting analysis of the treaty.

22-4d Response: No countries have raised issues regarding U.S. compliance with the BWC. Also see responses to comments 22-4a, 22-4b and 39-8.

22-4e Comment: The DEIS cites several historical documents concerning BWC compliance. Unfortunately, the most recent is an excerpted version of the 26 January 1976 memorandum from President Ford concerning BWC adherence. Since that date the field of microbiology has changed dramatically. Culturing techniques have been greatly refined, and scientists can now insert genetic information from one organism into another. In light of these changes, DOD's assurances carry little weight without clarification of its current interpretation of the BWC.

22-4e Response: DoD is in full compliance with the BWC (see Section 3.3.4.3 and Appendix 1).

22-4f Comment: The preparers of the DEIS lack legal credentials.

22-4f Response: Legal credentials for preparation of an EIS are not requirements of the NEPA process. However, the internal DoD review procedures included a legal review, and legal counsel participated throughout the EIS process in decision-making and analysis of issues with legal compliance considerations.

43-8b Comment: Indeed, it is only the quantitative and not the qualitative amount of such viruses that distinguishes offensive versus defensive. Given that very gray area, there seems to be another important alternative which is to declare that certain research is unclear in terms of the 1972 convention and until that is clarified, a moratorium on any such work until that can be clarified. And finally, a full examination of how the current program goes beyond the possible scope and restraining ourselves from any such research until that has been obtained.

43-8b Response: Comment is not true. The sweeping generalization that research aimed at developing a defense against biological weapons is undistinguishable from research aimed at creating the biological weapons has only a mere kernel of truth. At the most basic level of biology, the studies to culture a virus will be the same regardless of the intention of the investigator, be it offensive or defensive in nature. However, when one progresses beyond the basic studies, to more applied research, e.g. development of vaccine or drug versus enhanced virulence and delivery systems, then the difference between defensive versus offensive research becomes very clear at once. The BDRP is an open UNCLASSIFIED program (see Sections 2.1 and 4.2.2). It is difficult to envision in this kind of setting how an offensive program could be conducted and not be widely known and recognized. As discussed in the responses to comments 22-4a, 22-4b, 22-6d and 39-8, there are many differences other than quantity which distinguish offensive research, and the BDRP has none of those characteristics.

43-8a Content: And finally, I think that one of the alternatives not mentioned is one that their belief is that much of the current genetic engineering technology doesn't fit in the 1972 Convention. This has been stated by Douglas Fyffe and even former Secretary Weinberger.

As such, this is again another reason to declare a moratorium on the genetic engineering experiments currently going on in the Department of Defense.

If there is some doubt, as the Administration has expressed, that there can be significant control in the use of genetic engineering as an offensive biological weapon, surely we should be in the forefront, because we are in the forefront of this research.

The forefront of the international community not even giving the appearance of creating such novel agents or using genetic engineering to create this novel agent, particularly when the Department of Defense admits itself that in the early stages of research that it is impossible to distinguish between offensive

and defensive work.

43-8a Response: Genetic engineering is a research technique not a product of research as this comment implies. The BWC does not specify permitted or prohibited research methodology, techniques, etc., but rather prohibits development, production and stockpiling of microbial or other biological agents or toxins that have no justification for prophylactic, protective or other peaceful purposes and also prohibits weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict, (see Articles I, and X of the BWC). The BDRP is, and always has been, in compliance with the BWC. Also, see response to comment 24-4a.

24-1a Comment: What is not addressed is the greatly increased danger of accidental escape that would result if there were a proliferation of military facilities studying BW agents around the world. Once a biological weapons race got started, it would not be constrained by cost or technological accessibility; nor would it be likely to exclude efforts to develop novel agents using genetic engineering. Proliferation is a very grave danger - not just because it could lead to biological warfare, but also because shoestring operations carried out with varying degrees of technical competence and responsibility, in multiple locations and sometimes inadequate facilities, are almost certain to result in breakdown of containment. Against the resulting possibility of global epidemic or the establishment of new diseases, military defenses would be largely useless.

24-1a Response: A hypothetical arms race resulting from purely defensive research is beyond the scope of the BDRP-EIS. Maximum credible events, which include consideration of the accidental escape of organisms from a BDRP facility, are discussed in Appendix 9. Conduct of BDRP studies under the controls described in Section 3.3 was not found to present significant impacts to the environment.

24-1b Comment: The DEIS does not consider the relationship of the BDRP to such a multiplied threat to the global environment.

When the DEIS says that the BDRP enhances the national defense posture, it is looking at a very narrow segment of national security. It speaks of deterring the use of BW by our protective capacity and protecting troops in the event of BW attack. These are fine goals, but only to the extent that they do not interfere with other aspects of national security something that is never taken up in the DEIS.

It is important to recall that BW have not been considered militarily useful because of their "massive, unpredictable, and

potentially uncontrollable consequences" that could "produce global epidemics and impair the health of future generations" (according to President Nixon). The new biotechnologies do not alter this. Consequently, it is the population that is at risk, and more at risk than troops because the long delay before microbiological agents take effect makes their battlefield use unlikely. Military defenses cannot protect the public. Therefore it is of primary importance that the military defense program should not undermine our primary lines of defense: the BWC and deterrence by other weapons.

24-1b Response: There is no credible evidence to suggest the BDRP is fostering an offensive BW arms race. We believe the relationship is the reverse of that suggested.

7-3c Comment: Secondly, perhaps most importantly, civilian control over the program would go a long ways to allay any suspicion or concerns that the world has about America's goal. So it would be done, I think, with greater safety, given their safety record, and their background and they are much more scientifically-based facilities and secondly, the '72 biological warfare treaty, the convention is very weak in enforcement capability and I think this country needs to lead in avoiding secrecy wherever possible and in assuring the world that civilians are in control of our research program.

7-3c Response: This comment is beyond the scope of the BDRP There is no data that suggests the CDC/NIH, for example, has any safer or less safe record than that of the BDRP, (see Appendix 8). Also, as stated in Sections 2.1 and 4.2.2, the BDRP is an open UNCLASSIFIED program. Also, see response to comment 30-10b below.

30-10b Comment: The terms of the 1972 Biological Weapons Convention should be reviewed and strengthened, particularly in light of new capabilities for genetically engineering biological warfare agents and organisms. We must not lose this valuable start towards the elimination of an entire means of waging war against our fellow man simply because we continue to amplify mistrust out of fear or ignorance.

30-10b Response: Comment noted. While strengthening the Biological Weapons Convention is outside the scope of the BDRP EIS, it is agreed that the Convention is a valuable instrument in the arena of arms control. Because the U.S. is strongly committed to promoting and strengthening the BWC, the U.S. representatives (who included DoD personnel) to the two BWC review conferences (1980 and 1986) and follow-on technical experts session (April, 1987) played an active role in supporting measures to facilitate information exchange and program openness

among the States parties to the Convention.

48-5 Comment: The BDRP and, in particular, the construction of the BL3 lab, in particular, has immense international significance. Perhaps these considerations should play a more essential role in these discussions, as well.

48-5 Response: Comment noted. As stated in Section 1.1 "defense against biological weapons is considered a vital component of the overall defensive posture of the U.S. and its allies" and in Section 5.2.1.4 "because BW is the only threat for which the U.S. possesses no capability for retaliation in kind, the existence of an active defensive research program serves as the only deterrent to potential adversaries in planning for indiscriminate use of bioweapons in operational war plans."

39-12 Comment: My concern is the creation of a military coterie of biological warriors, military and civilian, whose career- prestige interests are motivated or rewarded by fostering a new arms race. It is your career interest.

39-12 Response: Since there are no weapons, no weapons research and no plans to develop such weapons, the motivation hypothesis is moot.

29-12 Comment: All biological warfare activities should be required to be unclassified. All research should be publicly disclosed and all results should be publicly reported. This will ensure full public access to activities conducted under the Biological Defense Research Program and, at the same, provide reassurance to other nations that the United States is in fully complying with the provisions of the 1972 Biological Weapons Convention.

29-12 Response: As stated in Sections 2.1 and 4.2.2 the BDRP is an open UNCLASSIFIED program. Only results which identify vulnerabilities or defensive deficiencies and could impinge on National Security are subject to classification.

39-5b Comment: If one side uniquely possesses a novel pathogen and the vaccine to it, that side has an offensive weapon. Vaccines are likely to be more useful for the offense than the defense.

39-5b Response: This comment is incorrect. Possession of an organism and a vaccine to it in no way constitutes an effective

biological weapon. Also, see responses to comments 22-4a, 22-4b and 39-8/

39-5c Comment: The criticism of vaccine development by the military or under contract to the military applies also to biosensor development for specific pathogens.

39-5c Response: Possession of an organism or a biosensor to detect it, in no way constitutes an effective biological weapon. See also the responses to comments 22-4a, 22-4b and 398.

39-6 Comment: In the context of the arms race and the information age, knowledge of pathogenic organisms and their treatment is a potential weapon if that knowledge is held exclusively by one side.

39-6 Response: One of the most significant strengths of the BDRP is that it is an open, unclassified program, where the results of studies on diagnosis, treatment and disease prevention for pathogenic organisms are published in the open scientific literature and presented in national and international forums.

39-1a Comment: The key issue regarding biowarfare is that the US and USSR are on the verge of an arms race in a new area.

39-1a Response: See responses to comments 20-3 and 39-6.

39-1b Comment: On the surface the situation regarding biological warfare is good. Both the US and USSR have signed a treaty pledging, amongst other things, that they will not pursue offensive biological warfare. Unfortunately, the integrity of the treaty is being threatened by the new developments in the Biological Warfare "defensive" research program in the US and possibly within the USSR as well.

39-1b Response: See response to comment 57-1d.

39-1c Comment: US military Biological Warfare research conducted under the rubric of threat assessment contains elements that would form part of a program aimed at establishing an offensive capacity, this constitutes a de facto violation of the treaty irrespective of intent.

39-1c Response: Comment is not related to a NEPA issue. See responses to comments 24-3a, 22-4a, 22-4b, 39-8.

39-1d Comment; Actions that appear to violate the treaty could easily inspire counter actions and soon degenerate into a new arms race. The new test facility proposed for Dugway and the entire Biological Warfare program could easily appear to be directed towards actions that are a violation of the treaty. The program's advocates claim that only work within the confines of the treaty will be conducted, but the program as proposed appears ideally suited for work that is not within the confines of the treaty. Even if the program is honest in its intent, the facility could frighten the Soviets into noncompliance which in turn would engender US response and so on.

39-1d Response: The comment cannot be addressed in a NEPA context. Also, see responses to comments 41-1d, 26-1, 26-6, 22-4a, 22-4b, 39-8.

39-1e Comment: Both the US and USSR have pledged to forego offensive biological warfare. However the institutional measures necessary to prevent the development of offensive biological warfare are inadequate, both inside the US and the USSR.

39-1e Response: As stated in Section 2.1, verification on an international level is difficult and is not specified in the BWC. The U.S., and the BDRP, are in full compliance with the BWC.

39-1f Comment: The best defense would be for the US and USSR to honor their treaty obligations and to be well assured that the other superpower is honoring the same obligations. To accomplish this goal the US and the USSR ought to forego any classified work in molecular biology (including exotic technologies not envisioned at the time the treaty was negotiated).

39-1f Response: All work in the U.S. BDRP is unclassified, see response to comment 14-10.

39-1g Comment: Improvements in protective technology might also be of civilian benefit for health care workers and scientists who work with pathogens. Because there is as yet no new offensive technology in existence it is a very practical time to end military secret research and to be open about defensive technologies that are developed.

39-1 Response: We agree that improvements in protective technology benefit health care workers and scientists who work with pathogens. There is no "secret research" which relates in any way to protection for U.S. workers and scientists. To the contrary, safety advances developed within the BDRP have contributed significantly to the health of U.S. civilian workers at many levels (see Sections 1.5 and 5.2.1.4 of the EIS). Also, see responses to comments 39-1f and 14-10.

29-5e Comment: These activities are provocative, destabilizing and may be reasonably perceived to undermine the 1972 Biological Weapons Convention:

29-5e Response: Research activities under the BDRP are conducted in compliance with the 1972 Biological Weapons Convention (see response to comment 26-1, and Sections 1.1, 1.6.2, and Appendix 1).

Sub-category D - Questions unique to the BATF

40-1 Comment: Therefore, we strongly oppose the building of the proposed Biological Aerosol Test Facility at the Dugway Proving Ground. It would move us in the wrong direction. We would be escalating the arms race to a frightening new level. It is a morbid misadventure with deadly implications....The essential point is that the building of this facility will only heighten the fears and tensions that exist between nations.

40-1 Response: There is no credible evidence to suggest that construction of the BATF, or any other aspect of the BDRP, would stimulate an international arms race. The BATF is the subject of a separate Environmental Impact Statement, see Section 1.6.4.

42-5 Comment: And that's why I oppose the development of this biological testing lab here.

42-5 Response: Opposition to the BATF is not an appropriate comment for the BDRP-EIS. This comment is more correctly addressed to the BATF-EIS.

55-4 Comment: The third reason stated in here for building this is to build a defensive system, obviously this can't be done without a medical defense. So therefore, there are no reasons to build this lab and this proposed lab is not safe. If it is perfectly safe, why build it out in the middle of the desert, why not in New York City? Lives in Idaho and central Utah are just as important and valuable as any other lives and to say that the

winds are just going to blow down the central Utah and no big deal, I don't think carries much weight.

55-4 Response: Questions specific to the proposed BATF should be addressed to the BATF-EIS and not the BDRP-EIS.

46-1 Comment: I would like to make a couple of points about the process that has gone on in discussing what the future of the biological program is going to be.

The main comment I would like to make, and I think cannot be ignored a little too much, is that we have heard a lot the last few months about new openness in the Army, new concerns for the feelings and sentiments of the public and now the Army is trying very hard to allow the public to have its appropriate input. I think that's what's wrong with the whole process that we are here tonight as part of. And that is that the process is a little more than a mess. I think it's important to realize that the Dugway facility was proposed and originally planned, and there would have been no hearing out here for the public to have any kind of input. The only reasons we had hearings is because you got yourselves into court and a Federal Judge said you had to meet certain conditions and one of those was to allow the public to have its input.

I know it's also important to realize that one of the reasons we are here tonight is not because the Army is concerned about what the residents of the State have to say about your overall biological program, but because a few politicians in this State demanded that you hold some hearings, and it would have been bad public relations for you to do otherwise and I think that -- another point that I think is very relevant, and that is the whole question of your credibility. I am a life-long resident of this State and one of the first things I remember saying, I didn't like kindergarten class in a little town called Enterprise, and watching a panel in uniforms and medals tell us why we had to put up with nuclear testing next door in Nevada and how serious that was and how without it the Russians would be here in the morning and we would all be dead. Some 30 years later the Russians still aren't here and a hell of a lot of us are dead. The phrase there is no danger is an appropriate epitaph to put on a lot of Utah headstones and we here tonight have that. It's such a victory that the Army will give us a BL3 instead of a BL4, but it really doesn't matter what you give us. It's not going to change much. A lot of the people say this is a great victory for the residents of the State of Utah. What victory and for us or for you? It's not even going to be the public relations triad as you figured it is. The public concern about Dugway is not based on your facility that you are proposing to build. The concern over Dugway is based on a three decade long legacy of lies and deceit by the United States government and defense industry to the citizens of this State.

The words about how the BL3 facility will provide enough safety and how there will never be any BL4 work done is a little more than idle words and broken promises. The same types that have greeted Utahns with each new deadly defense program over the last three decades. What we have been asked for those three decades, to give our support and to be patriotic Americans and to support what is needed to protect this country and what have we got for our patriotism and support, we've been A-bombed, nerve gassed and we've been lied to, and when we have been hurt by your programs, we have watched you quickly and rapidly first deny that you had anything to do with it and then smilingly inform us that you are immune from any and all accountability.

Today, sadly, nothing has changed. What difference does it make? A containment level on a building does not alter a track record of lies and deceits. The only protection the public has in any reality is their opposition to your deadly proposal. Public opposition has forced you to downgrade your facility to a BL3 level. You were running scared from public opposition. It is our sincere hope that you will continue to keep running back to Washington, D.C. We have been helpless guinea pigs in your deadly experiments long enough. Enough is enough. Thank you.

46-1 Response: This comment is not an appropriate BDRP-EIS issue. The commentor states that the concerns expressed are based on historical distrust of the government and DoD rather than on any specific item related to the BDRP.

47-3 Comment: My own research specialty is in ecology and population biology and I was a bit somewhat distressed with the EIS statement from last year about the level 3 facility, which is still the facility we have and one example is that in the EIS statement Dugway was noted as being isolated in the desert and therefore safe. Well, in fact, it's isolated in a sea of vectors. Actually, a study carried out at Dugway by Army biologists showed that the rodent populations have extremely high densities here, the 50 percent capture rate, which is among the highest you will find anywhere in the country. Also, the diversity of the rodents is enormous, many of them being bats, which are certainly capable of dispersing long distances and the others which populations are widespread throughout the Utah and the southwest desert, many of these are known reservoirs for the pathogens that we have been discussing and they could easily be picked up by those local populations of rodent and we wouldn't know it. Even under a low probability of an accidental release, either having rodents or people infected, we may not be able to detect this until it's too late, particularly if it's a non-human infection. This is a lesson that we should have learned from the many studies, both of human and non-human populations, where diseases have been followed. It's also a basic principle of ecology, which is logarithmic population growth in which populations are known to show an s-shaped growth curve, so at

very low population densities population growth is actually very low.

So if rodent populations were infected, that would be very difficult to detect for some period of time following this lag phase, as it's called in the population growth. There is an exponential growth rate which can be very rapid, enormous doubling and once an infected population is in this phase, it may be out of control before we can detect it and do something about it and by then it would probably be too late. And, in summary, I would like to say that much of the past research that has been done in the biological warfare program has gone on without much public scrutiny or much public knowledge and I think this is beginning to change and I am sure it must seem like a big nuisance to you all, but I think it's definitely for the good and by having public input from both scientists, as well as just concerned citizens, could help the program in general and certainly improve the safety of local citizens. Thank you.

47-3 Response: Comment is apparently addressing statements contained within the BATF-DEIS and should more properly have been addressed to that document. Consideration of accidental or intentional release of an organism from studies conducted under the BDRP were considered in the BDRP-EIS in Appendix 9. While such an event cannot be ruled out, its likelihood is literally less than one chance in a million. It cannot be determined that a spread of disease such as that postulated would have the consequences suggested.

48-3 Comment: The three potential areas of concern which arise from reading the DEIS are aerosol released into the atmosphere, exposure of an animal vector, an exposure of a laboratory worker to an organism. Before discussing these possibilities individually, it is appropriate to mention that in spite of the most advanced containment technology, quote, "there is no substitute for good technique," unquote. This is a letter written for this statement. This means that everything discussed is subject to human error.

Although thought by the preparers of the DEIS to be too small to warrant even a contingency plan, a review of the preliminary hazard analysis, in Appendix 4 of the Dugway report, and I think it applies to this because it does refer to the testing, the testing procedures that were done, reveals that physical damage to the building, expansion and contraction of the building and its electrical system would cause a, quote, "catastrophic," unquote, release of pathogens, quote, "sometime in the life of the system," unquote.

We are sure that there is natural barriers to the spread of these pathogens. This is, in fact, not the case. The weather, in spite of averages, can be anything but benign. The dry desert

soil is ideal for the spores of anthrax; in fact, there continues to exist a source of anthrax spores not far from Dugway originating from a cattle drive in the late 1800's. "Q" fever -and I wonder if we are not going to look back in 100 years and say, there's that anthrax collection left over from the Dugway experiments earlier on. "Q" fever, if my reading is correct, was discovered in Utah and numerous vectors exist for tularemia as well. The executive summary of the DEIS does not even mention the huge populations of arthropods which can serve as reservoirs for disease.

For several reasons, the preliminary hazard analysis lists as, quote, "probably," unquote. The potential for the entrance of entomological or small animal penetration not only into the outer building, but also into the inner building. This comes as no surprise to those of us who see flies in the hospital intensive care unit. As the analysis suggests, this would be a critical event. There is, however, no contingency plan for this event in the DEIS.

The most likely vector for the escape of organisms from the lab would be man himself and this is given elaborate attention in the DEIS. Exposure through a rip in the safety suit or accident in the biosafety cabinet are rated as, quote, "critical events," whose occurrence would be, quote, "frequent to probable, unquote. Although vaccinations and treatment plans are outlined, little consideration is given to the concept of latent infection. As opposed to the immediate onset of symptoms when one is exposed to a toxin, symptoms from infection may not occur until days or weeks after exposure. This can be compared to infection with human immunodeficiency virus, AIDS to most of us, during which one may harbor the virus for months before the infection manifests itself. This concept is important as lab workers may expose other individuals before they know they have been infected themselves. Although the contingency of lab worker infection has been addressed, the plans do not deal with the possibility of latent infection.

With these considerations in mind, I feel that it is reasonable to conclude that, one, the experimental organisms are extremely dangerous, even though one is given the impression in the DEIS of, quote, "routine," unquote, BL3 experiments. Two, the natural and physical environment surrounding Dugway Proving Ground is not only not hostile to these organisms, but actually favorable to their survival in many cases. Three, vector and aerosol release of these organisms may be more probable than is implied in the DEIS. Four, exposure of lab workers to these organisms is probable, but the concept of latent infection is not addressed in the DEIS. Five, all safety mechanisms are dependent on human performance and that human error has been at the root of many disasters in the past.

48-3 Response: Most statements in this comment refer directly or indirectly to statements contained in the BATF-DEIS and should

more appropriately be addressed to that document. Accidental or intentional release of an organism from studies conducted under the BDRP was considered in the BDRP-EIS, see Appendix 9. Organisms of interest to the BDRP have markedly different characteristics from those of HIV-1 (the causative agent of AIDS), and are not known to cause latent infections as described in the comment. In keeping with the requirements of the CDC/NIH guidelines for BL3 laboratories, laboratory insect and rodent control programs are implemented as safety measures to prevent the accidental transmission of disease outside of the laboratory.

As a point of scientific accuracy, the clinical disease, Q fever, was first described in Queensland, Australia (Burnet, F.M. and Freeman, M., Experimental studies on the virus of Q fever, *Med. J. Aust.* 2:299-315, 1937 and Derrick, E.H., Q fever, a new fever entity: clinical features and laboratory investigation, *Med. J. Aust.* 2:281-299, 1937.) Throughout the first half of the 20th century, Q fever posed significant problems to the dairy and cattle industries. A survey of the historical literature shows that the causative organism, *Coxiella burnetii,* was isolated and described in several laboratories worldwide during the early 1950's (see for example Dyer, R.E., Similarity of Australian "Q" fever and a disease caused by an infectious agent isolated from ticks in Montana, *Pub. H. Repts,* 54:1229-1237 (1937). We must also note some semantic differences. The term "catastrophic release" as used refers to total failure of all safety measures (about a 1 in 10 to 20 billion possibility). Even with this total failure, it appears that an infective dose of a disease causing organism could not be dispersed beyond the boundaries of Dugway Proving Ground.

49-1 Comment: Unfortunately, I just received the statements last night and in plowing through them it got to be fairly heavy reading and I didn't get time to prepare a statement as I fell asleep with the data.

One of the things that I wanted to do was, briefly to make some comments about the data that was in here regarding the proposed organisms to be tested. What I found is -- I am also an instructor in infectious diseases and so I felt fairly confident in reading some of this. Some of the organisms they were talking about were anthrax and in the Army statement they said that what made it safe was the relative humidity in the desert, but if it's less than 20 to 40 percent, it becomes -it's no longer a productive organism. That precisely the relative humidity below 20 percent when it becomes a sporulating organism which makes it more virulent when it gets to people. So, precisely in the data, what made it more safe is what I would suggest what made it more risky.

In terms of the data regarding *Franciscella tularemia,* this

is a disease that is most commonly spread through rabbits and we know there are no rabbits in Utah.

The next thing is discussion of *Yersinia pestis*, or commonly know to us as the plague. In review of the Army's literature, what they talked about as the vectors was mammals. That is not the case, the vectors are ticks and lice. And in the Army's -in their reports on data, they have said that it was very probable that some lice and ticks may get into the testing areas.

What I feel and understand is in terms of aerosolized testing. If some of the organisms, such as Coxiella or "Q" fever, if one organism can be infectious and the fatality rate can be up to 100 percent, how do you control an aerosolized testing. You can't just take the air that this is in, regardless of where it is, and suck it up in a bottle and send it away somewhere. I just fail to understand how one organism in an aerosolized test can be controlled.

And finally, you know, certainly in terms of some of the things that Dr. Sayres mentioned, some of the latent infections, as those of us who have taken care of AIDS patients are fully aware, it's not a nice disease to have, we didn't know it was being transmitted at the time it was reaching epidemic ratings. Some of these diseases, the equine encephalitis virus that are being tested we just don't know and I think in those settings, although I would hate to discourage anything that may have some medical break-throughs, certainly diseases like AIDS, I fail to understand how biological testing can have any defensive capabilities. It just doesn't seem to me that this should be something that is in Army or military hands, it seems like it is more National Institutes of Health or medical care, and again, hopefully, I can give you some more on this. Maybe I can come up with some more information later. Thanks.

49-1 Response: Comment appears to relate more to statements in the BATF-DEIS than to the BDRP-DEIS and should more appropriately have been addressed to that document. Consideration of accidental or intentional release of an organism from studies conducted under the BDRP were considered in the BDRP-EIS, (see Appendix 9). The spore form of *Bacillus anthracis* the organism that causes anthrax, is not more virulent to people than the vegetative form of the organism. For an anthrax spore to produce infection in a host, it must be exposed to conditions that are conducive to the germination of the spore and growth of vegetative organisms. Cutaneous, pulmonary or gastrointestinal forms of anthrax can result from exposure to either spores or vegetative organisms. Of these three recognized forms of human anthrax infections, the latter two are considered to be quite serious clinically because they are not as responsive to antibiotic therapy as the cutaneous form, which is readily treatable. Anthrax spores are no more or less dangerous than anthrax organisms.

Aerosol testing of pathogenic organisms in a biocontainment laboratory is controlled in several ways. The primary level of containment of the aerosol, or primary barrier, is the equipment in which the aerosol is generated, typically a closed metal chamber smaller than a household refrigerator. This equipment has airtight seals, which are tested for leakage (with common industry methods) prior to use. The equipment itself is contained within a secondary barrier, such as a class III biosafety cabinet, which itself is airtight, and contained in a laboratory room with limited access and filtered air flow. Air effluents from a biosafety cabinet containing the aerosol study equipment are either passed through high efficiency particle filters, which remove particles and microdroplets in the size range that presents the potential hazard to the pulmonary tract, or are incinerated to ensure removal and/or destruction of any organisms present. The aerosol equipment itself is decontaminated by appropriate methods, such as paraformaldehyde exposure or autoclaving, as described in Appendix 13 of the BDRP EIS. The laboratory facility in which any such aerosol studies are conducted is engineered with the appropriate safety controls described in the CDC-NIH Guidelines for laboratory facilities criteria for each biosafety level.

Biological testing in and of itself is not envisioned to constitute a defensive capability; testing of medical defenses, such as vaccines and therapies, and of protective equipment and detectors contributes to the development of those medical and physical materiel that constitute solid defensive capabilities.

50-1 Comment: Well, first I would like to speak to the subject at hand, the EIS, and give you what I consider a few suggestions for altering it in the light of what I consider misinformation and misperception, and whatever else you want to call it.

First of all, I think that you need to establish the need for -- firmly for this type of research. For example, very little is said about the Russians going in opposition to the Geneva Accord. Nothing is said about the accident at Sverdlosk in April of 1979, when several hundred Russians near that community were killed by a biological bomb that had been prepared in opposition to the Geneva Accord.

There are several other things that ought to be stated in there to make that stronger. I think that you should strengthen your mitigating circumstances on accidents. For example, I think you should say more about the decay of these fragile organisms, particularly the Dugway environment and the good doctor that just spoke about anthrax being more virulent in the sporulating form doesn't know what he is talking about. Spores are not nearly as infective, in fact, they have to vegetate before they can even cause an infection and I think that that's largely what we are dealing with here is most of the people that have spoken so far, in my mind, don't know what they are talking about.

I think you need a better description of the affected environment, particularly wind direction and speed. For example, we are worrying about the 70 miles, that is always brought up, the 70 miles from that lab to Salt Lake -- the Wasatch Front. What percentage of the time does the wind blow from the lab to the Wasatch Front in that direction? Virtually never. Virtually never. The types of winds that you have at Dugway are prefrontal winds that blow up into Idaho, several hundred miles before you get to anything of any population. Post-frontal winds would be from the northwest that would blow way down into central Utah, a few farming communities might be affected some 200 miles away. Why isn't this brought out? You see, even if you have a worse case situation, the chances of wind taking that to a populated center is practically zero, not counting the low relative humidity that you have at Dugway. That is bound to mitigate any kind of accident. I think that you should say more about the decay rate of all of the organisms that you intend to use in the laboratory because all of them are extremely low. You mentioned what you consider, I guess, a worse case situation of "Q" fever. You could have mentioned anthrax, probably, and even worse ones, but even under that circumstance, the chances of them getting outside the fence around Baker lab is practically nil, let alone get to the fence of Dugway and getting to Salt Lake City is just -- it's beyond the realm of imagination, you see.

I would like to remind the good member of Congress here that I am also a citizen of the State of Utah -- I should say, by the way, I am a private citizen. I have no connection with the Army. The Army doesn't tell me what I can say and I can't say, thank God, because I spent 31 years having to be quiet and thank the Lord I can say something now because I am sorry, Representative Owens, but we are talking about a military problem here, and it is being solved by civilians. People that are in the labs are civilians. Very few people that actually do work are military. The requirements come from military because they are the ones that have to use them, that have to -- they are the ones that have problems. They are the ones that we are speaking to.

Now, we want realistic requirements, but nobody ever told me for the eight years that I ran the lab at Dugway that I -whether or not I could do one thing or another. I acted in a civilian capacity just like the people at NIH, and what makes you think that the military aren't as patriotic and concerned about the people of this Nation as civilians? Really -- well, I can't understand it.

Now, I feel that I need to speak to some of the other statements that have been made. I realize that this doesn't have anything to do with the EIS, but I don't think any of those statements had anything to do with the EIS and I think somebody needs to rebut some of the ridiculous statements that have been made and that's all they are, and that's in the category of ridiculous. I think, for example, Brian Moss thinks of going to

Washington, he better get his facts straight because he doesn't know what he is talking about. He is going to get cut to ribbons by the Washington crowd when he gets back there. You know, I was thinking of voting for him because I didn't like Hatch's ideas either, now, I don't know who to vote for.

Well, I have to agree with Dr. Gubler. I think the Army rolled over and played dead by giving up the BL4 lab. I don't think that you have reduced the safety of the people along the Wastach Front one iota because there was no safety problems to begin with, with or without the BL lab.

The Downwinders. You know, all of this is rabble-rousing and has very little to do with the lab. I feel sorry for the people down in St. George and I admit that the government, not the Army or Dugway, probably did them a bad turn. So why should we -- why should we limit what we do at Dugway in terms of defense just because somebody has got a bone to pick? Really, it just doesn't make any sense. You know, he improved the training of the people at Dugway. Four of those are young native sons of Utah that were trained at Utah State specifically as aerobiologists and I don't know what kind of training he is looking for. For example, I have over 50 publications in this area. I am recognized as an international aerobiologist by the community of aerobiologists and these are the people who know what they are talking about, not you guys that are working on emotion and rabble-rousing. So, I don't know what inadequate training you are talking about, he talks about the anthrax on the Salt Flats. Dugway put sheep on that salt flat. Right on the spot, kept them there for how long I don't know, six months. Not a one of them came down with anthrax. Not a one of them. I would take my 19 grandchildren and have a picnic on that spot, that's just how much I think its -- how safe I think it is.

Now, Steve Erickson, you also talk about biological arms race. What biological arms race? I don't know of any biological arms that the United States is producing and yet you keep bringing this up. What is biological arms race? You see, why don't somebody, including you, worry about the dozens of chlorine-laden trucks that come through Salt Lake City. The 18- that are carrying cyanide -- you know, that one that went off -- that wrecked down in central Utah, that can just as well have been in Salt Lake City. Why don't you worry about that.

Dr. Sayres talked about one organisms of anthrax causing a disease. Boy, I would like to have that strain. Wouldn't the Army like to have it. We know that it takes 10 to 15,000 -

[Moderator terminated comment]

50-1 Response: Comment noted. Comment concerns the BATF and insofar as questions are raised, they should more appropriately have been addressed to the BATF-DEIS.

56-1 Comment: Enclosed is a copy of a resolution passed by the membership of the Utah Public Health Association at its annual (1988) conference. The language and intent of the resolution, I believe, is quite compatible with the "Statement of the Utah Department of Health Concerning the Draft Programmatic Environmental Impact Statement, Army Biological Defense Research Program," submitted to you on September 30, 1988.

I hope and trust you will earnestly and favorably consider the position of the Department of Health and our association. (Resolution is reprinted in Appendix 14.)

56-1 Response: Comment noted. The wording of this resolution speaks to the construction of the BATF and is not appropriate for the BDRP-EIS. This comment should more properly have been addressed to the BATF-DEIS.

29-8 Comment: The CRG has addressed the environmental impact of the use of large aerosols of dangerous biological agents in its comments on the Draft environmental Impact Statement for the Aerosol Test Facility, Dugway Proving Ground, March 14, 1988. We found that the Draft EIS for the Aerosol Test Facility to be inadequate because I) it did not address the risks of using genetically engineered organisms designed for military purposes in the facility; ii) the description of the range of organisms to be used in the facility appears to be in conflict with the public testimony of Department of Defense officials before Congress; iii) there are no provision for protection of personnel other than those directly engaged in aerosol tests in the facility; iv) there are not provisions for monitoring disease outbreaks in hospitals and clinics throughout Utah; v) there is a contradiction between claims that Dugway provides a natural barrier to possible environmental or public health dangers and the documentation provided in the Dugway EIS of the presence in the area of animals and insects that may act as carriers of disease.

29-8 Response: This comment is on the BATF-DEIS and more appropriately should be addressed to that document. There are no "large aerosols of dangerous biological agents" involved with the BDRP at DPG or any other location. If, by "military purposes" is implied the deliberate enhancement of virulent properties by genetic engineering for offensive purposes, this is not being done, therefore analysis of the risks of such work would be inappropriate in the BDRP-EIS as well as the BATF-DEIS. As stated in Appendix 10, the deliberate creation and testing of such organisms is prohibited by the NIH guidelines for Research Involving Recombinant DNA. The DoD is in full compliance with

those guidelines. Also, see responses to comments 14-15, 24-13a, 24-14 and 30-5.

55-8 Comment: I would like to see a nonmilitary overseer of the plant. I think that this is necessary in order to prevent overzealous military people, such as Colonel North and also just -- it's just common sense.

55-8 Response: Such external review, intended to satisfy a public credibility concern, is beyond the scope of the BDRP-EIS.

Sub-category E - Offensive Research/Trust

24-2b Comment: The possibility that exploratory research may already be going on at Fort Detrick to determine the military potential of genetic engineering is one that needs to be addressed in the EIS. Either it must be explicitly disavowed or its environmental impact must be considered. The medical work, of course, provides defense benefits as well, but a medical defense can also be viewed as necessary for offensive use of BW. In addition, suspicions inevitably arise as to whether the medical work produces offensive information as a by-product, or provides a cover for potentially offensive activities such as the development of novel agents.

24-2b Response: As stated in Section 1.3 "the purpose of the BDRP is to maintain and promote a solid national defense posture"; in Section 1.4 "the need for the BDRP is to conduct necessary RDT&E of defensive measures and materiel"; and in Section 2.1 "emphasis was placed on improving the defensive posture in the areas of biological agent detection, treatment, protection and decontamination." No where in the BDRP-EIS is there any remote suggestion that efforts are underway at Ft. Detrick or anywhere else to explore the military potential of genetic engineering. The BDRP is not conducting offensive BW research using genetic engineering or any other methodology. Also see responses to comments 26-1 and 22-4a. No purpose is served in the examination of activities that do not take place and are not planned to be part of the BDRP.

24-2c Comment: In this light it is clear that the transfer of all medical activities to a civilian agency could provide a reassuring and significant alternative to the present program.

24-2c Response: Transfer of the program to a non-DoD agency because of suspicion of DoD motives by some elements of the public is not a justifiable reason for such consideration. The alternative of transferring a part or all of the BDRP to another

Federal agency such as NIH was examined, see Section 4.2.2 and response to comment 22-1a.

38-1a Comment: The main issue which has not been seriously considered is the distinction between defensive and offensive research. Offensive research is anything which gives that appearance to foreign powers, and which is not directly necessary for protection of our own troops. In addition to being against the treaty, offensive research is dangerous and pointless.

38-1a Response: See responses to comments 26-1 and 22-4a. The U.S. is not conducting offensive biological research. Offensive biological research is defined in Article I of the BWC as biological agents or toxins "of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes," and, more concretely, as "weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict."

38-1b Comment: Aerosol research on pathogenic organisms with no known cure, ... is difficult to justify as defensive research.

38-1b Response: There is a significant difference between aerosol research for offensive purposes, where methods of dissemination, agent stability, effects of temperature, humidity, etc., on the aerosol and its dispersion would be studied, and defensive research requiring the use of aerosol mythologies, such as the evaluation of vaccines, detection equipment and protective equipment as is done in the BDRP. The BDRP-EIS was prepared by considering the types of studies conducted, the potential hazards of conducting studies on the organisms/toxins of concern and the potential environmental factors that might be impacted. See responses to comments 31-8 and 24-5c.

38-1c Comment: Aerosol research...on genetically manipulated organisms is difficult to justify as defensive research.

38-1c Response: Aerosol research per se is not done in the BDRP, see responses to comments 38-1b, 31-8 and 24-5c Genetic engineering is a system of methodologies inherent in any quality biomedical research program. The employment of genetic engineering in the BDRP is necessary in this context.

34-2 Comment: Especially when one learns that modern genetic technology is being used to separate pathogenic characters from immunologic characters, in order to have safe organisms for use

in immunizing. Unfortunately, the same steps used to separate can also be used to reassemble, in new and unpredictable combinations. If the Army contracts out innocent parts of the operation to innocent scientists in universities and industry, we do not know how the innocent pieces may be reassembled when they are returned to Army labs.

34-2 Response: It is true that the same techniques would be utilized in the identification of both immunologic characteristics and pathogenic characteristics. However, the nature of the underlying experimental hypothesis and of the actual experiments performed and results collected would be completely different. It is also likely that modern genetic technology could be used to assemble pathogenic traits in new combinations, but that is not being done. Such studies would be counter to the NIH guidelines on recombinant DNA research, see responses to comments 24-4a and 27-6a. Such an experiment was reported recently in *Nature* 334: 522-525, 1988, by a Swedish scientist.

26-13 Comment: DEIS section 5.2.1.4 at page 5-6 admits that the BDRP is engaged in the process of identifying and counteracting so-called "potential threat agents." Yet, once again, the American people have no guarantee that the Department of Defense is using GEMs to produce a vaccine as opposed to the weapon itself. DEIS page 5-9 admits that BDRP uses of recombinant techniques are with the goal of producing "a less virulent strain." But then a fortiori, using the same recombinant techniques, the BDRP can certainly produce a "more virulent strain." What independently verifiable Guarantees can the Department of Defense provide to the American people that this is not going to happen under the aegis of the BDRP?

26-13 Response: DoD is obligated to adhere to the NIH Guidelines for Research Involving Recombinant DNA. Such studies as the commentor suggests would violate these guidelines, which is not being done. An "independently verifiable guarantee" is not an element in NEPA examinations and agencies which are operating within applicable laws and regulations have no obligations in this context to show evidence that they are doing so. See responses to comments 22-9, 27-20, and 34-2.

24-10c Comment: DoD should renounce, absolutely, any work to develop or use novel agents except for cloning purposes in unclassified medical projects.

24-10c Response: If commentor means that novel agents should not be developed for non-defensive purposes, this is already the situation. There is thus no need to "renounce" such prohibited development of novel agents. All work conducted under the BDRP,

including that which involves genetic engineering is unclassified and conducted solely for defensive purposes. Also see response to comment 34-2.

24-2d Comment: It does say that no work with genetically engineered microorganisms is performed or planned at Dugway, while acknowledging that the program is ongoing and changes can be expected. A changed policy at Dugway can be anticipated if the proposed BL4 aerosol testing facility is built. Or perhaps not. But so it appears to interested observers around the world. The option remains open to develop genetically engineered novel organisms for ambiguous defensive purposes such as threat assessment, and their development may even now be underway. In such a situation, as Lt. Col. Wyatt Colclasure has said, "you do get information, and like a lot of information, you can put it to different uses" *(Science* 226, 1178, 1984). Thus, the suspicion of offensive activity.

24-2d Response: See responses to comments 24-3a and 27-20. The U.S. is not conducting offensive biological research, (see Section 1.6.2). The Army announced on 19 September 1988 that the preferred alternative for construction of the Biological Aerosol Test Facility would be construction to meet BL-3 standards. The Army has not been engaged in offensive research since 1969 (see Appendix 1).

14-6 Comment: According to a recent U.S. Army announcement, a decision has been made to build the BATF to BL3, rather than BL4, specifications. The Utah Department of Health endorses this change. A BATF built to BL3 specifications will not support research with highly dangerous exotic or novel pathogens. This substantially reduces the public health risk should microorganisms escape. The final Programmatic Environmental Impact Statement should make note of this change.

Construction of a lower-containment level (BL3 instead of BL4) BATF at Dugway Proving Ground. As noted above, this should remove the possibility of conducting aerosol testing with highly pathogenic novel or exotic organisms. This option could produce more trust in the BDRP in addition to removing some risks to the public health. The DPEIS says very little about the BATF and does not acknowledge the recent decision to build it at a lower containment level.

The decision of the Department of Defense to build the Dugway Biological Aerosol Test Facility to BL3 rather than BL4 specifications alleviates some safety concerns regarding future research. We recommend that this decision be acknowledged in the Programmatic Environmental Impact Statement.

14-6 Response: Research conducted under appropriate BL-4 conditions does not pose a significant increased risk to human health or the environment. The Army announced on 19 September 1988 that the preferred alternative for the BATF facility would be construction to meet BL-3 standards. Also, see response to comment 24-4a. The BATF proposal is addressed under separate NEPA documentation (see Section 1.6.4).

24-2a Comment: However, international confidence in the BWC is being eroded by suspicions that offensive research, possibly involving the use of genetic engineering techniques to create novel pathogens with weapons potential, is being carried on under the guise of defensive activities.

It behooves the US, and other nations as well, to make every effort to dispel such suspicions. Otherwise, smaller nations may decide that they too must acquire "the poor man's nuclear bomb." We are at a critical point in the history of biological arms control. Biotechnology is new, nothing has happened yet, and there is strong international concern and desire to strengthen the treaty regime. The recently undertaken confidence-building measures, involving the exchange of information, are a prelude to the establishment of measures to verify compliance and resolve complaints. The stringent provisions already agreed to in the BWC negotiations provide a model.

But the Department of Defense in recent years has been generating rather than allaying suspicions by its imprudent and unjustified rhetoric on the military utility of BW and by certain aspects of the BDRP. Various changes in the BDRP could solve this problem, but because the problem is not acknowledged the DEIS casts off all possibilities of change.

24-2a Response: The erosion of confidence in the BWC is beyond the scope of the BDRP-EIS. The "stringent provisions" in the BWC do not extend to compliance verification, (see Section 2.1). The BDRP is open and unclassified (see response to comment 14-10) and scientific results arising from the program are presented routinely in various national and international forums. Under the provisions of the BWC, the U.S. reports all BL-3 and BL-4 laboratory facilities, their mission and a summary of yearly highlights to the United Nations.

42-3 Comment: More importantly, it means you have to build the offensive germs, the offensive weapons, if you will.

42-3 Response: Comment is incorrect. The United States is not conducting a biological weapons program. See responses to comments 26-1, 22-4a, 24-4a and 27-6a.

41-1a Comment: I am writing in strong opposition to the proposal to continue research into biological weapons. The record of the Army's research program is abysmal. Countless Utahns can attest to the inability of the Army to contain its research. As an experienced lab worker I am convinced that eventually human error will lead to deadly consequences if deadly biological weapons are developed for research purposes. The nebulous "benefits" of biological weapons research do not justify placing civilians or military personal at risk,

41-1a Response: The U.S. is not conducting research on biological weapons, (see Section 1.6.2). The safety record of the Army's biological defense research program is commendable, see Appendix 8. If the commentor is referring to alleged incidents not related to the BDRP, then those incidents would be outside the scope of the BDRP-EIS. The BDRP does not include any efforts to develop deadly biological weapons for research purposes.

33-4 Comment: Second, we must realize that when we are dealing with dangerous toxins, bacteria and viruses, the lines between offense and defense are easily blurred. If someone in your family is killed or mutilated by germs created for military purposes, it doesn't really matter whether they were spawned for "offense" or for "defense."

33-4 Response: See responses to comments 26-1, 22-4a and 272. The U.S. is not conducting an offensive biological research program, see Section 1.6.2. It should be noted that all of the disease-causing organisms studied in the BDRP occur naturally in various regions of the world. It is precisely because many of the biological materials studied in the BDRP fall in the category of "highly hazardous" that stringent and systematic biosafety and biocontainment facilities and procedures are used to prevent the exposure of laboratory workers and/or the environment to these materials.

32-2 Comment: To allay all suspicion and to reduce worldwide the vulnerability to biological warfare, it will be most valuable to make the DoD program open: reviewed and subject to approval by a non-military committee of physicians, scientists and citizens.

32-2 Response: The BDRP is an open UNCLASSIFIED program, see Sections 2.1 and 4.2.2. Investigators are encouraged to present and publish results of their research at open meetings and in refereed journals. In any event, openness or non-openness of the program does not alter any impacts on the health and well being

of man or the environment. In addition, the U.S. Congress specifically approves funding for and authorization of the BDRP and a report on the BDRP is presented annually to Congress in compliance with PL91-121, as amended by PL91-441, (see Section 2.3). An external review established merely to satisfy to a limited extent a public credibility concern is not appropriate for consideration in the BDRP-EIS.

24-18a Comment: If tests with pathogens continue, advance notice of each test, including the names of the organisms to be used, in the Federal Register would be a safety and confidence-measure.

24-18a Response: All tests with hazardous organisms are conducted in specially designed biocontainment laboratories, which meet the criteria described in the CDC/NIH guidelines, using equipment and procedures designed to minimize any risks to laboratory workers and the environment. Appendix 8 presents the safety record and risk assessment of the BDRP. Implementing such a notification practice would not alter any environmental considerations. Also, see response to comment 14-16.

24-18b Comment: Outside review by experts (without requiring secret clearance) of each intended use of pathogens or hazardous material, to verify the need, would be reassuring -a way to solve the "psychological" problem!

24-18b Response: Such external review, intended solely to satisfy a credibility concern is not appropriate for consideration in the BDRP-EIS. Also see response to comment 2418a.

24-18c Comment: The public has a right to know about every organism that is handled in each facility.

24-18c Response: Merely listing or identifying specific organisms or toxins at every site would not provide the public or decision-makers with meaningful information upon which to make an informed decision. What is meaningful is the biosafety level to which CDC/NIH has assigned an organism. The EIS discusses examples of organisms in Appendix 4, and indicates the highest potential hazard level for secondary sites in Appendix 3. See response to comment 27-26.

24-18d Comment: At a minimum, annual publication of an exhaustive list is a must.

24-18d Response: Annual publication of a list of specific organisms or toxins at every site would not provide the public or decision makers with meaningful information upon which to make an informed decision. See response to comment 27-26.

29-4b Comment: The investigation of dangerous pathogens for biological warfare purposes differs from their investigation for peaceful purposes since the former will almost certainly involve interest in exploring properties of increased survivability and decreased sensitivity to treatment.

29-4b Response: The commentor correctly states one of the crucial distinctions between offensive and defensive biological investigation. The BDRP is solely a defensive program, and there are no studies conducted to achieve the goals ascribed to offensive research.

29-4c Comment: The CRG believes that a complete EIS must take into account all the possible risks of every phase in any action that explores the properties of lethal biological agents, including strong indications that pathogenic microorganisms modified for military objectives will be investigated.

29-4c Response: Appendices 8 and 9 examine a wide variety of credible and historic risks. See response to comment 24-10c.

29-4d Comment: The character of biological warfare -- the intentional development of pathogenic agents and organisms that are difficult to control -- raises much deeper uncertainty, and therefore greater concern than would use of the same agents for civilian purposes.

29-4d Response: See response to comment 24-10c.

26-3 Comment: For example, the DEIS lists my institution, the University of Illinois at Urbana-Champaign, as a secondary research site for the BDRP. I inquired from your Command as to the nature of four contracts that have been let out by the DoD to researchers at the University of Illinois as part of the BDRP. To my surprise, I discovered that two of these contracts (viz., DAMD 1782C2179 and DAMD 1785C5224) relate to tricothecene mycotoxins, which are said to be the active ingredients of so- "yellow rain." Yet, since it has already been established that "yellow rain" is nothing more than bee feces, there is absolutely no legitimate reason whatsoever for these researchers

to be engaged in toxicological studies related to tricothecene mycotoxins for the DoD. At the very least, it seems to me that this weapons-specific research is what the DoD likes to call "dual-use": that is, it generates results that can be put to both offensive and defensive purposes depending upon the mere intention of the researchers involved or of the DoD. The fact that there has never been an offensive "yellow rain" threat to the United States indicates to me that perhaps the purpose of such "yellow rain" research is to generate results that can be put to prohibited uses. What concrete assurances can the DoD provide to the American people and to the University of Illinois community that such is not the case beyond DOD's own self- disclaimers?

26-3 Response: See responses to comments 26-2 and 27-30.

36-1b Comment: Because of the potential for unlimited varieties of biological agents, we agree with scientists who claim that the idea of defensive biological warfare is misleading.

36-1b Response: Although there are numerous different individual infectious organisms and toxins, many of these agents share, as families or groups, the unique characteristics responsible for their pathogenicity or toxicity and many act through common mechanisms of action at the cellular level. For example, in the case of viruses, members of a given virus family not only share common physical (shape, size, etc.) characteristics but also share common genetic, biochemical and immunological characteristics, most notably protein composition, size and type of nucleic acid in the genome, mechanism of replication in an infected cell, and serological cross-reactivity (Murphy, 1985). Because of these shared genetic, biochemical and immunological characteristics, it is reasonable to postulate, at least for a given group of viruses, that a common site susceptible to inhibition by an antiviral drug can be identified, or that a common protective epitope can be identified for development of a broadly protective vaccine. Likewise, the toxins group naturally into families on the basis of shared characteristics such as parent organism (bacteria, various snake genera, plants, etc.), biochemical type (e.g. protein, alkaloid), amino acid sequence (in the case of protein toxins), and, most importantly, mechanism of action. For example, many of the bacterial toxins share a similar protein structure, a similar route of entry into cells, and similar enzymatic activities through which they exert their toxic effects once inside a cell (Middlebrook and Dorland, 1984). The same is true for the different families of snake venom neurotoxins (Ishikawa et al., 1977). Thus, it is reasonable to focus on these common characteristics in the development of toxin therapies and prophylaxes.

Although cell and molecular biologists continually discover

new complexities in the function and regulation of various cellular pathways and events, the emerging theme is the discovery of common, albeit complex, pathways through which many cellular functions are controlled. For example, many different cell surface receptor systems have been found to be linked to a much smaller set of the so-called second messenger systems such as cyclic AMP, cyclic GMP, calcium turnover, protein phosphorylation and phosphatidyl inositol turnover. At the cellular and subcellular levels, multiple toxins may actually act at one locus or site. For example, the postsynaptic snake neurotoxins all apparently bind to the same site on the acetylcholine receptor and compete with acetylcholine for that site (Neumann, 1986; Mulac-Jericevic, 1988). Indeed, the common teleological argument with respect to toxins is that toxins have evolved to mimic beneficial biomolecules to the advantage of one species and disadvantage of another. Many toxins appear to gain entry into cells by binding to receptors on the cell surface. These receptors presumably exist for some benefit to the cell, and not primarily for the purpose of binding a toxin. The same logic can be extended to viruses, for many viruses use this same mechanism to gain entry into a cell. Thus, the argument that generic approaches to the development of medical defenses are scientifically invalid is specious. Scientific approaches that 'seek to discover the fundamental or crucial properties of a group of organisms or toxins where intervention can provide a prophylaxis or therapy are legitimate and sound.

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20-2 Comment: The Army seeks to reassure the public with two assertions: its purpose is strictly defensive, and it will use genetic engineering to create weaker, not stronger, pathogens (5.2.2.1, p. 5-9). These claims are inherently unconvincing.

Biological diversity is astronomical: we cannot hope to foresee the specific pathogen an adversary might use. Yet while

neither side can foresee the other's offensive choice, it can prepare innoculation against the specific weapon it plans to use offensively. Rightly or wrongly, a nation might calculate it would be free to launch a biological attack while protecting its troops and possibly its population. No matter what the Army says, this is how objective observers and other nations will interpret the Biological Defense Research Program's pursuit of genetic engineering.

Similarly, the Army's claim that it will use genetic engineering to develop less virulent, not more virulent, strains of pathogen is objectively unconvincing. The research and development on one can be converted into the other -- in far less time than is the case for atomic or conventional weapons problems. The hand-and-glove dilemma described above remains.

20-2 Response: See response to comment 36-1b above, which addresses the issue of the development of defensive medical measures against "astronomical biological diversity." In addition, it has been noted, particularly in the arena of genetic engineering of agriculturally important organisms, that there is only a limited amount of genetic modification that can be tolerated by a given organism before that organism is impaired in its ability to thrive or survive. Thus, the idea that genetic engineering can be used to produce organisms with properties that are vastly different from those of the parent organism is scientifically unrealistic. It is precisely because one can not predict what pathogen an adversary might use that the BDRP includes efforts to develop field detectors, and efforts to develop rapid medical identification and diagnostic methods, as well as protective measures and devices. Also see responses to comments 26-1, 22-4a and 27-20. The BDRP is not conducting offensive BW research using genetic engineering or any other methodology.

14-2 Comment: The DPEIS does not describe the decision criteria used when the Army elects to conduct research with a BL4 microorganism. Since such organisms carry highest levels of , it would be appropriate for the BDRP to formulate specific criteria to justify research with a BL4 microorganism. The mere existence of a BL4 pathogen may not call for Army research to address it. In some cases, other research centers may be able to conduct research more appropriately.

14-2 Response: The inclusion or exclusion of a decision criteria for the study of BL-4 organisms, other than employing the appropriate BL-4 safety criteria, would not affect the environment and is therefore, not included.

36-1a Comment: We fear that other countries will suspect that

U.S. intentions are to develop offensive weapons because of the building of a *BL 4* facility. Thus they will embark on or expand bioweapons development of their own.

36-1a Response: The "fear that other countries will suspect that U.S. intentions are to develop offensive weapons" is beyond the scope of the BDRP-EIS.

20-4 Comment: One must also view with dismay the Army's charges about the activities of other nations. Its unwillingness to substantiate these in public must engender skepticism. Since military defense is not available for reasons stated above, the allegations are in any case invalid as justifications for the U.S. biological warfare program. Moreover, they create an international climate of inevitability about biological warfare and thus weaken inhibitions worldwide.

Any charges must follow a scrupulous and responsible assessment of the evidence, and then must be brought to the appropriate international body and, if confirmed, serve as the basis for severe sanctions. The United States will have no diplomatic credibility in the effort if it itself pursues the Biological Defense Research Program.

20-4 Response: Section 5.2.1.4 states "Because BW is the only threat for which the U.S. possesses no capability for retaliation in kind, the existence of an active defensive research program serves as the only deterrent (emphasis added) to potential adversaries in planning for indiscriminate use of bioweapons in operations war plans." Also, see responses to comments 26-2, 3010a, and 36-1b.

48-4 Comment: Finally, vis-à-vis the program as a whole, it is my view that oversight should be through the NIH or another independent agency. Just as physicians have shown that they can only poorly police themselves, the possibility of a conflict of interest makes it unlikely that the Army can monitor this program in an unbiased fashion. The cavalier tone of the DEISs, both of them, in fact, in discussing experiments of extraordinary nature, only serves to reinforce the concern.

48-4 Response: Transfer of the program to a non-DOD agency because of suspicion of DOD motives by some elements of the public is not a justifiable reason for such consideration. The alternative of transferring a part or all of the BDRP to another Federal agency such as NIH was examined, (see Section 4.2.2). See also response to comment 22-1a.

35-1 Comment: The proposal that we increase our capacity in research into biological agents to be used as weapons or defenses reveals the insanity of our situation. Since the development of recombinant DNA, we must know that there is no defense possible to the use of biological agents. Recombinant DNA can be the Manhattan Project of biological weaponry. We must not allow that to happen.

By genetic engineering -- gene splicing - we can produce an endless spectrum of biological agents for which no conceivable vaccine or antidote would be possible. Many simple means exist to distribute or deliver such agents, means so utterly pervasive as to make defense impossible. Aerosols of great variety can spread dread plagues across a nation. No amount of exotic clothing, masks, or vaccines can really be expected to protect troops in the field. No conceivable means exist or could ever be developed to protect civilian populations throughout a nation. No continental astrodome can protect our air, our water, our people.

Yet real defenses do exist against the use of biological agents as weapons. These defenses, however, are hurt -- not helped -- by continued research on the use of biological agents as weapons or defenses against such agents, the distinction between such offensive or defensive use being impossible to maintain.

Most immediately and least important, there simply is not a realistic situation in which an enemy of the United States would use biological agents against us when other and better weapons are readily at hand. Biological agents would not immediately immobilize our forces. Our reaction, even after infection, could be swift and lethal with conventional or nuclear weapons. Second, biological agents are not reliable nor containable. Perhaps such agents would be rendered impotent by any one of many environmental factors: heat, cold, rain, wind. If lethal against an enemy, within a short time such a plague would incapacitate friends of the aggressor state and then that country as well. The effects of such agents cannot be controlled or contained.

The potential users of such heinous weapons who might not be deterred by such practical considerations are terrorist groups or completely irresponsible, dangerous states with little to lose at the specter of mass uncontrolled carnage. Our own research, with that of the Soviet Union and other nations, simply adds to the information ultimately available to other states and other groups. The notoriety our own actions give by the continued development of biological agents as weapons make their acquisition and eventual use by some terrorist group or terrorist state more likely, not less so.

Meanwhile, the immediate cost to those of us nearby -the possibility of accident, natural disaster through earthquake, or targeting by foreign enemy or terrorist group -- is

substantial. In other words, we bear the burden of possible great harm, intentional or accidental, while the result of this effort provides our country with less security, not more.

Far more important, however, is the harm we inflict upon ourselves in participating in this particularly senseless system of most gruesome mass death. Our greatest hope against biological agents being used against us is that the huge mass of humanity recoils at the suggestion that we would inflict such horror upon each other, fellow human beings. As we continue research into such monstrous weapons we make ourselves and each other less human. We lose the sensate qualities of our own humanity. We assume that others will let loose upon us plagues that might destroy millions of human beings. By projecting our fears onto others, we then justify our own actions that otherwise would be abhorrent and inconceivable to our own humanity.

We must overcome our own fear. I fear our fear. I fear our fear more than I fear Russians or Chinese or Libyans. When I fear the worst, my own consequent actions fulfill the worst fears of my enemies. Then their actions fulfill my own first perceptions. And so on.

The answer is not in developing still more weapons of mass destruction -- biological plagues to take their place in a ghastly gallery alongside mustard gas and nuclear weapons. Instead, somehow, we must learn how we might define ourselves without the use of an enemy, the Other, without whom we seem to have no content and no purpose. As individuals and as a nation, we must discover at our own core, our center, our identity; an identity so wonderfully human that we see purpose and direction without fearful projection onto another.

We beg your pardon for asking that you spend part of your lives in developing such use of biological agents, or the impossible task of inventing defenses against such agents, on our behalf.

For your own humanity and for ours as well, we ask that you stop.

35-1 Response: See responses to comments 36-1b and 20-2. The U.S. is in full compliance with the BWC. Also, see responses to comments 26-1 and 22-4a.

43-4c Comment: This is important for another reason, which is, as the Appendix A of the Environmental Impact Statement carefully states, there is no real difference between offense and defense if work is being done at Department of Defense facilities.

Certainly when, as they did in Fiscal Year '87, the Department of Defense starts cloning, analyzing snake venom from

sea snakes.

43-4c Response: The BDRP-DEIS contained no Appendix A. Presumably, Appendix 8 was intended, and the error is in the transcript. In contrast to the sense of the comment, Appendix 8 emphasizes differences in scope and type of research conducted in an offensive program versus a defensive program. Cloning and analysis of snake venom from sea snakes is undertaken as part of the effort to understand such toxins in general in order to develop vaccines and therapies for them.

43-4d Comment: This is research at the cutting edge of possible passage into military significance and those of us in the public sector, of course, do feel distrustful that this work is solely being done for defense purposes without a showing that there is some offensive intent by some other nation to develop sea snake venom as a meaningful weapon.

43-4d Response: See responses to comments 26-2, 26-1, 22-4a, 27-30 and 43-4c.

31-4c Comment: The budget for BW has increased nearly 500% since 1980, and more of that budget (60%) is contracted to private and university labs than ever before. Research into GEMs is increasing. All of this puts the lie to the Army's position that they only seek to maintain the status quo with the preferred alternative. The "real", underlying preference is to continue to expand research facilities, budgets, contracts, and research into GEM warfare agents. The Army's failure to admit the obvious, and to give the public a chance to review the real preferred alternative.

31-4c Response: The comment is incorrect. We note that there is no U.S. "BOO" program. The U.S. is not conducting studies into GEM warfare agents as stated in this comment. Also, see responses to comments 43-7 and 48-1.

24-10a Comment: The DEIS does not disavow the use of genetic engineering to create novel organisms with weapons potential.

24-10a Response: The DoD does not use genetic engineering to create novel organisms with weapons potential. Such studies would be in violation of the NIH recombinant DNA guidelines, see responses to comments 27-6c and 24-4a.

45-5 Comment: Another evaluation in this particular document is

that there is no integration and no control, so where's the program going....I think we have to question the credibility of the people who are in charge of this program. You know, the credibility issue is critical of all of this and I didn't see it anywhere in the EIS.

45-5 Response: Comment focuses on credibility, which is not a NEPA issue. Commentor is referring to the Army Science Board report as related in the Salt Lake City Tribune and the specific comment is a misinterpretation of the Army Science Board report (see page 5 of the Army Science Board report). "There does not presently exist within the Army an adequate mechanism for assuring the systems integration of the total BD program and the authority to control the programs' collective directions and outputs to assure this integration does not exist below DA level." This integration and control does not affect the health and safety of the environment. The Army does not attempt to centrally manage fire safety, vehicle safety, or many other safety programs at contractor's premises, all of which are more proximate hazards than is the laboratory management.

Sub-category F - Questions about classified research

14-10 Comment: A formal policy whereby neither the nature of BDRP research nor its results are classified as secret, the only exceptions being research on materiel where necessary. It is important that results of BL3 and BL4 pathogen or toxin research not be classified, especially if such research has involved recombinant DNA technologies. The DPEIS falls short of endorsing complete openness in publishing results of biological experiments. Maximum openness regarding the nature and design of BDRP research is important for state and local health officials and, also, for the public and the larger scientific community.

14-10 Response: The comment is incorrect. The BDRP is an open UNCLASSIFIED program. Only few, specific results which impinge on National Security may be classified, (see Sections 2.1 and 4.2.2) in accordance with the criteria for classification described in Army Regulations. Research on BL3 or BL4 pathogens, or toxins, is not classified in any case, nor is research involving recombinant DNA. Investigators are encouraged to present and publish results of their research at open meetings and in refereed journals, and annually present scores of papers under BDRP sponsorship.

38-5 Comment: The secrecy with which research decisions are made is not healthy. All research goals should be formally reviewed by a panel of respected non-military scientists, for example, National Academy members. This is partly to insure scientific quality, as is done by NSF and NIH, and partly to

allow a reasonable watchdog evaluation. This would greatly improve the government's credibility. What are the objections to this type of review?

38-5 Response: Improving the government's credibility is beyond the scope of the BDRP-EIS as is a response to a policy question "what are the objections to this type of review?" An external review merely to satisfy to a limited extent a public credibility concern is also beyond the scope for the BDRP-EIS.

24-9a Comment: Although the DEIS states repeatedly that all work under the BDRP is unclassified, the DOD Director of environmental and Life Sciences, Thomas Dashiell, says "Normally, our threat assessment and equipment vulnerability work is classified" *(Science* 226, 1178 (1984).

24-9a Response: As stated in the BDRP-EIS Sections 2.1 and 4.2.2, "the BDRP is an open UNCLASSIFIED program. Only results that impinge on National Security are classified. The exclusion of results (not the work itself) involving U.S. vulnerability, fits into the "impinge on National Security" category. The two areas of effort identified in the comment constitute only a small fraction of BDRP efforts, on the order of 1 or 2%. Also, see response to comment 24-9c.

24-9b Comment: Furthermore, secret clearance is required for the members of the Dugway Institutional Biosafety Committee (*BATF* DEIS, VIII-2).

24-9b Response: The BDRP is an open UNCLASSIFIED Program. However, the IBC members at DPG require access to classified threat information involving areas other than the BDRP in order to carry out their duties fully, and thus require a secret clearance.

24-9c Comment: The DEIS does admit that "those results which impinge on the national security may be classified." How are the work and the results separated?

It is important to recognize that secrecy or uncertainty about activities with offensive potential is provocative, regardless of the actual intentions and actions of the Army.

24-9c Response: Work is the conduct of the study - results are the products of the work. Results of tests may be classified in accordance with the criteria outlined in AR 380-86, if they reveal significant materiel or operational deficiencies in U.S. biological defense posture, training, and readiness. For

example, test plans, which include identification of the microorganism or toxin studied, are unclassified, but the compiled results of the test could be classified if they reveal deficiencies. As an example, if a detector under study failed to operate satisfactorily under certain environmental conditions, or if it worked well on some organisms and poorly on others, such results might well be classified as being of military value to a foe. Such classification does not obscure any environmental issues.

24-9d Comment: Since the BDRP is said to be unclassified, it should not be difficult to find means for making its activities more open. Testing, in particular. It is widely assumed that the main incentives for secret testing are to obtain offensive information and to keep secret the defensive capabilities needed for offensive use of BW. Increased openness, including declassification of results, would be an important step in preventing the erosion of the BWC.

24-9d Response: While preventing the erosion of the BWC might be a political concern, it is beyond the scope of the BDRP-EIS. Secret testing is not conducted under the BDRP. As stated in the BDRP-EIS Section 2.1 and 4.2.2, "the BDRP is an open UNCLASSIFIED program." See also responses to comments 14-10 and 24-9c.

Sub-category G - Scientific Validity

38-1d Comment: There is no way to anticipate the particular organism used by enemies, so vaccines or detection systems cannot be developed.

38-1d Response: The comment is not accurate either from a military intelligence viewpoint or scientifically, see responses to comments 36-1b and 20-2.

39-5a Comment: The development and the testing of novel organisms is justifiable under the programs defensive rubric as follows: "If we develop a novel organism and develop defenses to it, then if the enemy develops the same organism we will already have a defense."

The statement quoted...above has problems: One of the routes to be pursued in defense against novel organisms is via the development of vaccines. Vaccines are quite specific. The target of vaccines is one of the targets that might be varied via genetic manipulations. It would be hard to anticipate the target changes that an adversary would make, relatively easier to make your own.

39-5a Response: The question posed in quotes presumably was created by the author of the comment because it is not in the BDRP-DEIS. The hypothesis of the commentor does not portray what the BDRP considers defensive research. See responses to comments 36-1b and 20-2 which discuss the scientific basis for development of defensive measures.

40-3 Comment: The Army claims they need this facility to develop antidotes to deadly germs that could be used against our troops. While on the surface this motive may appear sound, in reality it is folly. First, pathology experts have testified that it is virtually impossible to create antidotes for even a small portion of the various strains of a virus. Second, to create antidotes for new viruses means creating new viruses for offensive use in violation of the Geneva Accords of 1972.

40-3 Response: The comment really pertains to the BATF-DEIS; however, the premise contained in it is scientifically invalid. Just as broad spectrum antibiotics are now available, broad spectrum antiviral compounds, many of which seem to have family- activity are available or in the drug development pipeline, e.g., ribavirin. The second premise of creating "new viruses for offensive use" is a patently unsubstantiated statement. The BDRP does not include any efforts to create "new viruses" in order to find antidotes for them.

41-1c Comment: Ineffectiveness. As I have studied molecular biology I have become convinced that research into defenses against genetically engineered pathogens is futile. The almost infinite number of possible mutations in viral coat proteins, as an example, makes the development of effective vaccines nearly impossible. Filtration and other methods of preventing organisms from infecting a host already exist, and dangerous recombinant or natural organisms do not present any new external features not found in "safe germs" to these generalized defenses. Thus research using dangerous and recombinant organisms is pointless.

41-1c Response: Comment noted. Statement is one person's opinion, not shared by all scientists. There are many possible approaches that do not rely on the principle discussed. Also, see responses to comments 36-1b, 20-2 and 40-3.

55-3 Comment:...second reason for this is a development for medical defense. Obviously, this is ludicrous. There is no defense possible against a biological attack. Any scientist with any credibility can make a biological weapon that could devastate the country. There is no way that we could immunize everybody

against every possible concoction that science can dream up and germs tend to mutate, they change. So one defense that is adequate one day, the next day is not.

55-3 Response: Comment noted. Comment is an over statement of the problem without realistic scientific expectations. One does not have to have a defense against every possible organism for the defense to be of significant value. Also, see responses to comments 36-1b and 20-2.

47-2 Comment: A second extremely important point that has been raised is the fact that the research should be reviewed by a scientific but non-Army committee and this is done in all sorts of other Government agencies such as the NIH, and the NSF, and these are two reasons for this.

First of all, it helps assure a greater scientific validity and perhaps even a more appropriate methodology and second of all, by having outside review it does allow a watchdog-type of evaluation, and as has been brought up quite a bit tonight, the Army does have a credibility problem and this would be one way to solve that as well as perhaps to improve the science.

47-2 Response: An external review merely to satisfy, to a limited extent, a public credibility concern is beyond the scope of the BDRP-EIS.

SUBJECT AREA 5: MISCELLANEOUS

Sub-category A - Errors in Document

9-4 Comment: Page 5-20, section 5.3.3, paragraph one, states "The installation includes more than 800,000 acres in Tooele and Juab Counties..."To the best of our knowledge, DPG does not extend into Juab County.

9-4 Response: It is true that DPG does not at this time include any part of Juab County within its boundaries. A portion of the southeastern corner of the installation (formerly called the "joint use area"), whose use was shared between the Army and the Bureau of Land Management (U.S. Department of the Interior) in the past, was within Juab County. The installation boundaries were shown on Army maps as including that land and several Army publications (see Section 7) listed Juab County as one of the counties in which the installation was located. This is common practice when leaseholds and public domain withdrawals are a portion of a military installation, and does not always imply that the land is held in fee by the Army. The commentors are correct in their statements, and the text of the Final EIS has been modified accordingly. The economic region, however, does include Juab County, and a measurable portion of installation civilian employees reside there.

28-2 Comment: I seriously question the integrity of the data used to support the proposed action. I feel that the real issues were obscured by generalities and program specific "buzz" words making the document incomprehensible to the average reader. The document seems to be inconsistent and in some cases inaccurate, again lowering my comfort level and trust concerning the validity of the document. A small but significant example is the statement in section 5.3.3: "the installation includes more than 800,000 thousand acres in Tooele and Juab counties..." Juab county does not host DPG to the best of my knowledge.

28-2 Response: See response to comment 9-4.

26-4 Comment: Furthermore, it appears from the public description of the DOD studies at the University of Illinois that mycotoxins and bluegreen-algae toxin are being injected into pigs (viz. DAMD 1785C5224 and DAMD 1785C5241). Nevertheless, DEIS Appendix 3 lists the University of Illinois as a secondary site that falls into Risk Category VII, which is defined as "Other Program Research and activities," a term that is further defined as "*Includes either very low risk or non-risk activities which do not fit into the above [I-VI] categories." (page A3-1). Quite frankly, I find it completely misleading to say that the injection of pigs with mycotoxins and bluegreen-algae toxins are

"very low risk or non-risk activities" that only require the lowest degree of minimal protections according to DBRP procedures. The DEIS's obfuscation of the weapons-specific type of research that is really going on at the University of Illinois, together with the misleading description of such research as being low-risk or non-risk, call into question the entire categorization scheme for all of the contracts at the so- secondary sites in the BDRP. This section of the DEIS must be substantially revised and significantly more information on the exact nature of BDRP contracts and secondary site protections must be disclosed to the people inhabiting the nearby vicinities.

26-4 Response: Comment refers to conclusions drawn from a typographical error in the document. The University of Illinois should have been listed as participating in Category III as well as Category VII research. The Category III efforts are those related to toxins. The Category VII project involves the development of a database for diagnosis and medical treatment of toxins. It is correctly classified. Both types of efforts were shown in earlier drafts, but the first entry was omitted in the final typing of this table. The error of omission is regretted and has been corrected. The classification of all entries in Appendix 3 has been re-examined, and no additional corrections were necessary. No "weapons-specific" research is underway at the University of Illinois or at any other location. Also, see responses to comments 26-1 and 26-2.

Sub-category B - Agreement with the comment

13-1 Comment: I feel that you have adequately addressed the issue of environmental effects of the Biological Defense Research Program and that your research is potentially of great value to public health especially as it relates to the development of vaccines in the future. I understand that you were already involved in the development of Ribevirin for Lassa fever and that is a major contribution to the research program.

13-1 Response: Comment noted. No response required.

6-1 Comment: In accordance with Section 309 of the Clean Air Act, the U.S. Environmental Protection Agency (EPA) has reviewed the Army's Draft Programmatic Environmental Impact Statement for the Biological Defense Research Program. On August 28, 1987, I transmitted EPA's comments on the scope of this Draft EIS, and we are pleased that many of EPA's concerns are addressed in the Draft EIS.

In 1987, EPA expressed concerns about the possible exposure of workers and the general public to infectious diseases. The Draft

EIS does a thorough job of discussing these risks and the Army's efforts to mitigate them at Army and other DOD facilities. In particular, appropriate measures, such as vaccinations and disinfection, have been instituted to guard against accidental exposures.

6-1 Response: Comment noted. No response required.

5-4 Comment: The Impact Analysis Matrix (Appendix 6) was especially effective in presenting the assessment of risks considered by the EIS team. Based upon the information provided in the DEIS, we feel that the potential for adverse human health effects will be minimized.

5-4 Response: Comment noted. No response required.

5-1 Comment: We have reviewed the Draft Environmental Impact Statement LOUIS) for the Department of the Army Biological Defense Research Program (BDRP), and we are responding on behalf of the U.S. Public Health Service. We believe, in general, precautions specified for working with infectious agents, toxins, and genetically engineered microorganisms are in compliance with the most stringent practices.

From our review of the document, it appears that the classification of infectious organisms and the specific laboratory precautions are adequate for defined biosafety levels. Potential public and laboratory hazards, waste disposal, and physical security have also been adequately considered.

5-1 Response: Comment noted. No response required.

6-3 Comment: EPA also commented that all uses of pesticides within the scope of the program must be in accordance with the EPA-approved product labels. Disinfectants are considered to be pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and use of disinfectants and other pesticides are governed by that Act. The Draft EIS indicates that formaldehyde gas generated from heating paraformaldehyde powder will be used as a disinfectant at a concentration of 10,000 parts per million (by volume in air) for a contact time of 10-12 hours. The FIFRA Registration Standard for paraformaldehyde and formaldehyde (copy attached) lists this as a registered use and provides useful health and safety information. All use of registered pesticides must be in accordance with EPA-approved label directions. While general references are made in the EIS to the use of other antimicrobial pesticides for the decontamination of waste waters and laboratory

surfaces, no specific details were provided. Here again, label directions must be followed.

7-3 Response: Comment noted. EPA-approved label directions are followed.

1-1 Comment: We do not expect adverse impacts from either of the alternatives to National Forest System lands, Forest Service employees, or the environment in general.

1-1 Response: Comment noted. No response required.

2-1 Comment: We have reviewed the Draft Programmatic Environmental Impact Statement on the Biological Defense Research Program dated May 1988, and consider it adequate. While we would prefer a more detailed treatment of specific issues, we understand the facility of the broad programmatic approach to this type of action. We will be pleased to assist you further as you implement your "tiered approach" to future actions, and will comment on site specific proposals as they arise.

2-1 Response: Comment noted. No response required.

3-1 Comment: The Environmental Division has reviewed the draft programmatic environmental impact statement for continuation of the Biological Defense Research Program. We have no comments.

3-1 Response: Comment noted. No response required.

4-1 Comment: Thank you for providing the opportunity to review the Draft Programmatic Environmental Impact Statement on the Department of Defense Biological Defense Research Program. We do not intend to comment on the document.

4-1 Response: Comment noted. No response required.

15-1 Comment: He says: "I appreciate the opportunity to participate in this public process as we review the draft programmatic environmental impact statement on the Army's biological defense research program. I want to thank the Army for considering our request to hold a public hearing meeting on the BDRP in the state of Utah. I strongly support the public process which provides an opportunity for interested parties, like you and I, to comment on this proposed action affecting our

state and our citizens. I hope that the purpose of these hearings will be to consider the options very carefully. All questions raised must be answered, even the hard ones. Then and only then will the public process result in the correct decision regarding the Army's research program and ultimately Dugway's future in Utah.

"I strongly support a national defense and stated so at the public meeting held at Salt Lake City on March 22nd of this year. At that time, I also stated I opposed the Construction of a BL4 laboratory at the Dugway Proving Ground. With today's announcement that the Army will designate the BL3 lab as a preferred alternative, I commend the Army on their change of attitude regarding the biological aerosol test facility. This change will prevent the testing of dangerous organisms for which there's no known cure.

"I appreciate the Army's new found willingness to compromise with the people of Utah and to negotiate with me as governor on matters which affect the state and its citizen. I particularly appreciate the help of congressman Jim Hansen in communicating our concern to the Army and helping assure that the Army respond to our concerns.

"My office has also worked completely with Senator Garn, who is a member of the military construction's appropriations committee, and as a member, he has been working to ensure that the safety concerns and the need for Defensive Biological testing are being coordinated with my office. Senator Garn has closely followed this process for the people of Utah and we appreciate his efforts.

"My number one concern has always been the health and safety of the people of Utah. I will continue to work closely with the Army to ensure that the health and safety of the people of this state also remains one of the Army's primary concerns and they evaluate the biological research defense program. I will insist the open process continue and that the Army shares with the people in the state information regarding testing that is being performed in Utah. The Army has told me of their willingness to accommodate a Utah scientific civilian review committee that I first proposed during the March 22nd hearing. I, along with others, proposed the national review committee of the world's leading experts, but I am currently formulating a list of members for the Utah committee and will charge them to monitor and evaluate testing activities at the Dugway Proving Ground. I commend the Army and the individuals of Dugway for the open communications that have been established. I look forward to working with the Army such that they may accomplish their mission and in so doing protect the health and safety of the citizens of the United States."

15-1 Response: Comment noted. No response required.

17-1 Comment: I don't have any prepared statement, I have only a couple of comments I would like to make. I find it deplorable when KSL TV, under the guise of reporting the news, take that opportunity to editorialize it against Dugway. I think that is really an abuse of the journalistic license. Secondly, I find it deplorable that many of our citizenry would appear to give greater credit to foreign powers than to our own United States government and to our own military. Lastly, I would like to say that I am sorry that the Army did rollover and give in to the pressures of the news media and some of the politicians in changing to a BL3 rather than 4. I think the credibility of the military in the past and protection of our country and our security certainly is not beyond total criticism, but by and large it has been very exemplary. I am very supportive of them, I feel it's wrong for Congressman Owens to come across the Oakridge [sic, Oquirrh], he ought to stay over in the Wasatch Front and see if he can't hoodwink his constituents there.

17-1 Response: Comment noted. No response required.

21-1 Comment: I am pleased to provide the following comments concerning the draft Environmental Impact Statement on the Army's Biological Defense Research Program (BDRP). Before doing this, however, I should summarize my professional qualifications and interests in the area of biological toxins. As noted in my enclosed Curriculum Vitae I have been a professor of Pharmacology in the Section of Pharmacology and Toxicology at the University of Connecticut, School of Pharmacy since 1968.

I have well over 100 research publications many of them involving the use of snake venom and venom components, particularly the enzyme phospholipase A2. My interests and expertise extend, however, over the much broader field of toxins (animal, plant and microbial) as evidenced by the fact that I have been editor since 1970 of TOXICON, the official journal of the International Society on Toxinology (IST) and the only journal devoted exclusively to publishing research dealing with animal, plant and microbial toxins. I am also President-elect and as of August 4, 1988 will be President of the IST. Because of these professional commitments I am familiar with research using natural toxins both by American and foreign scientists. I have also had occasion during the past year to visit the Army's facilities at Fort Detrick and meet with many of their research scientists. I am also a member of the Life Science Committee of the U.S. Army Chemical Research, Development and Engineering Center. I would have wished to attend the meeting on July 25 in Arlington, Virginia to present these comments in person, however, because of prior commitments this is not possible. I feel, however, so strongly concerning the questions raised in the Environmental Impact Statement of the BDRP that I request your

consideration of these comments.

Before commenting on the impact statement *per se* I want to address the question of the quality and type of research being carried on at the Ft. Detrick facility. I feel confident that any unbiased peer review would comment favorable on the quality of research being conducted at the Army facility. It is as good or better than that being carried on at major universities throughout the world. There has recently been a burgeoning interest in studying toxins which is quite independent of any biological warfare threats. Highly toxic and specifically acting toxins (Ex. tetrodotoxin, α and β bungarotoxin, latrotoxin, botulinum toxin, pertussis toxin, etc.) are extremely useful tools with which to study biological processes. An understanding of the functioning of the nervous system and ultimately diseased states of the nervous system would be much less if scientists had not used in the laboratory tetrodotoxin to block the sodium channel of the nerve, a bungarotoxin to bind to the acetylcholine receptor, botulinum toxin to block nerve muscle transmission, etc. The group at Ft. Detrick has made major contributions to our knowledge of toxins and I might especially mention in this connection the research carried on by Dr. John Middlebrook and Dr. Leonard Smith. Because of his outstanding scientific contributions to the field of toxicology, I appointed Dr. Middlebrook to the Editorial Council of TOXICON. The focus of their research at Fort Detrick and their ultimate goal is the development of medical and physical defensive measures against biological warfare threats. However, most of their research represents high quality basic research of a similar type being carried on at many universities. The environmental impact and safety problems which they face are not unique and are shared by many laboratories throughout the world. Indeed the Army facility has formalized safety procedures which are better than that in the university community in general. The fact that "accidents" are so few and far between attests to the fact that scientists have voluntarily taken appropriate precautions in order to be sure that they neither poison themselves nor others. It would be a severe blow to the worldwide community of toxicologists if the BRDP were terminated. Genetic Engineering is a vital research tool if we are to understand the action of toxins and design appropriate safeguards against toxins. It would be folly to attempt to separate this part of the Army program from the rest of their program.

I found the Environmental Impact Statement to be very detailed and to reach conclusions which are justified on the basis of our present knowledge. I do not understand how someone can read this statement with an open mind and call it "completely inadequate." The authors of this document are to be complimented for the thoroughness of their analysis. As I noted above, the Army facility is carrying on good science while this Environmental Impact Statement demonstrates that they are also performing safe science. The BDRP program deserves to be continued.

12-1 Response: Comment noted. No response required.

23-1 Comment: In the 1967-1968 period, a small but vocal group of people began a campaign to bring about the abolishment of the offensive biological program. Their approach to this objective was to flood the media with a steady stream of charges regarding program safety and safety of the community which surrounds Fort Detrick. By 1969, an environment of hysteria had been created which prevent reasoned discussions with these people. I was one of many employees in this program who felt that our research and development were making an essential contribution to the defense of our country. I soon came to realize that these people were not interested in biological safety or any other aspect of the BW programs. President Nixon succumbed to these and other political pressures and abolished the offensive biological warfare program in November of 1969. Thus, the United States surrendered an entire weapons system.

I would like to digress from my prepared statement to address the comment of Dr. Rosenberg regarding the nonpredictability of biological warfare. I wish that the Department of Defense would declassify aerosol data collected in large scale field tests by Deseret Test Center in the 1960s. These data clearly demonstrate that aerosols behave according to the mathematical models developed by Calder and others. Preplanning before an attack is absolutely essential to success. When meteorological conditions are defined, the transport of an aerosol is quite predictable.

Today, some 20 years later, another small but highly vocal group of protectors seem to be targeting the defensive biological warfare programs for abolishment...particularly the medical defensive programs. Once again, safety seems to be their principal buzz word. But let me tell you, ladies and gentlemen, they cannot make it stick. Like one of the speakers at the recent Democratic Convention stated "that dog won't hunt."

During the offensive BW program at Fort Detrick, a small group of dedicated scientists established principles on which modern day safety technology and laboratory design were founded. Scientists such as Arnold G. Weedum, Riley D. Housewright, Charlie Phillips, and Everett Hanel, to name just a few, were truly heroic pioneers, and every person who works in an infectious disease laboratory today, owes these gentlemen a tremendous debt of gratitude. Their contributions are described in somewhat greater detail in Appendix 9 of the preliminary draft, *Environment Impact Statement.*

During 26 years of offensive BW studies at Ft Detrick, not a single person in the civilian community became infected. This demonstrates quite clearly that even 20 years ago, Ft. Detrick

did not pose a safety problem to the surrounding community. Yes...there were infections among the "at risk" laboratory workers...423 of them including three deaths from 1943 to 1970. The important factor here is that these were "at risk" personnel, people who worked in the "hot" areas of the laboratories. By contrast, administrative personnel, people like secretaries, budget analysts and supply clerks, who worked in "clean" areas did not become sick. This is an important factor because in most instances the clean area was separated from the hot area by a wall in the same building.

The medical defensive program for the entire Department of Defense is performed by and under the general direction of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick. USAMRIID has been able to take full advantage of the safety technologies and laboratory building designs of the defunct biological warfare laboratories and to extend these technologies and laboratory designs to a higher order of safety.

The safety record of USAMRIID is outstanding and is indicative of the safety measures being used in the study of some very nasty organisms. It's true that USAMRIID has had a few infections. No work is risk-free. Their safety record is significantly better than most industrial concerns. There have been no deaths and no disabling injuries. USAMRIID employees work in the most unique and best safety-engineered laboratories in the free world. These laboratories are designed with sufficient safety redundancy to prevent the escape of infectious or toxic products into the surrounding community. If old Fort Detrick labs did not cause infections in the community, you can be assured that the modern laboratories of USAMRIID will not also.

I would like to believe that those of you who oppose the programs of medical defense against biological warfare, do so on the basis of safety and out of concern for the community which surrounds Fort Detrick. There is a body of logic which can be drawn upon to alleviate your fears. However, if you have other motives such as stopping all defensive studies against biological warfare, I have no sympathy with you or your cause.

In the Iran/Iraq war, chemical warfare agents were used when it was in Iraq's self interest to do so and in spite of international treaties and international public opinion not to do so. BW agents could very well have been employed instead of chemical agents. The big difference between CW and BW is that the number of chemical casualties would have to be multiplied by a factor of 100 to 1000.

Biological defense, and particularly medical defense against biological warfare, remains as our country's only deterrent. If these defensive programs stop or are even reduced, the United States falls into a highly vulnerable position in an essentially

hostile and non democratic world.

23-1 Response: Comment noted. No response required.

37-1 Comment: I represent a research group which is an Army contractor. We have been conducting research at Utah State University on developing new drugs to cure virus infections of man. I should point out that much of the recent increase in Army expenditures on BDRP has been for the development of drugs - a most defensive (in opposition to offensive) research attitude.

I wish to make a statement regarding the safety aspects of our research, and the Army's interaction with us in this regard.

37-1 Response: Comment noted. No response required.

37-2 Comment: The disease we wish to cure is Rift Valley Fever - this is caused by a highly dangerous pathogen often lethal for man. At the Army's suggestion, we are using Punta Toro virus in our research. This is a less pathogenic, look-alike virus which is classified in the BL-2 category. Thus we are using a "substitute" pathogen as has been recommended tonight by several speakers.

37-2 Response: Comment noted. No response required.

37-3 Comment: Before we could work with this organism, I was invited, at Army expense, to visit Fort Detrick and meet with Dr. Ralph Kuehne, the Safety Engineer for that facility. I did so, accompanied by our campus architect. We were given an extensive tour of that facility, including many "behind the scenes" areas, in order to help us design an appropriate facility for our research.

37-3 Response: Comment noted. No response required.

37-4 Comment: Such a facility was then constructed on our campus. It is a designated BL-3 facility, with negative air, HEPA filters, pass-through autoclaves and total restriction of all but fully trained personnel. Again, I should stress that all organisms with which we are working are designated BL-2 agents, but all are being handled under full BL-3 conditions at the Army's request.

37-4 Response: Comment noted. No response required.

37-5 Comment: Our facility was inspected during construction by Dr. Gary Resnick of Dugway and later by Dr. Peter Canonico and Dr. Dominique Pifat of Fort Detrick. All concluded the laboratory was an acceptable BL-3 facility. Before opening it for research, we held an open house in which campus administrators, campus and Logan City police and fire department officers, and City officials were invited to tour the facility and ask questions about it.

In summary, we were impressed with the interest and concern of the U.S. Army Medical Research and Development Command for our safety and proper conduct of research they were sponsoring. Our group was never contacted by the Congressional Sub-Committee who investigated the Army's safety practices, so I must conclude the report was cursorily prepared and is not completely correct.

37-5 Response: Comment noted. No response required.

44-1 Comment: Good afternoon. With all due respect to the technical knowledge and expertise of the distinguished panel up front, I would appreciate your indulgence for about three to five minutes to express my views as a private citizen in regards to this DEIS thing. And I will read the statement from my notes.

Thank you for giving me the opportunity to respond to the statements made in the local Frederick County newspaper concerning the situation ongoing at Fort Detrick, Maryland.

I will only take approximately three to five minutes of your time to develop my opinion on the perspective and from the perspective of a typical average citizen of the United States.

Since I am a resident of Frederick City and also reside in a direct line geographically with the USAMRIID Laboratory. I'm in a position of knowledge as to the effect, environmentally speaking, of the conditions that presently exist there.

But, more importantly, I have a continuous awareness of its history and its total effect on the immediate Army community and its effect on surrounding neighbors such as myself.

As a public citizen, I am obliged to seek the necessary knowledge, to be an informed member of society concerning the laws, rules, and regulations governing civil order as duly constituted in the laws of our elected representatives who enact them, and these laws are binding on all the subjects of the state.

In relation to the observance of all our laws, whether just or whether unjust, a restatement of the virtue of patriotism is

essential in this particular hearing conducted today, namely that patriotism is simply the love of one's country, and a good citizen will not hesitate to face death in the defense of his country.

Now, I regard with mixed feelings the press' view of the situation that exists at the Laboratory. On the one hand, I as a member of the public am being informed of a condition that's viewed by the local press as worthy of being looked into, whereas on the other hand, the press wants to give the impression that a, quote, "problem exists," or has been existing for some time in the past.

My reaction to the press' view is that the press should exercise extreme care in the reporting of the truth of the matter so that the reading public can balance it with sincere concern for the U.S. Army and USAMRIID Laboratory interest and not be so quick to point out a picture of a real or imagined problem that may or may not exist.

Freedom of the press carries with it a supreme obligation to carry out its responsibilities in a totally truthful manner, regardless of a particular writer's or publisher's views or personal opinions on any given subject under discussion.

Especially careful should the press be when it reports on such topics on such paramount importance as the health and welfare of its citizenry. I am a reasoning member of the public and have a duty to inform myself of the situation as regards to whatever risks that I feel that I can live with and inform my family of the situation and take the necessary action to protect my family from those risks that exist at the Laboratory.

A concurrent view of the press is to not look at the magnitude of the situation at the Laboratory, so that the public at large becomes unnecessarily alarmed and gives expression to its alarm by means of civil protest and disobedience to the civil laws governing society.

Because I am not connected in any way with Fort Detrick, and because I represent myself and my family's health and welfare, and their best interests, I personally feel that there is no greater risk to me and my family's health and welfare with the present setup at the Laboratory and it appears to me as a member of the public, that the USAMRIID Laboratory poses no threat or risk to the public at large.

The constant idea that exists in the minds of the public concerning looking for fault and all that with the U.S. Government, and in particular looking for fault in the four branches of the military establishment is totally irresponsible and should be discouraged by all citizens of this great country and form of government that we all enjoy in fellowship and its privileges of citizenship.

The press should take a look at itself before it reports on its, quote, "alleged condition" that may or may not exist at Fort Detrick, Maryland and be more responsible to its own conditions of fairness and its responsibilities to the public at large, and its fairness to all sides of a given topic under scrutiny.

Let the people of Fort Detrick go on about their business of protecting the citizenry of the U.S. and participating in a very positive contribution so that all the citizens benefit from the research and scientific discoveries without any unnecessary interference from anyone, including all branches of Government, namely the Legislative, Executive, and Judicial branches.

In its basic and simplest terms, the Legislative branch of Government is unnecessarily interfering with the activities of another branch of Government, namely the Executive branch, and exacerbating a situation with its present views on the merits or demerits of the USAMRIID Laboratory situation.

Thank you very much for allowing me this time to speak as a private citizen from the perspective of typical citizen of the United States of America. Thank you very much.

44-1 Response: Comment noted. No response required.

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