DOE/EA-1364

Environmental Assessment for The Proposed Construction and Operation of a Biosafety Level 3 Facility at Los Alamos National Laboratory, Los Alamos, New Mexico

February 26, 2002

Department of Energy
National Nuclear Security Administration
Office of Los Alamos Site Operations

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EXPONENTIAL NOTATION: Many values in the text and tables of this document are expressed in exponential notation. An exponent is the power to which the expression, or number, is raised. This form of notation is used to conserve space and to focus attention on comparisons of the order of magnitude of the numbers (see examples):

1×10^{4}	=	10,000
1×10^{2}	=	100
1×10^{0}	=	1
1×10^{-2}	=	0.01
1×10^{-4}	=	0.0001

Metric Conversions Used in this Document

Multiply	By	To Obtain
Length		
inch (in.)	2.54	centimeters (cm)
feet (ft)	0.30	meters (m)
yards (yd)	0.91	meters (m)
miles (mi)	1.61	kilometers (km)
Area		
Acres (ac)	0.40	hectares (ha)
square feet (ft^2)	0.09	square meters (m^2)
square yards (yd^2)	0.84	square meters (m^2)
square miles (mi^2)	2.59	square kilometers (km^2)
Volume		
Gallons (gal.)	3.79	liters (L)
cubic feet (ft^3)	0.03	cubic meters (m^3)
cubic yards (yd^3)	0.76	cubic meters (m^3)
Weight		
Ounces (oz)	29.57	milliliters (ml)
pounds (lb)	0.45	kilograms (kg)
short ton (ton)	0.91	metric ton (t)

EXECUTIVE SUMMARY

The Department of Energy (DOE), National Nuclear Security Administration (NNSA) has responsibility for national programs to reduce and counter threats from weapons of mass destruction including nuclear, chemical, and biological weapons (bioweapons). NNSA's bioscience work at Los Alamos National Laboratory (LANL) in support of these missions require work with infectious agents, including those historically used for bioweapons. Pioneering technologies and capabilities at LANL, particularly in the synergy of biological science with engineering, computational, and physics capabilities, have been recognized by national leaders involved in planning and addressing the increasing national security concerns that focus on bioagent (biological agent) counter-terrorism technologies, and the countering of emerging natural diseases. As a result, the need to work with bioagents at LANL and within NNSA is growing. At this time, DOE does not have under its administrative control any microbiological laboratory facility capability beyond Biosafety Level (BSL)-2. BSL-3 facilities provide sites for safe and secure manipulation and storage of infectious microorganisms. The nature of BSL-3 work requires efficient sample processing, handling of a variety of organisms concurrently, and assurance of sample security and integrity. NNSA's mission requirements for sample integrity necessitates that the chances of cross-contamination and degradation of samples are minimized by reducing excessive handling and transportation. The few offsite BSL-3 facilities available to NNSA are often heavily committed to other projects or tailored to work with specific types of microorganisms. In order to more effectively utilize and capitalize on existing onsite facilities and capabilities at LANL, and ensure the quality, integrity and security of microbiological work, NNSA needs BSL-3 laboratory capability located at LANL.

The Proposed Action and alternatives differ in how the facility would be constructed. In each of the alternatives, the BSL-3 facility could be located in one of three potential locations at LANL. Two of the potential locations are within Technical Area (TA)-3 and one is within TA-58. Under all alternatives and at each location option, the facility would be designed and operated in accordance with guidance for BSL-2 and BSL-3 laboratories established by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). Physical security would be implemented commensurate with the level of work being performed within the facility. No radiological, high explosives, or propellant material would be used or stored in the BSL-3 facility and no research animals or plants would be housed in the facility. Sample shipments would only be received at the BSL-3 facility and only in compliance with all established shipping guidelines and requirements. The samples would be stored in the BSL-3 laboratory within a locked freezer, or refrigerator according to the needs of the sample for preservation. Biological wastes would be disposed of in accordance with CDC and NIH guidance.

The Proposed Action is to construct an approximately 3,000 square foot, one-story permanent facility which includes two BSL-3 laboratories with adjoining individual mechanical rooms separated by a central support BSL-2 laboratory; clothes-change and shower rooms; and associated office spaces. In all three potential locations the construction

and operation of the facility would be the same. It is estimated that the operational design life of the proposed building would be at least 30 years.

Under the Partial Prefabrication/Build Alternative, NNSA would purchase and install ready-assembled prefabricated BSL-2 and BSL-3 modular units to form a new BSL-3 facility. Transportation of the buildings, construction of their concrete footings, and the use of a crane to position the buildings would be required for this alternative. The estimated useful life span of the modular facility at the minimum would be about 20 years. This alternative would not be in accordance with the NNSA and LANL general initiatives against non-permanent structures but would meet NNSA's purpose and need for action.

Under the Prefabrication Alternative, the NNSA would purchase, install and operate a ready-assembled prefabricated BSL-3 laboratory modular unit as a stand-alone facility while constructing a permanent building onsite to house a BSL-3 facility as described by the Proposed Action. This alternative would require the delivery and installation of a small (less than 1,000 square foot) modular unit equipped to function as a stand-alone BSL-3 laboratory at one of the optional construction sites or at a similar LANL site where utility services were already available such as at TAs 54 and 16. The small modular facility would require the support of existing LANL BSL-2 laboratories and office spaces for some of the operational activities required. It is anticipated that the modular BSL-3 facility would be operated for about 12 to 18 months while the construction of the permanent on-site BSL-3 facility was undertaken. Upon completion of the permanent facility and the initiation of its operation, the small modular BSL-3 facility would be decontaminated and decommissioned or reused.

Under the No Action Alternative, NNSA would not construct or place a BSL-3 facility at LANL. In this event, NNSA would continue to have their BSL-3 laboratory needs met by existing or new BSL-3 laboratories located offsite from LANL. There would continue to be certain NNSA national security mission needs that could not be met in a timely fashion, or that may not be able to be met at all. The No Action Alternative would not meet the NNSA's identified purpose and need for action.

The environmental consequences from site preparation, construction and routine operation are minor and do not differ greatly between the three optional locations or among the Proposed Action and alternatives. Each of the three sites was selected for previous disturbance and availability of utilities. Potential effects to the environment from the proposed facility are mostly related to human health effects during operation. The potential human health effects of the proposed BSL-3 laboratory would be the same as those demonstrated for similar CDC-registered laboratories that are required to implement the guidelines established mutually by the CDC and NIH. Relevant human health information gathered from LANL's past experience with BSL-1 and BSL-2 laboratories, from the U.S. Bureau of Labor Statistics and from anecdotal information in published reports, indicates that while laboratory-acquired or laboratory-associated infections sometimes occur, they should be considered abnormal events due to their infrequency of occurrence (see Appendix F). As such, the potential human health effects from these events are discussed as Abnormal Events

and Accidents. No cases of illness are expected to result from implementing the Proposed Action as a result of an abnormal event or accident.

1.0 PURPOSE AND NEED

1.1 INTRODUCTION

The *National Environmental Policy Act of 1969* (NEPA) requires Federal agency officials to consider the environmental consequences of their proposed actions before decisions are made. In complying with NEPA, the United States (U.S.) Department of Energy (DOE), National Nuclear Security Administration (NNSA[1]) follows the Council on Environmental Quality regulations (40 *Code of Federal Regulations* [CFR] 1500-1508) and DOE's own NEPA implementing procedures (10 CFR 1021). The purpose of an environmental assessment (EA) is to provide Federal decision-makers with sufficient evidence and analysis to determine whether to prepare an Environmental impact statement (EIS) or issue a Finding of No Significant Impact. This EA has been prepared to assess environmental consequences resulting from the construction and operation of a Biosafety Level 3 (BSL-3) laboratory[2] facility within the boundaries of the Los Alamos National Laboratory (LANL) (Figure 1-1). LANL is one of the national security laboratories under the authority of the Under Secretary for Nuclear Security of the NNSA who serves as the Administrator for Nuclear Security and Head of the NNSA (50 USC Chapter 41, § 2402(b)).

The objectives of this EA are to (1) describe the underlying purpose and need for NNSA action; (2) describe the Proposed Action and identify and describe any reasonable alternatives that satisfy the purpose and need for NNSA action; (3) describe baseline environmental conditions at LANL; (4) analyze the potential indirect, direct, and cumulative effects to the existing environment from implementation of the Proposed Action and other reasonable alternatives; and (5) compare the effects of the Proposed Action with the No Action Alternative and other reasonable alternatives. For the purposes of compliance with NEPA, reasonable alternatives are identified as being those that meet NNSA's purpose and need for action by virtue of timeliness, appropriate technology, and applicability to LANL .

The EA process also provides NNSA with environmental information that can be used in developing mitigative actions, if necessary, to minimize or avoid adverse effects to the quality of the human environment and natural ecosystems should NNSA decide to proceed with implementing the construction and operation of a BSL-3 facility at LANL. Ultimately, the goal of NEPA and this EA is to aid NNSA officials in making decisions based on an understanding of environmental consequences and taking actions that protect, restore, and enhance the environment.

[1] The NNSA is a separately organized agency within DOE established by Congress in 2000 under Title 50 United States Code Chapter 41, Subchapter I, Section 2401.

[2] A biosafety level or BSL is assigned to an agent based upon the activities typically associated with the growth and manipulation of the quantities and concentrations of infectious agents required to accomplish identification or typing as determined by the Centers for Disease Control (CDC) and National Institutes of Health (NIH). Additional information about the various BSL assignments is provided in later sections and within Appendix A of this EA.

1.2 BACKGROUND

LANL covers an area of 43 mi^2 (111 km^2) in north-central New Mexico in a region characterized by forested areas with mountains, canyons, and valleys, as well as diverse cultures and ecosystems (Figure 1-1). LANL was originally established in 1943 as "Project Y" of the Manhattan Project with a single-focused national defense mission – to build the world's first nuclear weapon. After World War II ended, the Project Y Facility was designated a permanent research and development laboratory (known first as the Los Alamos Scientific Laboratory, it acquired the LANL name in the 1980s) and its mission was expanded from defense and related research and development to incorporate a wide variety of new mission assignments in support of Federal Government programs. The Federal Government Agency, with administrative responsibility for LANL, has evolved from the post-World War II Atomic Energy Commission to the Energy Research and Development Administration, and finally to the DOE, NNSA. The University of California (UC at LANL) is the current LANL Management and Operating Contractor and has served in this capacity since the facility's inception.

Current NNSA mission-support work provided by UC at LANL stems from its predecessor agency's original mission to build the world's first nuclear weapon. The work includes research and development work performed for a variety of programs within the NNSA, as well as cost-reimbursable work that is identified as "work for others." This designation, "work for others," encompasses non-DOE sponsored work performed in support of other Federal agencies, universities, institutions, and commercial firms, which is compatible with the NNSA mission work conducted at LANL and which cannot reasonably be performed by the private sector. Within DOE, the NNSA mission is "(1) To enhance United States national security through the military application of nuclear energy; (2) To maintain and enhance the safety, reliability, and performance of the United States nuclear weapons stockpile, including the ability to design, produce, and test, in order to meet national security requirements; (3) To provide the United States Navy with safe, militarily effective nuclear propulsion plants and to ensure the safe and reliable operation of those plants; (4) To promote international nuclear safety and nonproliferation; (5) To reduce global danger from weapons of mass destruction; and (6) To support United States leadership in science and technology" (50 USC Chapter 41, § 2401(b)). Work conducted at LANL provides support to these NNSA missions, with a special focus on national security.

The DOE Chemical and Biological National Security Program (CBNP) was initiated in FY1997 to engage the DOE and its laboratories more fully in the development and demonstration of new technologies and systems to improve U.S. domestic preparedness and response capabilities to chemical and biological attacks. The CBNP is a needs-driven program focused on addressing the highest priority area to counter chemical and biological threats. The CBNP was established in response to the *Defense Against Weapons of Mass Destruction Act* passed by Congress in 1996 (50 USC § 2301).

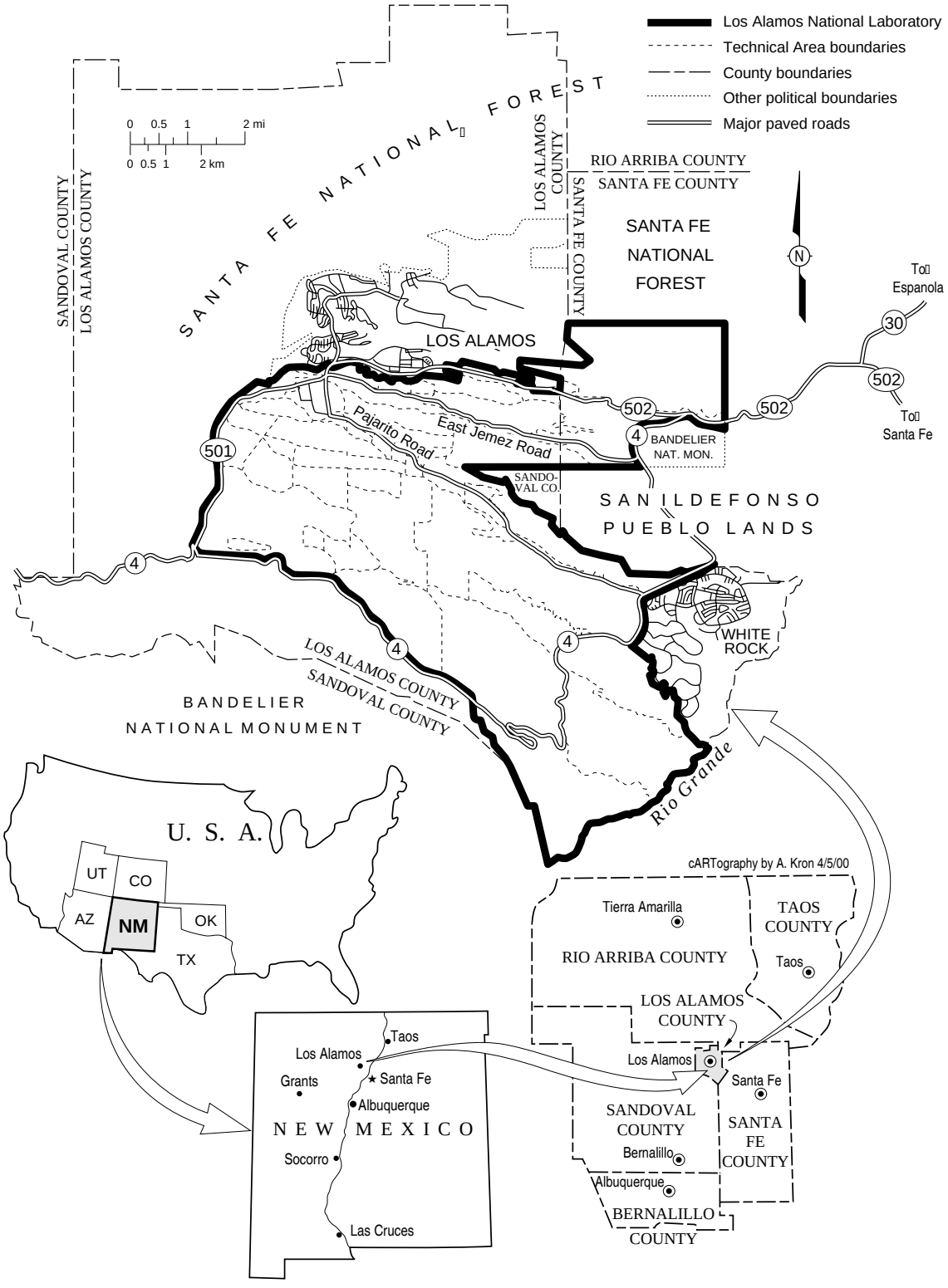

Figure 1-1. Location of Los Alamos National Laboratory (LANL)

DOE and the national security laboratories have a long history of supporting nonproliferation and national security policy. As part of its primary nuclear science and technology mission, DOE has developed extensive capabilities in chemistry, biology, materials and engineering science, and systems engineering at these laboratories. These capabilities, in areas such as genomic sequencing, development of new deoxyribonucleic acid (DNA[3])-based diagnostics, advanced modeling and simulation, and microfabrication technologies, as well as the nexus of these capabilities with expertise in nonproliferation and national security, form the basis of NNSA's role in combating the chemical and biological threat. In addition to the chemical and biological nonproliferation activities supported by this program, the national security laboratories conduct work in chemical and biological defense research for other government agencies.

The existing facilities and areas of expertise at LANL have evolved since its inception in the early 1940s. About 1,850 buildings and a variety of other structures have been constructed within LANL and are now operated in support of NNSA's diverse missions. About 12,000 employees occupy these buildings and structures (both UC at LANL and various sub-contractors to UC). Buildings and facilities are concentrated in the general vicinity of Technical Area (TA)-3 together with about one-half of the site employees. However, there are 46 additional TA's within LANL boundaries (Figure 1-2) where the remainder of UC at LANL and most of the sub-contract employees are located. Until the establishment of NNSA, UC developed facilities and expertise at LANL under direction of DOE to perform theoretical research, including analysis, mathematical modeling, and high-performance computing; experimental science and engineering ranging from bench-scale to multi-site, multi-technology facilities (including accelerators and radiographic facilities); and advanced and nuclear materials research, development, and applications, including weapons components testing, fabrication, stockpile assurance, replacement, surveillance, and maintenance (including theoretical and experimental activities). These capabilities now allow UC at LANL to conduct research and development activities for NNSA such as high explosives processing, chemical research, nuclear physics research, materials science research, systems analysis and engineering, human genome "mapping," biotechnology applications, and remote sensing technologies applied to resource exploration and environmental surveillance. Additional information regarding the DOE and NNSA work assignments at LANL is presented in the *LANL Site-wide Environmental Impact Statement for Continued Operation of the Los Alamos National Laboratory* (SWEIS) (DOE/EIS-0238) (DOE 1999a). This document and other related documents can be found in the DOE Reading Rooms in Albuquerque, New Mexico (at the Government Information Department, Zimmerman Library, University of New Mexico), and in Los Alamos (at the Community Relations Office located at 1619 Central Avenue).

NNSA has the responsibility for national programs to reduce and counter threats from weapons of mass destruction (nuclear, biological, and chemical weapons). Activities

[3] DNA is a polymeric chromosomal constituent of living cell nuclei that determines individual hereditary characteristics.

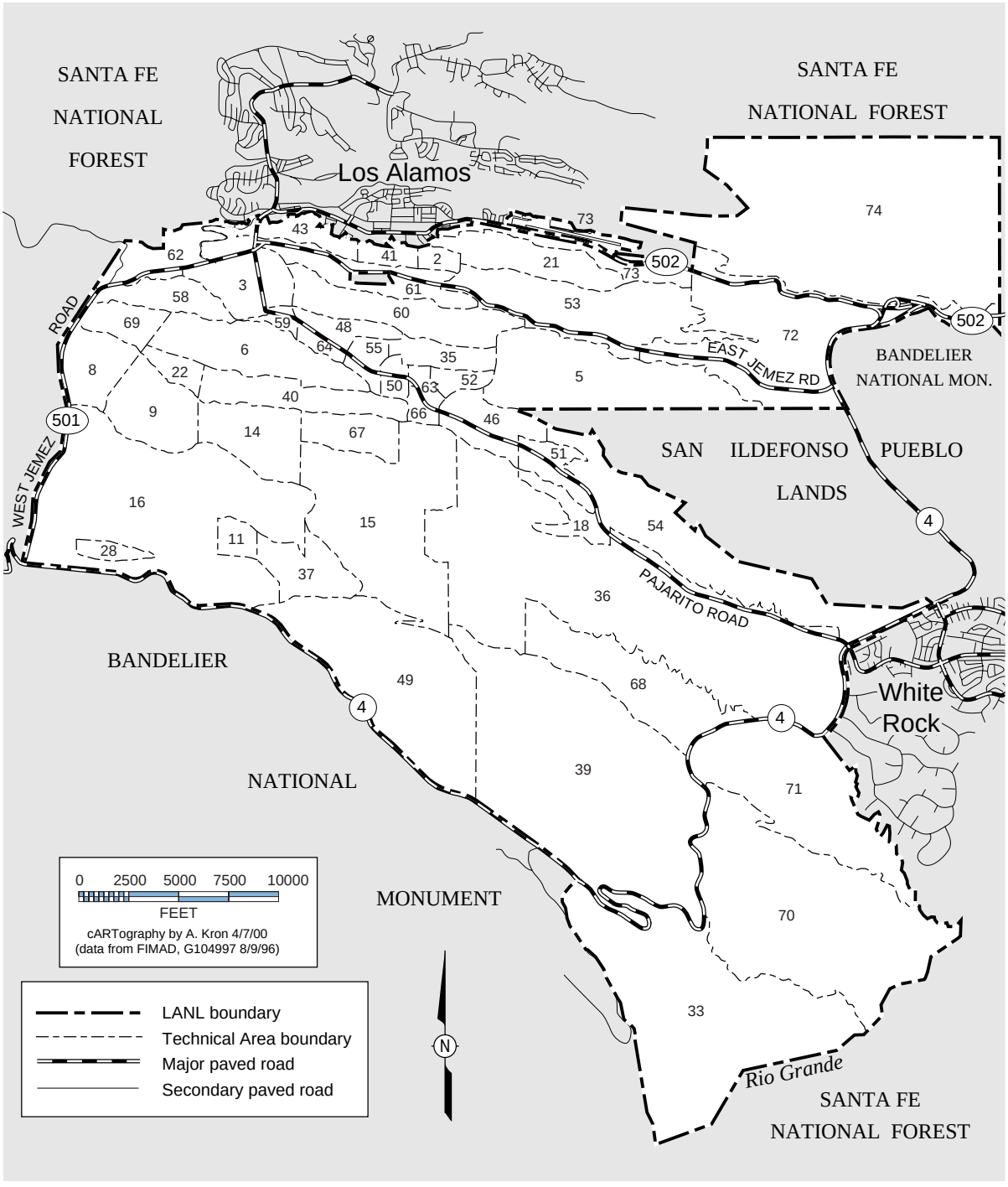

Figure 1-2. Los Alamos National Laboratory Technical Areas

conducted in this area include assisting with control of nuclear materials in states of the former Soviet Union, developing technologies for verification of the Comprehensive Test Ban Treaty (September 1996), countering nuclear smuggling, safeguarding nuclear materials and weapons, and countering threats involving chemical and biological agents.

UC at LANL has been assigned research and development activities in support of these NNSA responsibilities. UC at LANL employees have, among other work performed at LANL, provided much of the technology and expertise needed to verify treaties and implement various safeguards to ensure compliance with terms and conditions of treaties and agreements; undertaken satellite and remote sensing research to provide the technology to detect clandestine nuclear tests and other indicators of weapons proliferation; begun research aimed at countering nuclear smuggling and proliferation of chemical and biological weapons; assisted in the establishment, training and technology development for NNSA Nuclear Emergency Search Team and Accident Response Group, which provide vital emergency response capabilities; and performed studies of the human genome sequence and the structure of other biomolecules. Current research and technology development work conducted by UC at LANL targets both the reduction of the national threat from terrorism using biological weapons and enhances the Nation's public health capabilities. This work is focused on the development of scientific tools to identify and understand the pathogens of medical, environmental, and forensic importance. UC staff at LANL have performed mission-support work and also compatible work for others that has included analysis of DNA extracted from pathogens or from environmental, medical, or forensic samples suspected of containing pathogens or their non-viable remnants. This work was performed, in part, for the National Institutes of Health (NIH) to investigate biological processes and genetic material related to disease-causing organisms. Early detection and identification of organisms would greatly benefit the Nation's public health response. The capabilities for bioscience work at LANL benefits DOE and NNSA programs as well as collaborative efforts with academic institutions, other Federal agencies, and international peace-keeping missions through the State Department and the United Nations. Future work under the NNSA promises to expand opportunities to develop scientific tools addressing national health security issues and global concerns for emerging diseases.

The Bioscience Division has been assigned the UC at LANL responsibility for conducting work related to biological science research including work with national health security issues and emerging diseases. Work is conducted at five LANL locations but primarily within the Health Research Laboratory (HRL), which is located within LANL's TA-43, immediately adjacent to the Los Alamos Medical Center within the Los Alamos townsite. Research performed at this site includes structural, molecular, and cellular radiobiology, biophysics, biochemistry, and genetics research. The HRL was identified as one of LANL's "key facilities" as listed and defined in the 1999 SWEIS (DOE 1999a). Additional information about that facility and work performed therein, together with their environmental impacts, is presented in the LANL SWEIS analysis (DOE 1999a).

The HRL houses multipurpose laboratories, including BSL-1 and BSL-2 laboratories, in which a variety of molecular and cellular research is performed. LANL work in the biosciences arena is conducted according to the accepted national standards for biosafety work that have been developed by the U.S. Department of Health and Human Services, Public Health Service, through their subsidiary organizations, the CDC and the NIH. Details regarding BSLs and specific information and requirements for work in microbiological laboratories is provided in Appendix A of this EA. In addition, all experiments involving biological agents[4] are reviewed and must be approved prior to their commencement by the Institutional Biosafety Committee (IBC), which is made up of UC at LANL staff members, UC and community health care providers, an NNSA Federal member, and at least two members of the public. The IBC conducts periodic and at least annual research project review meetings that are open to the public. In general, BSL-2 facilities are used for working with a broad spectrum of biological agents (or bioagents) or biological toxins[5] commonly present in the community and may be associated with human disease of moderate severity. Examples include Hepatitis B virus, measles, and salmonellae. Limited access, separated from public areas with posted BSL-2 biohazard signs, waste decontamination facilities, together with standard and special microbiological practices, is required for these laboratories. Common examples of BSL-2 facilities are those located in hospitals, medical schools, veterinary schools, biology research institutions, and dental offices.

The importance of work performed for NNSA in bioscience research and development in support of their national security nonproliferation of weapons of mass destruction mission is increasing. The NNSA CBNP mission is to "develop, demonstrate, and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack." The threat presented by terrorists and rogue nations to the American people and our allies, including military personnel, amplifies the need for threat reduction research. Current work at LANL in bioscience research is limited to BSL-2. Work in support of the DOE and NNSA national security missions requires specialized facilities to safely and securely handle and store infectious organisms beyond that which can be provided by BSL-2. At this time, DOE does not have under its administrative control within the DOE complex any microbiological laboratory facility capability beyond BSL-2.

In February 2001, the DOE Office of Inspector General, issued an audit report (*Report on Department of Energy Activities Involving Biological Select Agents*, DOE/IG-0492, included in this EA as Appendix B). This Report stated audit findings and listed recommendations to DOE for corrective actions as follows:

"RECOMMENDATIONS: We recommend that the Under Secretary for Energy, Science, and Environment and the Under Secretary for Nuclear Security jointly:

[4] Biological agents or bioagents are organisms or the product of organisms that present a health risk to humans. These can be bacterial, fungal, parasitic, rickettsial, or viral agents, or prions.

[5] Biological toxins are toxic chemicals of biologic origin and are not self-replicating.

1. Identify the types and locations of activities being conducted by the Department involving biological select agents and select agent materials.
2. Initiate action to ensure: (a) appropriate Federal oversight; (b) consistency in policy; and (c) standardization of implementing procedures for biological select agent activities being conducted by the Department. Actions, for example, could include encouraging more interagency cooperation in this area and, similar to the approach taken by the U.S. Army, supplementing CDC guidance regarding activities involving biological select agents and select agent materials to address situations unique to DOE.
3. Ensure that required NEPA reviews are conducted prior to the start of biological select agent and select agent material activities and revised, as needed, when significant changes occur in the activities.
4. Initiate appropriate action to ensure the Department's laboratories, including those managed by the NNSA, receive timely and consistent information regarding current CDC guidance.

We also recommend that the General Counsel:

5. Determine the potential liability to the Department if contractor employees working with biological select agents refuse immunizations or if they do not sign a statement acknowledging the risks associated with the project, the availability of immunizations, and the individual's decision not to be immunized.
6. Determine the feasibility of requiring Department laboratory employees to be immunized in order to work with infectious agents.
7. Determine whether the Department has liability to third parties (e.g., spouses, families, members of the community) who may be infected as a result of coming in contact with a laboratory employee who works with biological select agents, but has refused to be immunized.

MANAGEMENT COMMENTS: The Department generally concurred with our recommendations. In comments dated December 12, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that while there is no indication that biological safety has been compromised at any DOE facility, the draft report correctly points out operational concerns and inconsistencies that existed during the review. He provided the following examples of actions completed by the Department within the last year to improve biosafety practices at its laboratories and said that the Department is already taking steps consistent with our recommendations:

- A biosurety program was initiated on December 1, 1999, at Albuquerque to strengthen the safety and security protocols used with biological select agents.

- Communications has been improved between DOE headquarters, the Operations Offices, and Department's laboratories, as well as between DOE and other Federal agencies involved with biological research.
- CDC select agent registration requirements are being clarified.
- The former Secretary [of Energy] established a Biosurety Working Group led by EH to recommend specific improvements in directives and contract language and other actions which will improve oversight and implementation of safe practices in potentially hazardous areas of biological research."

The audit report concluded with the following statement:

"INSPECTOR COMMENTS: We believe the corrective actions identified by the Department are responsive to our recommendations."

In a memorandum for the Secretary of Energy transmitting the report, the Inspector General stated:

"While we consider these findings to be serious, we found no evidence that current activities had adversely impacted the safety and health of the public or of the Department's Federal or contractor workforce.

Further, during the course of our review the Department took certain actions to improve biosafety practices at its laboratories. For example, the Department of Energy Biosurety Working Group, which was chartered on September 29, 2000, is considering revisions to current policies and procedures governing potentially hazardous biological materials and select agents. Also, a biosurety program was initiated at Albuquerque to strengthen local safety and security protocols. In addition, CDC biological select agent registration requirements are being clarified, and communications concerning biological research activities have reportedly improved among Department Headquarters, the Operations Offices, the laboratories, and other Federal agencies. While these are positive steps, the potential risks associated with the use of biological select agents warrant continued senior management attention."

DOE is continuing its efforts to improve and provide oversight to biosurety work conducted at facilities within the DOE complex. The Office of General Council is reviewing the Office of Inspector General's recommendations.

Facilities using CDC and NIH standards have demonstrated safe and secure working conditions with infectious agents. According to these standards for BSL-2 (CDC 1999) laboratories, the primary hazards to personnel working with agents at this level relate to accidental exposures through skin punctures or contact with mucous membranes, or ingestion. The organisms routinely manipulated at BSL-2 are not known to be transmissible, person-to-person by the airborne pathway. According to their standard for BSL-3 (CDC

1999), the primary hazards to personnel working with agents at this level relate to accidental injections, ingestion, and exposure through airborne pathway. In BSL-3, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. There are currently over 200 BSL-3 laboratory facilities in the United States at various non-DOE sites. BSL-3 laboratory facilities are specifically designed and engineered for work with bioagents with the potential for aerosol transmission that may cause serious or potentially lethal disease by inhalation if left untreated (such as the bacteria responsible for causing tuberculosis in humans). Examples of common BSL-3 facilities include hospital surgical suites, clinical, diagnostic, and teaching laboratories associated with medical or veterinary schools and pharmaceutical production laboratories. Requirements of operating a BSL-3 facility (CDC 1999) are detailed in Appendix A.

In the past, and currently, BSL-3 sample preparation work for DOE and NNSA research projects at LANL has been contracted to universities or private sector laboratories because of the lack of this capability within DOE. In the private sector, projects requiring higher BSLs are on the rise resulting in these laboratories being unable to accept as much outside work. Security is also an issue since some information associated with samples must have a very high degree of physical security not available through the use of contractor facilities. Lastly, sample procurement quality assurance has been problematic in the past for UC at LANL. The documentation of sample history from collection, to analysis, to the result is extremely important to the quality of the data. This chain-of-custody is key to the technology being utilized and is essential to verifying the data and interpreting the results. It is critical to understand that the quality and security of samples could in some instances be crucial to national security and therefore, sample quality cannot be left in question.

To further enhance the Nation's ability to detect and isolate microorganisms and treat victims of bioterrorism, additional NNSA work is required. Existing LANL bioscience facilities, infrastructure and personnel are sufficient to complete only a portion of the work. The capabilities existing onsite within LANL include describing and investigating genomes to complete strain identification and determine the source or geographic origins. Strain identification of microorganisms, including specific individual mutations, can be used to explain their ability to infect and cause disease. Experiments with genetic "finger-printing" require frequent routine laboratory interactions by researchers to facilitate gathering data and advancing the technology.

1.3 PURPOSE AND NEED FOR AGENCY ACTION

DOE conducts bioscience work at LANL in support of its national security and science missions and in support of CBNP. The NNSA CBNP mission is to "develop, demonstrate and deliver technologies and systems to improve domestic defense capabilities and, ultimately, to save lives in the event of a chemical or biological attack." This mission requires work with infectious agents, including those historically used for bioweapons. LANL's capabilities, in areas such as genomic sequencing, development of new DNA-based

diagnostics, advanced modeling and simulation, and microfabrication technologies, as well as the nexus of these capabilities with expertise in nonproliferation and national security, contribute to NNSA's role in combating the chemical and biological threat. Combining LANL's pioneering technologies and capabilities, current biological science work with engineering, computational, and physics capabilities, presents an opportunity for DOE to carry research and understanding of this field farther than before. The expertise, technology, and current capabilities at LANL have been recognized by national leaders involved in planning and addressing the increasing national security concerns that focus on bioagent counter-terrorism technologies, and the countering of emerging natural diseases. As a result, the need to work with level 3 bioagents at LANL and within NNSA is growing.

The nature of BSL-3 work requires efficient sample processing, handling of a variety of organisms concurrently, and assurance of sample security and integrity. NNSA's mission requirements for sample integrity necessitates that the chances of cross-contamination and degradation of samples are minimized by reducing excessive handling and transportation. The few off-site BSL-3 facilities available to NNSA are often heavily committed to other projects or tailored to work with specific types of microorganisms. Additionally, use of off-site BSL-3 facilities increases the risk of cross-contamination due to additional handling and transportation. A BSL-3 facility provides for safe and secure manipulation and storage of infectious microorganisms. In order to more effectively utilize and capitalize on existing onsite facilities and capabilities at LANL and to ensure the quality, integrity and security of microbiological work, NNSA needs BSL-3 laboratory capability within the boundaries of the national lab.

1.4 SCOPE OF THIS EA

A sliding-scale approach (DOE 1993) is the basis for the analysis of potential environmental and socioeconomic effects in this EA. That is, certain aspects of the Proposed Action have a greater potential for creating environmental effects than others; therefore, they are discussed in greater detail in this EA than those aspects of the action that have little potential for effect. For example, implementation of the Proposed Action would affect socioeconomic resources in the LANL area. This EA presents in-depth descriptive information on these resources to the fullest extent necessary for effects analysis. On the other hand, implementation of the Proposed Action would cause only a minor effect on waste disposal at LANL. Thus, a minimal description of waste disposal effects is presented.

When details about a Proposed Action are incomplete, as a few are for the Proposed Action evaluated in this EA (for example, the exact location of the facility within the identified TAs), a bounding analysis is often used to assess potential effects. When this approach is used, reasonable maximum assumptions are made regarding potential emissions, effluents, waste streams, and project activities (see Sections 2.0 and 4.0 of this EA). Such an analysis usually provides an overestimation of potential effects. In addition, any proposed future action(s) that exceed(s) the assumptions (the bounds of this effects analysis) would not be

allowed until an additional NEPA review could be performed. A decision to proceed with the action(s) or not would then be made.

1.5 PUBLIC INVOLVEMENT

NNSA provided written notification of its intention to prepare this NEPA analysis to the State of New Mexico, the four Accord Pueblos (San Ildefonso, Santa Clara, Jemez, and Cochiti), the Pueblo of Acoma, the Mescalero Apache Tribe, and to over 30 stakeholders in the area on February 5, 2001. This notification included information regarding a poster session held on February 22, 2001 at the Los Alamos Area Office to provide the opportunity for attendees to make scoping comments on this EA. Notification of the public poster session was also published in the local newspapers: the *Santa Fe New Mexican*, the *Los Alamos Monitor*, and the *Rio Grande Sun* before the meeting date. Additionally, notice of the public poster session was posted on LANL's electronic Newsbulletin. NNSA offered to provide separate project briefings to the four Accord Pueblos and the State of New Mexico as well.

Upon release of the Predecisional Draft EA on October 30, 2001, NNSA allowed for a 21-day comment period. Copies of the predecisional draft EA were sent to the State of New Mexico, the four Accord Pueblos, the Pueblo of Acoma, the Mescalero Apache Tribe, and other entities previously identified as desirous of receiving copies of the EA. Notification of the availability of the EA was made as well to stakeholders and members of the public previously identified as wishing to receive such notification, and notice was also published in the three local newspaper identified above. Another public discussion session was held to provide an opportunity for attendees to make comments on this Predecisonal Draft EA. The date (November 14, 2001) and time of this session were announced a week in advance of the session in the local newspapers listed above, as well as on the LANL Newsbulletin. Due to NNSA's inability to schedule all requested project briefings before the end of the original 21-day time period, NNSA extended the comment period for an additional 30-day period extending from December 17, 2001 through January 15, 2002. This additional review period was again advertised in the three local newspapers identified above and individual notification letters were mailed to all parties previously receiving notification of the availability of the draft document or copies of the document. Where appropriate and to the extent practical, concerns and comments received by the close of the comment period were considered in the Final EA. Additionally, NNSA has provided responses to public concerns that are presented in the next subsection of this EA.

1.6 COMMENT SUMMARIES AND DOE RESPONSES

The full text of the comments received by NNSA on the predecisional draft EA by stakeholders and members of the public are presented in Appendix C of this EA. Several topics raised by public comments were of broad interest or concern. These topics were categorized as general issues and represent broad concerns directly related to the environmental effects associated with implementing the Proposed Action analyzed in the EA.

Many commentors also raised topics that are not pertinent to the environmental review; however, for clarification, the NNSA addressed them to the extent practicable. Specific comments and concerns voiced by commentors were addressed through changes made to the document text to the extent practicable. Changes to the text are side-barred. General issues include the following topics:

- NEPA Compliance Issues
- LANL Safety/Security Concerns
- Anti-NNSA Mission Sentiment and Fear of Future Bioweapons Work/International Treaties Concerns
- Inspector General Report
- Terrorist Risk
- Institutional Biosafety Committee (IBC) Role
- Seismic Issues
- Transportation Issues

1.6.1 NEPA Compliance Issues

Several commentors were of the opinion that the analysis of the proposed BSL-3 facility does not support a FONSI. Other commentors stated that because the proposed action is one without precedent, a draft FONSI should be made available for public review for 30 days before the FONSI is issued in accordance with DOE's NEPA Implementing Regulations. Additionally, several commentors stated that because the proposed action is one without precedent at a nuclear facility that preparation of an EIS was needed. Commentors were of the opinion that the CDC must approve of the procedures used in NNSA biological research activities and, therefore, the DOE should designate the CDC as a cooperating agency in the preparation of the EA. Commentors believe that since the proposed BSL-3 facility proposal was not included in the SWEIS that a full EIS is needed complete with public hearings. Some commentors expressed the opinion that a Supplement to the 1999 LANL SWIES is needed. Commentors were of the opinion that they did not have an adequate time period in which to review the draft EA and that the comment period should be extended from 21 days to 120 days. Commentors also expressed the opinion that the comment period wasn't adequately publicized and public weren't notified of the availability of the draft document. Commentors stated that some advocacy groups did not receive copies of the EA although they had provided scoping comments to the NNSA. Commentors stated that they had not received all the information on existing LANL BSL-1 and -2 facilities previously requested and that EA reference documents have not been made readily available to the public. Commentors were of the opinion that, as biologically-related work for the NNSA "chemical and biological nation security program" is slated to take place at several locations within the DOE/NNSA complex, a programmatic EIS is required that would include a facility specific analysis for the proposed LANL BSL-3 facility.

Response: DOE believes that the analysis of environmental effects adequately supports a FONSI. After taking a hard look at the environmental consequences that could result from implementing the proposed BSL-3 facility project, NNSA has concluded that the proposed action is not a major federal action that significantly effects the environment. The EA analysis considered affects relating to human health, ecological resources, transportation, waste management, utilities and infrastructure, noise, socioeconomics, geology, soils, seismicity, visual resources, and air quality. Affects to these resource areas were minor in nature. Human health affects are expected to be no different from other U.S. CDC-registered laboratories operated according to CDC and NIH guidelines, which experience infrequent worker accidents with minor or no consequences to workers and members of the public. Ecological resources, transportation, waste management, utilities and infrastructure, noise, socioeconomics, geology, soils, seismicity, visual resources, air quality, cultural resources, environmental justice, environmental restoration, floodplains and wetlands, land use or water resources were identified as being unaffected by the construction and operation of the BSL-3 Facility; or as having potential slight affects that would be inherently mitigated by the project design; or as having minor effects that were mostly temporary and intermittent in nature. Because these affects are not significant in terms of context and intensity, the NNSA has concluded that the potential project effects warrant the issuance of a FONSI.

Between 250 and 300 BSL-3 facilities have been constructed and are in operation within the U.S. The proposed construction and operation of a BSL-3 facility at LANL is, therefore, not a newly invented action that is without precedent. The DOE's NEPA Implementing Regulations (10 CFR 1021.322 (d) and the Council on Environmental Quality's (CEQ) NEPA Implementing Regulations (40 CFR 1500.2 (d)) provisions regarding making a FONSI available for public review, which includes actions for which there is no precedent, are not applicable in this instance. The CEQ regulation in question does not refer to an individual agency's wealth of experience with regard to undertaking a proposed action but, rather, to whether the proposed action is one that has previously been conducted before.

There is no CEQ or DOE regulatory requirement that links the precedent of an action with a requirement to prepare an EIS. This is equally true for the siting of a proposed project at a particular geographic location where one has not previously been located, or for the co-location of a proposed project with any other activity or operation when the projects has not previously been sited nearby to such functions. The fact that there has never been a BSL-3 facility sited and operated at any DOE facility, nor one that was sited and operated at a research facility that stores and handles radioactive materials such as LANL, does not automatically require NNSA's preparation of an EIS for the proposed BSL-3 facility project.

The Council on Environmental Quality's NEPA Implementing Regulations state, with regard to cooperating agencies (40 CFR 1501.6): "Upon request of the lead agency, any other Federal agency which has jurisdiction by law shall be a cooperating agency. In addition any other Federal agency which has special expertise with respect to any environmental issue, which should be addressed in the statement may be a cooperating agency upon request of the lead agency". CEQ regulations do not explicitly discuss cooperating agencies in the context

of EAs. DOE and NNSA carefully considers extending the invitation for neighboring agencies and government entities to act as cooperating agencies on the preparation of NEPA documents for actions that involve its facilities. The NNSA Office of Los Alamos Site Operations (formerly the Los Alamos Area Office) in particular has a well established history of working with other local, state, federal, pueblo and tribal governmental agencies and entities in the preparation of its NEPA documents, including EAs. No fiscal reimbursement is made to cooperating agencies for their participation a cooperating agency and, as a result, these agencies and entities frequently must curtail or limit their involvement in other agency's NEPA analyses. When internal or local subject matter experts are available to NNSA, NNSA may chose to exercise its discretion with regard to requesting the involvement of a Federal agency in its NEPA process when a Federal agency does not have a local presence. The CDC certainly has expertise with regard to work performed in BSL-3 facilities and the attendant environmental issues associated with their operation. The CDC does not, per se, have jurisdiction by law over the NNSA with regard to their required approval of procedures used in NNSA biological research activities and does not have a local presence with regard to LANL. CDC staff members across the country were contacted during the preparation of the EA and these staff members provided information and data to NNSA representatives that were used in the EA analysis. The CDC will review detailed plans for the facility and will review the facility itself after it is constructed and before it operates. Additionally, the DoD has experience in operating BSL-3 facilities and DoD staff were similarly contacted and provided information, data, and reference material for NNSA's use in preparing the EA as well. Neither of these entities, however, has knowledgeable staff stationed in Los Alamos or close by. As a practical consideration neither of these two entities were invited to participate as cooperating agencies in the preparation of the EA.

The 1999 SWEIS included those actions that were ripe for decision and discussed those actions that were being contemplated at the time by DOE at LANL. Subsequent proposed actions require individual NEPA compliance. DOE and NNSA has prepared several environmental assessments and environmental impact statements that pertain to LANL since the issuance of the Final LANL SWEIS and its Record of Decision (ROD). The fact that the proposed actions, including the proposed BSL-3 facility, were not included in the SWEIS analysis is not itself a reason for the preparation of an EIS for these actions rather than an EA. Neither CEQ nor DOE NEPA Implementing Regulations automatically require this level of NEPA analysis. Therefore, DOE and NNSA must determine the level of NEPA analysis that is appropriate for each new proposed action. While each subsequent NEPA analysis for proposed LANL actions may tier from the 1999 SWEIS (that is, the analysis of a more narrow scope may tier from an analysis of a broader scope (40 CFR 1502.20)), a Supplement SWEIS is not required in this instance. A Supplement SWEIS for a proposed action(s) would be required only if the action would likely result in a substantial change(s) in the operation of LANL at the enhanced level chosen in the ROD such that it would be relevant to environmental concerns; or, if there were significant new circumstances or information relevant to environmental concerns and bearing on the enhanced level of operation of LANL or its impacts. The EA's analysis of the environmental effects likely

from the implementation of the proposal to construct and operate a BSL-3 facility do not support the need for a Supplement to the SWEIS based on these two criteria.

The predecisional draft EA for the proposed BSL-3 facility was issued for stakeholder review and comment and was made available to the public for a 21-day period beginning on October 30, 2001. This review period is within the designated time period (namely, 14 to 30 days) for state and tribal review of draft EAs promulgated in DOE's NEPA Implementing Regulations (10 CFR 1021.301(d)). After receiving an additional request for a tribal briefing that could not be accommodated within the original 21-day review period, DOE decided to reissue the predecisional draft EA for an additional 30-day period beginning on December 17, 2001. In both instances LANL stakeholders and members of the public were informed of the review period through notification letters sent to: previously identified points of contact with the State of New Mexico; the Governors and other governmental staff of local pueblos and tribes; additional local government and tribal representatives; and to previously identified interested members of the public. Paid advertisements were placed in three local newspapers, and electronic notification was placed on the LANL electronic bulletin board. Distribution of hard copies of the EA was made to all government, pueblo, and tribal representatives and to members of the public based upon their previous requests. Hard copies of the document were later distributed upon written or verbal requests. NNSA regrets that some parties did not believe that they could adequately review the document within the original 21-day review period. However, NNSA is of the opinion that the document was adequately written in plain language and that a four month (120 day) review period is excessive for a document of less than 100 hundred pages in length. The distribution of the EA to the State's designated Points of Contact and to their staff members has been deemed adequate by the State for several years (the Points of Contact have their agency's responsibility for distributing it internally according to their own management requirements). Similarly, the pueblos and tribal Governors and their representatives determine the distribution and number of copies of NEPA documents that they wish to receive and have the responsibility of distributing it internally as they deem appropriate. Members of the public that have identified to NNSA that they wish to receive copies of all NEPA documents prepared by NNSA that involve LANL operations, or for a special project, are sent copies of the document. Members of the public that have indicated that they wish to receive notification of the availability of such documents are not sent copies of the documents. Address forms were made available for attendees at the February 2001 scoping meeting held for the proposed BSL-3 facility EA on which attendees could designate whether they wished to receive copies of this EA or other NEPA documents. In an effort to conserve paper and postage expenses, hard copies of NEPA documents are not routinely supplied to scoping commentors or other members of the public unless they request the documents. The NNSA regrets any inconvenience of any group or individual that this cost saving measure might cause.

Some commentors stated that they had not received documents previously requested regarding existing LANL biosafety facilities. These requests were made of the University of California (LANL's management and operations contractor). The NNSA regrets any

inconvenience to the requester that may have resulted from the failure of the University of California to provide the requested information. The NNSA has taken action to respond to the request for information. Additionally, a copy of the information requested, specifically, a copy of the Hazard Control Plan for the BSL-2 facilities at LANL, has been added to this EA in Appendix D. Hazard Control Plans are "living documents"; they are subject to ongoing review and changed as needed and minimally are reviewed annually. Therefore, this hazard control plan should be taken only as generally illustrative of such plans.

At the time of the issuance of the predecisional draft EA on October 30, 2001 for state and tribal review and comment, all EA document references were available either in hard copy upon request, or electronically via the World Wide Web. At some point between October 30th and November 13th, some of the documents became inaccessible electronically. Many Federal agencies and other organizations, including the DOE/NNSA, have been reviewing information available on their websites because of the recent national security threats and either have restricted access to certain documents or removed them entirely from their websites. When this accessibility problem was brought to NNSA's attention, hard copies of the EA reference documents that are not readily available already at the LANL library and the DOE reading room were placed in the Los Alamos DOE Reading Room. Hard copies of the reference documents were also hand-delivered to the group requesting them. DOE/NNSA regrets any inconvenience this may have caused members of the public living distant from Los Alamos that depend on electronic accessibility of documents for easy document access. Currently, DOE/NNSA is restricting public access to its electronic documents that contain detailed site maps and certain other detailed information and it is unknown how long this restriction measure may be in effect. As policies are developed regarding electronic accessibility of documents and the appropriateness of their contents given the changed world security situation, NNSA hopes to better accommodate its offsite stakeholders and members of the public with enhanced electronic document access capability.

When considering the issue of preparing a programmatic NEPA analysis, a Federal agency must determine whether the program in question meets the Council on Environmental Quality's NEPA Implementing Regulations (40 CFR 1508.18 (b) (3)) (3) definition of a major federal action, which includes the: "Adoption of programs, such as a group of concerted actions to implement a specific policy or plan; systematic and connected agency decisions allocating agency resources to implement a specific statutory program or executive directive." These regulations also address when an agency must prepare a programmatic analysis, including the analysis of cumulative effects. A programmatic analysis is necessary where the proposals for federal action "are related to each other closely enough to be, in effect, a single course of action". Additionally, the CEQ regulation's speak to the scope of NEPA EISs (40 CFR 1502.5(a)(1)) and to connected actions as those that "automatically trigger other actions which may require EISs"; "cannot or will not proceed unless other actions are taken previously or simultaneously"; and "are interdependent parts of a larger action and depend on the larger action for their jurisdiction". DOE and NNSA conduct biological research at various facilities across the DOE complex of national security

laboratories and other research institutions. This research began in the late 1940s when the DOE's predecessor agency recognized the need for obtaining information about the effects of radiation on humans and other biota. As an outgrowth of this research, many studies and research projects have been conducted over the years both for the benefit of the DOE (and its predecessor agencies) and as "work-for-others" projects with sponsors from the private sector and other Federal agencies. Each of DOE's facilities has developed specialized areas of focus and expertise and on some occasions have contributed their expertise to performing portions of work that has been pulled together to answer complex questions or reach complex goals, such as the work performed recently to map the human genome. At this time, the NNSA believes that these research efforts consist of projects too diverse and discrete to constitute either a "major Federal action" or activities sufficiently "systematic and connected" so as to require a programmatic NEPA analysis, especially an EIS. Not only are the research projects diverse, they are discrete and independent in nature. They are separately operated. Approval of one project does not insure the approval of other similar projects. Success in one project area does not invariably affect the variety or direction of NNSA's research, inasmuch as NNSA's research program is largely reactive, designed to respond to the needs of NNSA, DOE and other user groups and consumers. While DOE responded to the1996 Congressional passage of the Defense Against Weapons of Mass Destruction Act, which authorized the DOE to establish a Chemical and Biological Weapons Nonproliferation Program, its research has continued to build upon existing research expertise present at its various research institutes. DOE and NNSA have not expanded their research such that their projects are concerted or systematic and connected. Mere commonality of objectives is insufficient under the Council on Environmental Quality's NEPA Implementing Regulations to constitute a "major Federal action" requiring NEPA compliance in the form of a programmatic NEPA analysis. While NNSA's biological research projects all pertain to biota and are ultimately directed toward the support of NNSA's national security mission, these rudimentary similarities are not sufficient to bind the universe of research projects conducted by DOE and NNSA into a "program" as this is identified by the Council on Environmental Quality's NEPA Implementing Regulations (40 CFR 1508.18(b)(3)). NNSA is therefore of the opinion that no programmatic NEPA analysis is necessary at this time for biological research conducted at its facilities and this EA is sufficient to met NNSA's NEPA compliance requirements with regard to the construction and operation of the proposed BSL-3 facility at LANL.

1.6.2 LANL Safety/Security Concerns

Commentors expressed the general opinion that LANL operators have a long history of mistakes, accidents and safety violations. Commentors were also of the opinion that LANL's record of protecting the environment and providing security for its activities doesn't warrant their trust. Commentors also expressed the opinion that LANL already oversees and undertakes more operations than it can safety and responsibly handle. Commentors believed that having increased numbers of shipments of microorganisms and related materials as part of the proposed action, and the dangerous nature of the microorganisms to be handled at the BSL-3 facility, would create increased LANL security concerns and accidental release risks

to public health and the environment. Commentors stated that independent competent personnel should perform periodic and no-notice facility inspections. Commentors also stated that the CDC should be doing BSL-3 work rather than placing such work at LANL under the control of the DOE.

Response: The University of California has operated LANL since the inception of the Manhattan Project, conducting experiments and research projects, both during World War II and thereafter. The work at LANL has occasionally resulted in serious mistakes being made, in the occurrence of accidents and even the death of LANL workers. Additionally, construction workers have been seriously injured at LANL over the 58 years of operation. These are irrefutable facts. LANL, and all DOE facilities currently operate according to Integrated Safety Management (ISM) principals. While mistakes and accidents will inevitably continue to occur, NNSA's goal is for the University of California to significantly decrease the occurrence of such events and to minimize their severity at LANL. To this end, very punitive contractual penalties have been instituted in the management and operations contract for LANL between the DOE and the University of California. NNSA regrets that members of the public do not trust the ability of the University of California to adequately perform their moral and contractual obligations. The University of California is tasked with conducting important research and development – research and development that frequently pushes at and steps beyond the present envelope of science. NNSA is confident that LANL can be operated safely and securely no matter the level of overall operations. The proposed increase in shipments of microliter and milliliter quantity samples (one milliliter is about equal to a teaspoon in quantity), which could include live cells of microorganisms suspended in a semi-solid agar culture media or frozen solid in culture media, and the overall operation of the proposed BSL-3 facility at LANL using select agents would not be likely to result in an increase in human health risks to the public or the environment. The EA analysis for the proposed BSL-3 facility does not support this concern; the accident analysis scenario presented in the EA addresses the potential effects associated with an accident in which potentially highly infectious cells would be disbursed into the environment from the proposed facility during its operation. The safe operation of nearly 300 BSL-3 facilities within the U.S., including a university research BSL-3 facility located in the middle of Albuquerque, NM, substantiates the analysis presented in this EA with regards to this issue. Representatives of the CDC periodically inspect all BSL-3 facilities. If constructed, representatives would also inspect the LANL BSL-3 facility, as would representatives of the NNSA. The CDC, which is an arm of the Department of Health and Human Services, is one of the work-for-others customers of LANL's biological research program. Other users of LANL's expertise in this area of research include the DoD, the Federal Bureau of Investigation (FBI), law enforcement agencies, fire departments, public health officials, universities, and research organizations.

The CDC provides guidelines for the operation of BSL-3 facilities, reviews building plans and the constructed building before operations begin, and then periodically inspects these facilities when they are operating, as an organization it actively operates very few laboratories. The laboratories the CDC operates perform work that is different from the

research work performed at LANL. Therefore, the CDC contracts with DOE and NNSA facilities, as well as with other government and private facilities, to perform much of its needed research work rather than duplicating these organizations research expertise within the Department of Health and Human Services. While some commentors would prefer to see BSL-3 work performed only by the CDC, this is neither cost effective or practical in today's world of shrinking budgets funded by Congress.

1.6.3 Anti-NNSA Mission Sentiment and Fear of Future Bioweapons Work/ International Treaties Concerns

Commentors expressed a general opposition to nuclear weapons and to performing biological work at LANL. Commentors also stated their opinion that neither a DOE or DoD facility should have a BSL facility. Commentors questioned whether work in a BSL-3 facility was the right role/mission for LANL and whether a nuclear facility was the right place for this type of work. Commentors expressed their fear with regard to the recent Presidential decision to pull out of the Biological and Toxins Weapons Convention Treaty discussions as the U.S. leadership has admitted to having conducted secret projects simulating offensive bioweapons efforts. Commentors were of the opinion that this BSL-3 facility adds to the perception that the U.S. intends to prepare bioweapons for offensive capability. One commentor stated that this type of facility adds to the fear of escalating bioweapons research with no end in sight. Commentors expressed their concern that siting at a weapons facility is indicative of the facility being a defacto bioweapons facility for weapons research. One commentor opined that an open and honest environmental assessment could not be made due to the security requirements for such a facility.

Response: NNSA acknowledges that many people are opposed to research, development and testing of nuclear weapons and weapons research and testing using live microorganisms. Congress directs DOE and NNSA with regards to their missions and work performed at their facilities must support the Congressionally mandated missions. Similarly, the DoD must respond to its Congressionally assigned missions. Departmental mission support activities have necessitated biological research projects in the past and this requirement will likely continue into the future for elements of both departments.

As stated earlier, LANL's Bioscience Division's biological work is performed partially to support DOE and NNSA mission requirements. This work has evolved over the years to meet the needs of DOE and NNSA, and DOE's predecessor agencies, as well as the needs of other customers under the "work-for-others" program conducted at LANL. The biosciences area of expertise at LANL is constantly being refined and honed. As described in the 1999 LANL SWEIS, LANL has a long-standing, existing bioscience capability and performs cellular biological research work (SWEIS, Chapter 2.2.2.12). Operation of the BSL-3 facility would not constitute a new role for LANL, nor would the operation of such a facility be inconsistent with existing DOE mission work evaluated in the LANL SWEIS Expanded Operations Alternative selected by DOE in the associated ROD. Having this type of expertise at a nuclear facility has, in the past, been readily demonstrated to benefit from its

synergic location with nuclear studies of non-biologic natures. NNSA and DOE believe that the mission support work conducted at LANL will benefit from the implementation of the proposed construction and operation of a BSL-3 facility at LANL and that LANL is, therefore, exactly the right place for this type of facility.

The NNSA acknowledges public concern over the recent Presidential decisions with regard to continuing to engage in negotiations of the international Biological and Toxins Weapons Convention Treaty. Certain individuals might see the proposed BSL-3 facility as adding to the perception that the U.S. plans to prepare bioweapons for offensive capability. However, the U.S. is a signatory to the Biological and Toxins Weapons Convention Treaty and has agreed that actual development and production of bioweapons will not be performed by this nation. Nonetheless, if this were the case and the U.S. were indeed planning a major departure in its offensive capabilities policy, such work would require a facility with a different functional capability and of a larger size than the proposed BSL-3 facility. The microbiological research sample preparation equipment being proposed for the LANL BSL-3 laboratory would not be the correct type of equipment needed to support a bioweapons production facility. Unlike the proposed BSL-3 facility at LANL, which would be constructed with about 800 square feet of BSL-3 laboratory space divided between two separate rooms, a facility capable of supporting a full blown national bioweapons offensive capability would require a sizeable amount of floor space. The expanded floor space would be needed to accommodate a sizable worker staff and multiple pieces of specialized equipment. Public fear of escalating U.S. bioweapons development research and LANL's contribution to this work, should NNSA implement the proposed BSL-3 facility at LANL, is unfounded – but no less real. Individuals with that viewpoint should seek remedy through their Congressional representatives to effect National policy decisions.

1.6.4 Inspector General (IG) Report

Commentors remarked that the IG Report regarding biological work at DOE/NNSA facilities warrants a pause in placing a BSL-3 facility at a DOE site. Commentors also expressed their opinion that the EA does not address the issues raised by the IG Report and these should be analyzed.

Response: The IG report cited by the commentors (DOE/IG-0492 dated February 2001, which appears in its entirety as Appendix B of this EA), states at the beginning of its Observations and Conclusions section: "We found no evidence that the Department's current biological select agent activities have adversely impacted the safety and health of DOE and contractor employees or the public". The IG observed that the Department had not developed and implemented policies and procedures that establish clear roles and responsibilities for the conduct of activities involving biological select agents and select agent materials. Additionally, the IG stated their opinion that the Department had not ensured that DOE laboratories, including those managed by the NNSA, follow "best practices" for the operation of these facilities. The concluding section of the IG Report, "Inspector Comments" section, contains the statement: " We believe the corrective actions

identified by the Department are responsive to our recommendations". By the date of issuance of the IG report in February 2001, the DOE had already corrected identified problems associated with its management of facilities at which biological select agent work was conducted.

As described in the draft EA, the IBC would have authority over approving projects conducted at the proposed BSL-3 facility. NNSA would also maintain strict adherence to the CDC and NIH guidelines for operating a facility of this nature. These actions would continue to be responsive to the recommendations made by the IG report.

1.6.5 Terrorist Attack Risk

Commentors stated their opinion that analyzing only maximally credible events and reasonably credible events in the EA with regard to accidents seemed inappropriate given the events of September 11, 2001 and the recent anthrax scare. Commentors were of the opinion that a credible terrorist risk analysis should be included in the EA. One commentor stated their opinion that, as LANL already presents more than few potential terrorist targets, having a BSL-3 facility at LANL could increase the appeal for attacking the site to would-be terrorists.

Response: The events of September 11, 2001 and the subsequent mailing of anthrax-containing letters have made it abundantly clear that America is vulnerable to terrorist attacks. An instinctive reaction to this would be to include analysis within future NEPA documents in anticipation of terrorist actions being taken. However, there are at least two reasons as to why terrorist attacks are not currently included in NEPA analysis, nor are they anticipated for inclusion in these analytical documents in the near future. The first reason is that accident risk analysis is performed for reasonably foreseeable events. While terrorist attacks are possible, these are not reasonably foreseeable events. There is not enough historical data to extrapolate conclusions about either the probability of possible future attacks occurring at any given locale within the United States, or about the probability of any particular type of attack mode. Nonetheless, regardless of the initiating event (whether naturally occurring or human-made through error or evil intent), the NEPA accident analysis scenario presented in this EA in which cells are disbursed into the environment from the proposed facility is bounding in effect and subsequent projected human health risk for operating the facility.

Furthermore, terrorist attacks come under the realm of security and therefore are appropriately evaluated in a vulnerability assessment. A vulnerability assessment will determine what, if any, security weaknesses exist for this proposed action and will dictate what steps should be taken to minimize the identified security weaknesses. This assessment document and its details are not available for public review since this would then defeat the purpose of performing a vulnerability assessment by making all security measures public knowledge. Terrorists could then use this information to plan their attacks – something that no one wishes to facilitate.

LANL, along with many other cities and industrial sites within the country, has several facilities that might attract the attention of potential terrorists. LANL is not believed to be particularly vulnerable to such attack, nor is believed to be particularly likely as one of the nation's most appealing targets for such activity. The remote location of LANL and its relative inaccessibility, two of the reasons the site was chosen 58 years ago, continue to contribute to its protection. Security at LANL in the wake of the September 11th events continues to be maintained at a heightened state and this will continue to be the case for as long as it is determined to be necessary, possibly well into the future.

1.6.6 Institutional Biosafety Committee (IBC) Role

Commentors expressed their opinion that, as the IBC meetings are held annually and are open to the public, project information could be withheld from the IBC due to security and classification issues. Commentors stated their opinion that some projects may bypass appropriate scrutiny and checks. Other commentors remarked that the IBC Charter must be fully complied with by LANL.

Response: IBC meetings are held periodically to review proposed research projects and a yearly review meeting is also conducted. The public is invited to attend the annual meetings, as they are not held as closed sessions. Project information subject to DOE security and classification restrictions is withheld from IBC members that are without appropriate security clearances, and is also withheld from IBC members with appropriate security clearances that have no need for the knowledge. Holding a DOE security clearance does not automatically give the clearance holder access to all restricted information. It is usually possible to give enough information about potential biosciences projects, as is true of proposed projects with regards to NEPA compliance, for the reviewer to understand the proposal sufficiently for the purposes of evaluating it without the need for divulging classified data. Where this is not possible, special arrangements are made by which appropriately cleared members of the IBC can review the information while maintaining the appropriate security of the information. If review and approval of the project by members of the IBC in some fashion is not possible, the project cannot be performed at LANL. All proposed microbiological research projects at LANL, even projects with classified portions, must undergo review and approval first by the LANL IBC with no exceptions. DOE and NNSA agree with the commentors that the IBC Charter must be fully complied with at LANL.

1.6.7 Seismic Issues

Commentors stated their opinion regarding the incompleteness of the draft EA because the document does not include a risk analysis of Rendija Canyon Fault activity within the range of less than 6 on the Richter scale. Commentors also cited the lack of a complete seismic activity and ground motion analysis as a flaw of the draft EA, as well as the lack of volcanic activity consideration. Commentors also stated that prefabricated buildings are not

earthquake proof, nor is their use consistent with the LANL Comprehensive *Site Plan for 2001 planning principles.*

Response: The draft EA states that the proposed facility, built as a permanent structure, would be built to meet or exceed the design requirements described in the LANL Facility Engineering Manual. These meet and exceed the Zone 2b Seismic code requirements denoted in the Uniform Building Code (UBC). Additionally, the facility would be designed to meet the requirements of a Performance Category 2 facility at LANL. There is no strict correlation between a structure being built to a certain UBC zone number with the degree and type of damage it would sustain in an earthquake of a particular magnitude. However, permanent structures built according to these stated requirements (taking into account local unknown factors such as proximity to epicenter and underlying soil and stratigraphy types) are designed to withstand a seismic event that has a recurrence event of once in every 1,000 years. For LANL, a once in every 1,000-year event would be roughly equivalent to a 5 on the Richter scale. A 6 on the Richter scale equates roughly to about a once in every 2,000-year event. As the chance for a seismic event moves from once in every 1,000 to once in every 2,000 years, the likelihood that the event will occur decreases. A Zone 2 structure is designed to also remain standing after a once in every 1,000- year event, but may have some noticeable damage. A building without windows may or may not have a breach in its outer walls after such an event – there are too many variables involved to be able to predict the potential extent of damages. The draft EA included an accident risk assessment based on an accident scenario by which microorganisms escaped from the facility. This means that the accident scenario bounds accidents of more possibly frequent occurrence but which could result in lesser environmental consequences, such as a minor earthquake that did not result in opening up a pathway for microorganisms to escape the confines of the building. An earthquake of a magnitude greater than 6 on the Richter scale would be expected to result in major damages to many of the buildings at LANL and would likely include fires either at the BSL-3 facility or nearby that could engulf the facility. Fire would be expected to kill any microorganisms in its path. An earthquake of this magnitude is by far not as likely an accident event initiator as human error. Therefore the human-error initiated event is bounding of that accident initiator as well.

Seismic studies of TA-3 cited as references in the EA include the proposed BSL-3 facility optional site locations. The analyses of the potential environmental effects associated with constructing the BSL-3 facility considered the currently available seismic activity and ground motion information regarding the Rendija Canyon Fault. None of the three optional sites would require that the BSL-3 facility structure be located over a fault line or within 50 feet of such an area feature. NNSA believes that the analysis is not flawed. The 1999 SWEIS analyzed naturally occurring accident event initiators including earthquake, fire, and volcanic action. This project specific facility analysis tiers from that larger scope analysis and it is not therefore necessary to repeat the presentation of analysis from that document in the EA. Prefabricated modular units, if used, would be required to be constructed to standards equal to those for a permanent on-site constructed facility, including earthquake and ground motion standards, which is stated in the EA. NNSA is pursuing the elimination

of most new construction using transportables or modular construction units at LANL as an outgrowth of several factors, including the loss of a number of these structures in the recent Cerro Grande Fire. The fact that the alternatives analyzed in the EA are not consistent with UC's LANL Comprehensive Site Plan for 2001 planning principles does not mean that NNSA could not, in this instance, pursue that course of action.

1.6.8 Transportation Issues

Commentors expressed their opinion that the increase in the volume of shipments of biological agents to and from LANL greatly increases the chances for shipping accidents. Commentors also expressed their opinion that the increase in shipments also increases the vulnerability of packages containing biological agents to terrorist seizure. One commentor remarked that the LANL, NNSA and DOE should extensively aid transportation agencies, such as the U.S. Postal Service, to develop their own safety and security measures. Another commentor expressed their opinion that the EA was incomplete because of the lack of complete analyses of transportation risk analysis for the different transportation routes both on-site and through neighboring communities. One commentor stated that transportation of either attenuated or live biological select agents through the U.S. Postal Service was unacceptable because of potential safety and terrorist risks and that NNSA must consider other transportation options such as secure federal couriers.

Response: The volume of shipments of microorganisms into the proposed BSL-3 facility would sharply increase when the facility first begins its operation then would taper off to levels that are only marginally higher than are experienced today in support of the existing LANL biosciences capabilities. Shipments out of the facility would also represent only a slight increase over today's levels of biological shipments. Both incoming and outgoing shipments are typically of milliliter or microliter size samples packaged inside several layers of containment per DOT shipping requirements. The packaged samples are shipped via the U.S. Postal Service and other commercial or private couriers and are tracked per DOT and CDC requirements. Any increase in incidence of shipping accidents due to the increased number of shipments to and from LANL as a result of implementing the proposed BSL-3 facility, would be undetectable given the volume of mail and packages transported by these services. Similarly, the any increase in vulnerability of packages containing biological agents to terrorist seizure would be undetectable given the volume of mail and packages transported by these services. Each organization or company has its own security measures as they recognize the need to safe guard the mail and packages for which they are responsible. When requested, the DOE and NNSA would be happy to share our knowledge and expertise regarding security issues with the shipping entities.

The EA analyzes the shipment of samples packaged in accordance with DOT standards. The packaging requirements required by DOT have already undergone extensive drop, crush and other accident condition testing, before the DOT determined what packaging was appropriate to assure safe transport of these types of samples. NEPA compliance for establishing the use of these packages is the responsibility of that agency. Using DOT standards for packaging

and using couriers that transport the shipments according to DOT requirements does not require duplicative NEPA compliance on the part of NNSA in this document. Transportation of microbiological samples to and from various points around the country and around the world, when performed according to DOT standards for packaging and shipment, should result in no human health or environmental effects to the carriers themselves or to the public along the routes. Secure federal couriers are not necessary to transport samples to and from the proposed facility. The U.S. Postal Service has been transporting appropriately packaged biological samples for many years both before, during and after the recent anthrax contaminated letters were mailed. Hospitals, laboratories, schools, universities and teaching facilities engage in the transport of biological samples every day in volume. Any increase in the risk of terrorist attack because of shipments associated with the proposed BSL-3 facility at LANL would be negligible.

2.0 DESCRIPTION OF ALTERNATIVES

Section 2.1 describes the Proposed Action for the EA that would allow NNSA to meet its purpose and need for agency action. Two additional alternatives are presented in Section 2.2 and 2.3, respectively. The No Action Alternative is presented in Section 2.4 as a baseline for comparison with the consequences of implementing the Proposed Action. Alternatives that were considered in this EA but were not analyzed further are discussed in Section 2.5, and related actions are identified in Section 2.6.

2.1 PROPOSED ACTION TO CONSTRUCT AND OPERATE A BSL-3 FACILITY AT LANL

NNSA proposes to construct and operate a BSL-3 facility at LANL to be operated for the purpose of preparing samples to be used in biological research projects (PC 2001j and 2001k). LANL's existing BSL-2 laboratory capability is primarily located at TA-43, HRL (PC 2001g) (see Figure 2-1). As proposed, the BSL-3 facility would be a pivotal asset for future advanced biological sciences research and development performed by LANL's Bioscience Division but would not replace the other biological laboratory capabilities at LANL. The Bioscience Division would continue to support current biological sciences initiatives at LANL through the existing BSL-2 laboratories.

Three locations at or near LANL's TA-3 (Figure 2-1) have been identified as potentially suitable sites for the BSL-3 facility in terms of accessibility to site utilities and infrastructure, engineering requirements (such as soil structure, stability and similar characteristics), seismic requirements, adequacy of construction space, space for vehicle parking, compatibility with other LANL functions, and other similar siting requirements. Each of the three potential sites is discussed in later subsections as optional sites for construction. In each instance, the building, parking, and access road could be sited anywhere within the identified optional sites. At all location options, the construction and operation of the facility would be the same (PC 2001l).

The BSL-3 facility would be designed as a state-of-the-art facility. It would include two BSL-3 laboratories with adjoining individual mechanical rooms separated by a central support BSL-2 laboratory, clothes-change and shower rooms, and associated office space. When complete, the BSL-3 facility would be about 3,000 ft^2 (279 m^2) in total size and occupied by no more than 10 workers. Up to five staff members from the existing HRL at TA-43 (Figure 2-1) could be relocated to the new facility while other part-time workers would retain offices at their current locations. Any difference in staffing may be made up by hiring locally or regionally, as necessary, to find qualified individuals.

The BSL-3 facility would be designed with a lifetime expectancy of 30 years (minimum) of operation. At the end of the facility's useful life, final decontamination and demolition would be performed as needed. A separate NEPA compliance review would be performed at

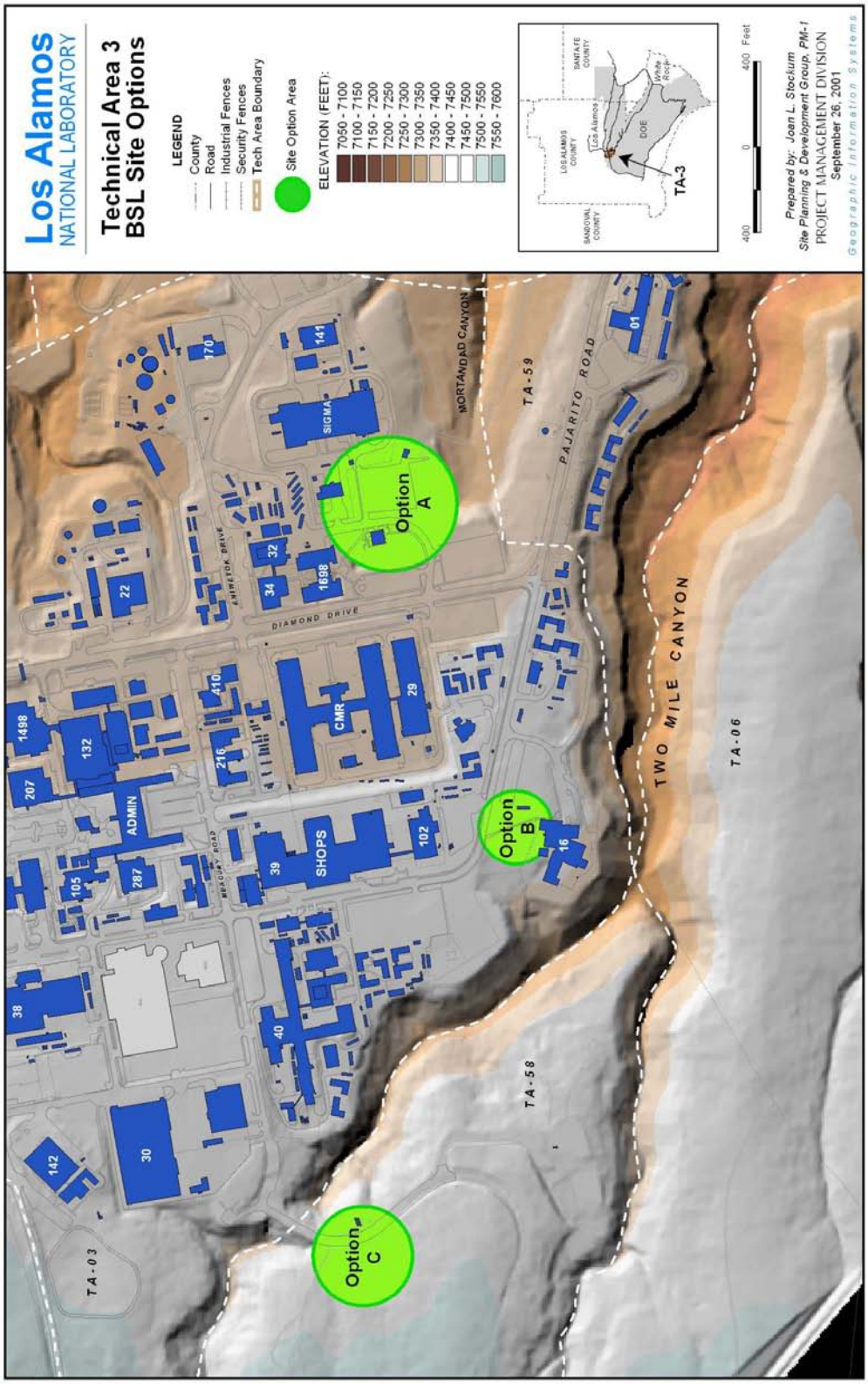

Figure 2-1. Three optional locations for the proposed BSL-3 facility at LANL.

that time. During the operational life of the building, the performance of routine maintenance actions would be expected.

The proposed BSL-3 facility would not be used to produce bioweapons. Additionally, the facility could not be converted for use as a BSL-4 level facility. Neither of these uses could be supported in a facility of this size and design and with the equipment that would be installed in the laboratory rooms as proposed. The facility would also not be used to support experiments that involve propellants or high explosives combined with microorganisms. The design of the facility would not facilitate work with such materials.

2.1.1 Proposed BSL-3 Facility Locations and Construction Measures

Option A: This proposed TA-3 location is adjacent to Sigma Road and the paved parking area southwest of the "Sigma" Building (Bldg. 3-66), north of the intersection of Pajarito Road and Diamond Drive (see Figure 2-1). During construction, approximately 15 parking spaces of the paved parking area would become temporarily unavailable for use (PC 2001c); this portion of the parking area would be required for construction material and equipment storage and used for BSL-3 facility pre-assembly activities. Less than 1 acre (43,560 ft^2 or 4,047 m^2) of previously disturbed land next to the parking area would be bladed over during the construction phase of the project (PC 2001c). The removal of some trees and ground cover would occur in selected portions of the site. Parking needs during the short construction phase would be met by having 15 to 20 parking spaces relocated to nearby parking areas (PC 2001d). Parking needs post construction would be adequately met by the existing parking lot. Utilities necessary for construction and operation of the BSL-3 facility would be available within 350 ft (107 m) of the construction site facility; this includes potable water within 350 ft (107 m), sewer within 350 ft (107 m), electricity within 275 ft (84 m), and telephone service within 250 ft (76 m). Trenches would have to be dug to bring utilities to the site with depths of about 4 ft (1.3 m) for potable water and sewer, 3 ft (1 m) for electrical power and 2 ft (0.6 m) for telephone and communications (PC 2001d). Infrastructure revitalization of LANL's "core planning area" which includes several TA's and all of TA-3 (this proposed site location) calls for near-term sewer line upgrades to current 10-in (25-cm) lines going to the wastewater treatment plant (LANL 2000b).

Option B: This proposed TA-3 location is just to the north of the "Ion Beam Facility" (Bldg. 3-16). The BSL-3 facility would be constructed on the west side of the building's northeast paved parking lot. The parking lot is also adjacent to the south side of Pajarito Road (see Figure 2-1). During construction, approximately 15 existing parking spaces would become temporarily unavailable (PC 2001d); this portion of the parking area would be required for construction material and equipment storage and used for BSL-3 facility pre-assembly activities. Less than 1 acre (43,560 ft^2 or 4,047 m^2) of previously disturbed land would be bladed over during the construction phase of the project (PC 2001c). The removal of some trees and ground cover could occur in selected portions of the site. Parking needs during the short construction phase would be met by having 15 to 20 parking spaces relocated to nearby parking areas (PC 2001d). Parking needs post construction would be

adequately met by the existing parking lot. Utilities necessary for construction and operation of the BSL-3 facility would be available within 100 ft (31 m) of the construction site. These include potable water within 50 ft (15 m) away, sewer within 10 ft (3 m), electrical power within 75 ft (23 m), and telephone service within 100 ft (31 m). Trenches would have to be dug to bring utilities to the site with depths of about 4 ft (1.3 m) for potable water and sewer, 3 ft (1 m) for electrical power, and 2 ft (0.6 m) for telephone and communications (PC 2001d). Infrastructure revitalization of LANL's "core planning area" which includes several TA's and all of TA-3 (this proposed site location) calls for near-term sewer line upgrades to current 10-in (25-cm) lines going to the wastewater treatment plant (LANL 2000b).

Option C: This proposed location is within TA-58, southwest of the TA-3 main administrative area (Figure 2-1). Less than 1 acre (43,560 ft^2 or 4,047 m^2) of previously disturbed land would be bladed over during the construction phase of the project (PC 2001c) for the construction of the facility and associated vehicle parking needs. The removal of some trees and ground cover could occur in selected portions of the site. No parking is currently available on this site, therefore, there would be no disruption of parking during construction activities and no necessity to relocate parking spaces. Utilities necessary for construction and operation of the BSL-3 facility would be available within 550 ft (168 m) of the construction site facility. This includes potable water within 350 ft (107 m) away, sewer within 550 ft (168 m), electrical power within 500 ft (152 m), and telephone and communications within 450 ft (137 m). Trenches would have to be dug to bring utilities to the site with depths of about 4 ft (1.3 m) for potable water and sewer, 3 ft (1 m) for electrical power, and 2 ft (0.6 m) for telephone and communication (PC 2001d). Infrastructure revitalization of LANL's "core planning area" which includes several TA's and all of TA-58 (this proposed site location) calls for near-term sewer-line upgrades to current 10-in (25-cm) lines going to the wastewater treatment plant (LANL 2000b).

Construction Measures: The project construction sites are located at areas that have previously been cleared of buildings or structures or within existing paved parking areas. No undeveloped (so called "green field") areas would be involved. No construction would be conducted within a floodplain or a wetland. The building would not be constructed over a known geologic fault or vertical displacement of a fault line, nor would it be sited within 50 feet of such a condition. No construction would be conducted within solid waste management units (SWMUs) or near SWMUs in a fashion that might preclude their cleanup.

The BSL-3 facility building, as well as the parking area (in the case of the TA-58 optional site location), would be designed in accordance with guidance for BSL-2 and BSL-3 laboratories established by the CDC and NIH (CDC 1999, NIH 2001). Detailed construction plans would not be undertaken before NNSA makes a decision to pursue the action. The CDC would review the detailed construction plans prior to their implementation and make any recommendations for changes necessary. The building structure would meet or exceed the design requirements for a new building described in the LANL Facility Engineering Manual , Chapter 5-Structural (LANL 1999a, DOE 2000c) with respect to Dead, Live, Snow, Wind and Seismic Load Conditions and Design Criteria. DOE Order O420.1 (DOE

1996b) also requires natural phenomena hazard mitigation for these non-nuclear facilities and was used for preparing the design criteria. The Natural Hazards Performance Category for this facility was evaluated by the LANL Preliminary Hazards Analysis (PHA) (LANL 2001b) as "Performance Category 2 (PC-2) "analogous to the design criteria for essential facilities (for example, hospitals, fire and police stations, centers for emergency operations)." The PHA also evaluated the facility using DOE STD 1021 (DOE 1996a) and concluded that the proposed facility would be an "Important or Low Hazard" building classification (LANL 2001b). Also, in accordance with the hazard assessment and definitions contained within LANL Implementing Requirements (LIR) 300-00-05.0 for facility hazard categorization (LANL 1999e), this facility was determined to be a "moderate hazard" facility showing "the potential for considerable on-site but only minor off-site consequences to people or the environment…" (LANL 2001b).

Sustainable design features would allow the structure to operate with improved electric and water use efficiency and would incorporate recycled and reclaimed materials into the construction as much as practicable while still meeting the requirements specified by CDC for laboratory interiors. For example, the facility could incorporate building and finish materials and carpets and furnishings made of reclaimed and recycled materials, low-flow lavatory fixtures to minimize potable water use, and energy-efficient lighting fixtures and equipment to reduce electric consumption. The finished landscaping of the involved construction area would utilize captured precipitation, reused and recycled materials, and native plant species. Utility services are sufficiently located adjacent to or near the proposed building sites and would require minimal trenching to connect them to the new structures.

Clearing or excavation activities during site construction have the potential to generate dust and encounter previously buried materials. If buried materials or remains of cultural significance were encountered during construction, activities would cease until their significance was determined and appropriate subsequent actions taken. Standard dust suppression methods (such as water spraying) would be used onsite to minimize the generation of dust during all phases of construction activities.

Construction of the facility (and parking lot in the case of the TA-58 optional site location) would be performed using common construction industry methods, as the operational use of these structures does not have potential hazards that would entail unique structural requirements. All construction work would be planned and managed to ensure that standard worker safety goals are met. All work would be performed in accordance with good management practices, with regulations promulgated by the Occupational Safety and Health Administration, and in accordance with various DOE orders involving worker and site safety practices. The construction contractor would be prohibited from using chemicals that generate *Resource Conservation and Recovery Act* (RCRA)-regulated wastes (40 CFR 261). Engineering best management practices (BMPs) would be implemented at the building site chosen as part of a Storm Water Pollution Prevention (SWPP) Plan executed under a National Pollutant Discharge Elimination System construction permit. These BMPs may include the use of hay bales, plywood, or synthetic sedimentation fences with appropriate

supports installed to contain excavated soil and surface water discharge during construction of the BSL-3 facility. After the facility is constructed, mounds of loose soil would be removed from the area.

During site preparation and construction noise levels would be consistent with single-story frame non-residential construction using metal studs and cross members. The use of welding equipment, graders, air compressors, riveting tools, and heavy equipment is reported to range from 65 to 125 dBA[6] continuous or intermittent noise. Power actuated tools (for example, those for setting fasteners into concrete) can go up to 139 dBA of impact-type noise near the point of generation (ACGIH 2000).

Vehicles (such as dump trucks) and heavy machinery (such as bulldozers, dump trucks, cranes, and cement mixer trucks) would be used onsite during the construction phase. These vehicles would operate primarily during the daylight hours and would be left onsite over night. If needed, temporary task lighting would be used. Wastes generated by site preparation and construction activities are expected to be nonhazardous. Soil would be staged at the building site or at the construction debris storage yards located at TA-60 along Sigma Mesa until reuse on the site or at other LANL or off-site locations. Non-reclaimable or recyclable wastes would be disposed of in the Los Alamos County Landfill or its replacement facility.

Construction of the BSL-3 facility is estimated to start in 2002 and take approximately 12 months to complete. Construction materials would be procured primarily from local New Mexico suppliers. Construction workers would be drawn from local communities and those across northern New Mexico.

After construction of the facility, gravel or other natural material may be placed at close-in areas to enhance site drainage away from the building. Landscaping materials would consist of native species planted with soil amendments as necessary, depending on the site chosen. Site soil and rock removed during construction would be returned and used as landscaping as practicable. The areas surrounding the building (and TA-58 parking lot) would be cleared of excess soil and landscaped. The landscaping would incorporate, to the maximum extent practicable, a design to capture and utilize area precipitation to minimize the need for permanent water augmentation. Low-pressure sprinklers may be required to supply water for the establishment of plants and grassy areas over the first year or two of growth. Native plants of the Pajarito Plateau would be used primarily where practicable. Other native New Mexico plants that may require drip system water augmentation could be used minimally.

[6] dBA refers to sound level in decibels measured on a sound level meter using the A-weighted scale as established by the American National Standards Institute (ANSI, 1983)

Figure 2-2. Conceptual floor plan for the proposed BSL-3 facility at LANL

2.1.2 BSL-3 Facility Description and Operations

Facility Description: The proposed BSL-3 facility would be a one-story building with about 3,000 ft^2 (279 m^2) of floor space (Figure 2-2) housing two BSL-3 laboratories, and one BSL-2 laboratory, as well as associated support office space, lavatories, and mechanical and electrical equipment areas. The BSL-3 facility would be constructed using concrete footing and stem walls with concrete slab-on-grade floors (PC 2001j). Walls would be steel stud framed and the roof construction would consist of metal decking over steel bar joists. The exterior walls would have an application of stucco and the painting of the building would be visually consistent with surrounding structures. The interior surfaces of walls, floors, and ceilings of the BSL-3 laboratory areas would be constructed for easy cleaning and disinfection. The walls would be finished with an easily cleanable material with sealed seams, resistant to chemicals and disinfectants normally used in the laboratory. Floors would be monolithic and slip-resistant. All penetrations in floors, walls, and ceiling surfaces would be sealed, or capable of being sealed to facilitate disinfection, aid in maintaining ventilation system air pressures and keep pests out. Laboratory furniture would be capable of supporting anticipated loading and use, bench tops would be impervious to water and resistant to moderate heat, chemicals used, and disinfection solutions. Spaces between benches, cabinets, and equipment would be accessible for cleaning. Figure 2-3 shows a conceptual equipment layout for the facility.

The two BSL-3 laboratories and the BSL-2 laboratory would each have two Class II biological safety cabinets[7] (BSCs) (CDC 2000b) (Figure 2-4) with thimble connections.[8] Class II BSCs provide their own airflow, have High Efficiency Particulate Air-Purifying (HEPA)[9] filtration internally within the cabinet and are designed to provide personal, environmental, and product protection (that is, the samples being processed). Exhaust air from the BSCs exits the room via the thimble connection to HEPA filters in the mechanical rooms, then outside the building. BSCs are designed to operate at a minimum inward flow of a 100 linear ft per min (30.5 linear m per min) at the sash opening (face) (CDC 2000b). BSCs would be located away from doors, room supply louvers, and heavily traveled laboratory areas (LANL 2001b). BSC interiors are cleaned by use of appropriate methods and could include ultraviolet light or chemical disinfection. No windows would be installed in the BSL laboratory's exterior walls. Non-opening observation windows on interior walls would be placed between the BSL-2 and BSL-3 laboratories (Figure 2-2). Centrifuges or other equipment that may produce aerosols would be operated in BSCs or with appropriate combinations of personal protective equipment (PPE) and other physical containment devices. Vacuums would be provided to critical work areas using portable vacuum pumps

[7] A BSC is a piece of equipment often referred to as a "hood," which is the primary means of containment developed for working safely with infectious microorganisms.

[8] A thimble connection is where an inverted cone-like duct with a flexible connector fits over the BSC exit duct with a 1 inch gap between the two ducts allowing for room air to be exhausted.

[9] HEPA is a disposable, extended-medium, dry-type filter with a particle removal efficiency of no less than 99.97% for 0.3-micron particles.

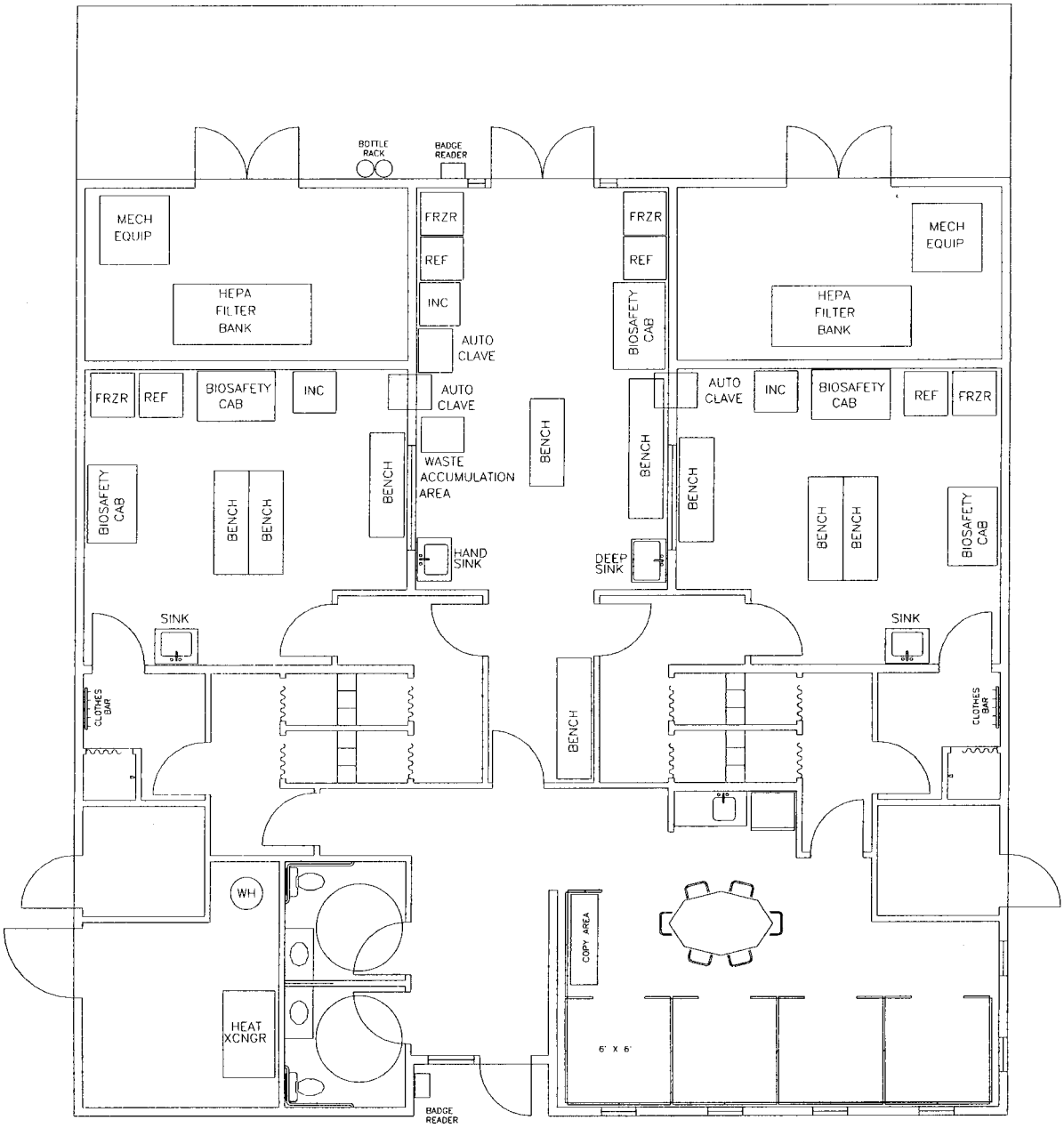

Figure 2-3. Conceptual floor plan showing equipment layout for the proposed BSL-3 facility at LANL

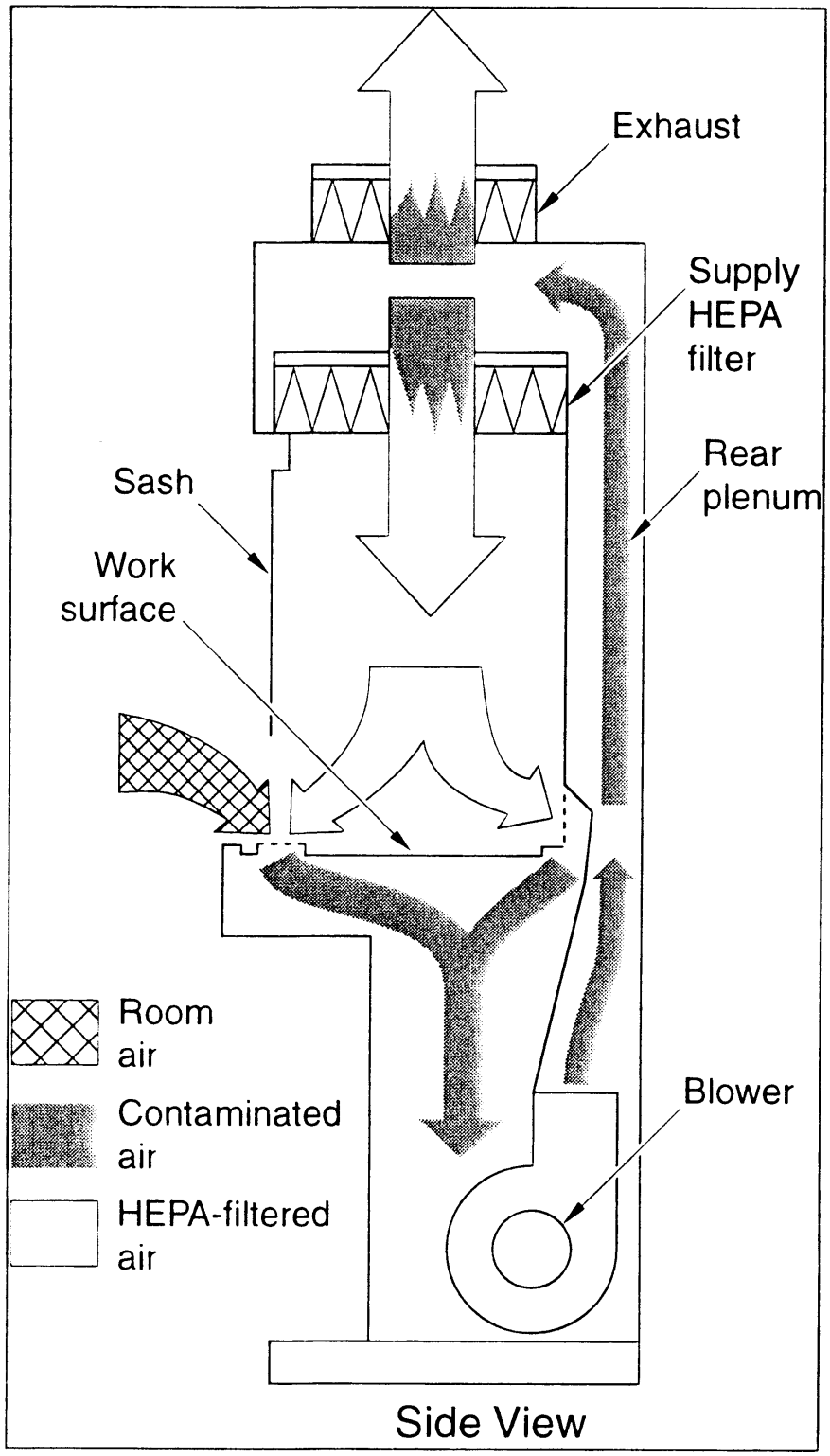

Figure 2-4. Schematic diagram of a typical Class II Type B3 BSC (CDC 2000b)

properly fitted with traps and HEPA filtration. Operation of all equipment is designed to avoid interference with the air balance of the cabinets or the designed airflow of the building (Figure 2-5). No "real time" monitoring instruments for microbes are presently available. When such instruments have been developed and become available they may be installed at the BSL-3 facility.

Physical security would be implemented commensurate with the level of work being performed within the facility. Examples of physical security measures could include badge readers, perimeter fencing and anti-vehicle collision barriers. In regards to national security the facility status would be based upon a security analysis. As in all facilities managed by the LANL Bioscience Division, security in the proposed facility would be maintained by limiting access to only authorized DOE-badged personnel. Employee qualifications and training are described in CDC-NIH guidelines (CDC 1999) along with appropriate management of security concerns.

Fire suppression for the BSL-3 facility would be provided by a standard wet-pipe fire sprinkler system. Waterflow alarms would be connected to LANL's fire alarm monitoring station so that designated responders would be notified. Water used for fire suppression that might become pooled on the building floor would be treated with chemical disinfectants. There would be no floor drains or subsurface sumps to collect this water (PC 2001g).

Separate mechanical rooms containing the facility air-handling systems are proposed for the BSL-3 facility with access provided only from the exterior of the building (Figure 2-5). The two BSL-3 laboratories would each have their own separate mechanical rooms that would also contain each labs' respective HEPA filter banks that would filter all room air one-time-through and provide secondary filtration for exit air from the BSCs. Routine maintenance of the filter bank would be conducted, including replacement of the filters. Replaced filters would be chemically sterilized prior to disposal. The BSL-2 laboratory and the rest of the facility would be on a separate mechanical air-handling system that would be exhausted without HEPA filtration. There would be only one electrical room with access from the exterior of the building. The BSL-3 facility would employ lightning protection designed to meet the requirements of the National Fire Protection Association (NFPA 1997 and 2000). Entry of personnel into the BSL-3 laboratories would be from the BSL-2 or office areas through two doors that are interlocked so that only one can be opened at a time. A rear entry area into the BSL-2 would permit entry of delivery items, access to compressed gas cylinders, and a 120 liter liquid-nitrogen container, and serve as a second point of egress from the building under emergency situations (Figure 2-3) (LANL 2001b).

The air-handling systems, including the heating, ventilation and air conditioning (HVAC) systems, would be designed to provide for individual temperature and ventilation control zones as required in the BSL-2 and BSL-3 laboratories and in accordance with LANL directives (LANL 2001h). A ducted exhaust HVAC system would draw air into the BSL-3 laboratories from the office areas toward and through the BSL-3 laboratories areas with no recirculation from the BSL laboratories to other areas of the building (Figure 2-5). The

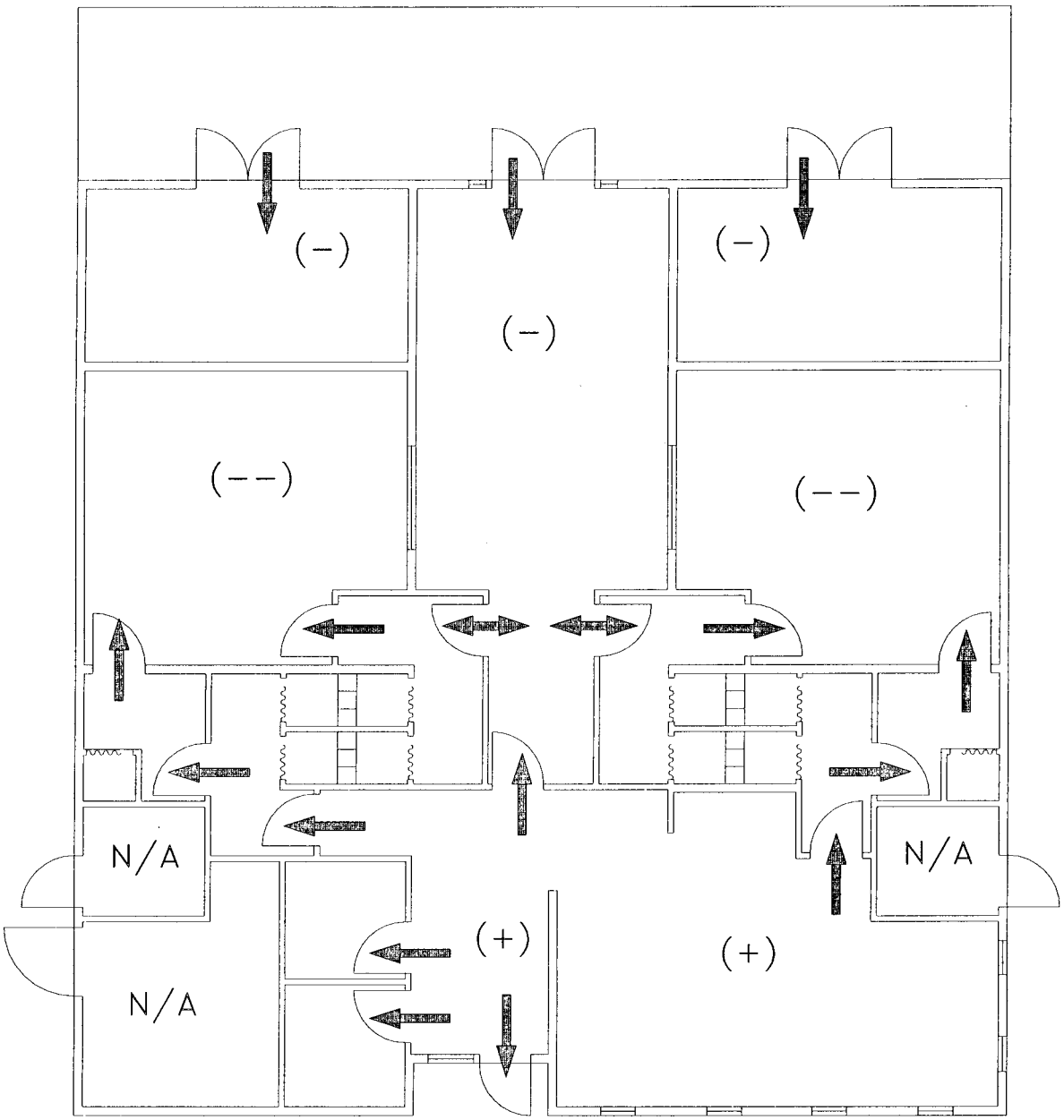

Figure 2-5. Schematic diagram of airflow in the proposed BSL-3 facility at LANL

BSL-3 laboratories would be under the most negative pressure with respect to all other areas of the building. Air exhaust would be dispersed away from occupied areas. Direction of airflow into the laboratories and the BSCs would be verifiable with appropriate gauges and an audible alarm system to notify personnel of HVAC problems or system failure. In the event of a power outage, all biological materials would immediately be placed in a "safe" configuration, such as confinement or chemical disinfection. The HVAC systems may be supplied with backup power from a dedicated BSL-3 facility diesel generator to minimize power supply interruption. Exhaust stacks would be placed well above the roof (10 ft or 3 m or greater) and away from the buildings' air intakes.

The non-laboratory areas of the building would be provided with separate air circulation. Should power be lost to the building and the HVAC system, the air supply system would shut down and zone-tight dampers would close automatically to prevent air migrating from the laboratory areas to other areas of the building. Interior doors located between the BSL-2 and BSL-3 laboratory areas would be equipped with interlocking hardware to prevent simultaneous opening.

All liquid waste from the BSL-3 laboratory work would undergo autoclaving in accordance with LANL waste management directives (LANL 1999b, 2000c) and would then be discharged into the sanitary waste disposal system through laboratory sinks. Tap water entering the BSL-2 and BSL-3 laboratories through spigots in the sinks would have backflow preventers to protect the potable water distribution system from contamination (PC 2001g). Biological cultures could be disposed of in the sinks after undergoing treatment with chemical disinfectants for at least one hour (PC 2001g).

At any of the optional locations the electrical requirements for the BSL-3 facility would be about 60 kilowatts (kW); the building would be equipped with a diesel generator sized to supply laboratories with electric power in the event of a power failure from the supply grid system. In the event of a power outage, the generator would immediately supply electricity to the laboratories so that workers could shut down the laboratories safely. The main building electricity supply would come from a 13.2-kilovolts (kV) overhead feeder line to the site. A 112.5-kV Amperage (kVA) pad mounted transfer and a 480-volt (V) distribution panel-board would be installed to provide 480 V electrical service to the building with transformers to drop the power to the 120 V and 208 V needed to operate facility equipment. This electrical power supply system would also be equipped with Transient Voltage Surge Suppression (TVSS) devices. HVAC systems, boilers, and heaters would use the 480-V service.

At all three optional locations, parking would be in a common-use lot with at least 10 standard parking spaces, plus two for handicapped accessible near the building entry (ANSI 1998) and two for visitors. Exterior lighting would be provided for all parking conforming to applicable building codes and minimizing light dispersion particularly towards canyons habitat areas (PC 2001l).

Operations: The BSL-3 facility would be operated according to all guidance and requirements established by the CDC and NIH (CDC 1999). Prior to operating the facility using select agents, the facility would be registered with a unique registration number from the Secretary of the US Department of Health and Human Services (HHS) according to the U.S. *Code of Federal Regulations* (CFR) requirements by providing "sufficient information that the facility meets biosafety level requirements for working with the particular biological agent" (42 CFR 72). The CDC is the supporting governmental agency under the HHS responsible for the management of the Laboratory Registration/Select Agent Transfer (LR/SAT) Program and would be the main point of contact for LANL's Facility Responsible Official. UC would be required to participate in the CDC LR/SAT Program for handling of select agents[10] and must follow the six LR/SAT components as appropriate, which include (1) the list of approximately 40 "select agents" that are "viruses, bacteria, rickettsia, fungi, and toxins whose transfer in the U.S. is controlled due to their capacity for causing substantial harm to human health;" (2) registration of the facilities; (3) filing of approved transfer form; (4) verification using audits, quality control, and accountability mechanisms; (5) agent disposal requirements; and (6) research and clinical exemptions (42 CFR 72). No select agents would be handled in the proposed BSL-3 laboratories without prior CDC registration and approval, and UC would be required to follow the LR/SAT requirements. Microorganisms that are not select agents would also be used in the BSL-3 laboratories but would still be handled according to CDC and NIH guidances and requirements (PC 2001g). Experimental microorganisms expected to be cultured at the BSL-3 facility would be the select agents, tuberculosis (certain *Mycobacterium spp*.), and influenza viruses (see Appendix E). The CDC and NIH guidances and requirements also extend to handling genetically altered microorganisms. All microbiology laboratories routinely alter microbial genomes in standard procedures approved by NIH (NIH 2001). It is likely the facility would receive genetically altered microorganisms. Before any infectious microorganisms would be handled in the BSL-3 laboratories, the IBC and the researcher, in accordance with CDC guidance, would perform a risk analysis. LANL occupational medicine and the local medical community would be informed of the microorganisms to be handled in the BSL-3 laboratories and would be aware of the methods of identification and control of associated diseases.

All work with infectious microorganisms in the proposed facility must be approved by the IBC and authorized by UC management in strict accordance with the following directives:

- Biological Weapons Convention Treaty (BWC 1972) permits defensive research for the purpose of developing vaccines and protective equipment
- DOE Biosurety Program provides oversight and guidance on biological programs within the DOE complex. This includes the recently issued DOE Notice N450.7 on handling transfer and receipt of etiologic agents at DOE facilities (DOE 2001c)

[10] Select agents are biological agents of human disease whose transfer or receipt requires a facility to be registered with the CDC under 42 CFR Part 72.6; select agents have historically been associated with weaponizing efforts.

- Appendix G of the UC Contract with DOE specifies among other things, Work Smart Standards, which include adopted standards from CDC (CDC 1999, 42 CFR 72), NIH (2001), and the U.S. Occupational Safety and Health Administration (OSHA) (29 CFR 1910, 29 CFR 1926)
- LANL Administrative Requirements, such as Laboratory Performance Requirements and Laboratory Implementation Requirements (for example, LANL 1999b, 1999d, 1999f, 1999g, 2000c, 2001d) provide partial frameworks for the operation of facilities
- LANL Institutional Biosafety Committee Charter reviews and approves of each biological research project before it can be undertaken at LANL
- When completed,[11] LANL safety and security documentation (Facility Safety Basis, Facility Safety Plans, Hazard Control Plans, Human Pathogens Exposure Program, and security assessments) would provide partial framework for operation of the BSL-3 facility
- When completed, division and facility specific protocols (for example, Laboratory Implementation Guidance, standard operating procedures, and technical memos) would provide partial framework for operation of the BSL-3 facility

Operation of the proposed BSL-3 facility would also be in compliance with a variety of state and Federal regulations. For example, these regulations would include those promulgated by the U.S. Department of Agriculture (7 CFR 330, 9 CFR 92), U.S. Department of Commerce (15 CFR 730), OSHA (29 CFR 1910.1030), U.S. Postal Service (USPS) (39 CFR 111), U.S. Department of Transportation (DOT) (49 CFR 171-178), and the HHS (42 CFR 72). NNSA, LANL, and CDC requirements would be certified as having been met before operations would begin at the proposed BSL-3 facility (DOE 1996a, 1996b; LANL 1999b, 1999c, 2000c, 2001c; PC 2001j, 2001k). Other non-governmental organizations that provide guidance for transportation of infectious agents include the *Dangerous Goods Regulations,* the *Infectious Substances Shipping Guidelines* of the International Air Transport Association (IATA 2001), and the *Guidelines for Safe Transport of Infectious Substances and Diagnostic Specimens* of the World Health Organization (WHO) (WHO 1997).

Once all the regulatory conditions are met and the required approvals' are obtained then operations would commence at the BSL-3 facility. A typical workflow for the use of the building's laboratories is outlined in the schematic diagram presented in Figure 2-6. The process steps are discussed in more detail in the following paragraphs.

Appropriate PPE used by employees entering the laboratories would include eye protection, gloves (in some cases the worker would be double-gloved), and disposable lab coat or clothing (including disposable booties and disposable cap). Workers' hands would be

[11] Safety and security documentation, as well as facility specific protocols, are not completed until after decisions have been made to construct and operate buildings and detailed building designs have been completed. Therefore, these are future documents that would be completed for the BSL-3 facility if NNSA decides to proceed with its construction and operation.

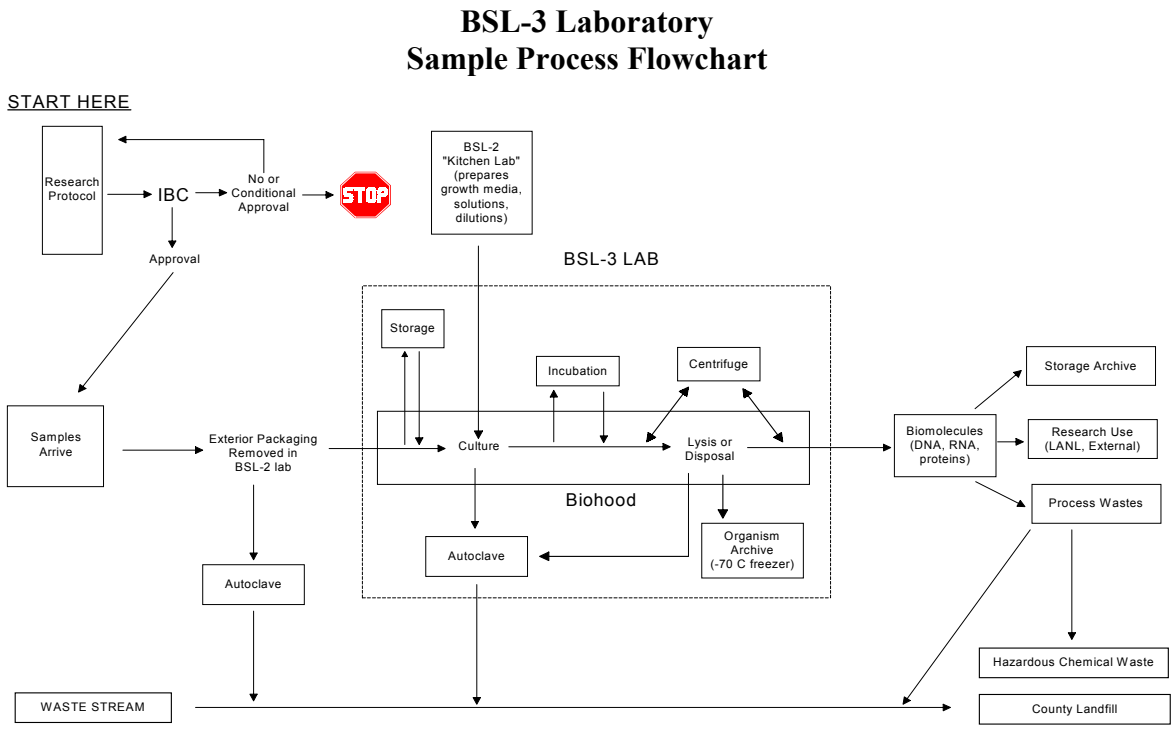

Figure 2-6. Conceptual workflow schematic for the proposed BSL-3 facility at LANL.

washed with disinfectant immediately before and after putting gloves on or after any potential contamination with infectious agents. Workers could shower after finishing their laboratory work upon removal of their PPE clothing. Worker's hair would be kept short or secured away from the face and no skin would be exposed below the neck; workers would be required to wear socks, closed shoes, and long pants underneath the disposable coverings. The majority of all materials used in the BSL-3 facility would be disposable, but some reusable laboratory apparatus, such as glass test tubes or culture dishes may be needed for sterile work. No open flames would be allowed within the BSCs. Work in the three laboratories would be scheduled and planned to avoid conflicts within the laboratory areas. All workers in the BSL-3 laboratory areas would be informed of what other workers are handling so that appropriate staging of work can occur. Open cultures would only be handled in BSCs. No "sharps" would be used in the facility (such as needles). There would be no procedures for these laboratories to intentionally produces aerosols that could cause microbes to become airborne. BSCs would be negative-pressure with respect to the room and airflow and would always be directed away from the worker and into the BSC. Workers would be offered appropriate immunizations for the microorganisms being handled, they would be tested for normal immunocompetancy[12], and would have medical treatment readily available in the event of an accidental exposure (PC 2001g). As part of LANL's Emergency Management and Response Program, DOE has agreements in place for the education and

[12] Immunocompetancy is the ability to have normal immunity from infection.

assistance of local hospital personnel to facilitate their participation in the event of any type of accident, including any accidental exposures from the operation of the proposed BSL-3 facility.

No radiological material would be used or stored in the BSL-3 facility. Additionally, no macroorganisms, such as research animals or plants, would be housed or used in the facility. UC does not maintain an animal colony at LANL. A pest program would be in place to control vector populations.

The BSL-3 facility would not be a large-scale research or production facility, which is defined as working with greater than 10 liters of culture quantities (NIH 2001). Quantities of each cultured microorganism would be further limited per experiment-specific IBC approval procedures. Samples would be provided by commercial suppliers, research collaborators, or other parties seeking culture identification. Samples may contain either previously identified or unidentified organisms or strains. Identification provides diagnostic, reference or verification of strains[13] of microorganisms present. Diagnostic and reference strains, which may include the geographic source of the sample, contribute to the understanding of the microorganism's ability to cause disease. Rapid, accurate reference or verification of strains improves containment of infection through early and effective medical intervention, potentially limiting the progress of illness for those exposed to pathogens.

The CDC would periodically inspect the facility over the life-time of its operation. The inspections would be performed by CDC staff or their contractors.

Samples Arrive at the LANL BSL-3 Facility for Processing: Sample shipments would only be received at the BSL-3 facility within all established guidelines and requirements. Select agents would only be accepted when the CDC form (EA-101) has been completed per regulations, registration verified, and the requesting facility responsible official had been notified in advance of shipment according to CDC registration requirements. Samples could only be shipped to LANL by commercial package delivery services, the U.S. Postal Service, other authorized entity, or delivered to the receiving area from an origination point within LANL by a designated LANL employee acting as a courier (39 CFR 111; 42 CFR 72; 49 CFR 171-178; LANL 1999b). Generally, shipment sample sizes would be small; a typical sample would consist of about a milliliter of culture media (agar solid) with live cells (a milliliter is about equal to a teaspoon in volume size). Smaller samples could be shipped that would be microliters in size; the maximum possible sample size would be 15 milliliters. Occasionally samples would be shipped frozen in culture media. Receipt of the select agents must be acknowledged electronically by the requesting facility responsible official within 36 hours of receipt and a paper copy or facsimile transmission of receipt must be provided to the transferor within 3 business days of receipt. Upon this acknowledgement, the transferor would be required to provide to the LANL-requesting-facility responsible official a

[13] Strains are the very lowest taxonomic (naming organisms) designation, it generally means cells descended from a single isolate which have not mutated from the exact DNA sequence of that original single cell.

completed paper or facsimile transmission copy of the CDC form within 24 hours to the registering entity (holding that facility's registration), in accordance with §72.6(c)(2) (42 CFR 72) for filing in a centralized repository.

All in-coming packages (regardless of origination point) containing infectious agents would have to have been packaged in DOT-approved packages (42 CFR 72) (see Figure 2-7). These packages would be about 6 to 8 inches (15 to 20 cm) in height and about 3-4 inches (8 to 10 cm) in cylinder diameter. All shipping containers would be made of plastic and the samples would be double or triple contained. Transportation and interstate shipment of biomedical materials and import of select agents would be subject to the requirements of the U.S. Public Health Service Foreign Quarantine (42 CFR 71), the Public Health Service and DOT regulations. Additionally, the U.S. Department of Agriculture regulates the importation and interstate shipment of animal or plant pathogens (7 CFR 330 and 9 CFR 92). Strict chain-of-custody procedures for samples arriving at the LANL receiving site would be followed.

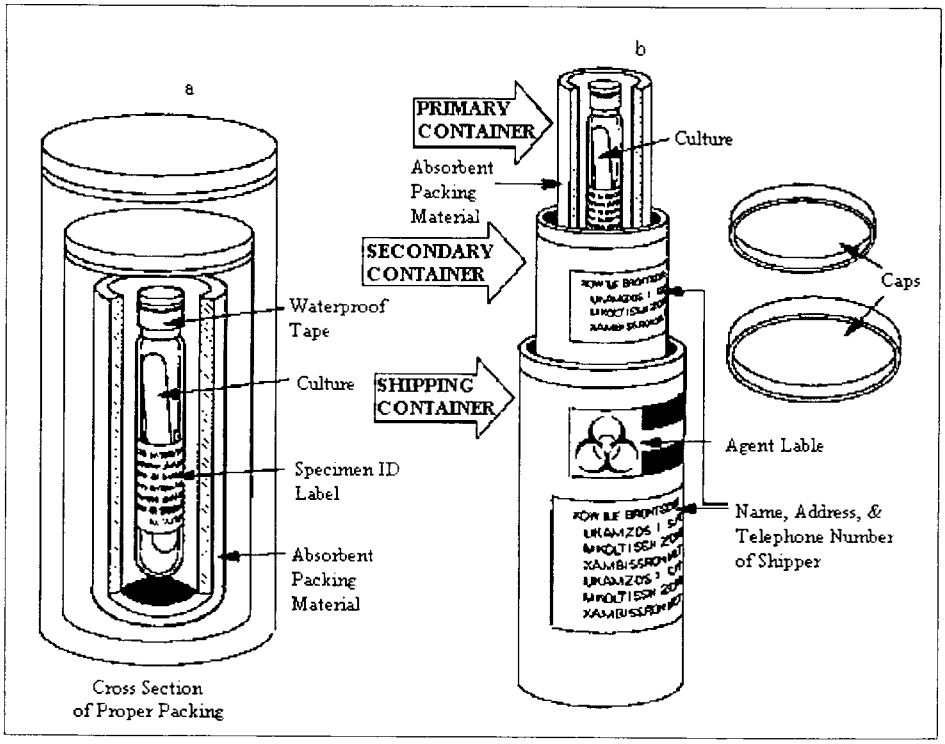

Figure 2-7. Example of a Primary Shipping Package.

The BSL-2 laboratory within the proposed facility would serve as the shipping and receiving point for biological samples and materials shipped from the facility or shipped to the facility. Biological shipments to and from LANL could initially be as much as ten times the current levels (4 in and 2 out per month now) of shipments to existing LANL biological research laboratories. Current estimates are that shipments to and from LANL would be about 10 to

60 per month (PC 2001i) for the BSL-3 facility. Once the facility became fully operational and "stocks" were established, the level of shipments would remain above current levels for these types of shipments but decrease from start-up levels. Due to the perishable nature of the samples at the BSL-3 facility, receiving and shipping of samples normally would only occur during weekday daylight hours and samples must be opened and used or restored (put in growth media) within 8 hours of arrival (PC 2001g). External packaging material from packages received at the facility would be inspected, removed, autoclaved,[14] and disposed of according to LANL waste handling procedures (LANL 1999b, 1999c, and 2000c). The biological material samples and their packaging would be left intact and in accordance with the established chain-of-custody record. The packages would be placed in safe and secure condition within the respective BSL-3 laboratory where workers would process them. Shipment of samples from the BSL-3 facility to other researchers or the CDC would require following the same guidelines and requirements for the sample shipment that applied to samples received at the facility.

The samples may arrive at LANL in various fresh, frozen, or "fixed" (for example, in formaldehyde) forms (shown in Appendix E-1, LANL-Proposed Action Microorganisms) including aqueous liquids, solids, or contained in bodily fluids (PC 2001g). Samples would normally only contain vegetative forms (active growing stage) of microorganisms but some spores could be present in samples. Other samples may contain proteins, DNA, or attenuated microorganisms (organisms that have been partially inactivated). Purified or diluted biological toxins work would not be planned for these BSL-3 laboratories, but incidental quantities may be present due to the microorganism producing them (PC 2001g).

Upon arrival at the BSL-3 facility, these samples would be examined for damage, logged in, and taken to the BSL-2 laboratory for removal of the external packaging material (LANL 2001b). Damaged packages would be handled in accordance with procedures for BSL-3 laboratories. The removed packaging would then be autoclaved and disposed as solid waste (LANL 1999c). The interior packing with the intact sample would be placed safely and securely in the respective BSL-3 laboratory under chain-of-custody procedure until the authorized researcher is ready to process the samples. Unpacking the select agent primary container would only be done in the BSC. The samples would be stored in the BSL-3 laboratory within a locked freezer or refrigerator, according to the needs of the sample for preservation. Inventories of all samples and cultures would be kept. Samples and cultures would be identified by a numeric or alpha-numeric code rather than by the name of the microorganism or source. Sensitive information about samples and results would be maintained elsewhere at LANL in a safe and secure manner in accordance with applicable NNSA and LANL security requirements. The samples could also be immediately processed, in which case the materials would be placed directly into culture media (such as a liquid or semi-solid nutrient material or media prepared in the BSL-2 laboratory). All preparations and manipulations of cultures or samples would only occur within a fully operating BSC either in a BSL-2 or a BSL-3 laboratory as appropriate for the microorganism. When the

[14] An autoclave is an apparatus using superheated steam under pressure to kill or sterilize microorganisms.

external packaging materials are removed they would be autoclaved within the facility and disposed of according to LANL's solid waste handling procedures (LANL 1999c).

Culture of Samples in a BSL-3 Laboratory: Once the samples would be removed from their primary containers in a BSC, a tube, flask or plate containing a specific nutrient media would be innoculated with the sample to create a culture. All culture work would be completed and cleaned up within one work shift (8 hours) except for materials being incubated. Culture and culture-storage containers would typically be made of plastic and always be double-contained. The culture container would be transferred to a temperature-controlled incubation chamber to grow the organisms (multiply the number of microorganisms) for a period lasting up to several days. Centrifugation of live, intact microorganisms would be conducted in sealed containers placed inside sealed tubes to minimize the potential for aerosolization[15] of microbes, or, if appropriate, centrifugation could be conducted inside a BSC. Cultured materials, which are sources for research materials, could be "lysed" (broken open) or killed (inactivated) by the addition of a variety of chemicals such as detergents or a chemical known as phenol. The lysed or killed cells could be processed into biomolecular samples that would later be analyzed by various research methods at various LANL bioscience research laboratories and other laboratories off-site. Following incubation (hours to days), all cultured materials would be cleaned up within one shift (8 hours).

Waste Generation at the BSL-3 Facility: It is expected that little soil and construction debris would be generated from site preparation and construction activities of the proposed BSL-3 facility that would require disposal and removal from the construction site. Construction debris that is generated would be sent to the Los Alamos County Landfill at TA-61 (or its replacement facility) for disposal or recycling as appropriate. Sanitary waste from portable toilets used during construction would be removed by commercial vendors and be disposed in a sanitary sewer system offsite from LANL in accordance with their permit requirements.

During operation of the BSL-3 and BSL-2 laboratories, the interior working surfaces of the BSCs would be disinfected after each use, which would generate waste products. All wastes generated in the laboratories of the facility (including sample packaging materials, culture materials, petri dishes, PPE, and associated process wastes) would leave the laboratories only after decontamination using the facility's autoclave or after being chemically sterilized. Additionally, waste regulated as "infectious" biological waste (20 NMAC 9.1) would be segregated from other wastes at the point of generation and would also undergo autoclaving. The autoclaving process involves placing waste to be autoclaved in a special container. When autoclaving occurs, an indicator strip on the container changes color. This allows facility workers and waste management workers to be able to tell at a glance whether waste has undergone autoclaving. Performance of the autoclave is automatically tracked

[15] Aerosolization is the process of converting a liquid into droplets that are small enough to become dispersed in the air. In this case the droplets may contain one or more microbes.

electronically to insure its effectiveness. This method is the same waste management method used by hospitals and similar facilities to sterilize their waste. These "treated" special wastes would be disposed of at the Los Alamos County Landfill or other appropriate facility. Solid waste landfills may accept autoclaved or chemically sterilized wastes for disposal according to their individual waste acceptance criteria and operating permit requirements. Alternatively, UC could contract to send sterilized wastes produced by the proposed BSL-3 facility to a commercial incinerator located offsite for waste disposal. These special wastes would have a production rate of about 50 lbs (23 kg) per week for a total of about 2,600 lbs per yr (1,200 kg per yr) (PC 2001g). Other "solid waste" generated in the offices and other non-laboratory portions of the facility would raise the total solid waste production to about 5,200 lbs per yr (2,360 kg per yr) (PC 2001g). Solid wastes would be disposed of at the Los Alamos County Landfill or its replacement facility.

Sanitary liquid waste, solid waste, and hazardous waste would be generated from the proposed BSL-3 facility. Sanitary waste would be generated from toilets, showers, and sinks in the building bathroom facilities. Sinks in each of the three laboratories would also generate sanitary waste. Soluble or liquid waste materials generated from laboratory operations could be disposed in the laboratory sinks after first being treated with disinfectants (PC 2001i). This waste, which would be about 300 gal per day, would be transported to the Sanitary Waste Systems Consolidation (SWSC) Plant via the LANL sanitary sewer system (see Section 3.3.4). No industrial waste and no radiological waste would be generated by the facility. None of the waste generation would be relocated from another LANL facility.

Wastes regulated by the State of New Mexico as "hazardous" would be generated when organic solvents (such as phenol, chloroform, and isoamyl alcohol) would be used to lyse cells for DNA, ribonucleic acid (RNA), proteins, and lipids research. These would be small volumes of materials (less than 10 ml per sample) that could amount to about 230 lbs per yr (104 kg per yr) (PC 2001g). Hazardous wastes would be collected at the site of generation in a satellite accumulation area and would be managed by the LANL waste management program (as are other waste types), then disposed of offsite at permitted commercial facilities. Removal of waste containers from the BSL-3 would occur only after the exteriors of the containers were wiped off with disinfectants. This step would only be conducted by the authorized BSL-3 laboratory technicians and researchers. Waste containers would then be moved to the satellite storage area for proper storage and disposal (LANL 1999c, 1999g, and 2000c). The effectiveness of disinfecting and autoclaving would be periodically tested.

Chemical disinfectants would be used to disinfect portions of the laboratories that are not readily accessible, such as the ductwork. These disinfectants would be in a gas form as appropriate for the respective chemical. The space to be disinfected would be sealed, personnel would be excluded and the gas would remain in the space for several hours before release to the environment. This procedure would be conducted by a certified technician using a standard protocol. The quantities of chemicals used would be well below the reportable quantities for both the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 300) and the Emergency Planning and Community

Right-to-Know Act (EPCRA) (40 CFR 350). For example, if paraformaldehyde is used, the CERCLA reportable quantity is 1000 lb. and for the vapor phase produced, formaldehyde, it is 100 lb. The EPCRA reportable threshold for formaldehyde is 10,000 lb. Formaldehyde is also listed as a Hazardous Air Pollutant (HAP) under the Clean Air Act Amendments. HAP's are limited to 10 tons per yr individually. Formaldehyde is also a volatile organic compound (VOC). Other disinfectants being considered for use in disinfecting the BSL-3 laboratories are ethylene oxide and hydrogen peroxide. Quantities used annually would not exceed reportable quantity volumes for any chemical disinfectant used by the BSL-3 facility. Decontamination of the facility would include the use of chemical disinfectants, as discussed in the previous paragraph. This would allow the facility to be decontaminated, decommissioned, and demolished using standard construction practices. The resulting waste could be disposed of at the Los Alamos County Landfill or its replacement facility.

2.1.3 BSL-3 Facility Decommissioning and Decontamination

The ultimate decommissioning or decontamination of the BSL-3 facility would be considered and a separate NEPA review would be conducted when the facility is no longer needed. It is estimated that the operational design life of the proposed building would be at least 30 years.

2.2 ALTERNATIVE ACTION TO INSTALL PREFABRICATED FACILITY UNITS (PREFABRICATION ALTERNATIVE)

The NNSA may choose to purchase and install ready-assembled prefabricated BSL-3 and BSL-2 modular units, which could be placed together with a modular units made up of offices, lavatories and other rooms required to form a new BSL-3 facility. No permanent on-site constructed facility, as described in the Proposed Action, would be built. Such a facility would be about the same size as the permanent on-site constructed facility described in the Proposed Action. These commercially available modular units would be nearly ready for occupancy when delivered to LANL. The units would be transported from their construction site by truck and delivered to LANL and could be operable within several months from the time of purchase.

As a general initiative, NNSA is pursuing the construction of permanent buildings in preference to temporary structures at LANL because the long-term cost savings associated with operating permanent on-site constructed buildings, combined with their longer expected useful life, makes this a more fiscally prudent action. Additionally, NNSA is encouraging the placement of new facilities away from forest interface areas at LANL and encouraging the construction of permanent facilities over the use of transportables or modular buildings in the wake of the Cerro Grande Fire. Permanent facilities can be constructed to house larger numbers of personnel and operations in structures that are readily defensible from wildfire, which is an important feature for the LANL site. The construction of new facilities with modular buildings is therefore inconsistent with the LANL Comprehensive Site Plan 2000 (CSP) planning principles (LANL 2000b), which calls for "Upgrade facilities by replacing

temporary, outmoded and substandard facilities with new, permanent or renovated facilities as appropriate." This alternative, while not a preferred method of construction at LANL, would meet the DOE's need to act quickly.

The requirements for the installation of a prefabricated modular BSL-3 facility at any of the three optional LANL facility sites (described in Section 2.1) would be the same as required for the on-site construction of the Proposed Action's permanent building. The same amount of land would require disturbance and utilities would be installed in the same manner as for the Proposed Action. The same construction standards would apply to the construction of the modular units. Concrete footings or a pad may be constructed at the site, depending upon the selected construction design requirements. Delivery of the modular units to LANL would likely require transportation by several trucks over a distance of no greater than 2,500 miles each way. This is roughly comparable to the number of miles of transport required to deliver building materials to LANL from in-state suppliers in order to build the Proposed Action's on-site constructed facility. Once delivered to the chosen facility site, a large crane would be required to remove each modular unit from the delivering truck and place it upon the previously prepared ground, concrete footings or pad. After all the modular laboratory units and the office units were installed, and all required finishing construction work was performed, the facility would be operated in the same manner as identified for the Proposed Action in Section 2.1. Construction time frame and time of installation completion for the modular units would be about the same as for the proposed action. Operation could commence about 12 months after the modular units were ordered.

Decontamination and either demolition, removal, or reuse of the modular facility would likely occur sooner than necessary for the facility described in the Proposed Action, as the useful life of modular units would not be as long as for that of a permanent on-site constructed facility. The estimated useful life span of the modular facility would be a minimum of 20 years as compared to the approximate minimum useful life span of about 30 years for a permanent on-site constructed building. After decontamination (which could include disinfection) the modular units could be disassembled and disposed of through the existing LANL program for excess government property. This would ultimately require that the facility's modular components be moved offsite from LANL. Alternately, the units could be demolished and disposed of in a solid waste landfill either at LANL or offsite. Another alternative would be the reuse of the facility, either in whole or in part by other LANL users. Additional NEPA compliance review would be required when the decontamination and further actions were ripe for decision.

2.3 ALTERNATIVE ACTION TO INSTALL AND OPERATE A PREFABRICATED BSL-3 LABORATORY UNIT AND CONSTRUCT AND OPERATE A PERMANENT ON-SITE CONSTRUCTED BSL-3 FACILITY (PARTIAL PREFABRICATION/BUILD ALTERNATIVE)

The NNSA may choose to purchase, install and operate a ready-assembled, prefabricated BSL-3 laboratory modular unit as a stand-alone facility while constructing a permanent building onsite to house a BSL-3 facility as described by the Proposed Action. This would

be a hybrid alternative to the Proposed Action and the Prefabrication Alternative, as it would involve elements of both. The Partial Prefabrication/Build Alternative would require the delivery and installation of a small (less than 1,000-square-foot) modular unit equipped to function as a stand-alone BSL-3 laboratory at one of the optional construction sites (described in Section 2.1) or at a similar LANL site where utility services were already available at TAs 54 and 16. The delivery, installation, and operation of this facility would proceed at about one-third the scale of activities for modular units described for the Prefabrication Alternative, with the exception of the installation of utilities. The same construction standards would apply to the construction of the modular unit. The installation of utilities would be required at both the stand-alone modular BSL-3 facility site and the site where the permanent on-site BSL-3 facility was constructed and would involve similar trenching and other installation as described for the Proposed Action. The small modular facility would require the support of existing LANL BSL-2 laboratories and office spaces for some of the operational activities required. From the time of ordering to the point of operation, the modular BSL-3 unit would require about 6 months or less. It is anticipated that the modular BSL-3 facility would be operated for about 12 to 18 months while the construction of the permanent on-site BSL-3 facility was undertaken over a 12 month period as identified for the proposed action. Upon the completion of the permanent facility and the initiation of its operation, the small modular BSL-3 facility would be decontaminated and decommissioned or reused. It would likely be disposed of through the LANL program for excess government property and remove off-site from LANL. It may be reused to provide additional LANL laboratory work at a BSL-2 or lower level, or for other laboratory-type work, yet unlikely at this time. Additional NEPA compliance review would be required when the decontamination and disposal or reuse of the modular unit was ripe for decision.

As a general initiative, NNSA is pursuing the construction of permanent buildings in preference to temporary structures at LANL because the long-term cost savings associated with operating permanent on-site constructed buildings, combined with their longer expected useful life, makes this a more fiscally prudent action. Additionally, NNSA is encouraging the placement of new facilities away from forest interface areas at LANL and encouraging the construction of permanent facilities over the use of transportables or modular buildings in the wake of the Cerro Grande Fire. Permanent facilities can be constructed to house larger numbers of personnel and operations in structures that are readily defensible from wildfire, which is an important feature for the LANL site. The construction of new facilities with modular buildings is, therefore, inconsistent with the LANL CSP 2000 planning principles (LANL 2000b) which call for "Upgrade facilities by replacing temporary, outmoded and substandard facilities with new, permanent or renovated facilities as appropriate." This alternative, while not a preferred method of construction at LANL, would meet the DOE's need to act quickly.

2.4 NO ACTION ALTERNATIVE

The No Action Alternative provides a description of what would occur if the Proposed Action were not implemented to compare with the potential effects of the Proposed Action.

It must be considered even when the Proposed Action is specifically required by legislation or court order (10 CFR 1021.321[c]). Under the No Action Alternative, NNSA would not construct or operate the BSL-3 facility. In this event, NNSA would continue to have their BSL-3 laboratory needs met by existing or new BLS-3 laboratories located offsite from LANL. It is expected that while the LANL workload would grow, no new workers would be hired within the Biological Science Division at LANL since the program would likely stagnate without growth potential. There would continue to be certain NNSA national security mission needs that could not be met in a timely fashion, or that may not be able to be met at all. The No Action Alternative would not meet NNSA's identified purpose and need for action.

2.5 ALTERNATIVES CONSIDERED BUT ELIMINATED FROM FURTHER ANALYSIS

Additional alternatives were considered but have been dismissed from detailed analysis in this document. These alternatives are discussed individually in Sections 2.3.1 through 2.3.5.

2.5.1 Use and Upgrade of an Existing Building at LANL to House a BSL-3 Facility

The alternative of upgrading an existing building or portion of a building structure at LANL to house a BSL-3 facility was considered for three different sites. A review of available space was made at LANL and "…no existing facilities were found that were appropriate for modification given the requirements of the BSL-3. The BSL-3 requires very special ventilation requirements and the mission on most existing buildings is not consistent with the work that is to be done in the BSL-3 Lab. The cost of upgrading existing facilities to the extent required for the BSL-3 would likely be as much or more than building a new facility even if an acceptable facility was found (PC 2001e)." The environmental effects of renovation-construction would be increased over new construction due to the amounts of waste construction debris likely to be generated that would require disposal at LANL or offsite. The environmental effects of operating a BSL-3 facility would likely be the same or very similar in either case of remodeling or building a new facility.

Discussions with CDC personnel (see Chapter 6) indicate that their experience with upgrading and retrofitting existing facilities leaves much to be desired both from the cost and end result. The biggest issues appear to be from HVAC retrofits and pest control. It is CDC's opinion (PC 2001a, 2001b) that their combined short- and long-term costs of modification and maintenance for existing structures tend to exceed the projected costs for new facilities and poses greater health risk. Their collective recommendation is to construct a new dedicated facility. Consequently, this alternative, while meeting the purpose and need for NNSA's action was dismissed from further consideration in this EA.

2.5.2 Construction and Operation of the Proposed BSL-3 Facility at More Remote LANL Locations or Within the Research Park at LANL

Construction of the proposed BSL-3 facility at locations more remote from public residences than the TA-3 area was considered. Available locations at LANL were identified that met the required construction requirements, including the close proximity of necessary utilities; however, there were other problems such as traffic concerns and greater vulnerability to wildfire. The environmental effect of construction and operation of a BSL-3 facility at these sites would be very similar to or greater than the Proposed Action. The potential site locations further from public residential populations offered no discernible advantages environmentally, and locating the facility at greater distances from the scientists that would use the facility who would be located at or near TA-3 would offer the disadvantage of added costs and environmental effects. This alternative was dismissed from further consideration in this NEPA analysis although it would meet the Agency's purpose and need for action.

The Research Park is an approximately 60-acre (24-hectare) tract of land located in TA-3 at LANL that has been leased by DOE to the Economic Development Corporation. The leased land would be used to establish a research park with facilities for a wide range of companies to work in the same geographic location and benefit from a well-planned environment suited to business needs. The intent of the lease is to assist Los Alamos County toward self-sufficiency by providing other options for offsetting the elimination of DOE annual assistance payments. This alternative is not considered viable since it would (1) require retrofitting of an existing structure (see discussion in Section 2.3.3); (2) would place operations in a less secure surrounding with regards to national security; and (3) would not meet public access and information-sharing requirements of the lease. This alternative for the BSL-3 facility was not considered further in the NEPA analysis.

2.5.3 Construction and Operation of the BSL-3 Facility at Another National Security Laboratory

The NNSA supports three national security laboratories: LANL, the Sandia National Laboratories at Albuquerque, New Mexico (SNL/NM) and Livermore, California (SNL/CA), and Lawrence Livermore National Laboratory (LLNL), at Livermore, California. Construction and operation of the BSL-3 facility at either SNL or LLNL to the exclusion of LANL was considered, as it is possible to construct such a facility at any of the national security laboratories at approximately the same cost and schedule. This alternative would not meet the purpose and need for NNSA's action to conduct future BSL-3 level work at LANL in support of its national NNSA security-and-science assigned mission responsibilities, however. Having a BSL-3 laboratory prepare samples offsite at either of the distant facilities for LANL experiments would require the samples to be shipped to LANL or in the case of SNL, they could be couriered to LANL (both SNL and LLNL are located at least 100 miles from LANL).

This alternative would almost be the same as the No Action Alternative with the exception being that work could be done under more precise quality assurance procedures and with the necessary national security requirements needed. However, it would not allow the work to be performed as fast as may be needed in all cases. Rapid, accurate reference or verification of strains improves containment of infection through early and effective medical intervention potentially limiting the progress of illness for those exposed to pathogens. LANL has qualified and experienced personnel and a sophisticated existing biological infrastructure. Placing the BSL-3 laboratory at another NNSA laboratory would require significant duplication of this capability. Work at each of the national laboratories is expected to complement rather than be duplicated at each of three national laboratories. While these other facilities may consider the construction and operation of a BSL-3 facility in the future, the operation of these laboratories would be directed toward meeting their individual mission work requirements and would not be identical to that performed by the other laboratories in the NNSA complex. Therefore, the alternative to constructing a BSL-3 facility at either of two other national security laboratories is not considered further in this EA analysis as it does not meet NNSA's purpose and need for agency action at LANL.

2.6 RELATED ACTIONS

UC at LANL, as required by DOE in 1997, conceived a draft LANL comprehensive site plan that included the revitalization of TA-3, along with other portions of LANL's technical areas. The draft comprehensive site plan was issued by UC on January 31, 2000 for stakeholder and public review (LANL 2000b). As conceived in 1999, the LANL draft comprehensive site plan would have required a level of funding that is not currently planned by NNSA and Congress in order to be realized in its entirety; an attempt to seek third party financing for site plan implementation was not successful. In January 2001, NNSA requested that UC at LANL, along with other NNSA site facility contractors, revise their facility comprehensive site plans according to new guidance for aligning the site planning process with budget formulation and execution, starting with the Fiscal Year (FY) 2003 budget planning. Consequently, UC submitted the new LANL 10-Year Comprehensive Site Plan to NNSA in October 2001. After NNSA approval is obtained, the plan would be issued to LANL stakeholders. As directed by NNSA, this 10-Year Comprehensive Site Plan will be revised annually to support the budget request for the following budget year. Given the nature of the 10-Year Comprehensive Site Plan as a constantly evolving tool for site planning and budgeting purposes, regulatory compliance strategies will not be developed for implementation as a whole. Review of each proposal would be made to ensue the project's overall consistency with the general LANL site planning process. To that end, the Proposed Action under consideration in this EA has been reviewed and found to be consistent with the LANL site planning process.

Construction activities are being considered, or, in some cases, are already underway within the general TA-3 location at LANL and would be ongoing or nearing completion in the same timeframe as the proposed BSL-3 facility. Currently being proposed for construction at TA-3 are new replacement structures for the existing Building 3-43 (known locally as the "main

administration building"). This construction action was considered in a separate EA issued this year along with a Finding of No Significant Impact (DOE 2001d). The relationship of the new structures to the Proposed Action being analyzed in this document is one of general location and general construction timeframe only, the two proposals are independent of each other in all other aspects. The anticipated timeframe for construction is from 2002 to 2005. Currently under construction for the replacement structures for Building TA-3-43 is the Strategic Computing Complex (SCC) building along the south end of TA-3 near the Proposed Action's Option B site. Completion of this structure is expected in late 2001, which is slightly in advance of the possible construction for the proposed BSL-3 facility should NNSA decide to implement the Proposed Action. Next to the SCC, construction is underway for the new Non-Proliferation and International Security Center (NISC). The anticipated completion date is late 2002. If the NNSA decides to implement the Proposed Action analyzed in this document, construction of the BSL-3 facility could overlap with the final stages of construction on the NISC. In separate EAs and FONSIs issued in December 1998 and July 1999, respectively, DOE analyzed the construction and operation of the SCC and NISC. Other small-scale construction activities are also being planned or are underway at more-distant LANL locations that may overlap with the construction period contemplated for the Proposed Action, should NNSA implement this action. These, as well as the SCC, NISC, and the new replacement building for building 3-43, will be considered in the cumulative effects analysis contained in this document.

A new Emergency Operations Center (Center) is under construction at LANL within TA-69. The Center, when completed in 2003, will serve as a state-of-the-art facility for UC staff and County of Los Alamos staff. It will house the LANL Emergency Management and Response Staff. A final EA and FONSI for the Center were issued on July 26, 2001.

3.0 AFFECTED ENVIRONMENT

The *Site-Wide Environmental Impact Statement for Continued Operation of the Los Alamos National Laboratory* (LANL SWEIS) (DOE 1999a) provides a detailed discussion of the affected environment at LANL. It supports the Record of Decision (DOE 1999c) for the level of operation known as the Expanded Alternative and includes new construction activities that were far enough along in planning to have been included in that analysis. While this Proposed Action for constructing and operating a BSL-3 facility was not considered in that EIS, much of the affected environment described therein provides the affected environment baseline for this EA. As much as reasonably possible, this EA tiers off of the LANL SWEIS or includes by reference the information presented in that document. Additionally, immediately after the May 2000 Cerro Grande Fire burned portions of LANL, NNSA issued a Special Environmental Analysis (SEA) (DOE 2000b). Information from the LANL SWEIS and the subsequent LANL SWEIS Yearbooks (LANL 2000e), as well as the SEA will be included when necessary to provide a basis for environmental consequence or accident analysis later in this EA. These documents may be found in the LANL library.

This chapter describes the environmental resources that may be affected as a result of implementing the Proposed Action to construct and operate a BSL-3 facility. Resources are described using the sliding scale approach with more detail provided for resources that might be most affected. Resources are either addressed in this Chapter or eliminated from consideration, as shown in Table 3-1 in Section 3.2.

3.1 REGIONAL AND LOCAL SETTING

LANL is located on a 43-square-mile (111-square-kilometer) area in Los Alamos County, in north-central New Mexico, approximately 60 miles (97 kilometers) north-northeast of Albuquerque, 25 miles (40 kilometers) northwest of Santa Fe, and 20 miles (32 kilometers) southwest of Española in Los Alamos and Santa Fe Counties (Figure 1-1).

The Jemez Mountains to the west and the Sangre de Cristo Mountains to the east dominate the area (Figure 3-1). The Rio Grande lies between these two mountain ranges and bounds part of LANL to the east. LANL is situated on the Pajarito Plateau, a volcanic shelf on the eastern slope of the Jemez Mountains at an approximate elevation of 7,000 feet (2,135 meters) (DOE 1999a). Thirteen steeply sloped and deeply eroded east-to-west oriented canyons containing intermittent streams dissect the Pajarito Plateau. One of these, Los Alamos Canyon, separates the main LANL industrial area, TA-3, from the LANL townsite.

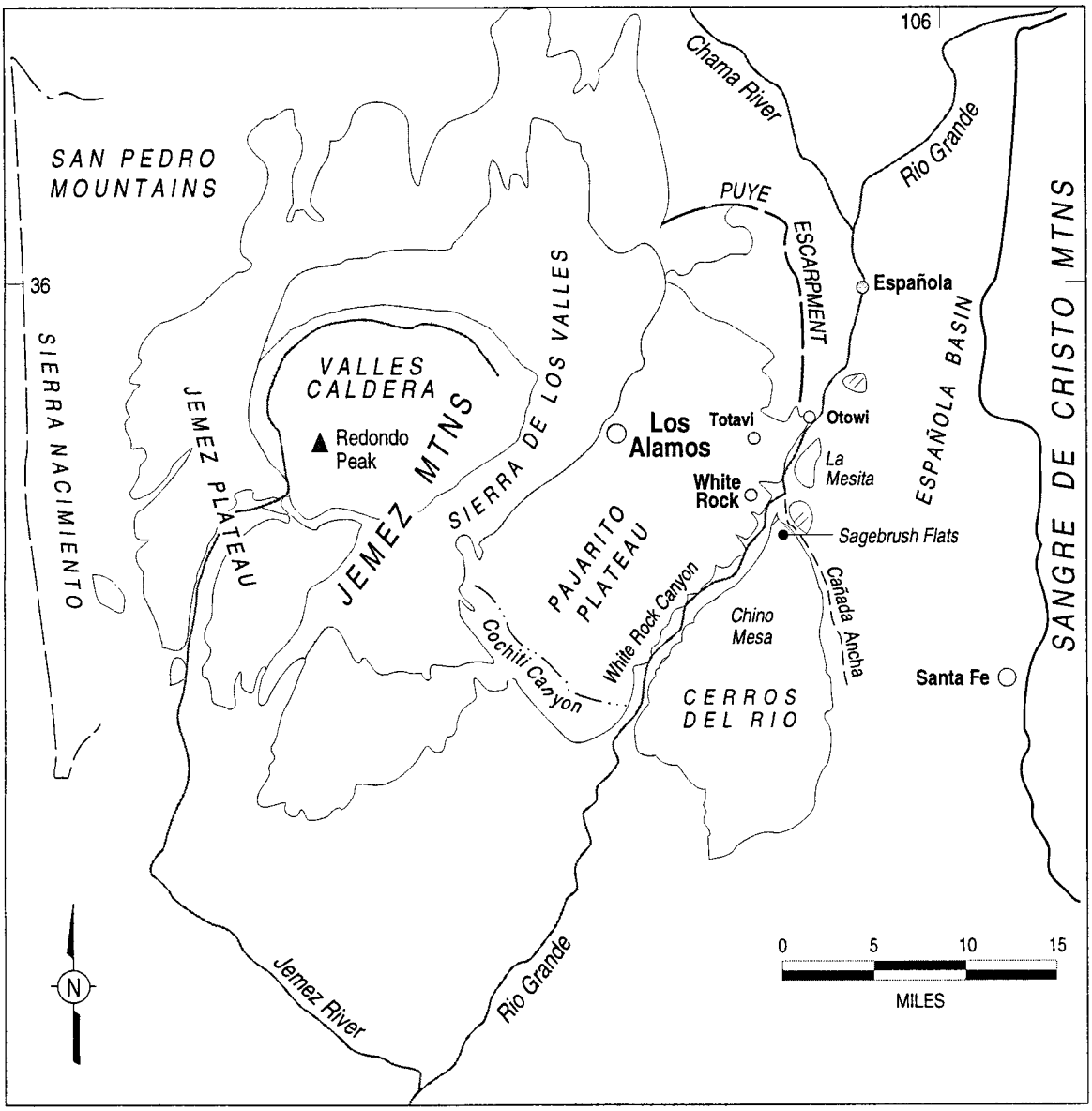

Figure 3-1. Geographic location map showing topographic features near LANL

3.1.1 Climate and Meteorology

Los Alamos has a temperate, semi-arid mountain climate characterized by seasonable, variable rainfall. Precipitation measured at the current official meteorological weather station on the mesa top at TA-6 ranges from 10 to 20 inches (25 to 51 cm) per year with approximately 37 percent of the rainfall occurring in the rainy summer season. Meteorological conditions are influenced by the elevation of the Pajarito Plateau with warmer temperatures near the Rio Grande and cooler near the mountain peaks.

Winds are variable averaging about 7 miles per hour (3 meters per second) with lowest winds in December and January and highest in the spring (March through June) due to the intense storms and cold fronts. Surface winds vary dramatically with the time of day, location, and elevation due to the complex terrain. Winds are generally upslope over the Pajarito Plateau in the morning. By noon, winds from the south usually prevail over the entire Plateau. Cold air drainage from the Jemez Mountains to the west of LANL produces nighttime winds from the west-southwest to the northwest over the western portion of the Plateau. This air flow from the mountains is observed about 75 percent of the time during the night and continues for an hour or two after sunrise until an up-canyon flow develops. Nighttime canyon flows are predominantly weak drainage winds from the west. Because of the stability of these nighttime canyon flows and the relatively weak mesa top winds, the development of rotors (whirls) at night in the canyons is rare (LANL 1992). However, this flow can develop into a turbulent longitudinal rotor that fills the canyon when the wind over the canyon has a strong cross-canyon component.

The irregular and complex terrain of the Pajarito Plateau is accentuated by forested surfaces in upland areas having a significant affect on dispersion or the atmospheric spreading by turbulent motion of the air. The terrain produces an increase in both horizontal and vertical turbulence and dispersion, whereas lower elevation terrain is smoother and less vegetated causing less turbulence. Clear skies and light winds, typical of the summer season, enhance daytime vertical air dispersion (DOE 1999a) (Figure 3-2).

Light wind conditions under clear skies can create strong, shallow surface inversions that trap the air at lower elevations and severely restrict dispersion. These light wind conditions occur primarily during the autumn and winter months, with intense surface air inversions occasionally in the winter (Figure 3-3). Air inversions are most severe during the night and early morning (DOE 1999a).

3.2 ENVIRONMENTAL RESOURCES NOT AFFECTED

Discussion of the Affected Environment is limited to existing environmental information that directly relates to the scope of the Proposed Action and the alternatives analyzed. Table 3-1 shows the resource categories and whether they are not discussed (that is, NA, and why not) or where they are discussed if they have a direct bearing on the analysis.

3.3 ENVIRONMENTAL RESOURCES POTENTIALLY AFFECTED

3.3.1 Human Health

According to the New Mexico Department of Health in the *State of Health in New Mexico: 2000 Report* (NMDH 2001), in early part of the 20th century health conditions in the New Mexico Territory were not good and infectious diseases such as tuberculosis, smallpox, typhoid fever, measles, diphtheria, pertussis (whooping cough), and dysentery were

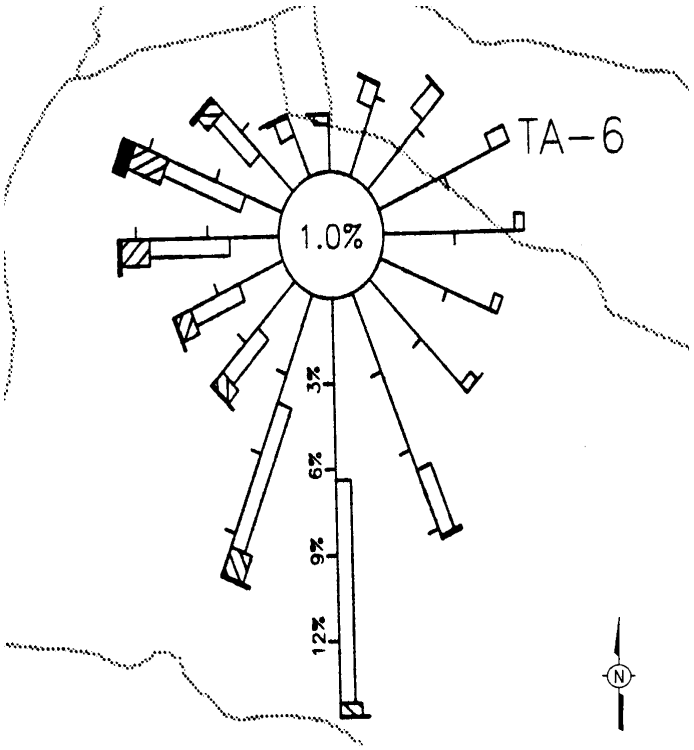

Figure 3-2. 1999 daytime wind rose for TA-6 (LANL 2000d)

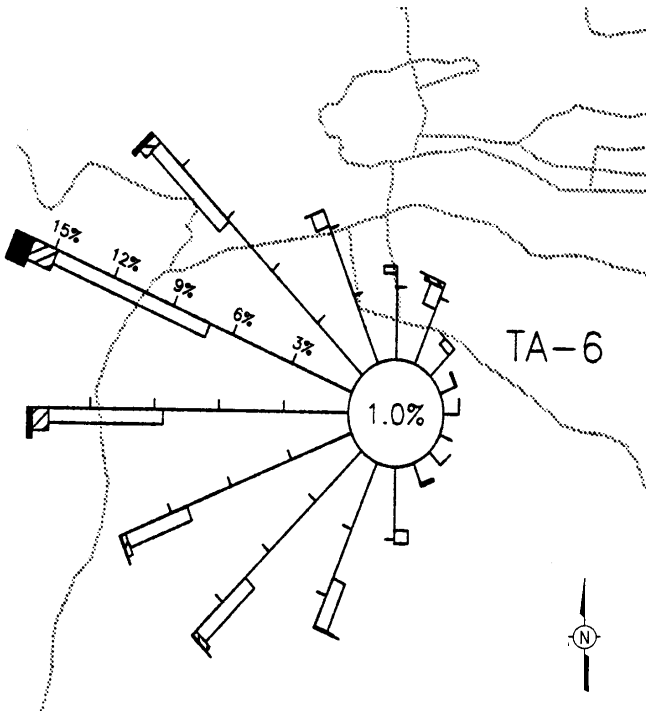

Figure 3-3. 1999 nighttime wind rose for TA-6 (LANL 2000d)

Table 3-1. Applicability of Resource Categories to the BSL-3 Analysis

Resource Category	Applicability	BSL-3 EA Section
Air Quality	Yes	3.3.10
Ecological Resources	Yes	3.3.2
Geology/Soils/Seismology	Yes	3.3.8
Human Health	Yes	3.3.1
Noise	Yes	3.3.6
Socioeconomics	Yes	3.3.7
Transportation	Yes	3.3.3
Utilities/Infrastructure	Yes	3.3.5
Visual Resources	Yes	3.3.9
Waste Management	Yes	3.3.4
Cultural Resources	All three sites would be within or adjacent to the well developed area of TA-3. No cultural issues would be located at or adjacent to these sites (LANL 2001e).	NA
Environmental Justice	There is no disproportionately high or adverse human health or environmental effects on minority or low-income populations (DOE 1999a).	NA
Environmental Restoration	There are no potential release sites at or adjacent to the three optional locations (LANL 2001e).	NA
Floodplains/Wetlands	There are no floodplains or wetlands at or adjacent to the three optional locations (LANL 2001e).	NA
Land Use	The area surrounding each of the proposed LANL sites is made up of office buildings, laboratories, storage and warehouse facilities, and parking lots, all illuminated at night. The proposed construction and operation of a BSL-3 facility would not alter the character of the site areas or introduce new land use elements (LANL 2000b).	NA
Water Resources	There would be no effect on surface water or groundwater quality and no perceptible increase in potable water use. A stormwater prevention plan would be enforced during construction. BMPs such as the use of straw bales, silt fences and other similar devices would control sediment/surface water runoff into local arroyos, canyons, and streams. There are no outfalls on these proposed locations (LANL 2001e).	NA

common. The leading causes of death were infectious diseases. Vaccines other than for smallpox didn't exist, antibiotics hadn't been discovered, water supplies were untreated, and public health treatments were largely unavailable. Sanitation, pasteurization, and vaccination made headway in the 1930s to 1950s and many diseases saw significant reductions or eliminations. New Mexico had one of the Nation's highest rates of hepatitis A, a viral disease of the liver, for many years. Today, rates of the disease in New Mexico are below the national average. New Mexico has a relatively low vaccination rate, but this has not led to any known outbreaks or increases in most diseases (NMDH 2001). However, New Mexico has a persistent problem with pertussis with a reported 224 cases in 1999. New Mexico is also known for its rodent-borne diseases and leads the Nation in hantavirus (57 total cases) and plague (232 total cases) (NMDH 2001).

DOE and NNSA maintain equipment and procedures to respond to situations where human health or the environment is threatened. These include specialized training and equipment for the local fire department, local hospitals, state public safety organizations, and other government entities that may participate in response actions, as well as specialized response teams. These programs also provide for notification of local governments whose contingencies may be threatened. Additional information regarding the Emergency Management and Response Program is provided in the 1999 SWEIS (DOE 1999a).

Because of nationwide concerns about terrorist attacks using biological warfare agents (for example, anthrax, plague, smallpox) or chemical agents, health departments around the country are upgrading their healthcare programs. The New Mexico Department of Health is using Federal Government grants to upgrade public health laboratories, disease surveillance systems, and public alert networks. For example, LANL UC staff are collaborating with several institutions SNL, University of New Mexico Emergency Medicine Department, and the New Mexico Department of Health, Office of Epidemiology on the Rapid Syndrome Validation Project (RSVP) to support these efforts. The RSVP is a system that provides early warning and response to emerging public health threats from infectious diseases. The RSVP includes:

- Network-based reporting that is extremely fast and easy to use in the clinical setting
- Syndrome-based reporting rather than diagnostic-based reporting to facilitate physician participation
- Rapid analysis of information, preferably in an automated fashion
- Interconnectivity between multiple participants to tie disparate and geographically separated sources of information together to provide a clear understanding of the evolving situation
- Clear understanding of the natural background of infectious disease in the general population

- Ability to characterize a disease outbreak and trigger appropriate responses within 24-48 hours

The New Mexico Department of Health, Office of Epidemiology feels that while these efforts would hopefully not be needed for terrorist actions, they would be valuable in helping to detect and respond to future routine infectious-disease outbreaks (NMDH 2001).

Additional information on human health conditions at LANL can be found in the LANL SWEIS (DOE 1999a), Section 4.6, Human Health: Worker and Public Health in the Region Affected by LANL Operations. The supporting information for this is presented in Appendix D of the LANL SWEIS. That analysis, which evaluated continuing operations and projected future operations, looked at several possible exposure scenarios.

Radiation. Workers and the public working or visiting LANL receive a radiation dose from LANL operations. Chapter 3 of the 1999 LANL Environmental Surveillance Report (LANL 2000d) states: "Health effects from radiation exposure have been observed in humans only at doses in excess of 10 roentgen-equivalent man (rem). We conclude that the doses calculated here, which are in one one-thousandth of a rem (mrem) range, would cause no human health effects. They are also much smaller than typical variations in the background radiation dose." The calculated maximum off-site radiation dose to a member of the public from LANL sources in 1999 was 0.7 mrem, which is less than 1 percent of the DOE dose limit of 100 mrem in Section 208 of 10 CFR 835 (§ 835.208 *Limits for members of the public entering a controlled area*) and also well below the level at which health effects would occur. The calculated on-site maximum individual exposure in 1999 to a member of the public who passes along Pajarito Road near the TA-18 Criticality Facility is 3 mrem (LANL 2000d). Information about radiation in respect to microorganisms in the environment appears in Section 3.3.2.

Chemicals in the Environment. Chemical emissions at LANL operations have been sufficiently small that they are not routinely measured (DOE 1999a). Environmental media and foodstuffs have also been selectively analyzed for chemical contaminants since the early 1990s. For those chemicals in the surveillance program, there are no significant differences in concentrations between media at the perimeter of LANL and those of the general region (DOE 1999a).

3.3.2 Ecological Resources

LANL is located in a region of diverse landform, elevation, and climate-features that have contributed to producing one of the most diversified plant and animal communities. Plant communities range from urban and suburban areas to grasslands, wetlands, shrublands, woodlands, and mountain forest, and provide habitat for a wealth of animal life. The richness of animal life includes herds of elk and deer, bear, mountain lions, coyotes, rodents, bats, reptiles, amphibians, invertebrates, and a myriad of resident, seasonal, and migratory bird life. Because of restricted access to LANL lands and management of contiguous

Bandelier National Monument (BNM) for natural biological systems, much of the region provides a refuge for wildlife (DOE 1999a).

No threatened or endangered species habitat or buffer areas are located at or adjacent to the three proposed BSL-3 facility optional locations (DOE 1999d; LANL 2001e). Historically, however, the Pajarito Plateau has undergone habitat fragmentation[16] as a result of land clearing for agricultural use (DOE 1999a). These flat areas have subsequently been used by LANL for buildings, roads, and experiment areas. The three location options for the proposed BSL-3 facility would be located on previously cleared areas. Most LANL development is within the piñon-juniper woodland and ponderosa pine forest (DOE 1999a) vegetational zone.

A literature search did not establish the microflora content of soils on the Pajarito Plateau. Although not usually considered as such, soils are an ecological resource (Burden and Sims 1999). Soils are known to naturally contain a diversity of numbers and types of micro-organisms. The range is substantial as it depends upon the environmental conditions, which dictate the bacteria and fungi microflora (plant microorganisms) that can survive. Microbial ecologists have identified ranges or "Critical Environmental Factors" which represent the conditions necessary to support microbial growth. These factors show that a soil must be moist (25 to 85 percent of water holding capacity), have sufficient oxygen (greater than 0.2 milligrams per liter and minimum air-filled pore spaces of 10 percent), be neutral in acidity (pH between 5.5 and 8.5), contain sufficient (non-limiting) nitrogen, phosphorus, and other nutrients, and maintain a temperature between 59 and 113 degrees Fahrenheit (°F) (or 15 and 45 degrees Celsius [°C]) (Burden and Sims 1999). Fungi are more tolerant of soil moisture and acidity (less than pH 5.0) than bacteria (Gray 1978). Various genus[17] and species[18] of bacteria can be found in soils from the most common genus *Arthrobacter* and *Bacillus* species (spp.) to the least common, *Staphylococcus* and *Mycobacterium spp*. Although most types of fungi can be found in soil, the most common include genus *Imperfecti*, *Ascomycetes*, and *Basidomycetes spp*.

Infectious microorganisms can also be found in soils. One of the most well known infectious microorganisms through ancient history is *Bacillus anthracis* (*B. anthracis*), which causes the disease anthrax. Prior to the advent of antibiotics, anthrax was the foremost cause of uncontrolled death in herbivores (plant-eating mammals) such as cattle, sheep, goats, horses, and pigs worldwide (WHO 1998). *B. anthracis* is unique as a bacteria in that it forms spores which can survive in the environment, reportedly for decades (Cieslak and Eitzen 1999). Spore forming conditions exist where slightly acidic (pH less than 6.0) organic rich soils

[16] Habitat fragmentation is the division of natural habitat areas into smaller segments or the destruction of animal access corridors between natural areas.

[17] A genus is the usual major subdivision of a family or subfamily in the classification of plants and animals, usually consisting of more than one species.

[18] A species is the major subdivision of a genus or subgenus regarded as the basic category of biological classification, composed of related individuals that resemble one another and are able to breed among themselves but not able to breed with members of another species.

undergo dramatic climatic variations of abundant rainfall followed by prolonged drought (Cieslak and Eitzen 1999). Anthrax zones in the United States reportedly follow cattle drive trails of the 1800s (Coker et al. 1998). Herbivores may acquire the disease from grazing in soils containing *B. anthracis* spores possibly derived from the mechanical spread of the organism by vultures eating carcasses containing *B. anthracis* spores, or from the bite of certain flies. In the United States there have been sporadic human cases of anthrax in South Dakota, Nebraska, New Mexico, and Oklahoma apparently related to old graves of individuals that died from anthrax. Since 1991, there have also been deaths in California, Kansas, Mississippi, and Arkansas (Hugh-Jones 1998). In 2000 there were several cases of humans contracting anthrax in Minnesota and North Dakota (WHO 2001).

B. anthracis spores are resistant to extremes of heat, cold, pH, desiccation, chemicals, irradiation, and other adverse conditions (WHO 1998). It is through the uptake of spores that animals and humans contract anthrax. The process of spore formation (sporulation) mainly occurs in the affected animal carcasses but can also occur outside the carcass if conditions are right. However, researchers believe that germination, multiplication, and resporulation are unlikely to occur very often under natural conditions (WHO 1998).

Radiation. As radioactive materials have been and are used at LANL, there is some public interest in the effects of radiation on microorganisms. According to the CDC (CDC 2001a), "When microbes are subjected to irradiation, the energy from the rays is transferred to the water and other molecules in the microbe. The energy creates transient reactive chemicals that damage the DNA in the microbe, causing defects in the genetic instructions. Unless it can repair this damage, the microbe would die when it grows and tries to duplicate itself. Disease-causing organisms differ in their sensitivity to irradiation, depending on the size of their DNA, the rate at which they can repair damaged DNA, and other factors." Also: "The size of the DNA 'target' in the organism is a major factor. For instance, parasites and insect pests, which have large amounts of DNA, are rapidly killed by extremely low doses of irradiation…" (CDC 2001a). It takes more irradiation to kill bacteria because they have a somewhat smaller DNA, and viruses have so little nucleic acid that they are hard to kill (CDC 2001a). The safety of irradiating microbes in food has been tested in mice, rats, and dogs for over several generations. "There is no evidence of adverse health effects in these well controlled trials" (CDC 2001a). The safety of irradiating food to kill microbes has been endorsed by the World Health Organization (WHO), the CDC, the Assistant Secretary of Health, the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA) (CDC 2001a).

Radiation effects on infectious microorganisms have been studied extensively with regard to the irradiation of foods (CDC 2001a). The killing effect of irradiation on microbes is measured in D-values. One D-value is the amount of irradiation needed to kill 90 percent of that organism, 2-D kills 99 percent, and 3-D kills 99.9 percent. D-values are different for each organism, and vary by temperature and the material containing them. The amount of radiation needed for one D-value is a thousand or more times the amount of radiation dose given to a person for a single chest x-ray (CDC 2001a). The maximum individual

radiological exposure to a member of the public at LANL, mentioned in Section 3.3.1, for a passer-by in 1999 was 3 millirems which is a fraction of the dose from a chest x-ray which is estimated at about 53 mrems (LANL 2000d).

These data help describe why there would be no reason to expect negative effects to microbes in the environment. Radiation-induced genetic changes to naturally occurring microorganisms are not expected.

Wildfire Protection. Aside from the Cerro Grande Fire in May 2000, there have been four other major wildfires in the Los Alamos area (DOE 2000a). Concerns about these wildfires that were considered during the preparation of the LANL SWEIS (DOE 1999a) and the occurrence of a major wildfire in 1996 (the Dome Fire) led to the undertaking of several activities to reduce the threat of wildfire to LANL. The UC created firebreaks along State Road (SR) 4 near LANL's boundary with the Santa Fe National Forest around key facilities determined to be at risk, and expedited its routine maintenance of fire roads to enhance forest accessibility. UC has recently begun to lower the density of trees (thinning) on about 10,000 acres (4,047 hectares) of LANL and has a goal of reducing the current 400 to 800 trees per acre to 50 to 150 trees per acre within LANL boundaries. Forests needing thinning are predominantly ponderosa pine and mixed conifer. Tree thinning activities have been prioritized through an assessment of facility vulnerabilities combined with knowledge of the chemical and radiological inventories. Tree thinning and brush removal has been initiated at TA-3 and at TA-59 in the areas near the locations for the proposed BSL-3 facility. No structures were burned or destroyed during the Cerro Grande Fire within the areas surrounding the three proposed optional locations for the Proposed Action (DOE 2000b).

Additional post-Cerro Grande Fire forest treatment thinning activities at LANL are planned to be ongoing over the next several years of the Wildfire Hazard Reduction Program (WHRP) (DOE 2000a). Almost all of the TAs at LANL will be included in areas treated by the WHRP, especially areas at LANL burned during the Cerro Grande Fire and on the remaining ponderosa pine and piñon-juniper woodlands. Activities conducted for the WHRP will include mechanical thinning of trees and thinning of trees using hand-held tools (primarily within such areas as those with sensitive resources or steep slopes); construction of access roads and fire breaks; the installation of various BMPs for prevention of erosion and resource protection in treatment areas and beyond; the removal of wood materials and disposal of wastes generated; and end-state conditions and post-treatment assessments. The initiation and conduct of periodic long-term maintenance projects to maintain the desired end-state conditions of the subject forest areas will be ongoing after the initial forest treatments have been completed. Implementation of the WHRP and the subsequent long-term maintenance projects would drastically reduce the potential risk and damages from an uncontrolled and catastrophic wildfire within the boundaries of LANL.

3.3.3 Transportation

Vehicles. Motor vehicles are the primary method of transportation and highways are the primary access to LANL and the rest of Los Alamos County. LANL has a number of roads, including major thoroughfares which allow public access. However, since NNSA controls the entire area within the LANL boundaries, NNSA has the option to restrict traffic on LANL roadways and does for certain on-site radioactive shipments (DOE 1999a). There are four main access points to LANL that convey about 43,000 average daily trips (ADTs). These roads and their average daily trips are shown in Table 3-2. The State of New Mexico reports that Los Alamos County has an annual average of 118 accidents per 100 million vehicle miles (161 million kilometers) driven (NMTSB 1998). The total number of accidents in Los Alamos County from 1990 to 1994 ranged from 258 to 387 with about 90 percent of them being accidents with privately owned vehicles. LANL Government vehicles were involved in about 5 percent of these accidents (DOE 1999a).

Table 3-2. LANL Main Access Points

Location	Average Daily Trips (ADT)
Los Alamos Canyon Bridge	28,000
Pajarito Road	8,000
East Jemez Road	6,000
State Road 4/West Jemez Road from the west	1,000
Total	**43,000**

The proposed BSL-3 facility locations would be accessed from Diamond Drive or Pajarito Road. Traffic on these roadways can be heavy, particularly during peak commuting hours. At present, the intersection of Diamond Drive with West Jemez Road exhibits considerable congestion during peak traffic periods (DOE 1997b). Adequate parking is also an issue around TA-3. The current parking area at location Option A is full for the better part of the day as it is the closest parking outside Building 3-66. Parking for location Option B is currently unoccupied most of the time. There is no parking area at location Option C.

LANL Shipments. During routine operations, all types of materials and wastes are shipped to and from LANL. Commercial carriers (cars, trucks, and air-freight) transport these shipments offsite while Government-owned vehicles do most onsite. Numerous regulations govern the transportation of hazardous materials including those of the U.S. Department of Transportation (DOT), DOE, Federal Aviation Agency (FAA), and the International Air Transport Association (IATA). During 1990 through 1994, an average of about 1,000 shipments per year (including waste shipments), of which about 800 were hazardous. These are tracked in the LANL Shipment Mobility/Accountability Collection (SMAC). The designated hazardous materials route for Los Alamos County is East Jemez Road to SR 4 to SR 502 (DOE 1999a).

Currently, the LANL Bioscience Division operations sends out about two samples per month and receives four samples per month of select and non-select agent DNA and non- select agent microorganisms. There have been no reported incidences at LANL related to the shipment of biological samples (PC 2001g).

3.3.4 Waste Management

UC has established procedures for compliance with all applicable laws and regulations for collecting, storing, processing, and disposing of sanitary liquid wastes, solid wastes and hazardous wastes for LANL. These three waste types are discussed in the following paragraphs.

Sanitary Liquid Waste. The sanitary liquid waste or sewage from LANL TA-3 is processed at the LANL Sanitary Waste Systems Consolidation (SWSC) Plant located at TA-46 (Figure 2-1). The SWSC Plant is capable of processing approximately 600,000 gallons (2.27 million liters) per day; its current use is an estimated 0.3 million gallons (1.1 million liters) per day (LANL 2000e). There is an existing 8-inch (20-centimeter) sanitary sewer in place along Pajarito Road about 100 feet (30 meters) south of Mercury Road. The capacity of this line is approximately 0.442 million gallons (1.673 million liters) per day and its present peak flow is 0.084 million gallons (0.318 million liters) per day (DOE 1999b). Sanitary sewer liquid waste from all three optional locations would discharge into this line.

Solid Waste. Solid waste is regulated under RCRA (40 CFR 261). Solid waste generated at LANL is currently disposed of at the Los Alamos County Landfill, which is operated by the county on land within the LANL boundaries. The landfill receives an average of about 18,850 tons (17,100 metric tons) per year of solid waste with LANL contributing about 2,860 tons (2,600 metric tons) per year. The county maintains a separate location at the landfill for construction debris that is available for salvage and reuse by individuals or companies. In 1996, an estimated 11.8 million pounds (5.35 million kilograms) of construction debris were disposed of at the county landfill (DOE 1997b). Waste from the Cerro Grande Fire also went to the county landfill and has reduced its capacity. Los Alamos County plans to close the landfill by June 30, 2004, but may maintain a part of the landfill site as a transfer station. Other existing landfills will be used for LANL waste disposal after this one has been closed. Several existing landfills within New Mexico could possibly be used after 2004, such as the one located at Rio Rancho, which is about 85 highway miles (137 kilometers) south of Los Alamos.

Hazardous Waste. Hazardous waste is regulated under the RCRA Subtitle C (40 CFR 261). From 1990 through 1995, LANL generated an annual average of about 1.9 million pounds (860 thousand kilograms) of hazardous chemical waste (DOE 1999a). Included in these numbers is chemical waste from what is now the Bioscience Divisions, HRL facility, which produced from 10,000 to 34,000 pounds (4,600 to 15,000 kilograms) of chemical waste per year for an average (baseline) of 11,000 pounds (4,900 kilograms) per year. A subcategory

of hazardous waste is biomedical waste. HRL contributed about 40 to 1,500 pounds (18 to 705 kilograms) per year of biomedical waste with an average of about 287 pounds (130 kilograms) per year (DOE 1999a) of the total of hazardous waste generated by LANL through 1998. In 1999, HRL had a zero generation rate when LANL eliminated their animal colony and the associated waste which had been previously incinerated. All biomedical waste generated by HRL is now converted to solid waste after treatment with autoclaving (PC 2001h).

3.3.5 Utilities and Infrastructure

LANL has about 8 million square feet (743,200 square meters) of structural space. Approximately 7.3 million square feet (678,000 square meters) of this total exists in 1,835 buildings, and about 0.7 million square feet (65,000 square meters) in 208 other structures (such as meteorological towers, manholes covers, and small storage sheds). According to LANL's Needs and Institutional Plan, the administration area in TA-3 occupies 25 percent of LANL space; storage and support services including power generation occupy about 23 percent. Thus, almost half of LANL's structural space is occupied by the utilities and infrastructure; most of this is located in the TA-3 area or within TA's immediately adjacent to TA-3 (DOE 1999a).

Electrical power service to LANL comes from an electrical power generation and transmission pool with Los Alamos County. This pool has a contractually limited capacity of 73 (winter) to 95 (summer) megawatts. This capacity is provided by external transmission lines owned by the Public Service Company of New Mexico (PNM) and the Plains Electric Generation and Transmission Cooperative over two 115-kV power transmission lines from the Norton substation near White Rock, and the Bernalillo-Algodones substation near Albuquerque (LANL 2000b). A steam and electrical power plant is located at LANL's TA-3 for use on an as-needed basis. Approximately 34 miles (55 kilometers) of 13.2 kV distribution lines connect to low-voltage transformers around LANL (DOE 1999a). The existing electric transmission system has been evaluated and found to be deficient (DOE 1999a). Therefore, all facilities that require safe shutdown capability for power outages are equipped with emergency generators to assure their needs are met (DOE 1999a). An additional 114-kV electric transmission line is planned for LANL but may not be operational for several years.

The natural gas system includes a PNM-owned high pressure main and distribution system to Los Alamos County and DOE-owned pressure reducing stations at LANL buildings. About 90 percent of the natural gas used at LANL is for heating (steam and hot air) and the rest for electric power generation (LANL 2000b). The natural gas-fed TA-3 steam plant has the capacity of producing 200,000 pounds (91,000 kilograms) of steam pressure per hour to generate electricity and steam for heating with two boilers in operation and one on standby. On-site electrical generating capacity is 12 megawatts in the summer and 15 megawatts in the winter. The peak winter demand on the plant is 125,000 pounds (57,000 kilograms) of steam pressure per hour (DOE 1999a).

In 1997, LANL used only about 71 percent of the water rights and rights to water available through water supplied from the deep wells and surface water (LANL 2000b). The DOE water rights were transferred in 1998 to Los Alamos County and LANL no longer tracks Los Alamos County water usage. The general TA-3 area is supplied by water service for both potable and fire protection by a network of 10-in (25-cm) lines or larger. There is an existing 10-in (25-cm) water main located along Pajarito Road. Fire hydrants are in place all around TA-3 (LANL 1998a).

3.3.6 Noise

Noise generated by LANL operations is regulated by Los Alamos County ordinance and by LANL worker protection standards established in *LANL Performance Requirements* (LANL 2001d). The standard unit used to report noise or sound pressure levels is the decibel (dB); the A-weighted frequency scale (dBA) is an expression of adjusted pressure levels by frequency that accounts for human perception of loudness. Los Alamos County has promulgated a local noise ordinance that establishes noise level limits for residential land uses. Noise levels that affect residential receptors are limited to the maximum of 65 dBA during daytime hours and 53 dBA during nighttime hours (between 9 p.m. and 7 a.m.). Activities that do not meet these noise standards require a permit (DOE 1999a).

Noise levels to protect worker hearing at LANL are based on DOE orders (DOE 1984), OSHA regulations (29 CFR 1910.95), U.S. Air Force Regulations (USAF 1973), and recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH 2000).

Noise levels at the optional locations for the proposed BSL-3 facility would be generated primarily by vehicle traffic and facility HVAC systems except during facility construction. Ambient noise measurements taken nearby at the NISC location averaged 52 dBA during morning and evening rush hours; 51 dBA during non-rush hours; and 47dBA during nighttime hours (PC 1999a). These measurements are typical of a lightly industrialized area, such as TA-3, and are comparable to outside noise levels generated at urban centers during daytime hours and common indoor sounds such as the background noise in a large occupied conference room. Measurements were also taken before and after construction activities along the perimeter fence at the SCC adjacent to the NISC (Knight and Vrooman 2000). Before construction the average sound level was 56.5 dBA. During construction the average sound level increased 25.6 dBA to 82.1 dBA, but measurements were only taken when heavy equipment was operating.

3.3.7 Socioeconomics

The UC at LANL is the largest employer in the tri-county region (Los Alamos, Santa Fe, and Rio Arriba Counties), directly employing approximately 12,412 workers, including Johnson Controls Northern New Mexico, Protection Technology Los Alamos, and other subcontract

labor personnel. LANL's activities result in a total increase in economic activity in New Mexico of about $3.2 billion dollars in 1998. Over half of the employees at LANL reside in Los Alamos County (LANL 2000b) accounting for over one third of the county residents (Table 3-3).

Table 3-3. Population of New Mexico and the Seven County Area of Los Alamos and Surrounding Areas

Counties	Total Population 1999	Increase Rate 1998-1999	Increase Rate 1990-1999	White Population 1999	Percent White 1999	All Other Population 1999
Bernalillo	523,405	0.8	8.6	469,494	89.7	53,911
Los Alamos	18,272	0.4	5.2	17,395	95.2	877
Mora	4,945	0.3	4.0	4,886	98.8	59
Sandoval	90,298	0.9	11.7	67,633	74.9	22,665
San Miguel	28,478	0.5	6.6	27,453	96.4	1,025
Santa Fe	124,193	0.7	7.6	117,859	94.9	6,334
Taos	27,123	0.5	6.8	24,818	91.5	2,305
New Mexico	1,740,071	0.8	9.4	1,501,681	86.3	238,390

Source: DOC 2001

The overall economic impact from operations at LANL was evaluated for FY 1996 (Lansford et al. 1999). In that year it was found that the following multipliers applied:

- For every dollar spent by DOE or its contractors on materials, labor, benefits, equipment, services, etc., another $2.39 is generated in the state.
- For every $1 of income, another $1.39 is generated in the state.
- For each person employed by LANL, another 2.62 jobs are supported in the state.

In the year of that economic impact evaluation (FY 1996), DOE expended approximately $149 million dollars in northern New Mexico in the construction sector (Lansford et al. 1999). Using these multipliers, this could have produced another $365 million dollars in New Mexico.

3.3.8 Geology, Soils, and Seismicity

LANL and the communities of Los Alamos townsite and White Rock are located on the Pajarito Plateau that abuts the north-south trending Sierra de los Valles Mountains on the west (Figure 3-4). Water erosion from these mountains formed east-west oriented canyons separating the Plateau into fingerlike mesas. The Plateau also lies within one of several

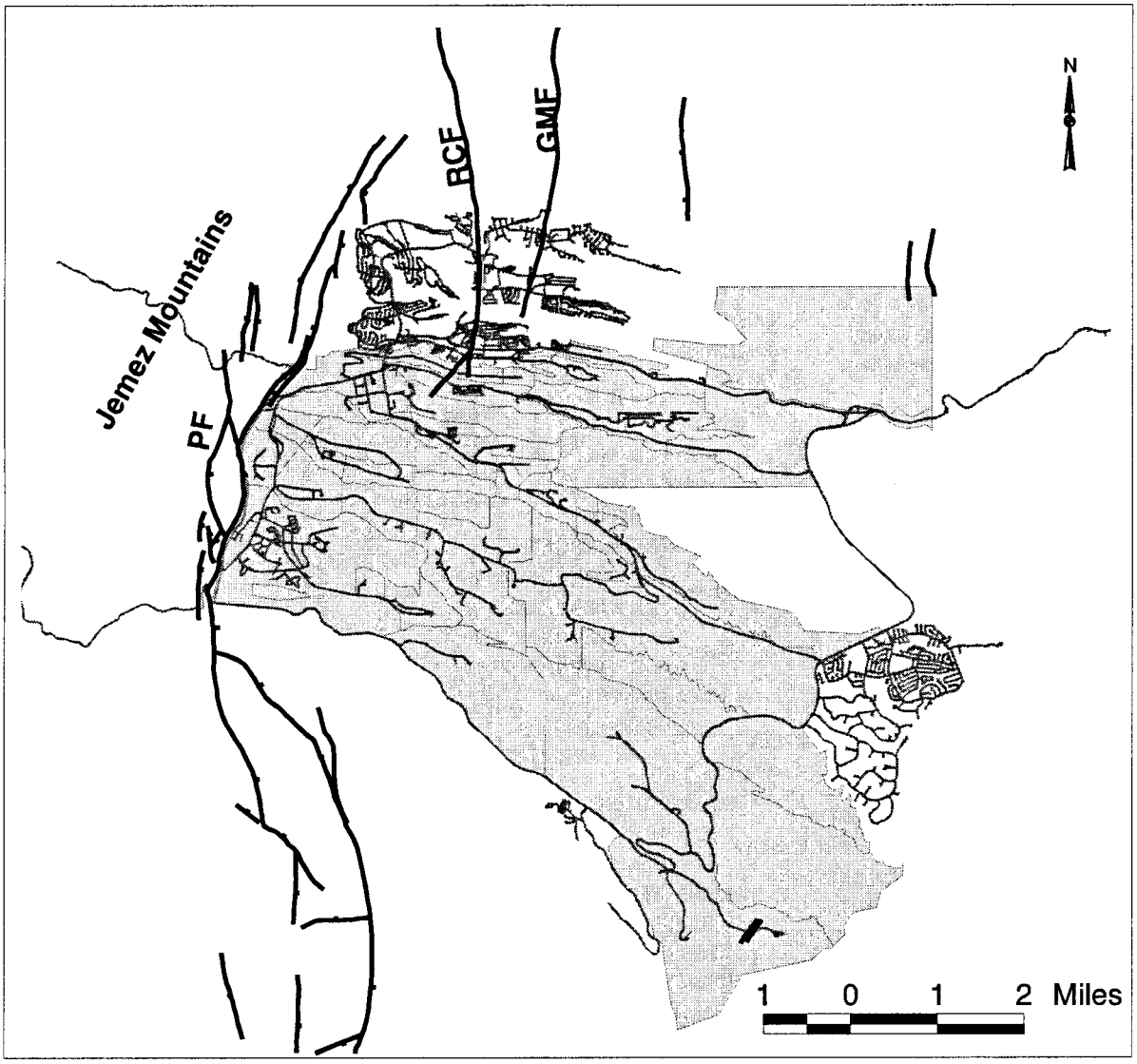

Figure 3-4. Map showing LANL and faults of the Pajarito Fault System (Krier et al. 1998a)

north-trending basins formed by the Rio Grande Rift because of the downfaulting of large blocks of the earth's crust (Dransfield and Gardner 1985). Faults are breaks in the earth's crust involving horizontal or vertical movement, or both, along a zone of weakness called a fault plane. There are three major faults and numerous secondary faults that cross the Plateau in a system known as the Pajarito Fault system. This system, formed by the rift, crosses the Plateau in a roughly north-south direction in a series of interconnecting faults that are nearly parallel.

The three optional locations of the Proposed Alternative would all be located on the South Mesa between Los Alamos and Mortandad Canyons. The near-surface geology of the

immediate area is comprised of volcanic and sedimentary materials. The uppermost volcanic rock unit is the Bandelier Tuff that is overlain by a veneer of clay-rich soils and sediments. All soils in the soil series identified at LANL (Reneau 1994) are well-drained and range from a very shallow 0 to 10 in (0 to 25 cm) to a moderately deep 20 to 40 in (51 to 102 cm) (Nyhan et al. 1978). None of the soils at the BSL-3 facility optional locations exhibit slope stability, subsidence, or soil liquefaction potential (DOE 1999a). During building construction activities at LANL it is customary for these soils to be removed. Only location option Site C has a significant amount of these soils due to it being the location used for temporary storage of fill excavation soils from previous LANL excavation projects.

A comprehensive seismic hazards study was completed at LANL in 1995 to evaluate earthquake hazards (Wong et al. 1995). Site-specific studies at TA-3 were completed in 1998 for the SCC, the NISC, and the Chemical and Metallurgy Research (CMR) Building (Krier et al. 1998a, 1998b). The 1995 study included a detailed assessment of uncertainties, including those associated with the rates of movement for earthquake faults around LANL. Results of both studies are summarized in the LANL SWEIS (DOE 1999a) in an appendix report entitled "Status and Implications of Seismic Hazard Studies at LANL." The studies identified only one major fault, the Rendija Canyon Fault, exhibited at TA-3 in the vicinity of the three potential locations for the Proposed Action. A 1999 study of the area extending from TA-3 to TA-55 was completed for seismic surface rupture potentials. Of the three site options, only the Option A site has any evidence of a subsurface fault trace within the identified option "circle" (along the southwestern edge of the site) (Gardener, et. al., 1999). The 1995 study reports that faults in the TA-3 area show vertical displacements ranging from 1 to 10 ft (0.3 to 3 m). While surface rupture indicated by near-surface vertical displacements can cause significant structural damage, surface rupturing earthquakes are low probability events (DOE 1999a). The 1998 study conclusions for the CMR building are that the probability of damaging ground motion is at least 20 times greater than the probability of damage caused by surface rupture. Design criteria established by DOE (DOE 1996a) and implemented through LANL requirements (LANL 1999a) take into consideration the ground movement associated with these low-probability events to minimize effects to the structure, if any, during earthquakes. The LANL SWEIS (DOE 1999a) indicates on the Observed Effects of Earthquakes Table 4.2.2.2-3 (pg. 4-32) it would take something like an earthquake of magnitude 6 to produce an effect of "damage moderate in well-built ordinary structures."

Volcanic activity has occurred in the Jemez Caldera region from about 1.22 million to 520,000 years ago followed by a dormant period of about 460,000 years (DOE 1999a, p. 4-27). The most recent volcanic activity occurred from 50 to 60,000 years ago. Volcanic activity levels of the order which occurred 100's of thousands of years ago would give years of prior warning. Activity like that of 50 to 60,000 years ago would give weeks or days of warning due to its much subdued level of activity. However, it is projected this type of activity also produced only ashfalls in the LANL area (DOE 1999a, pg. 4-27). In either case sufficient warning should exist to take precautions with hazardous materials.

The 1995 report also relates earthquake magnitudes to ground acceleration movement; however, the relationship is approximate. This seismic hazards study found that TA-3 would have ground accelerations as shown in Table 3-4 below, as a result of earthquakes centered within 10 mi (16 km) including earthquakes on the other two major faults on the Plateau.

Table 3-4. Peak Horizontal Ground Acceleration Corresponding to Return Periods from 500 to 10,000 years for TA-3

Return Period (years)	500	1,000	2,000	10,000	100,000 (est.)
Ground Acceleration (g)	0.14	0.21	0.3	0.56	>1.0

* Source: Wong et al. 1995

Although large uncertainties exist, an earthquake on the Pajarito Fault system with a magnitude greater than or equal to 6 on the Richter Scale is estimated to occur once every 4,000 years while a magnitude of 7 on the Richter Scale would occur once every 100,000 years (DOE 1999a).

3.3.9 Visual Resources

The area surrounding the three optional locations for the proposed BSL-3 facility around TA-3 is largely developed for research/industrial type purposes but still has unoccupied areas covered with natural vegetation (as shown in Figure 2-2). For security reasons, much of the development of the area is not seen by the general public except for the main administrative complex at TA-3. This administrative area is a visually discordant assembly of structures and functions, equipment, parking, and outside storage (DOE 1999a). More recent development in the area includes many facilities with designs and materials more visually appropriate and compatible with the natural environment (such as the SCC and NISC).

Most of the view of LANL property in the area of the three Proposed Action optional site locations is from well-traveled and publicly accessible roads within the core area of TA-3. Passing motorists or nearby residents can only see a fraction of the smaller buildings spread out over the TA-3 area. The proposed optional site locations would be adjacent to parking areas, gas transmission lines, and various other utilities. Where undeveloped, the location areas contain stands of ponderosa pine; the remaining disturbed or developed areas are either not vegetated or are bordered by young growth of ponderosa pine, grasses, and herbaceous plants. Diamond Drive and Pajarito Road both have views of the Sierra de los Valles at the eastern edge of the Jemez Mountains.

Those most likely to view the potential optional site locations would be workers at LANL facilities at TA-3, commuters on their way to and from work in Los Alamos townsite and White Rock, joggers and bicyclists along Diamond Drive and Pajarito Road, tourists visiting LANL, BNM, and the Jemez Mountains, and seasonally, some skiers driving to and from the Pajarito Ski Hill. Option C Site, however, would have minimal visibility from these roads.

Nighttime light pollution is an issue with respect to the TA-3 complex. The Los Alamos viewshed already has a substantial nighttime visual effect both directly related to the view of light sources and indirectly related to the cumulative and reflected light that creates an unnatural glow in the sky and reduces the visibility of stars and other celestial bodies (DOE 1999a). More detailed information about LANL and Los Alamos County light pollution can be found in the LANL SWEIS (DOE 1999a).

3.3.10 Air Quality

Air quality is a measure of the amount and distribution of potentially harmful pollutants in ambient air. Congress passed the *Clean Air Act* (CAA) to mandate that the U.S. Environmental Protection Agency (EPA) regulate those potentially harmful pollutants through the National Ambient Air Quality Standards (NAAQS) for pollutants of concern known as the criteria pollutants. EPA has identified six criteria pollutants: carbon monoxide (CO), sulfur dioxide (SO_2), nitrogen oxides (NO_x), ozone (O_3), lead (Pb), and particulate matter (PM). These pollutants are emitted primarily from combustion sources such as boilers, emergency generators, and motor vehicles. LANL and Los Alamos County are within attainment areas for the six pollutants, meaning that the concentrations of these pollutants are below the State and Federal maximum allowed limits. Only a limited amount of monitoring ambient air has been performed for nonradiological air pollutants within the LANL region. The New Mexico Environment Department (NMED) operated a DOE-owned ambient air monitoring station adjacent to BNM 0between 1990 and 1994 to record SO_2, nitrogen dioxide, O_3, and PM levels. LANL and NMED discontinued operation of this station in FY 1995 because recorded values were well below applicable standards (DOE 1999a).

NMED has issued LANL a "Notice of Completeness" with regards to air emissions but has not yet issued LANL an operating permit. The purpose of the permit is to identify all State and Federal air quality requirements so that these can be monitored and tracked under one permit. As of the most recent reporting, nonradioactive air emissions are in compliance with the CAA and the *New Mexico Air Quality Control Act* (LANL 2000b).

The Proposed Action optional site locations would be located along Diamond Drive and adjacent to Pajarito Road. Automobile exhaust is a contributor to local air pollution, but within TA-3 the other major contributors to nonradiological air emissions are the LANL gas-fired steam plant, and the asphalt heater. Neither the steam plant nor the heater would be located adjacent to any of the Proposed Action optional siting locations.

4.0 ENVIRONMENTAL CONSEQUENCES

This section evaluates the environmental consequences of the Proposed Action, Alternative Actions and the No Action alternative. The Proposed Action is additionally evaluated for the effects of site preparation, construction, and operation at three optional locations. However, the environmental consequences from site preparation, construction and routine operation are, but with one exception (transportation), no different for the three optional locations. Therefore, the difference between effects at optional locations will only be discussed for this one affected resource area.

4.1 ENVIRONMENTAL CONSEQUENCES OF THE PROPOSED ACTION

4.1.1 Human Health

Site Preparation and Construction. Human health effects during site preparation and construction for the proposed BSL-3 laboratory would be the same as for any small single-story construction project at LANL. The effects would be very localized and affect only site workers or visitors to the site. There would be no public human health effects. Routine construction activities have the potential for exposing workers or site visitors to a number of common hazards including, for example:

- Biological hazards (snake bites, poison ivy, and insect stings)
- Electrical hazards (temporary electrical drops, excavations in areas with underground utilities, heavy equipment lifting with overhead utilities)
- Fire and explosion hazards (portable gasoline containers for generators and other gas-powered equipment, fuel transfers for onsite heavy equipment operation)
- Physical hazards (slips-trips-falls, walking-working surfaces, powered hand-tool operation, pinch-points, hoisting, motor-vehicle operation, excavations, ladders, noise, heat stress, cold stress, sunburn, dust and particulates)

These hazards would be reduced or eliminated by compliance with Federal Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1910.12, 29 CFR 1926, 29 CFR 1990), National Fire Protection Association (NFPA) codes (NFPA 1997, 1998, 2000) and the DOE directives which mandate these worker protection requirements for DOE facilities (DOE 1997c, 1998).

UC workers at LANL would not be directly involved in the construction of the BSL-3 facility, but they would be active in management, site inspections, and utility hookups. Approximately three peak-period UC workers would support construction activities. Because of the limited involvement of UC workers in the construction of the new buildings, no effects on these workers is anticipated.

The Proposed Action is expected to have no effect on the health of any non-UC construction workers under normal operation conditions. Approximately 15 peak period construction workers would be actively involved in potentially hazardous activities such as heavy equipment operations, soil excavations, and the handling and assembly of various building materials. Construction activities would take approximately one year to complete. Appropriate personal protection measures would be a routine part of the construction activities, such as personal protection device use (such as gloves, hard hats, steel-toed boots, eye shields, and ear plugs or covers).

Potentially serious injuries are possible during the construction phases of the Proposed Action. Adverse effects could range from relatively minor (for example, lung irritation, cuts, or sprains) to major (for example, lung damage, broken bones, or fatalities). To prevent serious exposures and injuries, all site construction contractors are required to submit and adhere to a Construction Safety and Health Plan (Plan). This Plan is reviewed and approved by UC staff before construction activities can begin. Following approval of this Plan, UC and DOE site inspectors would routinely verify that construction contractors are adhering to the Plan, including applicable Federal and state health and safety standards. In addition, UC staff would provide site-specific hazard training (for example, construction safety, waste handling, etc.) to construction contractors as needed. Adherence to an approved Plan and completion of appropriate hazards training are expected to prevent any major adverse effects on construction workers. UC at LANL has been successful in reducing its OSHA-recordable injury and illness rate per 100 full time employees over the last 4 years from 4.37 cases per 100 full time workers in 1997 to 1.51 cases per 100 full time workers in 2000 (LANL 2001l). These low rates for daily operations (including construction activities), reflect UC at LANL's effectiveness in implementing a comprehensive health and safety program to assure worker safety. Due to the nature of this construction project (single-story frame construction), no fatalities and only an extremely small incidence of minor injuries would be expected. In comparison with the LANL injury and illness rate, data from the U.S. Bureau of Labor Statistics (BLS) reports nonfatal injury and illness industry rates for nonresidential building construction (employing at total of about 650,000 workers in 1999) went from 11.2 cases per 100 full time workers in 1997 to 8.9 cases in 1999 per 100 full time workers (BLS 2001). In 1999, about 85 percent of the total number of nonfatal injuries and illness were due to injuries and 15 percent were due to illnesses.

Operations. The type and rate of injuries and illnesses expected during operation of the proposed BSL-3 laboratory would be the same as those demonstrated for CDC-registered laboratories, U.S. Army Biological Defense Research Program (BDRP) laboratories and existing biological research laboratories operated by LANL. While the most obvious potential concern of operating a BSL-3 laboratory involves handling of infectious organisms (listed in Appendix E), the proposed facility would have attributes of most laboratories in that it would have identified physical, electrical, and chemical hazards. The proposed laboratory would not use radioactive materials, propellants, or high explosive materials, and the quantities of hazardous chemicals to be used would be less than 230 lbs per year (104 kg per year) (LANL 2001b); hazardous chemicals would be handled according to established

LANL procedures (LANL 1999g, 2001b). The potential for injuries and illnesses involving routine laboratory operations presents a greater health risk to workers than does the potential for injury and illnesses associated with handling infectious substances. Moreover, the combination of utilizing the guidelines, standards, practices and procedures established by the CDC, NIH, Human Health Services, and public health services together with BSL-3 safety equipment and facility safety barriers, results in the an overall potential risk of illness to site workers or visitors from operations involving select agents that would be best characterized as minor. There would be no discernable public human health effect from routine BSL-3 laboratory operations at the proposed facility.

There has been an extremely low incidence of acquired-infections associated with operations in CDC-registered laboratories since the implementation of CDC-developed guidelines issued in 1974 (See Appendix F). Specifically, a recent bibliographic database (Collins 2000) based on reports starting from about the beginning of the 20th century and continuing up through August 2000 reveals substantial reductions in laboratory-acquired infections reported in the 1990's. There is a particularly notable lack of reported cases in the literature relating to laboratory acquired infections in the United States in the last 10 years.

The experience of the U.S. Department of the Army (DA) at their BDRP facilities over several decades provides further insight to the potential for laboratory-acquired infection. The DA program underwent a programmatic NEPA evaluation in 1989, the *Final Programmatic Environmental Impact Statement Biological Defense Research Program* (BDRP)(PEIS) (DA 1989). Since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within the DA BSL-3 facilities, although in 1980, one focal infection with *F. tularensis* occurred at the site of a puncture wound (DA 1989)." The BDRP PEIS (DA 1989) also estimated laboratory-acquired infection rates for their U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) facility for different biocontainment levels (roughly equivalent to the CDC BSL levels) over different periods of time. For their BSL-3 equivalent laboratory operations from 1960 to 1962 they estimated there were six laboratory-acquired infections for a rate of 2 per million man-hours worked. For their BSL-4 equivalent laboratory operations from 1960 to 1969, they estimated seven laboratory-acquired infections for a rate of 1 per million man-hours worked. These infections included sub-clinical infections and mild illnesses where hospitalization was not required (DA 1989).

Overall, the BDRP PEIS estimated the rate of public infection from USAMRIID as less than 0.001 per 1,000,000 person-years and the risk of death to a laboratory worker for the Defensive Period (1970 to 1989) as 0.005 per 1,000,000 person-years (DA 1989). By way of comparison, the Offensive or Weapons Period (1954 to 1964) was associated with values for the risk of death to laboratory workers of about 5 orders of magnitude higher (DA 1989).

Experience with biological research laboratories at LANL spans a period of several decades of biological studies. Based on information provided by the LANL Safety Group, ESH-5, LANL has operated BSL-1 and BSL-2 equivalent laboratories for at least the last 20 years

without any exposures or infections associated with their operation (PC 2002a). In addition, there were no releases to the environment or public associated with the LANL biological research laboratories. Additionally, the LANL Biological Safety Officer reviewed available Occurrence Reporting and Processing System (ORPS) Reports (2566 reports from the past 10 years) and the Occupational Medicine Exposure Incident Log for LANL (2283 entries from the past 10 years), and the LANL Injury and Illness Program Manager also reviewed the LANL Occupational Safety Health Administration (OSHA) 200 log (from 1993 forward to the present) for information regarding laboratory acquired infections by LANL workers. These reports and logs include information on workers at BSL-1 and -2 laboratories. The results of these reviews was that there have been no incidences of laboratory acquired infections recorded for LANL workers (PC 2002a).

As part of the preparation of this EA, NNSA contacted the University of New Mexico's (UNM's) School of Medicine regarding their BSL-3 laboratory operations. This contact was initiated to obtain operating experience information involving a BSL-3 laboratory facility located in a major metropolitan area with regional proximity to the proposed LANL BSL-3 laboratory facility. NNSA ascertained information indicating no incidence of laboratory acquired infections reported over the last 8 years (PC 2002b).

Anecdotal reporting of human health issues elsewhere at BSL-3 or similar laboratories have indicated that while laboratory-acquired or laboratory-associated infections (specifically, the "all other" category of nonfatal injury and illness rates reported by the BLS) do occur, they should be considered abnormal events due to their infrequency of occurrence (see Appendix F). As such, the human health effects of these events are discussed within this chapter in Section 4.2, Abnormal Events. There are a number of reasons that routine BSL-3 laboratory or similar laboratory operations do not normally produce infectious disease-related health effects to workers, their families, or the general public. In general, these are a result of the implementation of the comprehensive CDC and NIH guidelines (see Appendix A) that were based upon historical published accounts (anecdotal information) over many decades of experience in medical and bacteriological laboratories (CDC 1999) (see Appendix F).

Potential Pathways for Infectious Agents to Escape BSL-3 Containment. Potential means for infectious agents to leave the BSL-3 containment and possibly cause human health impacts would include five pathways. These are direct transmission,[19] vector-borne transmission,[20] vehicle-borne transmission,[21] airborne transmission[22], and water-borne transmission.[23]

[19] Direct transmission: Direct and essentially immediate transfer of infectious agents to a receptive portal of entry through which human or animal infection may take place. This may be by direct contact such as touching, biting, kissing or sexual intercourse, or by the direct projection (droplet spread) of droplet spray onto the conjunctiva or onto the mucous membranes of the eye, nose or mouth during sneezing, coughing, spitting, singing or talking (usually limited to about 1 meter or less) (Benenson 1995).

[20] Vector-borne transmission can include mechanical or biological transmission of infectious agents. Mechanical transmission includes carriage by crawling or flying insects through soiling of feet or proboscis or

Direct Transmission. Operations as described minimize opportunities for direct transmission. Direct transmission would first require a worker to be exposed to an infectious agent. The likelihood of a worker inhaling or otherwise becoming exposed (for example, through cuts in the skin or ingestion) to an infectious agent would be extremely remote. While it would be very unlikely that a worker would be exposed, if exposed with a sufficient dose, it would be possible for them to be carriers[24] for those agents and through direct transmission expose others. This potential is further reduced through the intervention of effective vaccines or therapeutic measures (CDC 1999).

Vector-borne Transmission. The facility would be designed to severely limit the potential for possible vector-borne transmission through insects and rodents. The use of pest control programs (Appendix G of CDC 1999) would limit the potential for transmission of infectious agents from animals to humans.

Vehicle-borne Transmission. The primary concern for vehicle-borne transmission would be by the workers clothing or skin and hair, as all other materials leaving the BSL-3 must go through a sterilizing autoclave. The guidelines established by the CDC and NIH, which would be followed by the proposed BSL-3 facility, are designed to reduce this potential method of transmission. This substantially reduces any potential for a worker to unknowingly transport infectious microbes from the facility.

Airborne Transmission. All air leaving the BSL-3 laboratories during normal conditions would exit through ductwork that is HEPA-filtered prior to emission through stacks on the building roof. The number of viable vegetative microorganisms after HEPA filtration would be near zero. HEPA filters are rated as 99.97 percent efficient. The rating efficiency point is at the particle size where the filter is least efficient and is certified by removal of 0.3 microns[25] diameter dioctylphthalate (DOP) particles (NSC 1996). This means that HEPA filters remove 99.97 percent of all the particulates that hit the filters. The remaining particles can penetrate or pass through the filters. Filters are made from randomly laid non-woven

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by passage of organisms through its gastrointestinal tract. This does not require multiplication or development of the organism. Biological transmission includes the propagation (multiplication), cyclic development, or a combination of these (Benenson 1995).

[21] Vehicle-borne transmission is the transmission of infectious agents through contaminated inanimate materials or objects such as handkerchiefs, soiled clothes, surgical instruments, water, food, and biological products (Beneneson 1995).

[22] Airborne transmission is the passage of microbial aerosols to a suitable portal of entry, usually the respiratory tract. Microbial aerosols are suspensions of particles in the air consisting partially or wholly of microorganisms (Benenson 1995).

[23] Water-borne transmission is the transmission of infectious agents through contamination of water. It can be considered a subcategory of vehicle-borne transmission.

[24] A carrier is a person or animal that harbors a specific infectious agent without discernable clinical disease and serves as a potential source of infection (Benenson 1995).

[25] A micron, also known as a micrometer, is one millionth of a meter or four hundred thousandths of an inch.

natural or synthetic fiber materials made into a flat sheet that is pleated and placed into a filter container. Pleating increases the surface area and improves filter loading and reduces air resistance. HEPA filters have fiber diameters ranging from 0.65 to 6.5 microns in three diameter groupings. The process of aerosol filtration does not simply rely on the size of the opening between fibers, but uses a number of physical properties of air movement around fibers to capture the particles. These forms of capture are called interception, sedimentation, impaction, and diffusion. Electrostatic attraction also plays a part in capturing small particles and the fiber material is often selected specifically to enhance this effect (for example, electret fibers and wool resins). The exact combination of capture mechanisms varies. Larger particles are generally removed by impaction and interception while light particles are removed by diffusion and interception. These mechanisms remove essentially all particles larger than 0.6 microns in diameter and low flow rates let diffusion effectively remove all particles below 0.1 micron (NSC 1996). A most "penetrating particle size" exists between 0.2 and 0.4 microns which is the reason for testing and certifying HEPA filters for particle removal at 0.3 microns (NSC 1996).

HEPA filters at the BSL-3 facility would be replaced routinely and checked periodically for any malfunctions. Given the proposed operations of the facility, there is no expectation that the HEPA filters would become moisture-saturated or torn – the two major reasons for HEPA filter failures.

Regardless of the presence or failure of HEPA filters, many environmental factors effectively kill airborne microbes in their vegetative state. These factors include ultraviolet light, dehydration, high temperatures, freezing temperatures, and the presence of free oxygen. Together these factors account for a substantial reduction in the number of microorganisms. While outdoors the sun, temperature, and other atmospheric conditions ensure that microbial populations die off quickly, generally within minutes. Mathematical predictions of the potential survival of microorganisms in the environment estimate that only about 0.01 percent are able to resist the chemical or physical inactivation found in the outside environment (Mitscherlich and Marth 1984).

Water-borne Transmission. Potable water would not be affected by the implementation of the Proposed Action. Facility design features, such as backflow preventers and State of New Mexico-adopted uniform plumbing code requirements would prevent microbes within the facility from migrating back through the water supply piping to the public. Also, none of the effluent water from the Sanitary Wastewater Systems Consolidation (SWSC) treatment plant contributes directly to any potable water source. Potable water supply wells for Los Alamos County are a good distance from the proposed facility and the LANL sanitary sewer system discharge point. Water exiting through the sink drains would be combined and diluted by sanitary waste in the sewer system at the LANL facility and would undergo a series of treatment steps prior to discharge. These treatment steps consist of aeration, secondary clarification, disinfection, dechlorination (for environmental discharges), water reuse system, effluent holding ponds, and sludge drying beds (JCNNM 2000b). A portion of the SWSC treated water is diverted to cooling towers located at TA-3 where it is reused after

undergoing additional treatment. It is very unlikely that aerosol mists from cooling towers would contain discernable quantities of infectious agents due the extensive water treatment and dilution with other wastewaters.

According to the EPA Surface Water Treatment Rule (40 CFR 9, 141, and 142) public water treatment systems must physically remove or inactivate 99.9 percent of the cyst-forming protozoans *Giardia spp*. and *Cryptosporidium spp*. Treatment system operators comply with this rule by determining the amount of chlorine and contact time along with temperature and pH that it takes to produce the required killing of pathogenic microorganisms. Contact time on the order of hours along with a measurable free available chlorine means that all but the most resistant pathogens would likely be killed. It is anticipated that there would be no discernable effects from water-borne transmission.

4.1.2 Ecological Resources

As stated in Section 3.3.2, no threatened or endangered species habitat or buffer areas would be located at or adjacent to the three proposed BSL-3 laboratory facility optional locations (DOE 1999d; LANL 2001e). Furthermore, the implementation of the Wildfire Hazard Reduction Program (WHRP) and subsequent long-term maintenance projects would drastically reduce the potential risk and damages from an uncontrolled and catastrophic wildfire within the boundaries of LANL. Therefore, neither of these are considered potential effect areas and will not be further evaluated.

Site Preparation and Construction. An estimated one-half to one acre (0.2 to 0.4 hectares) of previously disturbed land would be used for site preparation, utility installation, and other construction activities at Option A or B sites (PC 2001c). It would be expected that continuous and impact noise (described in Section 4.1.6) could have temporary effects to wildlife. However, these minor effects would not be long term.

Site preparation and construction would have some effect upon the resulting soil characteristics. Some soil horizons would be removed entirely where they would be under foundation footings and other parts of the building.

Operation. The operation of the proposed BSL-3 facility would have little if any biota effects. Infectious microorganisms handled in the proposed facility might be introduced into the environment under two conditions. The first is the disposal of sanitary wastewater to the SWSC plant discussed previously. Sanitary waste passing through the wastewater treatment plant undergoes several stages of treatment that would inactivate any microbes that survived the initial disinfectant treatment at the BSL-3 facility (see discussion of water-borne transmission in Section 4.1.1 Human Health).

The second relates to emergency response operations. There is a potential for micro-organisms to be introduced into the environment if they were not contained within the laboratory during a fire-response event. However, even if they did escape containment, there

are a number of environmental factors that effectively kill microorganisms in the vegetative state. These are enumerated in Section 4.1.1. They include ultraviolet light, dehydration, high temperatures, freezing temperatures, and the presence of free oxygen. The survival or death curves indicate that microbial populations die off quickly (DA 1989).

It is unlikely that natural or man-made radioactive materials in the soil or air would have any perceptible effect on microbe growth or viability either in the environment at the proposed BSL facility or within the laboratories themselves. The effects of radioactive materials and naturally occurring radioactive environments on microorganisms was discussed in Section 3.3.2.

4.1.3 Transportation

Site Preparation and Construction. While there would be some material hauling trucks coming and going to deliver construction materials, the size of the BSL-3 building (about 3,000 ft^2 or 279 m^2) would indicate that these would account for only a very small fraction of the vehicular traffic in comparison to the nearby construction activities (specifically the NISC, SCC, and the Research Park). These deliveries and the vehicles from the construction crews would cause an imperceptible increase in traffic on LANL's main access points (see Table 3-2). Also, waste generation (such as soil and construction debris) for the single-story construction would require few trucks for waste removal and disposal since much of the excavation material would likely be reused onsite for landscaping. The sum of these daily trips would be minor in comparison with the approximately 43,000 ADTs associated with the four main access roads (Table 3-2).

As with any construction project, the installation of utility lines may cause some temporary delays in traffic movement. Road closure or traffic slowdowns would have the most effect at the Option B location, since it is adjacent to the most heavily trafficked LANL road, Pajarito Road. The Option A location would also have some possible traffic slow-down effects on Sigma Road during utility trenching depending upon the exact construction corridors at this location.

Parking spaces would not be an issue at location Option C during the construction phase. This location currently has no parking spaces, and therefore, would have no parking effects from construction of the facility at this site. At the Option B location, none of the parking spaces are currently being utilized since building TA-03-16 is not being used. Approximately 15 parking spaces would be taken out of use during the site preparation and construction activities at both the Option A and Option B locations (PC 2001d). These would easily be accommodated at the other existing and future LANL parking lots and structures. The number of relocation parking spaces for individuals currently using these parking lots would be between 15 to 20 spaces (PC 2001d).

Operation. Vehicular traffic due to the operation of the proposed BSL-3 facility would have little effect on the TA-3 traffic congestion. At least half of the 8 to 10 workers expected for

the proposed facility would be relocated from the HRL building (see Section 2.1). These workers already contribute to the ADTs at the LANL main access points (Table 3-2). Some of the other expected site workers might come from other LANL jobs or be hired from out of town. The increased traffic from these additional workers would also have minimal impact on the traffic congestion in the area.

Fourteen parking spaces would become available upon completion of the BSL-3 facility. This would be an increase to the overall TA-3 parking capability only if the Option C location was chosen. Overall, LANL parking would be unaffected by implementing the Proposed Action at either Option A or B locations.

4.1.4 Waste Management

Site Preparation and Construction. The incremental increase in waste materials produced during this phase of work would be minimal with respect to the waste production of the entire LANL facility. Construction debris primarily comprised of wood, metal, asphalt, paper and plastic would be the typical waste expected to be generated during construction of the BSL-3 facility building and any associated parking area. This solid waste would be disposed of either at the Los Alamos County Landfill or at another appropriate replacement solid waste landfill. Additionally, the project would generate excess uncontaminated soil from excavation activities. The soil could be stockpiled onsite or at a location on Sigma Mesa (TA-60) or other approved material management area for future use.

Operation. No additional waste disposal facilities would be developed as a result of the Proposed Action. Waste quantities and disposal practices were discussed in Chapters 2 and 3. The incremental waste production associated with the operation of the facility would be minimal with respect to the total waste volumes generated by the entire LANL facility and disposed of at existing waste disposal facilities.

4.1.5 Utilities and Infrastructure

Site Preparation and Construction. Temporary water and electrical utilities would be provided to the selected site during the construction phase. These temporary services would be removed and replaced upon completion of the construction. Minimal additional site disturbance would result from the installation of permanent utilities on the site.

Operation. The effect of providing utilities to the proposed facility would be nearly imperceptible relative to the demands of other existing facilities in the TA-03 area with high computing and HVAC utilities demands. Effects to infrastructure would include the need for personnel support by LANL facilities management, computing, occupational health and safety, emergency response, and authorization basis personnel. This effect is captured in Section 4.1.7, Socioeconomics, of this EA.

4.1.6 Noise

Site Preparation and Construction. Measurements made at construction sites by LANL personnel showed decibel values that peaked over 100 dBA with a minimum of about 38 dBA (Knight and Vrooman 2000). It would be expected that noise levels would exceed at least for periods of several minutes at a time the 8-hour 85 dBA threshold limit value (TLV) (ACGIH 2000), but only during daylight hours. Members of the public would be exposed to lower noise levels because of the substantial drop in noise with distance from the source. Residential areas would not be exposed to noise levels exceeding the Los Alamos County standard of 65 dBA during the daytime and 53 dBA at nighttime.

Heavy equipment such as front-end loaders and backhoes would produce intermittent noise levels at around 73 to 94 dBA at 50 ft (15 m) from the work site under normal working conditions (Cantor 1996; Magrab 1975). Construction truck traffic would occur frequently but would generally produce noise levels below that of the heavy equipment. The finishing work within the building structures would create noise levels slightly above normal background levels for office work areas. Noise levels may go up to around 80 dBA at the work site if light machinery is used in this stage of construction (Cantor 1996). Workers would be required to have hearing protection if site-specific work produced noise levels above the LANL action level of 80 dBA for steady-state noise. Sound levels would be expected to dissipate to background levels at the LANL boundaries or nearby residential areas. The additional construction worker personal vehicular traffic would not be expected to increase the present noise level produced by vehicular traffic on Diamond Drive or West Jemez Road during rush hour. The vehicles of construction workers would remain parked during the day and would not contribute to the background noise levels during this time. Therefore, noise levels are not expected to exceed the established permissible exposure limit (PEL).

Operation. The expected noise levels during operation of the proposed BSL-3 facility would be consistent with other existing facilities (see Section 3.3.6). Noise studies for these facilities have indicated sound values of about 50 dBA during rush hours and nighttime averages in the 40 dBA range. These noise levels would be due to vehicular traffic passing through the facility area and from the facility's HVAC system operation. Residential areas would not be exposed to noise levels exceeding the Los Alamos County standard of 65 dBA during the daytime and 53 dBA at nighttime.

4.1.7 Socioeconomics

Site Preparation and Construction. The total estimated cost to NNSA of designing, preparing all appropriate documentation and construction of the proposed BSL-3 facility is $3.5 million (PC 2001c). It is conservatively estimated (using a 1.5 multiplier, see Section 3.3.7) (Lansford et al. 1999) that this expenditure would result in more than $5.25 million in revenue to the State of New Mexico. While all of these expenditures are not specifically site preparation and construction they would be considered pre-operational costs.

The Proposed Action would not have a major long-term effect on socioeconomic conditions in the LANL area. Only an increase of up to five UC employees is anticipated as a result of the Proposed Action. The additional revenue generated by the construction projects would be limited in duration resulting in a short-term effect only. Construction of the BSL-3 facility would generate jobs and revenue into the local economy. Most building supplies would be purchased in New Mexico. During peak construction, approximately 15 construction workers may be working on these new facilities. Close to $5 million would be spent on construction and design and oversight contracts. Approximately one-half of this amount would be for labor and one-half for materials. Construction is scheduled to take approximately one year beginning in about mid-2002. The additional 15 peak construction jobs would be likely be drawn from the regional work force, residing in Los Alamos, Rio Arriba, and Santa Fe Counties. Because these temporary jobs would be filled by an existing regional work force, there would be no effect on area population or increase in the demand for housing or public services in the region.

Operation. Operational costs for the proposed facility are estimated at an annual cost of about $400,000. Other personnel costs for site safety support, monitoring of the authorization basis, issuance of work orders and other administrative costs would be approximately $200,000 per year (PC 2001f). This would result in a yearly operating cost of about $300,000. It is also estimated that there would be an additional one-time startup cost of $200,000 (PC 2001f). Therefore, the first year of operation would result in expenses of $800,000 and a conservatively estimated revenue within the State of New Mexico of $1,200,000. Subsequent year expenses would be estimated at $600,000 resulting in revenues within the state at $900,000 per year. Operation of the proposed facility would also potentially create about five new jobs. The effect of the expenditures of the BSL-3 facility would not be discernable in relation to the NNSA's annual input to the local economy of $3.2 billion (LANL 2000c).

4.1.8 Geology, Soils, Seismicity

Site Preparation and Construction. Except for the temporary disturbance of 0.5 to 1 acre (0.2 to 0.4 hectares) of land (PC 2001c) during site preparation and construction, there would be little effect upon geology, soils, or seismicity. Soil erosion prevention measures would be in place during the construction phase to minimize erosion from stormwater. Also, dust suppression measures would be employed to minimize wind erosion. The disturbed construction area would be reseeded.

Operation. There would be little effect from the proposed BSL-3 facility operation on geology, soils, or seismicity. Soils surfaces which are not paved would be landscaped to control erosion from stormwater runoff at the facility.

4.1.9 Visual Resources

Site Preparation and Construction. During site preparation and construction there would be temporary effects to the viewshed due to the clearing of land, excavation of footings, and the erection of the building structure. When completed, the application of stucco and paint to the building would result in a facility that would be visually compatible with surrounding structures. Landscaping around the building would contribute to the visual merging of the proposed facility into the surrounding area. As the BSL-3 facility would be a one-story structure, it would not be a visually disruptive element against the natural lines of the background landscape as seen from distant vantage points.

Operation. During operation the proposed BSL-3 facility would fit into the LANL TA-3 viewshed with minimal effects since its building footprint and height would be small relative to surrounding structures. Site lighting would be minimal and serve only to illuminate the facility and associated parking spaces.

4.1.10 Air Quality

Site Preparation and Construction. During site preparation and construction, the use of heavy equipment would generate combustive-engine exhausts that would contribute to air pollution. However, since there would be very few of these pieces of equipment and their use would be limited in time the potential effect to air quality would be temporary and localized. During construction there would be a temporary increase in particulate emissions. Operation of construction vehicles such as dump trucks, bulldozers, cranes, and waste disposal actions would also produce temporary and localized emissions of other air pollutants. Construction activities, which are not considered stationary sources of regulated air pollutants under the air quality requirements, are exempt from permitting under Title 20 of the New Mexico Administrative Codes, Sections 2.72 and 2.70. Mobile sources, such as construction and waste transport vehicles, would produce other air pollutants (such as sulfur oxide), but the emissions would be expected to be similar to those from other recent construction actions, such as those involved in the construction of the Administration Building, SCC and NISC buildings at LANL.

Operation. Air quality effects during the operation of the facility relate in part to the generation of gas-combustion engine emissions from private motor vehicles during workers' commute to and from work. About one-half of the workers would be relocated from HRL so there would be no net effect to air quality from these individuals. The addition of three to five new workers would not produce a substantial contribution to the Los Alamos County air emissions since the area is well within the attainment area for the six state and nationally regulated pollutants (see Section 3.3.10). The emergency generator for the proposed BSL-3 facility would also emit pollutant air emissions, but its operation would be expected to account for only very few hours per year for testing purposes and therefore, contribute little to air pollution. Periodic use of disinfecting gases could be part of the routine operation of the facility. These gases or vapors, such as formaldehyde (from paraformaldehyde) and

hydrogen peroxide, would not effect the overall local air quality. Effects of these gases would be temporary and localized and would dissipate quickly. There would be no increase in steam or power production from the TA-3 power plant that would cause increased emissions of regulated pollutants. Since vehicle use would not change substantially as a result of operating the new facility, emissions from automobiles would not noticeably increase within the TA-3 area.

4.2 ANALYSIS OF ABNORMAL EVENTS AND ACCIDENT SCENARIOS

4.2.1 Site Preparation and Construction

Section 4.1.1 describes the injury and illness statistics for nonresidential building construction. These take into consideration the routine type of accidents that occur on construction sites (for example, slips, trips and falls). They do not take into consideration accidents with more substantial consequences, such as those resulting from catastrophic events. The area in and around the three optional site locations has potential for earth movements due to earthquakes. The predicted ground acceleration due to a 2,000-year return period earthquake is 0.30 g (see Table 3-4). This magnitude of earthquake could cause damage to the proposed one-story building during construction and could injure construction workers. However, no RCRA-regulated hazardous materials would be present onsite and therefore, no exposures would result to workers or the public from a seismic event that occurred during construction.

4.2.2 Operation

This section evaluates potential abnormal event scenarios for operation of the BSL-3 facility that has a reasonable probability of occurrence. These abnormal events are all selected on the basis of historical knowledge at similar facilities over many years of operation or from concerns expressed by members of the public. The first discussion covers the potential for laboratory-acquired infections which in the literature is considered both a routine health risk and as an accident due to the frequency of exposures through, for example, needle-sticks. The routine aspect of operating the facility is discussed in Section 4.1 and the accident potential is discussed in Sections 4.2.2.1 through 4.2.2.3. The following sections discuss the potential for laboratory-acquired infection, a laboratory accident, the potential for transportation accidents, and the potential for terrorist actions.

LANL's Emergency Management and Response Program is responsible for operating an Emergency Operations Center (Center). NNSA recently broke ground on the construction of a state-of-the-art Center. To effectively operate during an emergency of any kind, memorandum of understanding have been established among DOE, Los Alamos County, and the State of New Mexico to provide mutual assistance during emergencies and to provide access to medical facilities. To assist emergency responders, the Emergency Management and Response Program and maintains a database with facility-specific information that includes information such as building managers, phone numbers, building locations, and

chemicals or materials of concern. In addition, the Emergency Management and Response Program has an Emergency Management Plan that contains all procedures for mitigating emergencies and collecting response data. Operational accidents at the BSl-3 facility would be adequately managed by knowledgeable, trained emergency responders.

4.2.2.1 Analysis of Abnormal Events and Accidents for Facility Operation

Laboratory-acquired infection. Laboratory-acquired infections are those infections acquired by workers due to the routine performance of their duties. When the exposure to an infectious agent occurs during an event it is often considered an accident (such as a needle-stick). When the exposure occurs incidentally during contact with a contaminated surface it is considered a routine health risk (see Section 4.1.1.1). The following discussion deals only with the accidental laboratory-acquired infection.

Many sources were reviewed that compiled laboratory-acquired infection statistics (CDC 1999; Collins 2000; Collins and Kennedy 1999; Pike 1979, 1976; Pike et al. 1965; Sewell 1995; and Sulkin and Pike 1951, 1949). Much of these data are reviewed and discussed in Appendix C, Section 1.1. The most recent bibliographic compilation of microbial disease reports (Collins 2000) covers the period from the turn of the century up until August of 2000, and shows a noticeable lack of laboratory-acquired infection reports in the United States during the last ten years. The Department of the Army (DA) *Final Programmatic Environmental Impact Statement, Biological Defense Research Program* (BDRP) (PEIS) (DA 1989) states that since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within BSL-3- and BSL-4-equivalent BDRP laboratory facilities. The DA estimated the risk to their workers for laboratory-acquired infection for the period from 1970 to 1989 as 0.005 per 1,000,000 person-years (DA 1989). This was a period of heavy activity using large volumes of infectious agents. The incidence of infection is much lower today in large part due to decreased laboratory activity levels since 1968.

Control of infection in laboratories has achieved a high level of sophistication, to the point that virtually no reports of infection occur in microbiological laboratories. The CDC says that common acceptance of standard laboratory practices indicates that laboratory-acquired infections should be virtually non-existent today (CDC 1999). However, they do still occur and the primary route of exposure is through autoinnoculation or the unintentional injection or needle-stick (Sewell 1995). Needles would not be used in the proposed BSL-3 facility, but broken glass with sharp edges could result from accidents with infrequently used glassware. Broken glass presents a low likelihood of exposure but infections could be promptly treated with antibiotics, antiviral drugs or other appropriate medical strategies. The potential for accidental laboratory-acquired infection would be reduced to the improbable level of occurrence.

The Laboratory Release Accident Scenario. The proposed BSL-3 facility would be unique at LANL and throughout the DOE complex in that the material at risk would be non-

radiological and non-chemical. The potentially hazardous material would consist of infectious microorganisms in containers holding liquid suspensions or on semi-solid media. Accident scenarios usually envisioned for DOE facilities, that would normally be seen to exacerbate or enhance a release or spread of the hazardous materials, would for the BSL-3 facility potentially render these materials innocuous (heat, fire, and wind). These are not applicable for work with microorganisms and would usually result in microorganisms being killed. Consequently, catastrophic events such as earthquake, fire, explosions and airplane crashes, normally considered as initiating events in DOE accident analyses, were viewed as having the potential to reduce the consequences of releases. An earthquake, explosion, or similar event that would result in a breech or rupture of the facility's walls would be bounded by the following accident analysis of a *Coxiella brunetti* release from the structure. The probability of catastrophic events (due to earthquake or volcanic activity) is very low. The potential for volcanic activity is such that forewarning would allow putting the facility in a safe mode and hence making a microorganism release scenario extremely unlikely. Likewise the low probability of an earthquake capable of rupturing the facility containment, coupled with an additionally low probability of such an event having to occur during an activity where microorganism containment would be vulnerable, also makes it an unlikely event. The proposed laboratory accident release scenario, which itself is very unlikely due to the simultaneous occurrence of several factors that must be combined to produce a release, bounds the catastrophic release scenario. Appendix F provides background information on microbiological accidents.

The BSL-3 facility would have only a few operations or activities that would hypothetically place larger (up to 10 liters) quantities of material containing infectious organisms at risk at any point in time. These operations or activities would occur at infrequent times and a release to the environment from a catastrophic event would require several simultaneous conditions to coexist: a worker is transferring a quantity of infectious material when the catastrophic event occurs; the containers aren't properly sealed; the entire set of containers is dropped; the containers break open; and the catastrophic event simultaneously causes a structural breach in the BSL-3 containment walls. Engineering and procedural controls minimize opportunities for this hypothetical scenario. For example, culture samples would be kept in locked freezers or within incubation chambers most of the time and would not become aerosolized in such an event. Therefore, catastrophic events capable of resulting in a substantial release of microorganisms from the confinement of the facility (specifically at greater than infectious dose quantities) are unlikely to occur.

A literature search and discussions with BSL-3 laboratory regulators and operators (CDC, NIH, and the U.S. Army) revealed no incidents of infectious materials released from catastrophic accidents at microbiological laboratories. According to the U.S. Army (DA 1989), the likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable. No such event has occurred in the more than 50 years in which the military has been conducting biological defense research activities (DA 1989). Based on this historical information, this hypothetical scenario was not analyzed further in this EA.

Historical information suggests that other types of accidents would be reasonably foreseeable; these could involve infectious material, and would have a relatively higher probability of occurrence than a catastrophic event. Accidents involving the production of aerosols during the use of normal laboratory equipment such as centrifuges, blenders, homogenizers, shakers, sonicators, and mixers are reported. According to *Laboratory-Associated Infections and Biosafety*, this is the second most common route of exposure after laboratory-acquired infection due to needle-sticks (Sewell 1995). Even though these accidents are more frequently reported, they rarely result in workers actually contracting diseases due to the use of vaccines and drug therapies.

Appendix F describes accident scenarios used in other NEPA documents for analysis of BSL facilities. One accident scenario that was analyzed involved the release of a biotoxin from the common soil bacterium *Clostridium botulinum* (BMI 1993). The accident scenario analysis resulted in an estimated potential release of biotoxin that was several orders of magnitude lower than the dose at which "no effect" resulted. UC at LANL is not proposing to handle biotoxins at LANL except as a collateral production during the growth of *Clostridium spp*. Another NEPA document (DA 1996) accident scenario postulated the release of *Brucella spp*. bacteria transmitted by direct contact with animal secretions. The qualitative analysis indicated no release to the public.

Another relevant NEPA accident analysis was prepared by the U.S. Army for its BDRP PEIS covering several facilities across the United States and is considered most relevant to the Proposed Action. The DA has for decades operated a series of the most extensive infectious agent laboratory facilities in the world. This PEIS addresses the entire BDRP, including multiple facilities, and involves a far greater level of operations than NNSA proposes at LANL. The reason this accident analysis should be considered relevant to the proposed BSL-3 facility at LANL is because the PEIS analyzed BSL-3 facilities with engineering and operating characteristics similar to those proposed for LANL, such as similar HVAC system designs for negative pressure and air turnover; the facilities have similar HEPA filtration; the facilities would operate under the same procedures established by CDC (CDC 1999; 32 CFR 627); and the facilities would be designed to handle the same types of microorganisms.

Important differences between the DAs accident analysis modeling and the conditions at the proposed LANL BSL-3 facility would be due to the model's input parameters (also called modeling assumptions) associated with the meteorological conditions and the proximity to non-involved workers and the public. The DA's accident assumes to have essentially non-windy site conditions and nearby non-involved facility workers and members of the public. The LANL site is usually windy and the proposed facility would not be located next door to another LANL facility. Members of the public would usually be several hundred feet away at the location of the maximally exposed individual. The differences in the DA's modeling assumptions and the conditions at LANL result in the accident analysis being more conservative than one that more accurately reflects LANL conditions. Therefore, the effects

of such a scenario, if it were to actually occur, would be less adverse at LANL than those hypothesized for a DA site.

The BDRP PEIS accident scenario is referred to as the Maximum Credible Event (MCE) in accordance with the DA's *Biological Defense Safety Program, Technical Safety Requirements* (32 CFR 627). The microorganism chosen for the MCE accident is *Coxiella burnetii (C. burnetii)*, the organism responsible for causing Q fever. According to the *Control of Communicable Diseases Manual* (Benenson 1995), this organism has an unusual stability, can reach high concentrations in animal environments, and is relatively resistant to many disinfectants. The CDC states that *Coxiella burnetii* probably presents the greatest risk of laboratory infection. The organism is highly infectious and remarkably resistant to drying and environmental conditions. The estimated HID with a 25 to 50 percent chance of containing the disease through the inhalation route for Q fever is 10 organisms (CDC 1999).

The rickettsial microorganism*, C. burnetii,* is considered representative of all types of BSL-1, BSL-2, and BSL-3 laboratory microorganisms (bacteria, rickettsia, viruses, fungi, parasites, and prions) because it is highly durable, infectious, and transmissible, and has excellent environmental survivability. Other types of microorganisms were considered for accident scenarios but rejected for specific analysis because they represent a relatively lower human health hazard (fungi and parasites) or have a generally lower environmental survivability (specifically, the prions and viruses). All prions and parasites are BSL-1 or BSL-2 microorganisms. Only one fungus identified by the CDC requires BSL-3 and all the rest are BSL-2 or below (CDC 1999). Many viruses require BSL-3 but cannot survive long in the environment without a host such as a human or other animal. Bacteria and their subcategory, rickettsia, represent a high risk to human health and many require BSL-3 or BSL-4.

Of the bacteria, *C. burnetii* is a durable rickettsia that can be handled in the laboratory with little or no loss in viability. It can survive being aerosolized and remain viable, although once separated from a nutrient food source, it dies off at a slow rate. This microorganism can be as infectious as any other microorganism. The CDC reports that exposure to only 10 microorganisms can cause an individual with normal immunocompetancy to develop symptoms of disease. Others report this to be as low as five microorganisms or possibly even one (CDC 2001b). *C. burnetii* has the added advantage of being one of the CDC select agents (42 CFR 72) and is considered a critical biological agent[26] (CDC 2000a).

The scenario for the MCE (detailed in Appendix F) involves an instantaneous release of a fixed amount of infectious material as follows. A worker uses a BSC to place a 1-L slurry of *C. burnetii* into six 250 ml polypropylene centrifuge tubes. The worker fails to insert the O-rings or tighten the centrifuge caps which are the screw-on type. The worker takes the tubes

[26] The CDC Strategic Planning Workgroup has prepared a plan to address the deliberate dissemination of biological and chemical agents. Certain organisms are designated as "critical biological agents" and are assigned priority ratings based on characteristics that pose a risk to national security.

out of the BSC and inserts them into a free-standing centrifuge and turns the equipment on. All six tubes leak, with some of the slurry leaking into the rotor, and some leaks into the centrifuge compartment. Most of the slurry that is not aerosolized settles (99 percent) and 90 percent of that which settles becomes droplets inside the chamber. The worker opens the centrifuge and notices the leak. The worker obtains help from two workers, and four more workers enter the laboratory not knowing what has happened. The room air exhausts to the outside of the building through a stack on the roof after passing through two sets of HEPA filters that, for conservatism, were estimated to have a filter efficiency of 95 percent.

For the workers, the accident produces 9,900,000,000 (9.9×10^9) airborne HIDs at a 50 percent rate of contracting the disease (HID_{50} or ID_{50}) which occurs in a 3 ft^3 of space above and around the centrifuge. This volume of contaminated air then disperses throughout the room in response to the ventilation system flow characteristics (for example, the volume of air in the room and the HVAC ducting, and the room air turnover rates). The excited worker who opened the centrifuge is potentially exposed to 100,000 HID_{50} due to a higher rate of respiration at l5 L or 0.5 ft^3 per minute (normal is 4 to 6 L or 0.14 to 0.21 ft^3) (NSC 1996). The two co-workers coming to his assistance receive an only slightly lower dose. The other four workers incidentally exposed receive 100 to 300 HID_{50}.

The result to the general public was calculated by this scenario using a gaussian plume dispersion model under relatively calm wind conditions (stronger winds would dilute more readily). At the maximum air-concentration described above the model predicted less than 1 HID_{50} per liter of air at a distance of less than 7 ft (2 m) from the stack, less than 0.1 HID_{50} per liter of air at 53 ft (16 m) from the stack, and less than 0.01 HID_{50} per liter of air at a distance of 125 ft (38 m) from the stack. The concentrations dissipate readily after reaching these maximums since the accident scenario resulted in a one-time instantaneous release.

While not specifically mentioned in the PEIS, some conclusions can be drawn for the proposed LANL BSL-3 facility comparison. One is that members of the public would have a very low likelihood of being exposed to 1 HID_{50} due to the fact that this facility would be behind security fences that would be constructed at a distance of tens of feet away from the building. One very conservative assumption used in the model is the 95 percent filter efficiency resulting from filter failure. The HEPA filter for the proposed LANL facility would be much more efficient. *C. burnetii* would be effectively 100 percent removed even on a single-pass filtration. Adverse health effects to the public would be extremely unlikely to develop from this scenario. Similarly, adverse effects to the environment from the accidental release of non-indigenous organisms would be extremely unlikely as well.

4.2.2.2 Transportation Accident

Infectious substances (etiologic agents) in transit on the Nation's highways, railways, and airports are regulated by the U.S. Department of Transportation (DOT) regulations (49 CFR 171, 172, 173, and 178). These regulations are described in Appendix G-1. As a consequence of these regulations the DOT tracks and reports accidents and, in particular,

hazardous materials incident reports. The general population risk report by DOT from 1994 to 1998 from all hazardous materials transportation is 1 in 8,129,000, or as otherwise stated, 0.11 fatalities per million shipments (DOT 2001a). By comparison, the general population risk per year for motor vehicle accidents is 1 in 6,300 or 1.7 deaths per 100 million vehicle miles (161 million kilometers). The number of hazardous materials shipments is about 800,000 per day with at least 10,000 involving waste hazardous materials identified generally as medical wastes and various other hazardous materials. For the hazardous materials category that includes infectious substances, about 80 percent of these shipments are carried by truck with the remainder carried by rail (DOT 1998). There are an estimated 4,300 non-hospital waste generating facilities (laboratories) that are potential generators of medical waste and other kinds of infectious substances including diagnostics specimens. These facilities generate 73,037 tons per year of infectious medical waste and ship about 200 tons (181,000 kg) per day (DOT 1998). Additional detailed information is included in Appendix G-1.

Information extracted from the DOT Hazardous Materials Information System (HMIS) database (DOT 2001b) is shown in Appendix G-2. Information available on infectious substances transportation from 1995 to 1999 show that infectious substance incidents are too few to even be ranked except from some minor injuries that occurred in 1999. The number of infectious substance incidents from 1995 through 1999, is respectively, 2, 3, 9, 10, and 166. While low and not substantial in comparison to all other hazardous materials accidents, it is unknown why there is an apparent increasing trend. Only three minor injuries were reported in association with the incidents in 1999 and none resulted in infectious material exposures. Most of the accidents were due to human error and occurred on loading docks. New Mexico has consistently had about 1 percent of all hazardous materials incidents which is less than the neighboring states of Arizona and Colorado which range from 1 to 3 percent of the national incidents each year. Texas, which is very industrialized, tends to vary between 7 an 8 percent, nationally. There is also an apparent national increase in hazardous materials incidents, which rose from 14,700 in 1995 to 17,069 in 1999.

Accidents due to transportation of microorganisms are not expected to increase due to the Proposed Action. The addition of milliliter quantity samples shipped to and from the BSL-3 facility through the U.S. Postal Service or by commercial or private courier would not be expected to change the overall incidence of risk of transportation accidents. Samples could consist of cells in media contained within DOT-certified packages. The consequences of such accidents would be anticipated to be minor, based on the historical data.

4.2.2.3 Terrorist Action

Terrorist threats to LANL operations are taken very seriously by NNSA and UC. Sabotage as a threat to activities within DOE is an unfortunate but practical consideration in operations. DOE orders define the systematic approach used to address such threats at DOE and NNSA facilities. Graded protection is provided for all safeguard and security interests, classified matter, property and sensitive information from theft, diversion, industrial

sabotage, radiological sabotage, espionage, unauthorized access or modification, loss or compromise, or other hostile acts that could cause unacceptable adverse impacts on national security, our business partners, or on the health and safety of employees and the public. The defense-in-depth approach includes definition of the threat(s), vulnerability analyses, and a safeguards and security program that provides for numerous features designed to negate such threats through materials accountability, threat detection and assessment, a highly trained security force, and a variety of facility protective features. These systems are audited and tested periodically to ensure that high standards are applied and that the systems established are effective in addressing the threat of sabotage at a DOE or NNSA site.

Site specific security measures would be part of the Proposed Action as noted in Chapter 2 of this EA. Scenarios involving a deliberate terrorist attack are not considered and evaluated in the same way as potential accidents in a NEPA analysis. These latter events lend themselves to a conventional approach of qualitative or quantitative analyses of probability and consequence, so that the Federal Manager, and members of the public, can see the residual risks posed by the activity to the workers, public, and environment as required by NEPA. Other factors are considered by the Federal Manager in making decisions on potential actions, including mission compatibility, personnel resources, budget constraints, and infrastructure and security concerns. Terrorist scenarios are evaluated in security processes that evaluate potential threats and that then design measures to counteract these potential threats. The potential for terrorist attacks to postal workers or facilities, or other courier services would be minor. It is the responsibility of these organizations to safeguard their operations from theft and attack.

4.3 PREFABRICATION ALTERNATIVE

Construction: The environmental effects that would be likely to result from installing prefabricated units together to form the BSL-3 facility would be very similar to the effects from constructing the permanent BSL-3 facility onsite. The general type of machinery involved in the effort and the emissions would be almost the same for both alternatives; earth moving equipment would be required to clear the site; trucks and cranes would be required to set the modular units into place; hand-held tools would be required to join them together and finish them. Cement trucks may be brought onsite to install footer walls or a concrete pad. Potential air quality effects would be almost the same for both the Proposed Action and the Prefabrication Alternative. All other resource area effects would be the same from the construction stage.

Operations. The operation of the BSL-3 facility, if it were constructed of modular units, would be the same as for the Proposed Action. Effects discussed in Chapter 4, Section 4.1 are descriptive of the effects that could be expected from implementing the Prefabrication Alternative.

4.4 PARTIAL PREFABRICATION/BUILD ALTERNATIVE

Construction. The environmental effects that would be likely to result from installing a single prefabricated unit to serve as a BSL-3 laboratory while constructing the permanent BSL-3 facility onsite would be an additive to the Proposed Action alone. Implementing the Partial Prefabrication/Build Alternative would potentially require clearing of two previously disturbed sites instead of just one, and the installation of utilities to both sites instead of one. Additional air emissions would occur at both construction sites from heavy machinery used on construction effects at the sites. However, even with the small increase in emissions, the incremental effects would be negligible. Waste production would be slightly greater but the incremental effects would be negligible. Human health effects as a result of additional site worker activities is also expected to be negligible.

Operations. The operations of the BSL-3 laboratory would phase out as the new BSL-3 facility commenced operations. The overall result of implementing the Partial Prefabrication/Build Alternative would be to move up the time period of effects from the operation of such a facility by about one year in time. Otherwise the effects of the operation of the Proposed Action facility and the laboratory and facility described in the Partial Prefabrication/Build Alternative would be the same.

4.5 ENVIRONMENTAL CONSEQUENCES OF THE NO ACTION ALTERNATIVE

Under this alternative, LANL would continue contracting out all of the work proposed for the BSL-3 laboratory with no change in the level of operations at LANL. Optional site locations would not be used for construction and operation of the facility, and no site preparation or construction would occur. There would be no change from the current conditions with respect to human health, ecological resources, transportation, waste management, utilities and infrastructure, noise, geology, soils, seismicity, visual resources, or air quality.

However, there are some socioeconomic consequences of the *status quo*. Revenue to the contracted laboratories of $300,000 per year has a compounded positive effect in those communities ($450,000 using socioeconomic multipliers) by continuing to support employment at those locations, generating revenue for those businesses and organizations, and supporting a local, state, and Federal tax base (if other than non-profit) that helps support schools and other community infrastructure. Conversely, since that revenue is coming from LANL and going to another geographic area, it is a continuing revenue loss at the LANL area. While not considered a resource area, continuing problems with the quality of data produced by these outside laboratories (part of the purpose and need for action) could affect the ability of UC to conduct research on BSL-3 organisms and may additionally adversely effect NNSA's security mission capabilities.

5.0 CUMULATIVE EFFECTS

Cumulative effects on the environment result from the incremental effect of an action when added to other past, present, and reasonably foreseeable future actions, regardless of what agency or person undertakes them. These effects can result from individually minor, but collectively significant, actions taking place over a period of time (40 CFR 1508.7). This section considers the cumulative effects resulting from the implementation of the Proposed Action and reasonably foreseeable future actions in the TA-3 area and adjacent lands.

LANL Operations at TA-3 and TA-58. No new types of operations and few new personnel would be introduced into LANL as a result of the Proposed Action. Land use within TA-3 and TA-58 would remain unchanged. Local traffic congestion centered around West Jemez Road, Diamond Drive, East Jemez Road, and Casa Grande Drive would be affected by the addition of approximately 42 vehicle trips per day (assuming 0.45 cars per employee) during each morning and evening rush hour. The addition of the SCC, the NISC and the Research Park (located within the northern edge of TA-3 on property leased by the Los Alamos Economic Development Corporation that is within the LANL boundaries) will increase the TA-3 traffic congestion. Use of these facilities will add an estimated total of 2,300 to 3,000 vehicle trips per day when all three facilities are completed. SCC and NISC are scheduled to be completed in 2002 and 2001 respectively; the Research Park is planned to be completed by 2009. The TA-3 area already suffers from over-crowded intersections during rush hours. This problem will become more severe as the Research Park, especially, is completely developed. There may be a slight delay thereafter until full occupancy is achieved; the first building in the Research Park was completed in March 2001 and is expected to provide space for 300 to 400 workers. Additionally, within the next 4 to 5 years, construction of a new office building to replace the current DOE Los Alamos Area Office (LAAO) Building at TA-43 is being contemplated for TA-3. This would add about 100 new workers to the TA-3 traffic burden. Traffic studies of TA-3 have already identified several recommended changes that would help alleviate the traffic congestion within this area, but no road realignment work has been proposed and funded yet. It is anticipated that this may occur at some future date within the next decade.

Parking availability in the TA-3 general area would change from the current configuration due to the effects of new reconfiguration of industrial uses taking place over the next 10 years. The Proposed Action would not alter the overall TA-3 parking space availability. The addition of about 780 new parking spaces due to the combined relocation of government vehicle parking and the new parking structure that is a part of the proposed Building 3-43 replacement project would benefit the entire TA-3 area. Upon completion of the SCC and NISC, additional parking space that is now unavailable, due to its being used for equipment and building material lay down areas, will become available for vehicle parking. The Research Park will have its own parking spaces and will therefore have no affect on the rest of TA-3's parking needs. The new DOE LAAO Building would have its own parking for the 100 additional workers it would bring to TA-3 but may eliminate a number of parking spaces

currently used at that site. Other additional construction and demolition work conducted over the next 10 years within TA-3 would include several relatively minor activities that are anticipated to result in little overall effect with regards to parking space availability or needs. Actions would likely include the construction and removal of several small buildings and structures, and the decontamination and decommissioning of some other facilities.

The overall visual quality within TA-3 and TA-58 would change with the soon-to-be-completed SCC, NISC and Research Park structures. These buildings are anticipated to be constructed using modern designs and construction materials; as the first major buildings constructed in the last 40 years within TA-3, they are noticeably different from the designs and materials used in the older structures that make up the bulk of the TA-3 area. The addition of the new office building, parking structure and lecture hall proposed for the Building 3-43 replacement project would contribute further to the visual improvements in the TA-3 area, as would the demolition of the old Building 3-43. From a distance, though, the SCC, NISC, Research Park and the new office building and parking structure would cause an increase in the number of visually disruptive elements against the natural lines of the background landscape. The minor negative effects on viewsheds of regional development and slight increased lighting in the night sky would be considered a regional impact. The Proposed Action is not expected to be a major contributor to this effect; however, the building would be one-story and would therefore not be visible above the building outlines of nearby structures. Additionally, the parking area and the BSL-3 facility would require little nighttime lighting and those lights required would be designed to shine downward toward the parking lot and ground surfaces and away from the canyon bottom.

Implementing the Proposed Action would generate noise primarily during the daytime hours during construction activities. This noise generation would be mostly confined to the immediate TA-3 area of generation and would be mostly heard by the involved workers. However, there may be additional noise generation occurring at the Research Park at TA-3 within the same time period. Cumulatively, this noise may be audible for short periods of time during the daytime hours to workers within TA-3 and possibly beyond TA-3. Due to the general manner in which sound attenuates across mesas and canyons, residents located across the canyon from TA-3 should not be disturbed by the sounds originating there from these projects.

The Proposed Action, together with other planned or ongoing construction activities at LANL, are expected to have a cumulative benign or even beneficial effect on worker health at LANL under normal operations. Potential adverse health effects to construction workers should be minimal and cumulative; beneficial or adverse effects on public health are not expected to occur under normal conditions.

Workers at LANL would benefit from the replacement of facilities with new structures that meet current DOE and Uniform Building Codes and working conditions would be further enhanced by construction activities at LANL. Improved parking conditions within the TA-3 general area would also reduce the risk of pedestrian and automobile accidents from all

activities conducted. The cumulative increase in the amount of construction activity would increase the risk of construction worker injuries. However, because of rigorous health and safety requirements at LANL and based on industry injury rates of 0.04 deaths per 100 full-time construction workers, the potential for a major injury or fatality from all new construction activities at LANL would be expected to remain low. Since members of the public do not live or work in the vicinity of the Proposed Action or other new facilities at LANL, they would not be affected by these activities.

Nearby Areas Within LANL and Off-site Areas Administered by Others. Other activities that will likely occur at or nearby LANL over the next 10 years include the conveyance of most of TA-43 to Los Alamos County; the subsequent demolition of the existing DOE LAAO Building at TA-43; and the construction of new multi-story residential units in place of the DOE LAAO Building and over its immediately surrounding area. Construction of housing within Los Alamos County to replace housing units lost during the 2000 Cerro Grande Fire will likely continue over the next several years (until or through about 2005). These actions will add to the overall amount of construction activities within Los Alamos County and the number and availability of construction materials, workers and local housing in the vicinity. Traffic into and out of Los Alamos County is expected to increase over the status-quo due to the trips made by construction workers and the transport of materials. The visual character of the newly constructed buildings is expected to have a slight positive effect on the visual character of LANL and Los Alamos County, and is expected to only result in a very slight increase in nighttime lighting of the area. The overall footprint of urban development within Los Alamos County is expected to change slightly over the next 10 to 15 years with the possible development of Rendeja Canyon as contemplated by the County of Los Alamos when DOE conveys that tract to the County for their use (anticipated to occur before the end of 2007).

LANL, the U.S. Forest Service, BNM and Los Alamos County will all be conducting wildfire hazard reduction activities that will include forest thinning activities over the Pajarito Plateau (including within LANL) and possibly some prescription burns outside the areas of immediate LANL and urban interfaces within the forested areas nearby. The resulting forest areas in and around LANL will be much more open in appearance than currently, and the hazard from wildfires is expected to be reduced; although wildfires would still occur, they would be much easier to bring under control and manage as lower and mid-level fires rather than as crown fires of the type exemplified by the Cerro Grande Fire. Within LANL, forests will be managed according to the Wildfire Hazard Reduction and Forest Health Improvement Program, with specific project plans, such as the Wildfire Hazard Reduction Project Plan (LANL 2001m).

Use of the forest areas west and south of LANL and Los Alamos County for recreation, habitat management purposes, and timber production (only within the Santa Fe National Forest) should remain unchanged. Critical Habitat Areas for the Mexican spotted owl have been established by the U.S. Fish and Wildlife Service within the Pajarito Plateau areas outside of LANL. One area within LANL has been identified as being occupied by the

Mexican spotted owl as well. These areas will continue to be managed for the foreseeable future as appropriate for recovery of that species. Within LANL, potential or occupied habitat of federally-protected threatened or endangered species is managed in accordance with the LANL Threatened and Endangered Species Habitat Management Plan. Additional management plans for biota at LANL are being developed cooperatively by DOE and UC.

Within LANL, it is contemplated that there may be some facility construction over the next 10 years in the vicinity of TA-55. One Proposed Action is to build a new building at TA-55 to house the TA-18 critical assembly and material storage operations. Another Proposed Action is to construct a new electric power line from the general White Rock area upslope to the TA-8 area. Contemplated actions include possible building construction within the general TA-55 area of a replacement or partial replacement building for the activities conducted with the existing TA-3 Chemistry and Metallurgy Research (CMR) Building (with the demolition of the existing CMR Building possible) and the possible construction of a new building for pit manufacturing use (these actions are speculative at this time but are currently under general discussion). Also, there is general discussion and contemplation of a new waste management facility within TA-50 (next to TA-55). Proposed actions elsewhere within LANL include the decontamination and decommissioning of TA-18 facilities within Pajarito Canyon, and their possible demolition (in whole or in part); the demolition of the TA-2 and TA-41 structures and buildings within Los Alamos Canyon; and some small-scale building and structure construction and demolition activities within the TA-8 and TA-16 areas. Additional construction and demolition actions may be proposed at TA-3, TA-55 and other TAs at LANL to replace aging structures and facilities; these are currently only contemplated in very general terms. These generally contemplated actions could include some additional construction and demolition work as infrastructure, structures, and buildings approach 50 years of continuous use. Some of the facilities may include demolition of the CMR Building.

The overall footprint of development within LANL is expected to be only slightly expanded over the next 10 to 15 years. Overall, electric utility use and potable water use within LANL is expected to remain fairly constant after the SCC comes on line. Actions taken by UC to reduce usage of water and generation of waste during operations should actually decrease as various reuses of wastewater and waste materials is undertaken over the next several years. The recycling of treated effluent water from the LANL sewage treatment plant at the cooling towers for SCC is the first step.

Waste volume generation during the next 10 years from decontamination, decommissioning, and demolition of buildings and through environmental restoration efforts will be large. The waste will likely be of a variety of types including non-hazardous waste, hazardous wastes, mixed wastes, and radioactive wastes (of both low-level and transuranic [TRU] wastes). The Los Alamos County Landfill is expected to be closed within the next 3 years although this is not due to its having been filled to its capacity. LANL and Los Alamos County will have to contract for waste disposal with another solid waste disposal facility offsite. Low-level radioactive waste is disposed of at Area G at LANL; this disposal site has adequate room to

accommodate waste generation estimates beyond the next 10 years as identified in the 1999 LANL SWEIS (DOE 1999a) and Record of Decision (ROD) (DOE 1999c). TRU waste generated at LANL from environmental restoration activities would be managed and stored at LANL, but no disposal path is currently available for this non-defense generated waste type. Mixed wastes (both low-level mixed and TRU-mixed wastes) are managed and stored at LANL; there is currently no disposal of this waste type available. Hazardous wastes generated at LANL are managed and stored onsite and shipped offsite for treatment and disposal as adequate and appropriate facilities become available. Detailed projections of wastes by types are provided in the 1997 *Final Waste Management Programmatic Environmental Impact Statement for Managing Treatment, Storage, and Disposal of Radioactive and Hazardous Waste* (DOE 1997d) and DOE's subsequent RODs based on that analysis. Additionally, the waste generated at LANL over the next 10 years will be managed in accordance with the analysis provided in the 1999 LANL SWEIS and the DOE's ROD. The implementation of the Proposed Action considered in this EA together with other site waste generations would be in accordance with DOE's RODs and is not expected to result in any waste generation projection exceedences. Cleanup from the Cerro Grande Fire has mostly been accomplished; waste generation within the County of Los Alamos peaked in mid to late 2000 and early 2001. Waste generation is now within its historical range and no anticipated actions are expected that would result in greater than normal waste generation levels over the next 10 years.

Los Alamos County and LANL have historically been attainment areas for air quality with regards to criteria pollutants; also, visibility has always been excellent. Implementation of the Proposed Action is not expected to change the overall air quality of the Pajarito Plateau. With the anticipated increase in the number of acres of forest to be treated over the next 10 years across New Mexico, which will include the use of prescribed burns, the number of days when visibility may be lessened will increase but overall air quality should not be affected. The issuance of burn permits by the State of New Mexico will be coordinated so that burning in the immediate vicinity of LANL and Los Alamos County will be staggered among the agencies that use this treatment method. DOE does not currently use burning as a forest treatment method but may make a decision to do so within the next 10 years. If so, this forest treatment method would be coordinated with the State of New Mexico and the Interagency Wildfire Management Team, a cooperative organization of land stewards across the Pajarito Plateau formed to communicate and provide support and action recommendations.

Data and analysis of LANL surface and groundwater quality samples taken from test wells indicate that LANL operations and activities have influenced the surface water within LANL boundaries and some of the alluvial and intermediate perched zones within the LANL region. Detail on surface and groundwater quality can be found in the annual LANL Environmental Surveillance and Compliance Report (LANL 2000d). No LANL activities or projects are foreseen over the next 10 years that would cause an increase in deterioration of surface and groundwater quality in the region. Efforts underway to control erosion downstream from LANL and within the LANL boundaries resulting from the Cerro Grande Fire and its

recovery efforts are expected to address potential problems resulting from storm events until up-gradient vegetation has been reestablished.

Cultural resources are very prevalent over the Pajarito Plateau, particularly in the case of prehistoric sites. DOE and UC are in the process of developing the LANL Cultural Resource Management Plan; this plan will eventually include a detailed assessment of LANL's cultural resources. The Proposed Action is not expected to effect any cultural resources, nor would its implementation result in any changes to the resource management anticipated.

6.0 AGENCIES AND PERSONS CONSULTED

In the process of preparing this EA, DOE had discussions with various federal agencies and organizations including the CDC, NIH, General Services Agency (GSA), U.S. Department of the Army (DA), Utah Department of Environmental Quality, Colorado State University, and Lawrence Livermore National Laboratory. These contacts were made to gain an understanding about their respective experiences with BSL-3 laboratories and the operational and accident history of their own operations.

No consultation with the U.S. Fish and Wildlife Service was conducted in compliance with the *Endangered Species Act*, as the Proposed Action and alternatives would not be expected to affect either individuals of threatened or endangered species or their critical habitat. No consultation with the State Historic Preservation Office was conducted in compliance with the *National Historic Preservation Act* (36 CFR 800.5), as the Proposed Action and alternatives would not be expected to affect any cultural resource.

7.0 REFERENCES

7 CFR 330: Title 7 U.S. Code of Federal Regulations Part 330, "Agriculture, Chapter III – Animal and Plant Health Inspection Service, Department of Agriculture, Federal plant and pest regulations; general; plant pests; soil; stone, and quarry products; garbage," Washington, DC (January 1, 2001).

9 CFR 92: Title 9 U.S. Code of Federal Regulations Parts 92, 94, 95, 96, 122, and 130, "Animals and Animal Products, Chapter I – Animal and Plant Health Inspection Service, Department of Agriculture," Washington, DC (January 1, 2001).

10 CFR 835: Title 10 U.S. Code of Federal Regulations Part 835, "Occupational Radiation Protection; Final Rule," U.S. Department of Energy, Washington, D.C. (December 14, 1993).

10 CFR 1021: Title 10 U.S. Code of Federal Regulations, U.S. Department of Energy, "National Environmental Policy Act Implementing Procedures, "Washington, DC (January 1, 1999).

15 CFR 730: Title 15 U.S. Code of Federal Regulations Parts 730-799, "Regulations Relating to Commerce and Foreign Trade, Chapter VII – Bureau of Export Administration, Department of Commerce," Washington, DC (January 1, 2001).

20 NMAC 2.70-2.72: Title 20 New Mexico Administrative Code, Chapter 2, *Air Quality*, Parts 2.70 through 2.72, "Construction Permits," Santa Fe, NM.

20 NMAC 9.1: Title 20 New Mexico Administrative Code Part 9.1, VII. 706 Infectious Waste, Santa Fe, NM (January 30, 1992).

29 CFR 1910.1030: Title 29 U.S. Code of Federal Regulations Part 1910, Section 1030, "Bloodborne Pathogens," Washington, DC, with amendments as of (January 1, 2001).

29 CFR 1910.12: Title 29 U.S. Code of Federal Regulations Part 1910, Section 12, "Construction Work," Washington, DC, with amendments as of (January 1, 2001).

29 CFR 1910.95: Title 29 U.S. Code of Federal Regulations Part 1910, Section 95, "Occupational Noise Exposure," Washington, DC, with amendments as of (January 1, 2001).

29 CFR 1926: Title 29 U.S. Code of Federal Regulations Part 1926, "Occupational Safety and Health Standards for the Construction Industry," Washington, DC, with amendments as of (January 1, 2001).

29 CFR 1990: Title 29 Code of Federal Regulations Part 1990, "Identification, Classification, and Regulation of Potential Occupational Carcinogens," Washington, DC, with amendments as of (January 1, 2001).

32 CFR 627: Title 32 U.S. Code of Federal Regulations Part 627, U.S. Department of the Army, "The Biological Defense Safety Program, Technical Safety Requirements (DA Pamphlet 385-69)," Washington, DC (July 1, 2000).

36 CFR 800.5: Title 36 U.S. Code of Federal Regulations Part 800.5, National Archives and Records Administration, "Parks, Forests, and Public Property" Chapter VIII, "Advisory Council on Historic Preservation," Washington, DC (January 1, 1998).

39 CFR 111: Title 39 U.S. Code of Federal Regulations Part 111, U.S. Postal Service, "General Information on Postal Service," and incorporation by reference the *Domestic Mail Manual*, Washington, DC (July 1, 2000).

40 CFR 9: Title 40 U.S. Code of Federal Regulations Part 9, U.S. Environmental Protection Agency, "OMB Approvals Under the Paperwork Reduction Act," Washington, DC.

40 CFR 141-142: Title 40 U.S. Code of Federal Regulations Parts 141-142, U.S. Environmental Protection Agency, "National Primary Drinking Water Regulations" and "National Primary Drinking Water Regulations Implementation," Washington, DC.

40 CFR 1500-1508: Title 40 U.S. Code of Federal Regulations, Council on Environmental Quality, Executive Office of the President, "Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act," (Reprint 1992).

40 CFR 261: Title 40 U.S. Code of Federal Regulations Parts 261 through 272, U.S. Environmental Protection Agency, "Resource Conservation and Recovery Act," Washington, DC (1976).

40 CFR 300: Title 40 U.S. Code of Federal Regulations Parts 300, U.S. Environmental Protection Agency, "Comprehensive Environmental Response, Compensation, and Liability Act," Washington, DC (1980).

40 CFR 350: Title 40 U.S. Code of Federal Regulations Parts 350, 355, 370, and 372, U.S. Environmental Protection Agency, "Emergency Planning and Community Right-to-Know," Washington, DC (October 17, 1986).

42 CFR 71: Title 42 U.S. Code of Federal Regulations Part 71, "Foreign Quarantine," Washington, DC (October 1, 2000).

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APPENDIX A: CDC GUIDANCE ON BIOSAFETY LABORATORIES AND REGISTRATION REQUIREMENTS

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A.1 CDC BIOSAFETY LEVEL CRITERIA

The information in this appendix is taken from a Centers for Disease Control and Prevention (CDC) document which establishes the criteria for each Biosafety Level (BSL) of operation. This document, "Biosafety in Microbiological and Biomedical Laboratories" (CDC 1999), also known as the BMBL, presents the CDC and NIH recommendations and describes the combinations of standard and special microbiological practices, safety equipment, and facilities for Biosafety Level 1-4 laboratories. The BMBL "guidelines are now accepted as the international 'gold standard' for safely conducting microbiological research."

References to page numbers and appendices are for that document. References to the laboratory director should be interpreted as meaning the manager of the proposed BSL-3 facility. The following is excerpted from Section III of the BMBL, pages 17 through 36. References made within the following text to appendices refer to the BMBL document, not to the appendices of the EA.

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Laboratory Biosafety Level Criteria

The essential elements of the four biosafety levels for activities involving infectious microorganisms and laboratory animals are summarized in Tables 1of this section and Section IV (see pages 52 and 75). The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community.

Biosafety Level 1 (BSL-1)

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is neither required nor 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.

The following standard and special practices, safety equipment and facilities apply to agents assigned to Biosafety Level 1:

A. *Standard Microbiological Practices*

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments or work with cultures and specimens are in progress.

2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.

3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for hum an use are not permitted in the work areas. Persons who wear contact lenses in laboratories should also wear goggles or a face shield . Food is stored outside the work area in cabinets or refrigerators designated and used for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.

6. All procedures are performed carefully to minimize the creation of splashes or aerosols.

7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

8. All cultures, stocks, and other regulated wastes are de-contaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated outside of the immediate laboratory are pack-aged in accordance with applicable local, state, and federal regulations before removal from the facility.

9. A biohazard sign may be posted at the entrance to the laboratory whenever infectious agents are present. The sign may include the name of the agent(s) in use and the name and phone number of the investigator.

10. An insect and rodent control program is in effect (see Appendix G).

B. *Special Practices* None

C. *Safety Equipment (Primary Barriers)*

1. Special containment devices or equipment such as a biological safety cabinet are generally not required for manipulations of agents assigned to Biosafety Level 1.

2. It is recommended that laboratory coats, gowns, or uniforms be worn to prevent contamination or soiling of street clothes.

3. Gloves should be worn if the skin on the hands is broken or if a rash is present. Alternatives to powdered latex gloves should be available.

4. Protective eyewear should be worn for conduct of procedures in which splashes of microorganisms or other hazardous materials is anticipated.

D. *Laboratory Facilities (Secondary Barriers)*

1. Laboratories should have doors for access control.

2. Each laboratory contains a sink for hand washing.

3. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.

4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surface and equipment.

5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.

6. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

Biosafety Level 2 (BSL-2)

Biosafety Level 2 is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 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; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 2:

A. Standard Microbiological Practices

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.

3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.

6. All procedures are performed carefully to minimize the creation of splashes or aerosols.

7. Work surfaces are decontaminated on completion of work or at the end of the day and after any spill or splash of viable material with disinfectants that are effective against the agents of concern.

8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated off-site from the facility are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility.

9. An insect and rodent control program is in effect (see Appendix G).

B. Special Practices

1. Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents is in progress. In general, persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.

2. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements (e .g., immunization) may enter the laboratory.

3. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.

4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).

5. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

6. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

7. The laboratory director ensures that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural or policy changes.

8. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

    a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.

    b. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled

container for transport to a processing area for decontamination, preferably by autoclaving.

c. Syringes which re-sheathe the needle, needleless systems, and other safety devices are used when appropriate.

d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations.

9. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.

10. Laboratory equipment and work surfaces should be de-contaminated with an effective disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or pack aged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.

11. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

12. Animals not involved in the work being performed are not permitted in the lab.

Safety Equipment (Primary Barriers)

1. Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:

a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or embryonate eggs.

b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.

2. Face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC.

3. Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.

4. Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Disposable gloves are not washed, reused, or used for touching "clean" surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves.

D. *Laboratory Facilities* (Secondary Barriers)

1. Provide lockable doors for facilities that house restricted agents (as defined in 42 CFR 72.6).

2. Consider locating new laboratories away from public areas.

3. Each laboratory contains a sink for handwashing.

4. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are inappropriate.

5. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment.

6. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.

Chairs and other furniture used in laboratory work should be cove red with a non-fabric material that can be easily decontaminated.

7. Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause the biological safety cabinets to operate outside their parameters for containment. Locate biological safety cabinets away from doors, from windows that can be opened, from heavily traveled laboratory areas, and from other potentially disruptive equipment so as to maintain the biological safety cabinets' air flow parameters for containment.

8. An eyewash station is readily available.

9. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

10. There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside o f the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

Biosafety Level 3 (BSL-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 disease 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 competent 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 equipment. The laboratory has special engineering and design features.

It is recognized, however, that some existing facilities may not have all the facility features recommended for Biosafety Level 3 (i.e., double-door access zone and sealed penetrations). In this circumstance, an acceptable level of safety for the conduct of routine procedures, (e.g., diagnostic procedures involving the propagation of an agent for identification, typing, susceptibility testing, etc .), may be achieved in a Biosafety Level 2 facility, providing 1) the exhaust air from the laboratory room is discharged to the outdoors, 2) the ventilation to the laboratory is balanced to provide directional airflow into the room, 3) access to the laboratory is restricted when work is in progress, and 4) the recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed. The decision to implement this modification of Biosafety Level 3 recommendations should be made only by the laboratory director.

The following standard and special safety practices, equipment and facilities apply to agents assigned to Biosafety Level 3:

A. *Standard Microbiological Practices*

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

2. Persons wash their hands after handling infectious materials, after removing gloves, and when they leave the laboratory.

3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear con tact lenses in laboratories should also wear goggles or a face shield. Food is stored out-side the work area in cabinets or refrigerators designated for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.

6. All procedures are performed carefully to minimize the creation of aerosols.

7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

9. An insect and rodent control program is in effect (see Appendix G).

B. *Special Practices*

1. Laboratory doors are kept closed when experiments are in progress.

2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at

risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. No minors should be allowed in the laboratory.

3. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms.

4. When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be periodically collected, depending on the agents handled or the function of the laboratory.

7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

8. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural changes.

9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

    a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic-ware should be substituted for glassware whenever possible.

    b. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

    c. Syringes which re-sheathe the needle, needleless systems, and other safe devices are used when appropriate.

    d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

11. All open manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination with infectious materials.

    a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.

b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

13. Cultures, tissues, specimens of body fluids, or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories are decontaminated before disposal or reuse.

15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

C. *Safety Equipment* (Primary Barriers)

1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overtly contaminated.

2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

4. All manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs , etc., are conducted in a Class II or C lass III biological safety cabinet (see Appendix A).

5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

6. Respiratory and face protection are used when in rooms containing infected animals.

D. *Laboratory Facilities* (Secondary Barriers)

1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable (see Appendix F). A clothes change room may be included in the passageway.

2. Each laboratory room contains a sink for handwashing. The sink is hands-free or automatically operated and is located near the room exit door.

3. The interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

6. All windows in the laboratory are closed and sealed.

7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

9. A ducted exhaust air ventilation system is provided. This system creates directional airflow which draws air into the laboratory from "clean" areas and

toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

10. HEPA-filtered exhaust air from a Class II biologic al safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets (see Appendix A).

11. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

13. An eyewash station is readily available inside the laboratory.

14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

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A.2 CDC FACILITY REGISTRATION FOR TRANSFER OR RECEIPT OF SELECT AGENTS

The Regulation. Title 42 CFR Part 72.6 (Additional Requirements for Facilities Transferring or Receiving Select Agents) stems from the "Antiterrorism and Effective Death Penalty Act of 1996" (50 U.S.C. § 2301) which requires the Secretary of Health and Human Services to regulate the transfer of certain biological agents ("select agents") harmful to humans. The CDC is responsible to the Secretary for the management of the LR/SAT Program.

Background. *The Antiterrorism and Effective Death Penalty Act* of 1996, enacted on April 24, 1996, established new provisions to regulate transfer of hazardous agents and required HHS to issue rules to implement these provisions. The final rule was published in the Federal Register on October 24, 1996 and will become effective April 15, 1997. To comply with the final rule, commercial suppliers of select agents, as well as Government agencies, universities, research institutions, individuals, and private companies that transfer or obtain these agents, must register with the CDC. The rule also authorizes CDC to inspect those facilities seeking registration to determine whether the applicant facility meets the appropriate BSL requirements. In return for the certification and inspection, facilities are responsible for a site registration fee. This notice lays out those fees and provides technical clarification of related matters in the regulation.

Definitions. A facility is defined in 42 CFR 72.6(j) "as any individual or Government Agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a select agent subject to this part." For the purpose of assessing the site registration fees, facilities are broken down into three categories, small, medium, and large, depending upon the size of the facility, the number of personnel working in the facility, and the amount of work done in the facility. A small facility has one laboratory area including a BSC and supporting supplies and equipment, or one room housing one or more animals (animal room) doing work with one select agent, or group of closely related select agents, at one BSL, by one principal investigator and his/her support staff. If the one laboratory area is used by more than one principal investigator or for more than one select agent or group of closely related select agents, the facility is a medium facility, which has laboratory areas and may have animal rooms that total between two and five rooms. All laboratories must be under the supervision of one responsible facility official and must be located in the same single geographic site. These laboratories shall be used by no more than five principal investigators and their support staffs, for work on no more than five select agents/groups of closely related select agents during the 3-year registration period. If more than five principal investigators work in the laboratories or more than five select agents (or groups of closely related select agents) are used, the facility is a large facility. A large facility has laboratory areas and may have animal rooms that total more than five rooms. All laboratories must be under the supervision of one responsible facility official and must be located in the same single geographic site. Any facility working with select agents at BSL-4, whether small, medium or large, is assessed an additional fee. In addition, any facility that makes more than 50 select agent transfers per year, whether small, medium or large, is assessed an additional fee.

ADDITIONAL INFORMATION AND CLARIFICATION FROM CDC (WWW.CDC.GOV/OD/0HS/IRSAT/ADDINFO.HTM)

Overview: CDC has published regulations regarding access, use and transfer of select agents for research purposes. These regulations are designed to ensure these infectious agents and toxins are shipped only to institutions or individuals equipped to handle them appropriately and only to those who have legitimate reasons to use them, as well as to implement a system whereby scientists and researchers involved in legitimate research may continue transferring and receiving these agents without undue burdens.

The regulation includes six components:

1. A list of biological agents ("select agents") that have the potential to pose a severe threat to public health and safety. This list includes approximately 40 viruses, bacteria, rickettsia, fungi, and toxins whose transfer in the United States is controlled due to their capacity for causing substantial harm to human health.

2. Registration of facilities transferring these agents. Organizations that transfer or obtain these agents must register with the Secretary of HHS by providing sufficient information that the facility meets BSL requirements for working with the particular biological agent. Registered facilities will be issued a unique registration number to be used to validate all requests for transfer of these agents.

3. Process to document successful transfer of agents. The regulation requires both the shipping and receiving parties to complete an approved transfer form, which includes information on both parties, the agent being transferred, and the proposed use of the agent.

4. Verification procedures, including audit, quality control, and accountability mechanisms. Each facility shipping or receiving a select agent must have a "responsible facility official." This official must sign each request, certifying that the requestor of the agent is officially affiliated with the facility and that the laboratory meets guidelines for working with the requested agent. The "responsible facility official" sending the agent is required to verify that the receiving facility holds a currently valid registration number.

5. Agent disposal requirements. Facilities must have procedures in place for the appropriate disposal of select agents.

6. Research and clinical exemptions. Certain vaccine strains of select agents are exempt from the list of selected infectious agents. Transfer of clinical specimens for diagnostic, reference, or verification purposes is also exempt. Certain toxins, if used for research purposes, are exempt. Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, which utilize these select

agents for diagnostic, reference, verification or proficiency testing purposes, are exempt.

FACILITY REGISTRATION - SECONDARY SITES

Under the following conditions a secondary site could be covered under a single registration:

- The Responsible Facility Official is the same person at both facilities and would be available.
- The secondary facility meets the requirements set forth in 72.6 section "(j) Definitions" Facility", "... located at a single geographic site..." (e.g. same mailing address).
- Only personnel from the facility transport the select agent between the primary and secondary site.

If these conditions cannot be met, than the secondary site would have to register separately.

DESIGNATION OF AN ALTERNATE "RESPONSIBLE FACILITY OFFICIAL"

For the purposes of this regulation, the CDC recognizes a single person as the responsible facility official. The CDC realizes that this may not be practical in certain cases. As such, the CDC recommends that the responsible facility official designate one or more alternates and provide to the CDCs office those names in case there would be a need to verify an EA-101, the CDC would have the designated alternates on file. The designated alternate responsible facility official must also meet the requirements set forth in section "(j) Definitions" for "Responsible facility official" as follows:

"Responsible facility official means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility."

ATTENUATED STRAINS AND REQUESTS FOR EXEMPTIONS

The following statement is from the preamble of 42 CFR 72.6: *"CDC has determined that it is premature to issue blanket exemptions of attenuated, avirulent, or less pathogenic strains of agents on the restricted list at this time. Attenuated strains of select agents approved for human vaccination purposes by FDA or other recognized national or international organizations will be exempt. All other attenuated, avirulent, or less pathogenic strains will not be exempt at this time."*

The CDC interprets this to apply to veterinary vaccination purposes as well. Therefore, if the attenuated strain of the select agent that LANL would be working with has been approved by FDA or USDA for vaccination purposes, or has received an Investigational New Drug license with supporting documentation of safety in humans, than the CDC would consider this strain to be exempt from this regulation. If the strain of the select agent LANL would be working with does not meet the above criteria, than it would still considered a select agent and would not be exempt from the regulation. In this case, LANL may apply for an exemption as described in Appendix A of Part 72.6, under the section "Additional Exemptions." Individuals seeking such an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. A committee of experts would be convened to review the merits of the request. The proposed exemption would be published in the Federal Register to inform the public and solicit comment. Pending the completion of this process and its outcome, use of the agent must be in compliance with 42 CFR Part 72.6.

APPENDIX B: INSPECTION OF DEPARTMENT OF ENERGY ACTIVITIES INVOLVING BIOLOGICAL SELECT AGENTS

DOE/IG-0492

INSPECTION REPORT

INSPECTION OF DEPARTMENT OF ENERGY ACTIVITIES INVOLVING BIOLOGICAL SELECT AGENTS

FEBRUARY 2001

U.S. DEPARTMENT OF ENERGY
OFFICE OF INSPECTOR GENERAL
OFFICE OF INSPECTIONS

U.S. DEPARTMENT OF ENERGY
Washington, DC 20585

February 2, 2001

MEMORANDUM FOR THE SECRETARY

FROM: Gregory H. Friedman /s/
Inspector General

SUBJECT: INFORMATION: Report on "Inspection of Department of Energy Activities Involving Biological Select Agents"

BACKGROUND

The Department of Energy's laboratories, including those managed by the National Nuclear Security Administration, conduct research involving biological select agents and select agent materials (e.g., DNA or select agents and subunits of toxins derived from select agents). For example, the laboratories are currently working to develop detection and response systems to improve preparedness in the event of a domestic attack involving the use of a biological select agent as a weapon of mass destruction. Biological select agents include about 40 viruses, bacteria, rickettsia, fungi, and toxins whose transfer within the United States is controlled. This is because such agents pose a substantial threat to public health and safety.

The objective of our inspection was to determine whether the Department has implemented appropriate environment, safety, and health measures regarding the possession and use of biological select agents and select agent materials. During our inspection, we issued four interim reports regarding the Department's biological select agent activities based on our determination that certain issues warranted immediate management attention.

RESULTS OF INSPECTION

We concluded that the Department's biological select agent activities lacked organization, coordination, and direction. Specifically, the Department's activities lacked appropriate Federal oversight, consistent policy, and standardized implementing procedures, resulting in the potential for greater risk to workers and possibly others from exposure to biological select agents and select agent materials.

For example:

- Safety and security officials, as well as senior management officials, at the Department's Albuquerque Operations Office (Albuquerque) were unaware of experiments involving biological select agents and select agent materials that were conducted at two Albuquerque laboratories.

- Some Department laboratories were not adhering to the Centers for Disease Control and Prevention (CDC) requirements in effect at the time of our review for registration of certain biological select agents and select agent materials.

- Procedures for conducting research activities involving biological select agents and select agent materials varied significantly among the Department's laboratories. The Department had not developed "best practices" to provide minimum guidance to laboratories for the conduct of their biological activities.

- The Department faces potential liability issues relating to the work of its contractors with biological agents, including liability arising from potential exposure of contractor employees who decline recommended immunizations.

- The Department's laboratories are not always receiving timely and consistent information regarding CDC registration requirements. This matter was coordinated with the Office of Inspector General at the U.S. Department of Health and Human Services.

While we consider these findings to be serious, we found no evidence that current activities had adversely impacted the safety and health of the public or of the Department's Federal or contractor workforce.

Further, during the course of our review the Department took certain actions to improve biosafety practices at its laboratories. For example, the Department of Energy Biosurety Working Group, which was chartered on September 29, 2000, is considering revisions to current policies and procedures governing potentially hazardous biological materials and select agents. Also, a biosurety program was initiated at Albuquerque to strengthen local safety and security protocols. In addition, CDC biological select agent registration requirements are being clarified, and communications concerning biological research activities have reportedly improved among Department Headquarters, the Operations Offices, the laboratories, and other Federal agencies. While these are positive steps, the potential risks associated with the use of biological select agents warrant continued senior management attention.

MANAGEMENT REACTION

The Department generally concurred with our recommendations and agreed to take corrective actions.

Attachment

cc: Under Secretary for Nuclear Security/Administrator for Nuclear Security
Acting Assistant Secretary for Environment, Safety and Health
Acting General Counsel
Acting Director, Chemical and Biological National Security Program

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Overview

INTRODUCTION AND OBJECTIVE

Department of Energy (DOE) programs include activities to prevent and detect the spread of weapons of mass destruction, which include biological select agents, and to respond to emergencies if these weapons are ever used. The Department's laboratories, which include laboratories managed by the National Nuclear Security Administration (NNSA), conduct research involving biological select agents and select agent materials (e.g., DNA of select agents and subunits of toxins derived from select agents). The research is to develop detection and response systems to improve preparedness in the event of a domestic attack involving biological select agents. The NNSA, which was created by the National Defense Authorization Act for Fiscal Year 2000, was established within DOE on March 1, 2000. The national security functions and activities performed by certain elements of the Department, including several DOE laboratories, were transferred to the NNSA. A number of our findings involving laboratories managed by the NNSA relate to circumstances existing prior to the establishment of the NNSA.

Biological select agents have the potential to pose a severe threat to public health and safety. They include about 40 viruses, bacteria, rickettsia, fungi, and toxins whose transfer within the United States (U.S.) is controlled due to their capability to cause substantial harm to human health.

The purpose of our inspection was to evaluate the environment, safety, and health protocols at DOE laboratories, including those managed by the NNSA, that conduct research with biological select agents and select agent materials. The objective was to determine whether the Department has implemented appropriate environment, safety, and health measures regarding the possession and use of those agents and agent materials.

OBSERVATIONS AND CONCLUSIONS

We found no evidence that the Department's current biological select agent activities have adversely impacted the safety and health of DOE and contractor employees or the public. However, we found that safety and security officials, as well as senior management officials, at the Department's Albuquerque Operations Office were unaware of experiments involving biological select agents and select agent materials that were conducted at two Albuquerque laboratories. We also found that some DOE laboratories were not adhering to the Centers for Disease Control and Prevention (CDC) requirements in effect at the time of our review regarding the registration of certain biological select agents and select agent materials. In addition, we found that procedures for conducting research activities involving biological select agents and select agent materials varied significantly among the Department's laboratories. We determined that the Department had not developed and implemented policies and procedures that (1) establish clear roles and responsibilities for the conduct of activities involving biological select agents and select agent materials, and (2) ensure DOE laboratories, including those managed by the NNSA, follow "best practices" for the conduct of their biological select agent activities. We observed that, in the absence of clear direction from the Department, there were inconsistencies among the Department's laboratories regarding procedures being implemented to conduct biological select agent and select agent material activities. The failure of some DOE laboratories to implement "best practices" for the conduct of their biological select agent and select agent material activities has the potential to increase the risk to employees of exposure to these agents and materials.

We concluded that there was insufficient organization, coordination, and direction in the Department's biological select agent activities. Specifically, the Department's activities lacked sufficient Federal oversight, consistent policy, and standardized implementing procedures, resulting in the potential for greater risk to workers and possibly others from exposure to biological select agents and select agent materials maintained by the Department. Also, we observed that, in view of an ongoing reevaluation by CDC of their earlier interpretations of registration requirements for biological select agents, and the lack of timely responses by CDC officials to requests for information/guidance, DOE laboratories may not be receiving timely and consistent information regarding CDC registration requirements. We discussed our observations regarding CDC with a senior official in the Office of Inspector General, Department of Health and Human Services, which has cognizance over CDC.

On August 23, 2000, we issued our preliminary inspection findings to the Department in an initial draft report entitled "Inspection of Department of Energy Activities Involving Biological Select Agents." We received comments from the Department on September 28, 2000, and October 23, 2000. The Department's comments were included, as appropriate, in our final draft report, which was provided to the Department on November 14, 2000, for additional comment.

On September 29, 2000, the Secretary of Energy approved the establishment of a "DOE Biosurety Working Group." The Working Group, which was subsequently established by the Assistant Secretary for Environment, Safety and Health (EH), is considering revisions to current policies and procedures governing potentially hazardous biological materials and select agents. The Working Group is also seeking to enhance communication between sites and programs involved in managing biological hazards, as well as between the Department and other Federal and non-Federal entities, and will call attention to best practices and lessons learned across the Department.

During our inspection, we consulted extensively with CDC officials, as well as with officials at the U.S. Army Edgewood Chemical Biological Center and the U.S. Army Medical Research Institute of Infectious Diseases. The U.S. Army, which conducts the U.S. Army Biological Defense Program on behalf of the Department of Defense, has developed extensive guidelines, laboratory protocols, and "best practices" for the conduct of experiments involving biological agents. These guidelines, protocols, and practices may well be instructive for development and implementation of an effective program within the Department.

BACKGROUND

The Department has a number of ongoing activities involving biological select agents and select agent materials. These agents and materials include *Bacillus anthracis* (*B. anthracis*), *Yersinia pestis* (*Y. pestis*), *Brucella abortus* (*B. abortus*), DNA of select agents, and toxins of select agents, such as botulinum and ricin toxin.[1] For example, the NNSA Office of Nonproliferation Research and Engineering (NN-20) manages the Department's Chemical and Biological National Security Program (CBNP). The purpose of the CBNP is to develop, demonstrate, and deliver systems and the supporting technologies that will lead to major improvements in the U.S. capability to prepare for and respond to domestic chemical or biological attacks. Also, Department laboratories are conducting

[1] *B. anthracis* is the organism that causes the disease known as anthrax. *Y. pestis* is the organism that causes the disease known as plague. *B. abortus* causes herd animals to abort their fetuses. Botulinum toxin is secreted by the organism *Clostridium botulinum*, while ricin toxin is secreted by the organism *Ricinus communis*. Both of these toxins are poisonous.

Work-for-Others programs, Laboratory Directed Research and Development (LDRD)[2] projects, and Cooperative Research and Development Agreement (CRADA)[3] projects involving biological select agents and select agent materials. Most of the Department's activities to date have involved select agent toxins,[4] DNA of biological select agents, and nonviable (attenuated or dead) forms of biological select agents.[5] However, activities by DOE laboratories, including those managed by the NNSA, are beginning to involve infectious (potentially lethal) forms of biological select agents that pose a greater risk to employees. For example, two of the Department's laboratories are currently receiving intact botulinum toxin for experimentation, while another laboratory has initiated experiments with the infectious form of *Y. pestis* and *B. anthracis*. Although exact funding amounts were not available, our review of the Department's budget suggested that the cost in FY 2000 of the Department's biological agent-related activities was in excess of $90 million. We understand that of this amount, approximately $7 million involved work with specific biological select agents and select agent DNA.

The shipment, transfer, and receipt of biological select agents and select agent materials are controlled by CDC in accordance with Part 72, Title 42, Code of Federal Regulations (42 CFR Part 72). Prior to transferring or receiving a biological select agent or select agent material, a facility must register with CDC as being equipped and capable of handling that agent or material at the appropriate biosafety level. The CDC regulations are designed to assure that biological select agents and select agent materials are transferred only to facilities equipped to handle them properly, and only to those facilities that have legitimate reasons to use them. 42 CFR Part 72 also incorporates, by reference, the requirements in CDC's publication entitled "Biosafety in Microbiological and Biomedical Laboratories" (BMBL). The BMBL describes coordination of microbiological practices, laboratory facilities, and safety equipment, and recommends their use in four biosafety levels of laboratory operation with select agents infectious to humans.

During the inspection, the Office of Inspector General (OIG) issued three Management Alerts and a Letter Report regarding

[2] LDRD projects are relatively small, discretionary research and development activities conducted by the Department's laboratories, in addition to those projects provided for in a Department program or by specific designation in a Department contract.

[3] CRADAs are cost-sharing agreements between a Federal entity, such as a Department laboratory, and a private sector partner to engage in joint, scientific research aimed at providing mutual benefits to the partners, the Department, and the U.S.

[4] Select agent toxins, such as botulinum toxin, are chemicals secreted by biological select agent organisms and are poisonous, but not infectious.

[5] An attenuated form of a biological select agent is an extremely weakened form of the agent.

concerns with certain activities by the Department involving biological select agents and select agent materials. These are referred to in the following narrative.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that the Department recognizes that each of the three OIG principal findings points to areas where improvements are needed, and in fact, the OIG's review has already had the effect of drawing the attention of DOE managers more closely to these matters. He said that the Department has initiated several actions over the past year to improve coordination, oversight, and consistency in regard to biological research involving potentially hazardous materials. He also said that DOE acknowledges that there is room for improvement.

According to the Acting Director, the Department agrees that to the extent safety management systems are lacking in any regard, there is at least a theoretical potential for increased risk. He said that this is part of the reason why the Department is seeking improvements in existing policies and practices. He also said that the Department believes it is equally important to acknowledge, however, that in the specific instances covered by the OIG review there is no indication that any workers or the public were actually put at risk.

We found no evidence that the health of workers or the public was adversely affected by the Department's biological select agent activities. However, although the Acting Director stated that the biological select agents and associated materials used by DOE have "posed low risks," we identified projects that were categorized by DOE hazard analyses as having "moderate" risk. In fact, these projects were required to be conducted in a biosafety level 2 facility, which, according to CDC, is "for work involving agents of moderate potential hazard to personnel and the environment." As discussed below, we also learned that the Department has initiated projects involving more exotic biological agents.

One Operations Office Was Unaware Of Biological Select Agent Activities

We found that safety and security officials, as well as senior management officials, at the Albuquerque Operations Office (Albuquerque), were not aware of experiments involving biological select agents or select agent materials that were conducted at two of the three Albuquerque laboratories. Albuquerque laboratories include Sandia National Laboratories in California (Sandia-CA) and New Mexico (Sandia-NM), and Los Alamos National Laboratory (Los Alamos).

We were unable to determine the extent of biological select agent activities at Albuquerque laboratories from responses provided by Albuquerque officials to our inquiries. For example, a senior Kirtland Area Office (Kirtland) official told us in February 1999, and again in

November 1999, that the only activities being conducted by the Sandia National Laboratories involving actual biological agents were conducted by Sandia-CA. However, in a November 1999 response to a July 1999 OIG survey questionnaire to the Albuquerque Manager requesting information on biological agent activities being conducted at Albuquerque laboratories, we were advised by an Albuquerque official that Albuquerque laboratories "only has [sic] 'simulants,' not the real thing."

As discussed below, we subsequently learned that experiments were conducted with biological select agents or select agent materials at all three Albuquerque laboratories. We also learned that Albuquerque safety and security officials having oversight responsibility for safety and security at the laboratories, as well as senior Albuquerque and senior laboratory officials, were unaware of the presence of the biological select agents or select agent materials. In November 1999, we advised the senior Kirtland official that Sandia-NM had conducted experiments with the biological select agent *Y. pestis EV76.* According to a CDC official, the *EV76* form of *Y. pestis* required registration as a select agent with CDC. We were told that even though the Principal Investigator interpreted that the *Y. pestis EV76*, which had been used as a vaccine in the 1970s, was exempt from CDC registration requirements, the Principal Investigator had chosen to be conservative and registered the *Y. pestis EV76* with CDC. Following our notification of the senior Kirtland official, Sandia-NM safety officials, who had been unaware of the presence of the agent *Y. pestis EV76,* found some of the agent, which had been destroyed, stored in a formalin solution at the laboratory. After learning of the presence of this material, the Kirtland Manager requested that Sandia National Laboratories submit a list of all projects using or planning to use biological materials and the controls/requirements applying to their use. On March 13, 2000, the OIG issued a Letter Report entitled "Review of Applied Biophysical Lab at SNL, Albuquerque," INS-L-00-04, concerning the presence of this material.

The Albuquerque officials were also unaware of experiments being conducted at Los Alamos with attenuated *B. anthracis* and with DNA of several select agents. When we learned from a scientist at another laboratory in January 2000 that he had received select agent DNA from Los Alamos, we interviewed the Los Alamos Principal Investigator who had shipped the select agent DNA to the scientist. During the interview, the Principal Investigator acknowledged that Los Alamos had an extensive biological select agent program involving attenuated *B. anthracis*, as well as DNA of several biological select

agents. We were subsequently advised by another Los Alamos Principal Investigator that Los Alamos was proposing to begin experiments with an infectious form of *B. anthracis.*

Shortly after we advised Albuquerque officials of the experiments at Sandia-NM involving *Y. pestis EV76*, the Kirtland Environment, Safety and Health (ES&H) Team Leader, who was the Albuquerque official having line management oversight of safety for Sandia-CA and Sandia-NM, was informally tasked by the Kirtland Manager to determine the extent of work at the two laboratories with biological select agents. Also, according to an NN-20 official, a "biosurety initiative" was initiated by Albuquerque on December 1, 1999. This initiative, which was led by the Kirtland ES&H Team Leader, was to address concerns regarding biological select agent activities at the Albuquerque laboratories. We were told by the Kirtland ES&H Team Leader, however, that he did not receive formal tasking for the "biosurety initiative" from the Albuquerque Manager until early January 2000. This tasking was to conduct an assessment of all the biological select agent activities at Albuquerque. According to the Kirtland ES&H Team Leader, he was unable to spend much time on the "biosurety initiative" until April 2000, when he was able to pursue the assignment on a full time basis.

In July 2000, the Kirtland ES&H Team Leader briefed senior Albuquerque managers on his assessment of the biological select agent activities at Albuquerque. He found that, at that time, there was "no coordination or accountability between AL [Albuquerque] as a DP [Defense Programs] site, and NN-20 as the program direction organization." He also found that in the absence of such coordination, Albuquerque was unaware of what work was underway and was unable to provide safety or security oversight. Based on the Kirtland ES&H Team Leader's assessment, the work by Albuquerque laboratories with biological select agents and select agent materials appears to have been performed in the absence of safety and security oversight by Albuquerque officials.

According to an NN-20 official, his office did not provide safety and security oversight of the CBNP projects being conducted by the Department's laboratories, but instead depended on the Operations Offices to provide such oversight. In the absence of safety and security oversight of these projects by either Albuquerque or NN-20 officials, there appears to have been insufficient Federal safety and security oversight of the NN-20 work involving biological select agents and select agent materials being conducted at the Albuquerque laboratories. In September 2000, the NN-20 CBNP Director advised us that Albuquerque is "developing coordinated procedures and

processes needed to implement a comprehensive, integrated oversight program." He said that this will be structured from the "ground up" to provide effective Federal oversight while minimizing adverse impact to the laboratories and to sponsors in this important research area.

Inadequate Notification Of Biological Select Agent Projects

Albuquerque safety and security officials, as well as senior Albuquerque management officials, might not have known of the presence of certain biological select agents and select agent materials at two of their laboratories because NN-20 did not provide sufficient information to allow the Department's Operations Offices to identify CBNP projects that involved these materials. During our visit to Albuquerque in February 2000, we observed that the only mechanism in place to communicate NN-20 select agent project information to Albuquerque was via the CBNP Project Life Cycle Plans. However, the Deputy Assistant Secretary for Nonproliferation Research and National Security told us in April 2000 that there had been a "breakdown of communications" in NN-20, which resulted in a failure to provide Project Lifecycle Plans to the Operations Offices and a failure to include the Operations Office Managers in briefings regarding the CBNP projects. The CBNP Project Lifecycle Plans contain information such as the major project tasks conducted by each laboratory, the biological select agents involved, and associated funding. He said that he initiated corrective actions to address this lack of communication. He said that without Project Lifecycle Plans, briefings by NN-20 officials about the CBNP projects, and specific contract language regarding biological select agent activities, Albuquerque officials would have no way of knowing that NN-20 had contracted work to the laboratories involving biological select agents.

The Kirtland ES&H Team Leader's assessment for his July 2000 briefing to senior Albuquerque managers also found that NN-20 had not provided the field with any information on the projects proposed or underway, which he noted was an issue being pursued by the OIG. He believed that in the absence of such information or coordination "there is no ability of AL [Albuquerque] to provide oversight or security." Although we were subsequently advised in September 2000 by the NN-20 CBNP Director that copies of the CBNP Project Lifecycle Plans had been provided to the Operations Offices, he acknowledged that they had insufficient detail to identify the projects that involved the use of select agents or the DNA of select agents. In October 2000, we were told by the Kirtland ES&H Team Leader that Project Life Cycle Plans had been provided to Albuquerque budget personnel, but had not been distributed to the other Albuquerque organizations.

Although this might explain why Albuquerque safety and security officials, as well as senior Albuquerque managers, were unaware of

the CBNP research activities involving biological select agents and select agent materials that were funded by NN-20, this does not explain why these officials were unaware of other biological select agent and select agent material research activities, such as LDRD and Work-for-Others projects, that were being conducted at Albuquerque laboratories. According to the Kirtland ES&H Team Leader, all biological select agent activities "fell through the cracks" and were not reviewed by Albuquerque. He added that there had been no mechanism in place for biological select agent project information to reach him or the Albuquerque Manager.

In September 2000, the NN-20 CBNP Director advised us that the Albuquerque Laboratory Programs Division had been aware of these activities as evidenced by their programmatic review of pertinent program documents in Work-for-Others programs, LDRD projects and CRADAs. He also said that the Albuquerque Technology Development Division, which authorizes work for the CBNP, had been aware of work concerning "proposed" use of select agents. He acknowledged, however, that Albuquerque safety officials at the staff level, particularly at the Area Offices with line responsibility for laboratory activities, "were not necessarily aware of such activities."

According to the Kirtland ES&H Team Leader, his "special tasking" in January 2000 from the Albuquerque Manager to review all chemical/biological projects at the Albuquerque laboratories had been based on the recognition by the Albuquerque Manager of the "void in line management oversight" of biological activities at the laboratories and the related vulnerabilities. The Kirtland ES&H Team Leader acknowledged that none of the contracts with the Albuquerque laboratories specifically addressed biological activities and there was no requirement for laboratory officials to advise Albuquerque of their activities involving biological select agents. He said, therefore, that Albuquerque is developing specific language for their laboratory contracts that will require the laboratories to address issues related to biological work, such as safeguards and security, emergency management, and biosafety.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that the OIG's draft report correctly identifies communication lapses, and the OIG review has already spurred corrective actions, which began over a year ago. He said that today communication is significantly improved and getting better. According to the Acting Director, the discreet problems identified by the OIG have been resolved, and DOE is developing and implementing plans to improve communication in the area of

potentially hazardous biological research activities throughout relevant Departmental elements. He added that the Albuquerque Biosurety Initiative mentioned in the draft report is an example of this. He mentioned as another example, that the Project Lifecycle Plans provided to the Operations Offices by the Office of Defense Nuclear Nonproliferation now describe the projects in more detail than older plans.

CDC Requirements Were Not Followed

We found that some Department laboratories were not adhering to certain CDC requirements that were in effect at the time of our review regarding the registration of biological select agents and select agent materials. We identified two laboratories that had received biological select agents or select agent materials, but had not registered with CDC. We also identified one other laboratory that appeared to have provided potentially misleading information to CDC in its registration application regarding the biosafety level of the facility that would be used for work with a biological select agent.

Some Laboratories Did Not Register With CDC

The OIG issued two Management Alerts concerning the lack of registration by two of the Department's laboratories for the receipt of biological select agents and select agent materials. One Management Alert entitled "Management Alert on Inspection of 'Chem-Bio Safety Protocols at DOE' (S99IS040)," dated October 28, 1999, concerned work at the Department's Idaho National Engineering and Environmental Laboratory (Idaho Laboratory) with non-viable (dead) *B. abortus* cells received from the Department of Agriculture. Idaho Laboratory officials told us that they did not believe they had to register the receipt of the cells with CDC because the cells were dead. In fact, the Idaho Principal Investigator believed he had been told by CDC that registration of the dead cells was not required. However, in correspondence received from CDC in October 1999, a CDC official advised us that under 42 CFR Part 72, registration of the *B. abortus* cells was required regardless of whether the cells were alive or dead. According to the CDC official, CDC had consistently provided this guidance to all inquiries. After we issued our Management Alert, Idaho Laboratory officials registered with CDC for the receipt of the *B. abortus* cells.

The second Management Alert entitled "Management Alert on Inspection of 'Chem-Bio Safety Protocols at the Department of Energy' (S00IS010)," dated January 14, 2000, concerned receipt by Sandia-CA of subunits of biological select agents (A and B strains of botulinum toxin heavy chains and both subunits of ricin) in a dry, powder form. According to Sandia-CA officials, receipt of these toxin subunits was not registered with CDC because they believed the

shipments were exempt under 42 CFR Part 72 from registration due to their low toxicity and because the agent materials would only be used for biomedical purposes.

Following our November 1999 visit to Sandia-CA, we discussed the receipt of these toxin subunits by Sandia-CA with CDC officials, who expressed concern that Sandia-CA had not registered to receive these subunits. The CDC officials said, among other things, that registration for the receipt of either botulinum heavy chains or light chains is required because if both were ordered, these subunits could be reconstituted into highly toxic botulinum toxin. CDC officials said they planned to discuss the non-registration of these subunits with Sandia-CA officials. According to the Department's Lawrence Livermore National Laboratory (Lawrence Livermore) Biosafety Officer, he had received similar guidance from CDC officials concerning the requirement to register toxin subunits. We learned that both Lawrence Livermore and the Idaho Laboratory, which also had conducted work with subunits of these toxins, had registered with CDC for the receipt of the toxin subunits.

In September 2000, we were advised by the NN-20 CBNP Director that while CDC indicated in their opinion to the OIG that these heavy chains should be registered, no such opinion has been promulgated by CDC to either the Department's line management or to the general regulated community to date. He said that Albuquerque is evaluating the impact of this for registration under the select agent rule.

Although it was the view of CDC officials following our November 1999 visit to Sandia-CA that the receipt of either strain (strain A or strain B) of a botulinum heavy chain by Sandia-CA required registration, we recently learned that CDC is reevaluating its earlier position. During discussions with CDC officials in October 2000, we were advised that CDC has begun to reevaluate some of the interpretations it made in the process of implementing 42 CFR Part 72. We were told that, in the past, CDC recognized non-toxic subunits of toxins listed in Appendix A of 42 CFR Part 72 as subject to the rule if the subunits could be reconstituted with recovered toxicity. According to CDC officials, after careful reevaluation of this interpretation, CDC now recognizes subunits of toxins listed in Appendix A to be exempt provided that the subunit itself meets the exemption listed in 42 CFR Section 72.6 (h)(ii). We were told that the results of CDC's reevaluation regarding registration of the subunits of the toxins listed in Appendix A of 42 CFR Part 72 will soon be posted on the CDC Internet web site.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated, among other things, that the laboratories did not originally register with CDC for the materials in question because of reasonable interpretations that registration was not required. However, we note that Appendix A of 42 CFR Part 72 lists the select agents that require registration with CDC, as well as any exemptions to registration. In our view, if any form of the select agents listed in Appendix A is shipped or received, the material must be registered, unless specifically exempted. We believe that CDC should be contacted if there is a question regarding the need to register an agent or a form of an agent. We found no documentation from the Idaho Laboratory, however, that officials had requested or received any guidance from CDC regarding the requirement to register dead cells of *B. abortus*, nor did we find evidence that Sandia-CA officials had contacted CDC regarding registration of the subunits of toxins. Instead, officials at both laboratories made their own determination at that time that registration was not required.

Potentially Misleading Information in Registration Forms

As previously discussed, CDC regulations requiring registration for the transfer or receipt of biological select agents and select agent materials are designed to assure that infectious agents and toxins are shipped only to facilities equipped to handle them properly, and only to those which have legitimate reasons to use them. Registration includes providing sufficient information to indicate that the applicant facility is "equipped and capable of handling the agents" at the appropriate biosafety level, depending on the agent and the type of work being performed with the agents. The facility may be inspected by CDC and the registration withdrawn upon evidence that the facility is not capable of handling covered agents at the applicable biosafety level (BSL).

We learned that officials at the Department's Brookhaven National Laboratory (Brookhaven) submitted a registration application to CDC for receipt of intact botulinum toxin and stated on the application that the work would be conducted in a BSL-2 facility. We determined, however, that some of the experiments with the botulinum toxin were actually planned for and conducted in another on-site facility, the National Synchrotron Light Source (Light Source), which had not been approved as a BSL-2 facility.

The Brookhaven registration application states that minute crystals of the intact botulinum toxin within sealed multiple containment will be brought from a BSL-2 laboratory to the Light Source for x-ray diffraction analysis. It also states that after analysis, the crystals, in sealed multiple containment, will be returned to the BSL-2 laboratory

for disposal. The emphasis in the application is that the crystals are in sealed multiple containment when transported to and from the Light Source. The application, however, does not indicate that the crystals will be removed from the sealed multiple containment for experimentation in the Light Source, a non-BSL-2 facility. Although we found no evidence that Brookhaven officials intentionally tried to mislead CDC, we believe that the application, as it was written, provided potentially misleading information to the CDC such that they could not make a knowledgeable determination regarding the level of protection being provided for the material while in the Light Source.

The Department's Policies and Procedures Were Inadequate

We found that procedures for conducting certain research activities involving biological select agents and select agent materials varied significantly among the Department's laboratories. We determined that the Department had not developed and implemented policies and procedures that (1) establish clear roles and responsibilities for the conduct of activities involving biological select agents and select agent materials, and (2) ensure DOE laboratories, including those managed by the NNSA, follow "best practices" for the conduct of their biological select agent activities.

Required Responsibilities Not Performed

We found that individuals at several sites were not performing all their required responsibilities regarding certain biological select agent activities. For example, at Brookhaven, the individual designated as the "responsible facility official" understood her responsibility for signing the CDC form for transferring and receiving biological select agents. However, she was unaware of the additional management responsibilities that are assigned by CDC regulations to the "responsible facility official," which include notification to the shipper within established time frames of the receipt of the biological select agent, and formal notification to CDC when a biological select agent is consumed or destroyed. We did not find evidence that Brookhaven failed to make the required notifications to the shipper and CDC. However, we determined that the responsibility for making the notifications was improperly delegated by the "responsible facility official" to the Principal Investigator, who received the biological select agent. According to 42 CFR Section 72.6, the "responsible facility official" should be either a safety officer, a senior management official of the facility, or both, but should not be an individual who actually transfers or receives an agent at the facility.

Also, we determined that, at the time of our visit in February 2000, the Los Alamos Industrial Hygiene and Safety Group (ESH-5), which included the Los Alamos Biological Safety Officer, had not conducted the required assessments and evaluations of the laboratory's biosafety

program. The Los Alamos Laboratory Implementation Requirements (LIR 402-530-00.1) document entitled "Biological Safety (Biosafety)" specifies the Los Alamos Biosafety Program requirements to be implemented for research and operations involving bioagents/ biohazards. According to the Los Alamos Requirements document, ESH-5 shall "determine the effectiveness of the Biosafety Program through assessments and evaluations. . . ." The Los Alamos Biosafety Requirements document also specifies certain records that shall be maintained, to include, among others, "inspections or evaluations performed by the Biological Safety Officer and evaluations performed by other members of ESH-5." During our visit, we asked for copies of all reports regarding reviews of Los Alamos biological activities. None of the reports we were provided concerned assessments or evaluations conducted by ESH-5 members, including the Los Alamos Biological Safety Officer, regarding the effectiveness of the Los Alamos Biosafety Program. Also, at the time of our site visit, the Los Alamos Biological Safety Officer acknowledged that she had not conducted any independent inspections or evaluations of the Biosafety Program.

We were advised by the NN-20 CBNP Director in October 2000, that "in lieu of the internal program review for 1999, LANL [Los Alamos] and the DOE Albuquerque Operations Office agreed that a biosafety review would be conducted as part of the scheduled external DOE 'Integrated Safety Management Milestone Review' and would substitute for the internal review." He said that this review had been conducted in April 1999 by Albuquerque staff. He said that the next annual review was conducted by the Los Alamos Biological Safety Officer beginning in September 2000. However, our review of the Los Alamos Biosafety Requirements document determined that there was no requirement for an annual "internal program review" of the effectiveness of the Biosafety Program. Instead, as discussed above, the language in the Los Alamos Biosafety Requirements document implies a continuing series of assessments and evaluations, rather than a single annual program review. Therefore, we do not believe the external annual program review conducted by Albuquerque fulfills the requirement in the Los Alamos Biosafety Requirements document for ESH-5 to conduct assessments and evaluations to determine the effectiveness of the Biosafety Program.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that the reviews were conducted by Albuquerque with members of ESH-5 present, and were at least as comprehensive as the required internal review. However, the Acting Director's comments did not address whether the Albuquerque reviews

fulfilled the requirement for ESH-5 to conduct assessments and evaluations to determine the effectiveness of the Biosafety Program.

Inconsistent Receipt/Screening Procedures

We observed that certain Department laboratories had implemented procedures for screening biological select agents and select agent materials upon receipt and for handling agents received in damaged shipping containers, while other laboratories had not. We believe that the implementation of procedures for handling damaged shipping containers, along with appropriate screening procedures, could significantly reduce the potential risk to employees of exposure to possibly harmful biological select agents.

Select Agent Screening/Verification

While some of the Department's laboratories screened biological select agents and select agent materials to ensure the material that was received was the material that was ordered, others either had inadequate screening procedures or depended on certification by the shipper that the proper material was shipped.

According to the Kirtland ES&H Team Leader, there appears to be "undue trusting acceptance" that orders placed with vendors are filled with the correct material. He said that while shippers generally do a good job in that regard, there have been "several questionable receipts when DOE laboratory staff assumed material that was received was non-pathogenic." He said that the implications and possible consequences of an inadvertent shipment of a live agent that is unknowingly handled as non-pathogenic "could be grave."

The following incidents at three of the Department's laboratories illustrate the potential risk of relying on possibly inadequate screening procedures or shipper certifications.

Although one laboratory, Los Alamos, had a screening process for select agent DNA, on one occasion the Principal Investigator was unable to determine whether he had actually received the material he had ordered. During our February 2000 visit to Los Alamos, the Principal Investigator told us that he had worked with what he thought was DNA of a select agent for four months, only to learn that the material he had received was not what he had ordered. Later, in September 2000, the NN-20 CBNP Director clarified in comments to a draft of our report that, after work had been conducted with the material for four months, Los Alamos had found that the select agent DNA that had been received was, in fact, contaminated with the DNA from a common skin microbe prior to arriving at Los Alamos. He also

said that the shipment had been screened by Los Alamos using filter-sterilization, which removes microorganisms but does not eliminate DNA contaminants. He added that he did not view the contamination with the DNA of the skin microbe to be a potential safety hazard.

We are concerned, however, that the process used by Los Alamos to screen the shipment of select agent DNA did not alert the Principal Investigator that the shipment contained unknown biological material. Although in this case the material that was included in the shipment was only the DNA of a skin microbe, future shipments of select agent DNA could contain harmful material, such as select agent toxins, that might not be totally eliminated by the process used by Los Alamos to screen DNA shipments.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that the screening process used by Los Alamos is consistent with best practices in use elsewhere. He said that it is impractical to test for all possible contaminants, and there was no significant reason to routinely screen for the presence of DNA of a skin microbe. According to the Acting Director, the matter should be viewed in the context of shipper and receiver responsibilities, and while there is not an absolute guarantee that an error will never be made, the existing protocol provides significant and widely accepted assurance that risks are minimized.

We note, however, that according to the potential hazard assessment for the Los Alamos DNA project, the shipper only had to certify that the shipment was "microbe free." In view of the presence of a contaminant in the shipment received by Los Alamos, which only after four months was discovered to be the DNA of a skin microbe, we remain concerned with the adequacy of the Los Alamos screening process.

Also, in December 1999, a Principal Scientist at another laboratory, Lawrence Livermore, told us that he had the laboratory policy changed to require screening after he realized the quality and safety benefits that could be gained by screening select agent shipments. He described an incident that occurred after the screening process was implemented, which involved the screening of a shipment of attenuated *B. anthracis*. According to the Principal Scientist, the preliminary screening process indicated that the *B. anthracis* was potentially not attenuated. However, we were advised that the particular test is subject to "false positives" and rather than using additional tests to determine whether the *B. anthracis* was, in fact, the viable, infectious form of the agent, the sample was destroyed.

Although the test results were inconclusive whether the material that was received was the viable, infectious form of *B. anthracis*, we believe this incident highlights the potential hazards associated with the receipt of biological select agents and select agent materials.

A third laboratory, the Department's Lawrence Berkeley National Laboratory (Lawrence Berkeley), also had established a process to screen all samples of agents it received. In November 1999, a Principal Scientist told us of an incident when a shipment of attenuated *B. anthracis* was ordered, but did not pass the laboratory's screening process that would have verified that the material was attenuated. He said the agent was not tested to determine whether it was the viable, infectious form of *B. anthracis*, but was immediately destroyed. He said that because of this incident, a laboratory official decided that in the future, all employees working with attenuated *B. anthracis* should be offered immunization and subsequently, all were immunized.

Sandia-CA, however, is one Department laboratory that does not screen shipments of select agent materials. According to Sandia-CA officials, the laboratory depends on the certification of the shipper as to the type and quality of the material shipped.

Damaged Container Procedures

While some Department laboratories had developed and implemented specific procedures to handle damaged shipping containers containing biological select agents and select agent materials, other laboratories had not. We believe that implementation of specific handling procedures for damaged containers received at the Department's laboratories could possibly reduce the risk of exposure of laboratory personnel to harmful materials, particularly in the event that the materials received are not those that were ordered.

We learned that Sandia-CA had developed and implemented procedures for handling damaged containers containing biological select agents and select agent materials. Also, the Idaho Laboratory, which received shipments of botulinum toxin, had developed written procedures for handling damaged packages of the toxin after determining that such procedures were necessary. However, at least two Department laboratories, Lawrence Berkeley and Los Alamos, had not developed specific procedures for handling damaged shipping containers containing biological select agents and select agent materials. For example, we were advised by the Lawrence Berkeley Biosafety Officer in August 2000, that Lawrence Berkeley had not developed specific procedures to handle damaged packages containing

biological select agents because, at that time, the laboratory did not order "full blown lethal select agents."

Also, Los Alamos, which has worked with attenuated *B. anthracis* and DNA of biological select agents and is proposing to conduct activities involving the viable, infectious form of *B. anthracis*, has not developed specific procedures for handling damaged packages. We were told by the Los Alamos "responsible facility official" that Los Alamos has no special procedures or specific training regarding their receipt or shipment process for select agents. In addition, we were told by the Los Alamos Biosafety Officer that Los Alamos also lacked a "hazard control plan" for damaged packages containing biological agents received by the Los Alamos shipping department.

An incident at Los Alamos involving a shipment of select agent DNA illustrates the potential risk of workers being exposed to harmful biological select agents and select agent materials when damaged containers are received in the absence of specific procedures to handle them. A Los Alamos Principal Scientist told us that the laboratory shipping and receiving department received a shipment of select agent DNA with crushed inner and outer containers. The Principal Scientist said that he destroyed the shipment because of the possibility that the shipment could have contained more than just the DNA portion of the select agent that he had ordered. The Los Alamos "responsible facility official," however, said that he did not see a need for "special handling procedures." He told us that he believed there was "zero risk" regarding the receipt of select agent DNA and, therefore, no special procedures or specific training were necessary regarding the receipt or shipment process for handling these materials. He advised us that he believed that Los Alamos' general procedures were adequate.

CDC, however, requires a BSL-2 facility for receipt and containment of DNA from biological select agents because of the possibility that the shipments may include the actual agent as well. According to a CDC official, CDC is concerned with the reliability of the shipper to provide only the DNA of the biological select agent and the ability of the receiver to determine what was actually received.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that Los Alamos has a hazard control plan for the handling of regulated materials and the control of exposures to hazardous materials from damaged packages, which was prepared by the Shipping and Receiving Group. Further, the Group's Work Procedure specifically addresses requirements for the handling of damaged packaging containing hazardous materials.

As discussed above, however, the Los Alamos Biosafety Officer told us that Los Alamos lacked a hazard control plan for damaged packages containing biological agents received by the Los Alamos shipping department. Also, we were told by the NN-20 CBNP Director in October 2000, that the Los Alamos Hazard Control Plan for Shipping and Receiving workers generically addresses the handling of hazardous materials. We believe that due to the potential safety and health risks associated with biological agents, specific procedures should be developed to handle damaged packages containing biological select agents and select agent materials received by the Los Alamos shipping department.

Required Hazard Analysis Was Based On Incomplete Data

We determined that documentation describing activities involving biological select agents at Brookhaven did not contain a sufficient level of detail for laboratory officials to fully identify potential hazards. Specifically, documentation for a project submitted to the laboratory's Institutional Biosafety Committee (IBC), which reviews and approves biological select agent experiments, contained insufficient information for the IBC members and laboratory safety and health personnel to ensure that all hazards associated with the project were identified, analyzed, and determined to be either avoidable or manageable.

At Brookhaven, a Standard Operating Procedure (SOP) document was prepared for experiments in a BSL-2 facility using intact botulinum toxin. According to the "Material Data Safety Sheet" for the botulinum toxin, the acute effects of the material include "may be fatal if inhaled, swallowed, or absorbed through the skin. The toxin is among the most powerful paralytic poisons known, having irreversible effects." The SOP states that the botulinum toxin was to be transported in sealed multiple containment to another facility on the site, the Light Source, for additional experiments. We were told by a Brookhaven Industrial Hygienist, who managed the Light Source, that one tiny crystal of the botulinum toxin could cause death if ingested. As discussed previously, the Light Source was not an approved BSL-2 facility at the time of our site visit. Although the SOP did not state that the botulinum toxin would be removed from its containment while in the Light Source, we learned from the Principal Investigator that the botulinum toxin was, in fact, routinely removed from its containment for the Light Source experiments. We also learned that as many as 30 individuals, some at work stations located only 6 to 8 feet away, could have been working on other projects in the Light Source when the botulinum toxin was removed from its containment. We did not find evidence, however, that any of these individuals was harmed by the experiments.

We determined that the project description provided to the laboratory IBC, which had approved the botulinum toxin experiments, did not state that the botulinum toxin would be removed from its containment in the Light Source. We also determined that the document submitted to the laboratory's Experiment Safety Review Committee for its safety review did not mention that the botulinum toxin would be removed from its containment while in the Light Source. This document, "Biology Department ES&H Review of Experiments," contained a section for the Principal Investigator to specifically identify, describe, and analyze the potential hazards associated with the project. At the time of our visit in January 2000, both the IBC Chairman and the Manager of Brookhaven's Safety and Health Services Division told us that they did not know that the botulinum toxin was to be removed from its containment for the Light Source experiments. However, in September 2000, the NN-20 CBNP Director reported that the IBC Chairman had known that the toxin was being removed from its container in the Light Source.

Nonetheless, after we informed the IBC Chairman in January 2000 that the botulinum toxin was being removed from its containment and manipulated in the Light Source, he initiated several corrective actions. These were to revise the SOP to require freezing of the botulinum toxin to take place only in the BSL-2 laboratory, not in the Light Source as previously permitted, and to limit where in the Light Source the botulinum toxin could be removed from its containment. Prior to the revisions, the experimenter removed the botulinum toxin from its containment on a work bench area, with other experimenters working nearby. Under the revisions, the experimenter could only remove the botulinum toxin from its containment in one of the "hutch" areas of the Light Source, which was located away from other experimenters.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that during the procedure in question, the toxin crystal is attached to a glass support such that ingestion would be "essentially impossible." We agree with the Acting Director's comment that ingestion of the toxin crystal would be "essentially impossible" while the crystal is attached to a glass support. However, we do not believe the Acting Director's comments adequately consider the potential for exposure resulting from accidental breakage of the glass support, either through dropping or mishandling of the glass support during the time the material is removed from its containment. Accidental separation of the crystal from the glass support, in our view, has the potential to result in

exposure to the toxin, not only from ingestion, but also from inhalation and from absorption through the skin.

Inconsistent Policies Regarding Worker Immunizations

Occupational Medical Physicians told us that employees working with biological select agents have the right to decline immunizations, even when highly recommended by the facility Occupational Medical Physician and the Principal Investigator. According to an official in the Department's Office of General Counsel, there may be a potential liability for the Department if contractor employees working with CDC-controlled biological select agents do not sign a statement acknowledging the risks associated with the project, the availability of immunizations, and the individual's decision not to be immunized. We confirmed, however, that not all of the Department's laboratories require employees working with biological select agents and select agent materials to sign an acknowledgement statement. At the Idaho Laboratory, for example, three scientists working with botulinum toxin decided not to be immunized, even though they were aware of the potential dangers, and were not required by the laboratory to sign an acknowledgement statement. Also, Sandia-CA does not require Principal Investigators or other laboratory participants to sign a statement if they work with biological select agents and decline to be immunized.

Other Department laboratories, however, require employees to sign statements if they decline to be immunized. According to the Los Alamos Head Occupational Health Physician, for example, all at risk personnel at Los Alamos are required to sign a statement acknowledging the risks and benefits of being immunized versus not being immunized.

An even greater potential liability for the Department may result from allowing workers who decline immunizations to continue working with infectious agents and, therefore, possibly infecting themselves or others. As Department laboratories begin experimenting with indigenous or exotic biological select agents that may cause diseases having serious or lethal consequences (such as agents requiring BSL-3 containment), the consequences of laboratory personnel infecting their spouses and others should be considered. According to CDC literature, laboratories working with infectious agents have not been shown to represent a threat to the community. However, the CDC literature also cites isolated cases when laboratory workers became infected and subsequently infected their spouses or other members of the community. Because CDC only recommends immunizations for workers, and the Department does not require workers to be immunized, the potential exists for Department laboratory personnel

who work with infectious agents, but decline to be immunized, to infect others.

NEPA Reviews Not Conducted

We determined that National Environmental Policy Act (NEPA) reviews were not conducted at two Department laboratories for activities involving biological select agents.

The OIG issued a Management Alert on June 30, 1999, entitled "Inspection of the Chem-Bio Facility at ORNL," S99IS019. The OIG found that the Department's Oak Ridge National Laboratory (ORNL) had not conducted an environmental assessment for a BSL-3 laboratory that was being constructed for work with botulinum toxins, which were to be received as "lyophilized" (freeze-dried) powder. Based on the Department's implementing regulations for NEPA, the OIG believed that an environmental assessment was required before the procurement, installation, and commencement of biological operations at the BSL-3 laboratory. Oak Ridge Operations Office officials subsequently placed restrictions on the Chem-Bio Facility to exclude BSL-3 activities, and stated they will conduct an environmental assessment before any BSL-3 work is performed in the facility.

Also, as discussed in the OIG's March 13, 2000, Letter Report, the OIG found that, although a NEPA review had been conducted by Sandia-NM of the original scope of work for a Work-for-Others project, significant changes, such as changes in work location and introduction of the select agent *Y. pestis EV76*, had been made without an additional NEPA review. Subsequently, Albuquerque officials advised us that an analysis of the existing NEPA process is ongoing to determine how to ensure Work-for-Others projects are receiving appropriate NEPA review.

Observations

Lack of Timely Response From CDC

We had difficulty obtaining timely responses from CDC officials to our inquiries for clarification of registration requirements for certain biological select agent materials. On several occasions, responses were received from CDC more than a month after our inquiry. Also, although we requested written responses to our inquiries, in most cases CDC officials only provided verbal responses. We understand that Department and laboratory officials experienced similar difficulties in obtaining timely responses from CDC.

Changes to CDC Interpretations

In the absence of written responses from CDC regarding their interpretation of registration requirements, we found it difficult to determine current registration requirements. Discussions with CDC officials, for example, indicate that CDC is re-evaluating earlier interpretations of the requirements. Therefore, some of the materials that CDC currently requires to be registered may be removed from the list of materials subject to registration, while new materials may be added. For example, CDC is re-evaluating whether such materials as "dead" cells of biological select agents and subunits of toxins require registration.

Lack of CDC Inspections

We understand that CDC can conduct on-site inspections of laboratory facilities identified on the registration application for biological select agents and select agent materials for a three-year period from the date the registration application was approved. Among other things, these inspections ensure the materials are in facilities that provide the appropriate biosafety level. However, we learned of only one such inspection of a DOE facility by CDC. We believe that such inspections by CDC would assist the Department in its efforts to ensure the safety and security of activities involving biological select agents and select agent materials.

In view of the ongoing re-evaluation by CDC of their earlier interpretations of registration requirements, and the lack of timely responses by CDC officials to requests for information/guidance, we believe the Department should take appropriate action to ensure the Department's laboratories receive timely and consistent information regarding current CDC guidance.

We discussed our observations with CDC officials. We were advised that CDC plans to provide updated information on its Internet web site regarding its interpretation of registration requirements. Specifically, CDC will post written instructions for facilities that have questions about registration, as well as updates to the list of registered materials. CDC officials also stated that CDC will improve responsiveness to DOE and other agencies by

increasing staff in the office responsible for oversight of the registration process.

RECOMMENDATIONS

We recommend that the Under Secretary for Energy, Science, and Environment and the Under Secretary for Nuclear Security jointly:

1. Identify the types and locations of activities being conducted by the Department involving biological select agents and select agent materials.

2. Initiate action to ensure: (a) appropriate Federal oversight; (b) consistency in policy; and (c) standardization of implementing procedures for biological select agent activities being conducted by the Department. Actions, for example, could include encouraging more interagency cooperation in this area and, similar to the approach taken by the U.S. Army, supplementing CDC guidance regarding activities involving biological select agents and select agent materials to address situations unique to DOE.

3. Ensure that required NEPA reviews are conducted prior to the start of biological select agent and select agent material activities and revised, as needed, when significant changes occur in the activities.

4. Initiate appropriate action to ensure the Department's laboratories, including those managed by the NNSA, receive timely and consistent information regarding current CDC guidance.

We also recommend that the General Counsel:

5. Determine the potential liability to the Department if contractor employees working with biological select agents refuse immunizations or if they do not sign a statement acknowledging the risks associated with the project, the availability of immunizations, and the individual's decision not to be immunized.

6. Determine the feasibility of requiring Department laboratory employees to be immunized in order to work with infectious agents.

7. Determine whether the Department has liability to third parties (e.g., spouses, families, members of the community) who may be infected as a result of coming in contact with a laboratory employee who works with biological select agents, but has refused to be immunized.

MANAGEMENT COMMENTS

The Department generally concurred with our recommendations. In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that while there is no indication that biological safety has been compromised at any DOE facility, the draft report correctly points out operational concerns and inconsistencies that existed during the review. He provided the following examples of actions completed by the Department within the past year to improve biosafety practices at its laboratories and said that the Department is already taking steps consistent with our recommendations:

- A biosurety program was initiated on December 1, 1999, at Albuquerque to strengthen the safety and security protocols used with biological select agents.

- Communication has been improved between DOE headquarters, the Operations Offices, and the Department's laboratories, as well as between DOE and other Federal agencies involved with biological research.

- CDC select agent registration requirements are being clarified.

- The former Secretary established a Biosurety Working Group led by EH to recommend specific improvements in directives and contract language and other actions which will improve oversight and implementation of safe practices in potentially hazardous areas of biological research.

Regarding recommendation 1, the Acting Director stated that in consultation with CDC and the Department's laboratories, the Department has confirmed the location and types of current activities involving select agents. Moreover, the Department is establishing a process to ensure this information, as well as information about activities involving other biologically hazardous materials, is regularly updated and more readily available to managers.

Regarding recommendation 2, the Acting Director stated that the Department concurs with the need for appropriate Federal oversight, consistency in policy, and, when appropriate, standardized procedures for use with select agents. He said that mechanisms to improve oversight, coordination, and consistency are currently being reviewed by the Biosurety Working Group. He said that much of the Working Group's focus is on improving communication and consistency. In particular, the Working Group is drafting proposed changes to DOE's directives and contracts, and it is considering methods to improve

ongoing communication through appropriate levels of management. In considering these changes, the Working Group is examining policies and procedures developed within the Department and by other agencies, particularly CDC and the U.S. Army.

He also said that in parallel with the Working Group's actions, the Department's laboratory directors are confirming that biological research at their facilities is being appropriately addressed within their safety and health programs. Also, the Department is expanding Albuquerque's Biosurety Initiative to encompass the DOE complex and promote improved communication and sharing of lessons learned and best practices among laboratories.

In addition, he said that the Department continues to look to other agencies, especially the CDC, for direction and guidance. He said that the Department's laboratories that transfer or ship select agents are required, pursuant to 42 CFR Part 72, to follow the procedures outlined in the "Biosafety in Microbiological and Biomedical Laboratories" guidelines, unless certified by the Clinical Laboratory Improvement Amendment of 1988.

Regarding recommendation 3, the Acting Director stated that the Department is required to comply with NEPA. He said that the Department will "continue to address biological research within individual laboratory annual NEPA planning summaries and otherwise according to Departmental requirements" to ensure that appropriate consideration is given to NEPA compliance early in the planning process. In addition, the Department is acting to raise the awareness of managers to this particular area of research and expects that in doing so, NEPA compliance will be highlighted. For example, the Secretary recently tasked laboratory managers to certify that potentially hazardous biological research is appropriately addressed in annual NEPA planning summaries.

Regarding recommendation 4, the Acting Director stated that DOE concurs with the desire to have timely and consistent information from CDC, and the Department recognizes its obligation to implement CDC guidance. Through the Albuquerque Biosurety Initiative and the recently established DOE Biosurety Working Group, the Department and its laboratories are improving communication and coordination with other agencies. Additional steps will be taken, as they are identified, to better ensure the timely evaluation and appropriate adoption of any newly established CDC guidance.

Regarding recommendation 5, the Acting Director stated that staff members of the Office of General Counsel are in the process of

evaluating potential liability issues relating to the Department's contractors' work with biological agents. The issues being addressed include both potential direct and indirect liability, including such things as liability arising from the removal of contractor employees who decline to be immunized.

Regarding recommendation 6, the Acting Director stated that the Office of General Counsel is reviewing this matter. He said that the U.S. Public Health Service Advisory Committee on Immunization Practices issues current and updated recommendations for immunization. He said that the Office of General Counsel has made an initial conclusion that existing laboratory protocols should periodically be reviewed for compliance with this guidance. Where no such protocols exist, the development of protocols consistent with this guidance by qualified site professional, medical staff in consultation with at-risk individuals and the CDC is appropriate.

Regarding recommendation 7, the Acting Director stated that as discussed in his comments to recommendation 5, the Office of General Counsel is continuing to review questions of potential liability.

In addition to comments regarding the recommendations in our draft report, the Acting Director provided specific comments concerning the findings and language in our draft report. We have incorporated the Acting Director's comments in our final report, where appropriate.

INSPECTOR COMMENTS

We believe the corrective actions identified by the Department are responsive to our recommendations.

Also, in an earlier draft of our report, we had recommended that the Department determine whether overall responsibility for biological select agent activities should be centralized in one organization. In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program identified existing management systems, such as the Department's Integrated Safety Management program, that govern biological select agent research to ensure it is conducted safely and effectively, and stated that a new, centralized organizational structure to manage such research is not appropriate at this time. He said that creating such an organization would unnecessarily separate biological research from the management systems in place for other aspects of the Department's work. He said that, nonetheless, DOE recognizes the need to better ensure that existing management systems effectively meet the needs of this evolving area of the Department's research activities and is taking steps toward the goal.

In view of the Acting Director's comments and the establishment of NNSA as a semiautonomous organization within the Department, we agree that establishing a new, centralized organizational structure to manage biological agent research may not be appropriate at this time. Therefore, we deleted this recommendation from our final report.

Appendix A

SCOPE AND METHODOLOGY

This inspection was conducted from July 1999 through January 2001 at Department of Energy (DOE) laboratories, including National Nuclear Security Administration (NNSA) laboratories, that we identified as conducting experiments involving biological select agents and select agent materials. These laboratories included Brookhaven National Laboratory, Idaho National Engineering and Environmental Laboratory, Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, Oak Ridge National Laboratory, Sandia National Laboratories-New Mexico, and Sandia National Laboratories-California.

To accomplish our inspection objectives, we conducted a survey of selected Department Operations Offices to identify the extent of their activities involving biological select agents and select agent materials and conducted on-site reviews at the Department laboratories listed above. We interviewed Department Headquarters officials in the Office of the Deputy Administrator for Nuclear Nonproliferation; the Office of Environment, Safety and Health; the Office of Science; the Office of Environmental Management; the Office of the Deputy Administrator for Defense Programs; the then Office of Field Management; the Office of Intelligence; and the Office of General Counsel. We also interviewed contractor personnel at each of the Department's laboratories listed above. In addition, we interviewed officials at the Centers for Disease Control and Prevention, the U.S. Army Edgewood Chemical Biological Center, and the U.S. Army Medical Research Institute of Infectious Diseases. We also reviewed pertinent Federal, Department, and contractor environment, safety and health rules and regulations implemented at each site, and compared the criteria with the rules and regulations being implemented at facilities outside of the Department.

This inspection was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency.

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APPENDIX D: HAZARD CONTROL PLAN FOR BSL-2 FACILITIES AT LANL.

The following Hazard Control Plan, B-HRL-009-00, entitled "Biosafety Level 2 – Cell/Microbe Culture," is currently under review for renewal. It is expected that hazard control plans will be periodically reviewed and updated as needed; they are, therefore, considered to be "living documents." The subject hazard control plan expires in February 2002 and will be replaced. This plan is therefore included as an example of such a plan and should not be confused with the actual hazard control plan underwhich the LANL BLS-2 facilities may be currently operating. Attachments to the subject hazard plan have not been included herein. A hazard control plan would be written and implemented appropriate to BSL-3 facilities should NNSA proceed with implementation of the proposed BSL-3 facility at LANL.

Hazard Control Plan

Bioscience Division

B-HRL-009-00

TITLE OF WORK: BIOSAFETY LEVEL-2 CELL/ MICROBE CULTURE

Activity/ Task Identification Number(s): B-HCP-009-00

Statement of work:

This plan covers the culture/growth of cells that could potentially carry pathogenic disease organisms, the growth of infectious microbes, and recombinant DNA from infectious organisms. Culture and growth of cells and microbes is a standard part of basic biology and biochemistry research. Work with non-infectious organisms and cells (Biosafety Level-1) have been characterized in HCP-001-00. The culture of potentially infectious materials changes the risk to the worker, the public and the environment. Handling of potentially infectious materials requires a higher level of stringency be applied to operating procedures. The Center for Disease Control (CDC) in Atlanta, Georgia in conjunction with the National Institutes of Health (NIH) have developed a system of categorizing microbiological work according to the pathogenicity of the organisms being handled. Standard culture work is conducted at Biosafety Level -1, the least hazardous level (HCP-001-00). Biosafety Level-2 adds more stringent access, posting, procedures and engineering controls to the conduct of work. It also requires control of experimental wastes by decontamination prior to disposal.

Culture of pathogenic microbes (bacteria, fungi or viruses) can be safely conducted once the appropriate biosafety procedures and engineering controls are applied. Data collected over the past twenty years from medical laboratories handling infectious materials has shown these methods protect workers and the public. Engineering controls include restricting access to the area and conducting work in HEPA filtered biohoods. To conduct work at BSL-2, best laboratory practices apply and are coupled with engineering controls, decontamination of wastes and good housekeeping. Prior to the conduct of any cell or microbe culture work, protocols describing specific safeguards must be reviewed and approved by LANL's Institutional Biosafety Committee (IBC). Protocols that remain in use over multiple years must be re-approved annually. The IBC assures the institution, the public and workers that experimental work is done at the appropriate biosafety level.

Principal Author of the Plan: James P. Freyer, IBC Chair, and Julie S. Wilson

Initial Risk Estimate: <u>MEDIUM</u>

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List of Work Permits Required to Perform Work:

- **IBC APPROVAL**
- **HUMAN SUBJECTS REVIEW BOARD APPROVAL IF SUBJECT-SPECIFIC HUMAN CELLS ARE USED**
- **ANIMAL CARE AND USE COMMITTEE APPROVAL IF REQUIRED**

Residual Risk Estimate: **MINIMAL**

THIS WORK REQUIRES DIVISION DIRECTOR AUTHORIZATION.

Authorization Expiration Date: **February 2002**

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1. Work Definition

A. Summary of Statement of Work

Biochemical and microbiological research involving the growth, amplification and characterization of a variety of microorganisms, cellular organelles and biomolecules (proteins, nucleic acids, carbohydrates and lipids) occurs in many labs in HRL-1 and -20.Some labs have both BSL-1 and BSL-2 activities because the handling of potentially infectious materials or recombinant DNA is very limited or periodic. When handling involves potentially infectious materials the labs are posted. Specific tasks for the work vary according to the materials being handled they involve common techniques and operations referred to as "universal precautions" which are sufficient to contain the work . This permits the handling of "unknown" samples, which might or might not be infectious or harbor infective microbes. Work with these materials can be intermittent making lab areas BSL-2 on a temporary basis. Other labs are full-time BSL-2. All labs are posted when BSL-2 work is being conducted. Liquid wastes from BSL-2 operations must be decontaminated with bleach or disinfectant prior to disposal. All solid wastes must be autoclaved (heat sterilized) prior to disposal.

B. Definition of tasks (complete set of techniques- individual tasks vary)

1. Design and plan experiments, submit for IBC review/ approval
2. Inoculation and growth of cell/ microbial cultures using universal procedures
3. Isolation of cells/ microorganisms from growth media
4. Cell/ microbe lysis and sub cellular fractionation (varies according to experimental design). Sub cellular fractions (macromolecules) are NOT INFECTIOUS.
5. Clean-up of work areas to assure decontamination, wastes are deactivated by use of microbiocidal chemicals (bleach) or by heat-sterilization. Work surfaces inside biohoods must be sterilized with chemical cleaners or 70% alcohol then irradiated with ultra-violet light .
6. Personal hygiene (hand washing, lab coat) to assure no transfer of organisms to worker or personal clothing
7. Wastes must be decontaminated prior to disposal, add bleach/disinfectant to liquids and autoclave solids.

Tasks can take from minutes to hours. Growth of cultures can take hours to months. Tasks are routinely part of a cascade. Success or completion of experimental plans is dependent on completion of each individual task, resulting in considerable time and materials investment in each successive task. Careful work is required in all tasks.

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C. Instrumentation/ equipment used to execute work (not all are required)

1. Personnel Protective Equipment (eye protection, gloves, close-toed shoes, and protective clothing/ lab coat) where required
2. Protective barriers (biohoods)
3. Incubators and fermentors
4. Heating baths and blocks from ~40 degrees centigrade (C) - 100 degrees C
5. Centrifuges - low-medium- and ultra-speeds
6. Cell disruption devices (sonication or eletroporation)
7. Chromatography instruments
8. Spectrometers
9. Inert cryogens (liquid nitrogen, dry ice)
10. Compressed gas cylinders
11. Automated Sequencers
12. Electrophoresis instruments
13. Microscopes (light and fluorescence)
14. Ultra-violet light
15. Microwave ovens (heating medias, buffers and gels)
16. Vacuum pumps
17. Automated X-ray film processor or manual development process
18. pH meters
19. Balances
20. Open flames
21. Cold Room Work
22. Cell Counters
23. Pipettors
24. Vortex mixers

E. Location of Work

TA-43-HRL-1 260, 243, 127, 131, 126, B244, B116
TA-43-HRL-20 B104

F. Personnel Performing Work

Students, Technicians, Post-Doctoral appointees, Technical Staff Members and visitors who are trained to do this work either by completion of college level course work, degree and/or task-specific training. ALL PERSONNEL MUST BE IDENTIFIED IN IBC PROTOCOLS.

G. Constraints of the Facility and/or Location

1. Access to laboratory areas of HRL-1 and -20 is restricted to badge- or key-holders only. Access may be affected by badge-reader failure. All doors function with keys.

2. All biohoods hoods must be performance certified annually . Biohoods are unfunctional if electrical service fails.
3. Sinks drain to the sanitary sewer, no chemical disposal is permitted. Disposal into the sinks of growth medias, that do not contain hazardous materials and have disinfectant (10% bleach/ commercial disinfectant) added, is permitted.
4. Personnel comfort is maintained between 68 and 80 degrees, with about 6 changes of air per hour. Extremes of either cold or heat may occur during mechanical failures and will NOT require shutdown of work. Personnel may have to accommodate discomforts and scale work accordingly.
5. Exhaust from rooms stops if electrical service or mechanical systems fail.
6. All instrumentation, including autoclaves, utilize electrical service and will be inoperable if electrical service fails.
7. In the event of fire alarm or power failure during handling operations, cultures must be decontaminated immediately with addition of bleach or disinfectant.
8. Freezers containing valuable research materials can fail if electrical service is lost. Some units have "back-up power " to assure materials are not lost.

H. Effects on the Environment - None expected.

I. Legacy Issues Associated with Work - None expected

2. IDENTIFICATION OF HAZARDS AND CONTROLS

BIOLOGICAL HAZARDS

All work with biological materials must comply with LANL's Biosafety LIR (402-530-00). Work with primary cells is always assumed to have the potential for the presence of infectious organisms and is conducted at BSL-2 at a minimum. "Universal precautions" are required as defined in "Biosafety in Microbiology and Medical Laboratories" (ATTACHMENT A). Work with suspect or known pathogenic organisms at laboratory scale (in small volumes, not production) also requires this level of safety. Work with recombinant DNA from infectious organisms might require BSL-2. Work with biotoxins IS COVERED IN A SEPARATE HCP. All work has an Exposure Control Plan (ECP, ATTACHMENT B).

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PHYSICAL HAZARDS

__X__ Compressed Gases	__X__ Cryogens	__X__ Hot Surfaces
__X__ Ergonomics	_____ Lifting/Carrying	_____ Noise
____ Projectiles	__X__ Sharps	__X__ Open Flames
__X__ Pressurized Systems	__X__ Rotating/Reciprocating Systems	
____ Temperature Extremes	_____ Working at Heights	____ Confined Space

TYPE	CONTROLS
Compressed Gases on can poise several safety concerns.	Use with appropriate regulator, transport on cart with cap and properly secured. Reference "Gas Cylinder Handling" procedure B-.003-99
Cryogens can burn skin or eyes and can cause frostbite.	Use thermal gloves and face shield, reference procedure B-0004-99.
Hot Surfaces can burn skin or ignite fires.	Reference "Heating Procedures" B-007-99
Ergonomic injuries cause long-term soft tissue injury.	Long-duration repetitive tasks should be avoided and can workstations should promote good posture.

TYPE	CONTROLS
Sharps can cut or puncture skin.	Handle all sharps carefully, reference "Sharps Handling" procedure, LS-008-99
Open Flames can burn or ignite fires.	Reference LS SOP for "Open Flames".
Pressurized Systems can explode.	Autoclaves are high pressure, high temperature systems. Reference LS Autoclave HCP

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Rotating/ Reciprocating equipment can release projectiles or entangle fingers and arms.	Typically these are centrifuges. Follow manufacturers' instructions keep units clean and well serviced.

RADIATION HAZARDS

____ Criticality	_____ Ionizing Radiation	____ Lasers
____ High Intensity Light	___X_ Radio-frequency/***Microwave***	
___X Ultra-violet Light	_____ Infrared Radiation	

TYPE	CONTROLS
Microwave ovens can overheat liquids causing containers to break or explode.	Reference "Heating Operations" LS-007-99.
Ultra-violet Light can burn eye and skin.	Shield eyes and skin, wear safety glasses and lab coats.

ELECTRICAL HAZARDS (Definitions in Electrical Safety LIR)

____ Electromagnetic	_____ Energized Equipment	__X_ Shock

TYPE	CONTROLS
Shock can be debilitating opportunities even lethal. manufacturers' for condition.	Instrumentation and electrical service provides for contact, with electricity follow instructions and check cords

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CHEMICAL HAZARDS

____ Asphyxiant	_____ Beryllium	__X__ Carcinogen
__X__ Reproductive Toxin	__X__ Highly Toxic	__X__ Dusts/Powders
_____ Corrosive	_____ Hazardous Gas	__X__ Ignitable
__X__ Incompatible	__X__ Irritant	__X__ Mutagen
_____ Poison	_____ Oxidizer	_____ Other

TYPE	CONTROLS
Carcinogens can have effects on cells that lead to cancer.	Use is with micro-quantities, check MSDS, SOP(s) may apply.
Reproductive Toxins can affect fertility.	Use is with micro-quantities, check MSDS, SOP(s) may apply.
Highly Toxic materials poisons with immediate or near-term health effects.	Use is with micro-quantities, check MSDS, SOP(s) may are apply.
Dusts/ Powders can be allergenic or irritants.	Reference MSDS.
Ignitable materials can cause burns or fires.	Reference MSDS and "Open Flame Operations" Bioscience procedures,
Incompatibles can explode or have other violent reactions.	Reference MSDS
Irritants can cause skin, eye or mucous membrane damage.	Reference MSDS
Mutagens can cause cell damage with long-term potential for health effects.	Reference MSDS

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ENVIRONMENTAL HAZARDS:

____ Asbestos _____ Infectious Waste _____ Air Emission

__X__ Hazardous Waste _____ Waste water

____ Polychlorinated Biphenyls

TYPE	CONTROLS
Hazardous Wastes	Chemical wastes only. Biological materials in BSL-2 rooms wastes are autoclaved or treated with bleach. NO INFECTIOUS WASTES ARE GENERATED, decontaminated wastes (solid/ liquid) are disposed of as non-hazardous biological materials.

TRANSPORTATION

____ Hazardous Materials _____ Radiological Materials

Samples of experimental materials, typically DNA and mammalian cells, are shipped to and received from collaborators worldwide. All transport is according to DOT REGULATIONS AND LANL LIR 405-10-01.Some samples are shipped on dry ice, always less than 2 pounds. Samples being transported by researchers off-site conform to LIR 405-10-01. Samples are sent to HRL from collaborators and others, they conform to DOT regulations as managed by their institutions at point of origin.

3. RISK ASSESSMENT - By "What-If Checklist" Method

A. DETERMINATION OF ***INITIAL RISK:*** **MEDIUM**

The handling of primary human cells, cells from primary tissues of animals or humans and the culture of potentially infectious microorganisms can result in workers or the public contracting diseases. Therefore, the culture of potentially infected cells or known pathogenic microbes presents opportunities for transmission of infection from the work materials to the worker or their families or others. This level of safety permits handling of unknowns-, which could be harboring lethal organisms. The likelihood of accidental exposure would be occasional, but the severity would be critical.

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B. DETERMINATION OF ***RESIDUAL RISK:*** **MINIMAL**

Medical laboratory experience has demonstrated that Biosafety Level-2 containment practices dramatically diminish the occurrence of worker exposure or infection. Using the techniques provided by CDC/NIH in their publication,"Biosafety in Microbiology And Medical Laboratories", risk of exposure or infection is minimal. Vaccinations can be provided to further protect workers from unnecessary risks. The likelihood of getting exposed to sufficient quantities of infectious organisms is reduced to remote, but the consequences of any such exposure remains critical, particularly for lethal organisms.

-8- HAZARD CONTROL PLAN

4.0 Exposure Control Plan (ECP) for Bioscience workers who conduct work with human blood, tissues or fluids.

A. Roles and Responsibilities:

1) Institutional

- LANL has chartered an IBC, which must review all work for safety concerns and approve work as described.
- LANL provides an Occupational Medicine program, ESH-2, to support research programs where potential exposure to blood-borne pathogens exists.

2) Organizational

- Bioscience managers will direct workers to an occupational medicine program that, at a minimum, includes medical evaluations prior to, during and post- work.
- Bioscience managers will provide a safe environment for the work including administrative and engineering controls as appropriate, and suitable PPE.
- Bioscience managers will provide explanations of work including information on specific pathogens being handled or having the potential to be handled.

- Bioscience managers will provide, through ESH-2, free vaccination programs for affected workers who want to participate.
- Bioscience managers will provide for safe waste handling.
- Bioscience managers will provide training programs and training opportunities.
- Bioscience managers will post all work areas appropriately.

3) Workers
- will conduct work according to HCPs and/ or applicable protocols using "Universal Precautions"
- will handle wastes as required
- will use appropriate PPE
- will use engineering controls provided
- will adhere to postings
- will maintain good housekeeping in work areas
- will wash hands after work

B. Training and Information
1) ATTACHMENT C is 29 CFR 1910.1030
2) Written or oral work plans will include:
- explanation of symptoms and epidemiology of blood borne diseases
- modes of transmission
- explanations of tasks and modes of potential exposures
- explanation of use and limitations of controls
- complete review of the location, handling, decontamination and disposal of PPE
- explanation of the basis for selection of PPE
- information on available vaccinations including efficacy, safety, and benefits
- review of appropriate emergency procedures

C. Emergency Procedures:
1) In case of facility failure (loss of electricity for lighting and equipment) work must stop, materials must be secured either by closures of containers or addition of disinfectant then surfaces must be decontaminated. Access must be restricted and postings remain until normal operations resume. If evacuation occurs, provide specific information about materials being used and status of the space to emergency responders.

2) In case of fire concerns for personnel safety must prevail. Evacuate promptly if possible add disinfectant to any open containers. Should a fire begin at the site of this work workers may choose to attempt containment of the flames or evacuation and should not place themselves or others in danger . Evacuate and

find closest fire pull box, turn in alarm. Provide information about the specific materials in use and the status of the space for emergency responders.

3) In case of accidental spill or loss of containment add disinfectant (bleach or specific commercial product) to area. Close all open containers. Contain spill with barriers. Get help from co-workers to assure access control and notification of line managers and facility manager, but avoid opportunities for personnel exposures. Remove PPE, wash hands report incident to line manager and/ or facility manager. Notify EM&R (667-6211 or 911) if volumes or conditions of spill prevent local containment.

4) In case of exposure to workers remove contaminated clothing, wash exposed skin and report to Occupational Medicine (ESH-2) immediately, or go directly to Los Alamos Medical Center. See that your supervisor, line manager and facility manager are promptly notified. Other unaffected workers should call 911 to get containment assistance/ guidance. Control access and limit opportunities for others to be exposed.

All incidents that involve loss of containment or exposure MUST be reported to appropriate line managers and the facility manager. Potential loss of containment or exposure should be reported to line manager(s) for the purpose of conducting a lessons-learned evaluation for improvements.

APPENDIX E.1: BACKGROUND INFORMATION ON UNDERSTANDING INFECTIOUS MICROORGANISMS AND THE LANL PROPOSED ACTION MICROORGANISMS

Terminology and Lists of Microorganisms

There are a number of terms used in this document that pertain to infectious microorganisms and these are defined in either footnotes as they are presented in the text or in the glossary at the end of Appendix E.2. These include, biological agents, select agents, etiologic agents, biological warfare agents, and infectious agents. The terminology is often dependant upon the Federal Agency using the term and the Government regulation. For example, "select agent" is a CDC term defined as "a microorganism (virus, bacterium, rickettsia) or toxin…including genetically modified organisms" that can be found in Appendix A of 42 CFR 72. That CFR, however, is titled *Interstate Shipment of Etiologic Agents* and has another table in it (Table 72.3) listing "etiologic agents" as a "viable microorganism or its toxin which causes, or may cause, human disease." There are additional infectious microorganism lists or rankings that are proposed for codification (e.g., 49 FR 171-178).

General Information on Infectious Agents

An instructional guide on infectious diseases that explains many of the terms used in this EA is included as Appendix E.2, and is titled *Understanding Emerging and Re-emerging Infectious Diseases* (NIH 1999). The National Institute of Allergy and Infectious Diseases, one of the National Institutes of Health, prepared the document, which is in the public domain and may be reproduced without permission (NIH 1999). This document was prepared for the NIH Curriculum Supplement Series for Grades 9-12 and includes discussions on:

- The nature of infectious diseases
- Microbes that cause infectious diseases
- The occurrence of infectious disease
- Host defenses against infectious diseases
- Public health measures to prevent infectious diseases
- Treatment of infectious diseases
- Emerging and re-emerging infectious diseases
- Infectious diseases and society
- A glossary of terms

Risk Associated with Infectious Agents

A literature search identified three sources of information ranking infectious agents by risk category. These are from the CDC (CDC 2000a), the NIH (NIH 2001), and a summary compendium that includes an earlier version of the NIH ranking from the American Biological Safety Association (ABSA) (ABSA 1998). The microorganism list from the ABSA summary was used as a starting point for creating the tables in Appendix E.3. The literature search found this listing as the most complete and available from a reliable source. It does not contain all the microorganisms discussed or listed in the CDC BMBL (CDC 1999), nor does the BMBL refer to all the microorganisms listed in the ABSA list. Therefore, those preparing risk assessments should refer to both documents for relevant information. However, as a compendium of possible infectious organisms that might be handled in a microbiological laboratory, it is more than adequate. The tables in Appendix E.3 include some additional microorganisms from the newest CDC (2000a) and NIH (2001) sources. The following subsections briefly describe the three information sources.

CDC 2000 Ranking. The CDC ranking was described in the Johns Hopkins University's *Biodefense Quarterly* (JH 1999), as follows: "On June 3-4, 1999, the Centers for Disease Control and Prevention (CDC) convened a panel of experts in medicine and public health, military intelligence and law enforcement, and security for the purpose of identifying biological agents considered to be of greatest potential concern." The outgrowth of this meeting and subsequent interagency discussion resulted in a CDC *Morbidity and Mortality Weekly Report* (MMWR) that presented the panels recommendations for "critical biological agents" (CDC 2000a). The mandate of this panel was to identify the critical biological agents associated with bioterrorism, the resulting analysis focused on the relative risk between infectious agents that might be of concern.

The CDC segregated the list of agents they deemed most problematic into three categories. Category A included organisms that pose the highest risk. These can be easily disseminated or transmitted person-to-person, cause high mortality (i.e., death) with potential for major public health impact, and require special action for public health preparedness. Category A includes:

- *Variola major* (smallpox)
- *Bacillus anthracis* (anthrax)
- *Yersinia pestis* (plague)
- *Clostridium botulinum* toxin (botulism)
- *Francisella tularensis* (tularaemia)
- filoviruses (Ebola hemorrhagic fever and Marburg fever)
- arenaviruses (Lassa fever, and Junin or Argentine hemorrhagic fever and related viruses)

The second category Category, B, includes microorganisms that are moderately easy to disseminate, have moderate morbidity (i.e., ability to cause disease) and low mortality, but require enhanced disease surveillance. Category B includes:

- *Coxiella burnetti (*Q fever)
- *Brucella spp*. (brucellosis)
- *Burkholderia mallei (*glanders)
- alphaviruses (Venezuelan encephalomyelitis and eastern and western equine encephalomyelitis)
- ricin toxin
- epsilon toxin (from *Clostridium perfringens*)
- *Staphylococcus* enterotoxin B

A subset of Category B includes the food- and water-borne pathogens:

- *Salmonella* species
- *Shigella dysenteriae*
- *Escherichia coli* O 157:H7
- *Vibrio cholerae*
- *Cryptosporidium parvum*

The last and lowest risk category, Category C, includes emerging pathogens that could be engineered for mass dissemination because of availability, ease of production and dissemination, and the potential for high morbidity and mortality and consequent major health impact. These include:

- Nipah virus
- hantaviruses
- tick-borne hemorrhagic fever viruses
- tick-borne encephalitis viruses
- yellow fever
- multi-drug resistant tuberculosis

The NIH 2001 Ranking. The risk group ranking provided by NIH "is based on the potential effect of a biological agent on a healthy human adult and does not account for instances in which an individual may have increased susceptibility to such agents, e.g., pre-existing diseases,

medications, compromised immunity, pregnancy or breast feeding (which may increase exposure of infants to some agents)." This ranking is known as the *Classification of Human Etiologic Agents on the Basis of Hazard* and is included in Appendix B of the *NIH Guidelines: Recombinant DNA and Gene Transfer; Guidelines for Research Involving Recombinant DNA Molecules* (NIH 2001). Agents are classified into four risk groups (RG):

- RG1 includes agents that are not associated with disease in health human adults
- RG2 includes agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available
- RG3 includes agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may* be available
- RG4 includes agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available

The ABSA 1998 Ranking Table. The ABSA "Risk Group Classification for Infectious Agents" (ABSA 1998) was developed on the basis of relative risk. The factors that were taken into consideration were the: pathogenicity of the organism, mode of transmission and host range, availability of effective preventive measures (for example, vaccines), availability of effective treatment (such as antibiotics), and other factors.

The intent of the ranking table is to provide risk information for the research community as part of their biosafety risk assessments. The ABSA tables include four risk-group spreadsheets prepared in Adobe™ portable document format (pdf) that are downloadable from the world-wide-web (http://www.absa.org/riskgroups/). These tables provide information on infectious bacteria, viruses, fungi, and parasites (ABSA 1998). The bacteria table includes Rickettsia, and the virus table includes prions. The ranking information associated with listed microorganisms on these tables reflect the combined sources of information from the European Economic Community directives, the NIH Guidelines on Recombinant DNA, the Canadian Laboratory Biosafety Guidelines, and the CDCs BMBL. These tables are not included in this EA due to their large size.

LANL Proposed Action Microorganisms. LANL envisions that the proposed laboratory facility could handle any of the bacterial or viral infectious agents listed in the BSL-3 category by CDC in Section VII of the BMBL (CDC 1999) or future editions and revisions of that guidance. In addition, the proposed laboratories could handle other bacterial or viral infectious organisms not specifically or currently regulated by CDC or other Federal agencies such as those shown in the tables in Appendix E.3. Only by prior approval of the LANL Institutional Biosafety Committee (IBC), and after a risk analysis is conducted, would any infectious agent be considered for use in the proposed laboratories. Current plans are for these laboratories to handle

live microorganisms or their DNA, RNA[1], proteins[2], or attenuated organisms[3] in their vegetative forms[4] (PC 2001g). The following list provided by LANL (PC 2001g) identifies the bacterial microorganisms and viral diseases that would likely be used in the foreseeable future. (Note: the tables in Appendix E.3 also include these bacterial microorganisms and many of the possible agents that could cause these viral diseases):

- Bacteria
  - Select agents (42 CFR 72)
    - *Bacillus anthracis*
    - *Yersinia pestis*
    - *Burkholderia (Pseudomonas) mallei*
    - *Burkholderia (Pseudomonas) pseudomallei*
    - *Clostridium botulinum*
    - *Francisella tularensis*
    - *Brucella abortus*
    - *Brucella melitensis*
    - *Brucella suis*
    - *Clostridium tetani*
  - *Other bacterial agents listed in the BMBL (CDC 1999)*
    - *Mycobacterium tuberculosis*
    - *Bordetella pertussis*
    - *Helicobacter pylori*
    - *Legionella pneumophilia*
    - *Neisseria gonorrhoeae*
    - *Neisseria meningitidis*
    - *Salmonella typhi*
    - *Shigella spp.*
    - *Vibrionic enteritis*
- Virus
  - *Select agents (42 CFR 72)*
    - *Hantaviruses*
  - *Other viral agents listed in the BMBL (CDC 1999)*
    - *Influenza*
    - *Hepatitis*
    - *Herpesviruses*

[1] RNA or ribonucleic acid is similar and complementary to DNA in that it transcribes the encoded chromosomal information to create proteins. In certain viruses they take the place of DNA.
[2] Proteins are building blocks of cells and are used for support, storage, transport of substances, and defense against invaders.
[3] Organisms that have been deactivated by various means so that they have very limited growth potential.
[4] A vegetative form is one that is capable of actively growing.

- *Poliovirus*
- *Retroviruses*
- *Vesicular stomatitis*
- *Lentiviruses*

There are currently no plans for the proposed BSL-3 laboratories (PC 2001g) to intentionally handle or induce sporulation or the formation of endospores[5], nor are there plans to handle biological toxins except for those produced incidentally to the handling of certain microorganisms.

These microorganisms could be processed a number of ways, for example (PC 2001g):

- Selective culturing[6]
- Sample amplification[7]
- Chemical separation of parts (e.g., DNA, RNA, proteins)
- Centrifugation[8]
- Freezing
- Decontamination by autoclaving[9]
- Decontamination by chemical disinfection

[5] Endospores are a very tough, dormant form of certain bacterial cells that are very resistant to desiccation, heat, and a variety of chemical and radiation treatments that are lethal to vegetative cells.
[6] Selective culturing uses nutrients and environmental controls to enhance the growth of some microorganisms relative to others which might also be present.
[7] Amplification is the process to rapidly and significantly increase the number of microorganisms in a sample.
[8] Centrifugation is the process of spinning a sample at a high rate of revolution to cause a separation of materials based upon their density.
[9] Autoclaving is the process of using steam under pressure for a sufficient time to produce sterilization of materials.

APPENDIX E.2: UNDERSTANDING EMERGING AND RE-EMERGING INFECTIOUS DISEASE

Understanding Emerging and Re-emerging Infectious Diseases

The term "disease" refers to conditions that impair normal tissue function. For example, cystic fibrosis, atherosclerosis, and measles are all considered diseases. However, there are fundamentally different causes for each of these diseases. Cystic fibrosis (CF) is due to a specific genotype that results in impaired transport of chloride ions across cell membranes, leading to the production of abnormally thick mucus. Thus, CF is most accurately called a *genetic* or *metabolic* disease. Atherosclerosis, which can lead to heart attacks and strokes, may be considered a disease of *aging*, because it typically becomes a problem later in life after plaques of cholesterol have built up and partially blocked arteries. In contrast, measles is an *infectious* disease because it occurs when an individual contracts an outside agent, the measles virus. An **infectious disease** is a disease that is caused by the invasion of a host by agents whose activities harm the host's tissues (that is, they cause *disease*) and can be transmitted to other individuals (that is, they are *infectious*).

Nature of Infectious Diseases

Microorganisms that are capable of causing disease are called **pathogens**. Although microorganisms that cause disease often receive the most attention, it is important to note that most microorganisms do *not* cause disease. In fact, many probably provide some protection against harmful microorganisms because they effectively compete with the harmful organisms for resources, preventing them from growing.

A true pathogen is an infectious agent that causes disease in virtually any susceptible host. Opportunistic pathogens are potentially infectious agents that rarely cause disease in individuals with healthy immune systems. Diseases caused by opportunistic pathogens typically are found among groups such as the elderly (whose immune systems are failing), cancer patients receiving chemotherapy (which adversely affects the immune system), or people who have AIDS or are HIV-positive. An important clue to understanding the effect of HIV on the immune system was the observation of a rare type of pneumonia among young men caused by *Pneumocystis carinii*, an organism that causes disease only among the immunosuppressed.

The terms "infection" and "disease" are not synonymous. An **infection** results when a pathogen invades and begins growing within a host. **Disease** results only if and when, as a consequence of the invasion and growth of a pathogen, tissue function is impaired. Our bodies have defense mechanisms to prevent infection and, should those mechanisms fail, to prevent disease after infection occurs. Some infectious agents are easily transmitted (that is, they are very contagious), but they are not very likely to cause disease (that is, they are not very virulent). The polio virus is an example: It probably infects most people who contact it, but only about 5 to 10 percent of those infected actually develop clinical disease. Other infectious agents are very virulent, but not terribly contagious. The terror surrounding Ebola hemorrhagic fever is based on the virulence of the virus (50 to 90 percent fatality rate among those infected); however, the virus itself is not transmitted easily by casual contact. The most worrisome infectious agents are those that are both very contagious and very virulent.

In order to cause disease, pathogens must be able to enter the host body, adhere to specific host cells, invade and colonize host tissues, and inflict damage on those tissues. Entrance to the host typically occurs through natural orifices such as the mouth, eyes, or genital openings, or through wounds that breach the skin barrier to pathogens. Although some pathogens can grow at the initial entry site, most must invade areas of the body where they are not typically found. They do this by attaching to

Figure 3 Emerging and re-emerging infectious diseases threaten all countries. Ebola hemorrhagic fever emerged in African villages; schistosomiasis is re-emerging in Egypt, largely as a consequence of building the Aswan Dam; and legionellosis was identified after an outbreak of pneumonia among individuals attending a conference in Philadelphia.

specific host cells. Some pathogens then multiply between host cells or within body fluids, while others such as viruses and some bacterial species enter the host cells and grow there. Although the growth of pathogens may be enough to cause tissue damage in some cases, damage is usually due to the production of toxins or destructive enzymes by the pathogen. For example, *Corynebacterium diphtheriae*, the bacteria that causes diphtheria, grows only on nasal and throat surfaces. However, the toxin it produces is distributed to other tissues by the circulatory system, damaging heart, liver, and nerve tissues. *Streptococcus pyogenes*, the infectious agent associated with several diseases including strep throat and "flesh-eating disease," produces several enzymes that break down barriers between epithelial cells and remove fibrin clots, helping the bacteria invade tissues.

Microbes That Cause Infectious Diseases

There are five major types of infectious agents: bacteria, viruses, fungi, protozoa, and helminths. In addition, a new class of infectious agents, the prions, has recently been recognized. A brief review of the general characteristics of each of these agents and examples of some diseases they cause follows.

Bacteria. Bacteria are unicellular prokaryotic organisms; that is, they have no organized internal membranous structures such as nuclei, mitochondria, or lysosomes. Their genomes are circular, double-stranded DNA that is associated with much less protein than eukaryotic genomes. Most bacteria reproduce by growing and dividing into two cells in a process known as binary fission. Despite these commonalities that group them together in the Kingdom Monera, there is a wide range of diversity among the bacteria.

There are a variety of morphologies among bacteria, but three of the most common are bacillus (rod-shaped), coccus (spherical), or spirillum (helical rods). The energy sources for bacteria also vary. Some bacteria are photosynthetic and obtain their energy directly from the sun. Others oxidize inorganic compounds to supply their energy needs. Still other bacteria generate energy by breaking down organic compounds such as amino acids and sugars in a respiratory process. Some bacteria require oxygen (aerobes), while others are unable to tolerate it (anaerobes). Some bacteria can grow either with or without oxygen (facultative anaerobes).

Bacteria are frequently divided into two broad classes based on their cell wall structures, which influences their Gram stain reaction. Gram-negative bacteria appear pink after the staining procedure. Familiar pathogenic gram-negative organisms are *Salmonella typhi*, which causes typhoid

fever, and *Yersinia pestis*, which causes plague. Gram-positive bacteria appear purple after the Gram stain procedure. Examples of pathogenic gram-positive bacteria are *Staphylococcus aureus*, which causes skin, respiratory, and wound infections, and *Clostridium tetani*, which produces a toxin that can be lethal for humans.

Viruses. Microbiologists have found viruses that infect all organisms, from plants and animals to fungi and bacteria. Viruses, however, are not organisms themselves because, apart from a host cell, they have no metabolism and cannot reproduce. A virus particle is composed of a viral genome of nucleic acid that is surrounded by a protein coat called a capsid. In addition, many viruses that infect animals are surrounded by an outer lipid envelope, which they acquire from the host cell membrane as they leave the cell. Unlike organisms, in which the genetic material is always double-stranded DNA, viral genomes may be double- or single-stranded DNA (a DNA virus), or double- or single-stranded RNA (an RNA virus).

In the general process of infection and replication by a DNA virus, a viral particle first attaches to a specific host cell via protein receptors on its outer envelope, or capsid. The viral genome is then inserted into the host cell, where it uses host cell enzymes to replicate its DNA, transcribe the DNA to make messenger RNA, and translate the messenger RNA into viral proteins. The replicated DNA and viral proteins are then assembled into complete viral particles, and the new viruses are released from the host cell. In some cases, virus-derived enzymes destroy the host cell membranes, killing the cell and releasing the new virus particles. In other cases, new virus particles exit the cell by a budding process, weakening but not destroying the cell.

In the case of some RNA viruses, the genetic material can be used directly as messenger RNA to produce viral proteins, including a special viral RNA polymerase that copies the RNA template to produce the genetic material for new viral particles. Other RNA viruses, called retroviruses, use a unique enzyme called reverse transcriptase to copy the RNA genome into DNA. This DNA then integrates itself into the host cell genome. These viruses frequently exhibit long latent periods in which their genomes are faithfully copied and distributed to progeny cells each time the cell divides. The human immunodeficiency virus (HIV), which causes AIDS, is a familiar example of a retrovirus.

Just like other infectious agents, viruses cause disease by disrupting normal cell function. They do this in a variety of ways. Some viruses make repressor proteins that stop the synthesis of the host cell's proteins, RNA, and DNA. Viral activity may weaken cell membranes and lysosomal membranes, leading to cell autolysis. Some viral proteins are toxic to cells, and the body's immune defenses also may kill virus-infected cells.

Viruses are classified using a variety of criteria, including shape, size, and type of genome. Among the DNA viruses are the herpes viruses that cause chicken pox, cold sores, and painful genital lesions, and the poxvirus that causes smallpox. Significant RNA viruses that cause human disease include rhinoviruses that cause most common colds; myxoviruses and paramyxoviruses that cause influenza, measles, and mumps; rotaviruses that cause gastroenteritis; and the retroviruses that cause AIDS and several types of cancer.

Fungi. Fungi are eukaryotic, heterotrophic organisms that have rigid cellulose- or chitin-based cell walls and reproduce primarily by forming spores. Most fungi are multicellular, although some, such as yeasts, are unicellular. Together with bacteria, fungi fulfill the indispensable role of decomposers in the environment. Many fungi also infect plants and animals. Examples of diseases caused by fungi are ringworm and histoplasmosis (a mild to severe lung infection transmitted by bat or bird droppings). Yeasts of the *Candida* genus are opportunistic pathogens that may cause diseases such as vaginal yeast infections and thrush (a throat infection) among people who are immunocompromised or undergoing antibiotic therapy. Antibiotics reduce the bacterial population normally present in the throat and vagina, allowing the yeast to grow unchecked.

Protozoa. Protozoa are unicellular, heterotrophic eukaryotes that include the familiar amoeba and

paramecium. Because protozoa do not have cell walls, they are capable of a variety of rapid and flexible movements. Protozoa can be acquired through contaminated food or water or by the bite of an infected arthropod such as a mosquito. Diarrheal disease in the United States can be caused by two common protozoan parasites, *Giardia lamblia* and *Cryptosporidium parvum*. Malaria, a tropical illness that causes 300 million to 500 million cases of disease annually, is caused by several species of the protozoan *Plasmodium*.

Helminths. Helminths are simple, invertebrate animals, some of which are infectious parasites. They are multicellular and have differentiated tissues. Because they are animals, their physiology is similar in some ways to ours. This makes parasitic helminth infections difficult to treat because drugs that kill helminths are frequently very toxic to human cells.

Many helminths have complex reproductive cycles that include multiple stages, many or all of which require a host. *Schistosoma*, a flatworm, causes the mild disease swimmer's itch in the United States; another species of *Schistosoma* causes the much more serious disease schistosomiasis, which is endemic in Africa and Latin America. Schistosome eggs hatch in freshwater, and the resulting larvae infect snails. When the snails shed these larvae, the larvae attach to and penetrate human skin. They feed, grow, and mate in the human bloodstream; the damage to human tissues caused by the accumulating schistosome eggs with their sharp spines results in disease symptoms including diarrhea and abdominal pain. Liver and spleen involvement are common. Another disease due to a helminth is trichinosis, caused by the roundworm *Trichinella spiralis*. This infectious agent is typically ingested in improperly cooked pork from infected pigs. Early disease symptoms include vomiting, diarrhea, and fever; later symptoms include intense muscle pain because the larvae grow and mature in those tissues. Fatal cases often show congestive heart failure and respiratory paralysis.

Prions. During the past two decades, evidence has linked some degenerative disorders of the central nervous system to infectious particles that consist only of protein. These "proteinaceous infectious particles" have been named prions (pree-ons). The known prion diseases include Creutzfeldt-Jakob disease (in humans), scrapie (in sheep), and bovine spongiform encephalopathy ("mad cow disease" in cattle); all known prion diseases frequently result in brain tissue that is riddled with holes. While some prion diseases are inherited, others are apparently due to infection by eating infected tissue or inadvertently through medical procedures such as tissue transplants.

Occurrence of Infectious Diseases

Epidemiology is the study of the occurrence of disease in populations. Epidemiologists are concerned not only with infectious diseases, but also with noninfectious diseases such as cancer and atherosclerosis, and with environmental diseases such as lead poisoning. These professionals work to prevent or minimize the impact of diseases in the population. Their work may include such activities as identifying unusually high incidences of a particular disease, determining the effectiveness of a vaccine, and calculating the cost effectiveness of various means of controlling disease transmission. Occasionally, epidemiologists act as "detectives" who track down the cause of a "new" disease, determine its reservoir and mode of transmission, and help organize various health care workers to bring the disease under control.

Disease reservoirs. The reservoir for a disease is the site where the infectious agent survives. For example, humans are the reservoir for the measles virus because it does not infect other organisms.

Animals often serve as reservoirs for diseases that infect humans. The major reservoir for *Yersinia pestis*, the bacteria that causes plague, is wild rodents. There are also nonliving reservoirs. Soil is the reservoir for many pathogenic fungi as well as some pathogenic bacteria such as *Clostridium tetani*, which causes tetanus.

Modes of transmission. Infectious agents may be transmitted through either direct or indirect contact. Direct contact occurs when an individual is

infected by contact with the reservoir, for example, by touching an infected person, ingesting infected meat, or being bitten by an infected animal or insect. Transmission by direct contact also includes inhaling the infectious agent in droplets emitted by sneezing or coughing and contracting the infectious agent through intimate sexual contact. Some diseases that are transmitted primarily by direct contact with the reservoir include ringworm, AIDS, trichinosis, influenza, rabies, and malaria.

Indirect contact occurs when a pathogen can withstand the environment outside its host for a long period of time before infecting another individual. Inanimate objects that are contaminated by direct contact with the reservoir (for example, a tissue used to wipe the nose of an individual who has a cold or a toy that has been handled by a sick child) may be the indirect contact for a susceptible individual. Ingesting food and beverages contaminated by contact with a disease reservoir is another example of disease transmission by indirect contact. The fecal-oral route of transmission, in which sewage-contaminated water is used for drinking, washing, or preparing foods, is a significant form of indirect transmission, especially for gastrointestinal diseases such as cholera, rotavirus infection, cryptosporidiosis, and giardiasis.

These modes of transmission are all examples of horizontal transmission because the infectious agent is passed from person to person in a group. Some diseases also are transmitted vertically; that is, they are transmitted from parent to child during the processes of reproduction (through sperm or egg cells), fetal development, or birth. Diseases in which vertical transmission occurs include AIDS and herpes encephalitis (which occurs when an infant contracts the herpes simplex type II virus during vaginal birth).

Role of Research in Prevention

Infectious diseases can be prevented at a variety of points, depending on the infectious cycle for the particular disease (Figure 4). Basic research, such as that sponsored by NIH, reveals the specific infectious cycle and details regarding the

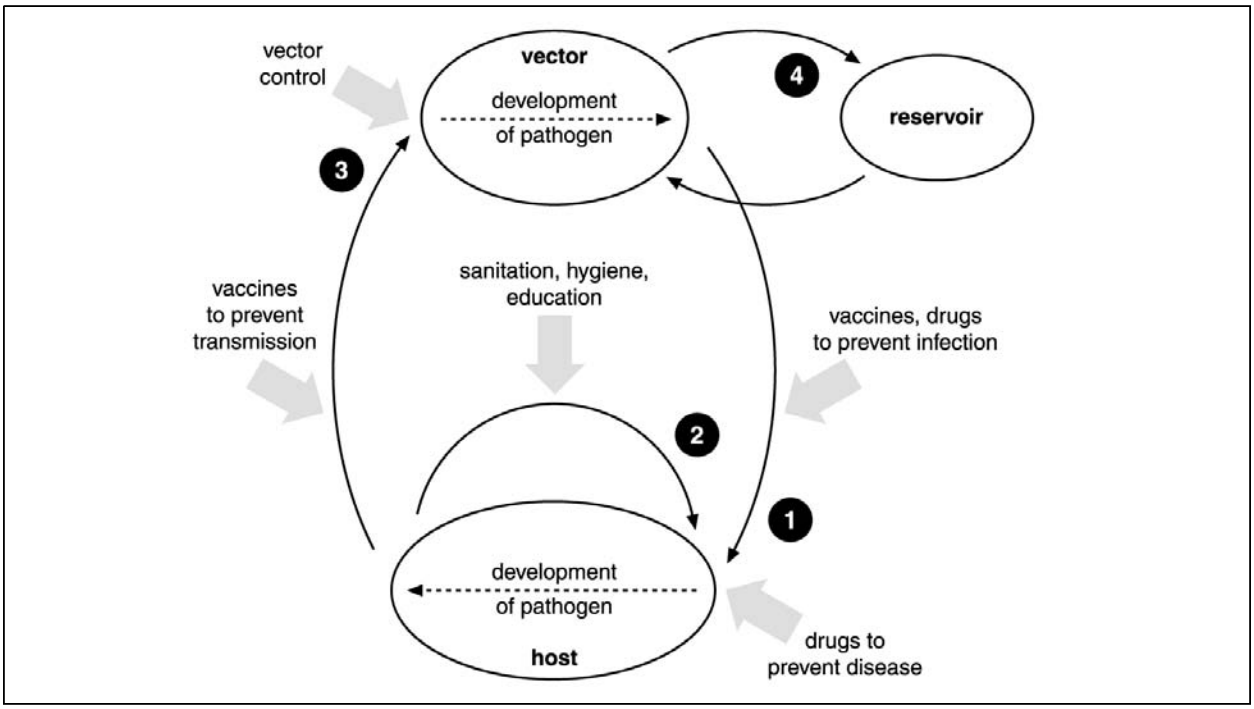


Figure 4 The black arrows illustrate a generalized infectious cycle; the shaded arrows indicate points where infectious diseases can be prevented. (1) A host is infected by the reservoir or a vector for the pathogen. This individual may infect (2) other hosts in a population or (3) new vectors. (4) The pathogen also may cycle between the vector and a reservoir.

activities of the pathogen that cause disease (for example, the particular cells, if any, that are attacked, and the toxins produced by the pathogen that damage host tissues).

Understanding the infectious cycle is critical in order to identify accessible targets for control strategies (Figure 4). For example, direct person-to-person transmission may be inhibited by proper hygiene and sanitary conditions as well as education. Vector-borne diseases may be prevented by control measures that either kill the vector or prevent its contact with humans. Infection by a pathogen or development of a pathogen within a host may be prevented by vaccination. Finally, drugs may be used to prevent infection or suppress the disease process.

In some cases, the tools, including drugs, vaccines and vector control methods, are already available to deal with these diseases. For other diseases, the methods for control are inadequate, undeveloped, or nonexistent. Scientists are trying to develop the new tools needed to banish these scourges of mankind. This requires basic research into the life processes of the pathogen and its interaction with the host in order to identify points within the life cycle where the pathogen is vulnerable to intervention, translational research to develop new tools (such as vaccines or antimicrobial drugs), and clinical research to test the safety and efficacy of these new tools.

Host Defenses Against Infectious Diseases

The human body has several general mechanisms for preventing infectious diseases. Some of these mechanisms are referred to as nonspecific defenses because they operate against a wide range of pathogens. Other mechanisms are referred to as specific defenses because they target particular pathogens and pathogen-infected cells.

Nonspecific mechanisms. Nonspecific mechanisms are the body's primary defense against disease. These mechanisms include anatomical barriers to invading pathogens, physiological deterrents to pathogens, and the presence of normal flora. An example of an anatomical barrier is the nasal opening to the respiratory system. This natural opening is a long, convoluted passage covered by mucous membranes that trap airborne particles and prevent most of them from reaching the lungs. Other anatomical barriers are the skull and vertebral column, which protect the central nervous system—few pathogens are able to penetrate bone. The skin also is a major anatomical barrier to microorganisms. The surface layer of dead, hardened cells is relatively dry, and skin secretions make the surface somewhat acidic. When sweat evaporates, salt is left behind on the skin. All of these conditions (low moisture, low pH, and high salinity) prevent most microorganisms from growing and multiplying on the skin. The major medical challenge in treating burn patients is preventing and treating infections that result because of the absence of skin that ordinarily would prevent invasion of microorganisms.

Natural openings also are protected by a variety of physiological deterrents. For example, tears continually flush debris from the eyes. Vaginal secretions are acidic, a hostile environment that discourages the growth of many pathogens. The eye, mouth, and nasal openings are protected by tears, saliva, or nasal secretions that contain lysozyme, an enzyme that breaks down bacterial cell walls. Blood, sweat, and some tissue fluids contain lysozyme as well.

In addition to lysozyme, the blood has many elements that defend the body from disease-causing organisms. The white blood cells include several types of phagocytic cells that detect, track, engulf, and kill invading bacteria and viruses, as well as infected host cells and other debris. These phagocytic cells are part of the nonspecific immune system. Blood plasma also includes clotting factors that initiate a clot at the injury site, preventing pathogens from invading the body further. Finally, the complement proteins in the blood participate in a cascade of molecular events that result in inflammation, the release of molecules that stimulate phagocytic cells, and the formation of a complex of proteins that binds to the surface of bacterial or infected host cells and lyses those cells.

The inflammatory response is another nonspecific defense mechanism that helps prevent infectious

agents from spreading in the body. Inflammation involves swelling, reddening, elevated temperature, and pain. Unfortunately, inflammation itself frequently causes tissue damage and, in severe cases, even death.

Finally, the protective role of the "normal flora" of microorganisms present on and in the body should not be overlooked. These organisms survive and grow on the skin and in the mouth, gastrointestinal tract, and other areas of the body, but do not cause disease because their growth is kept under control by the host's defense mechanisms and by the presence of other microorganisms. These organisms protect the host by successfully competing with disease-causing organisms, preventing the latter from invading host tissues. When the growth of the normal flora is suppressed (for example, due to antibiotic treatment), other "opportunistic" agents that normally do not grow in or on the body may be able to infect and cause disease.

Specific mechanisms of host resistance. When these nonspecific mechanisms fail, the body initiates a second, specific line of defense. This specific immune response enables the body to target particular pathogens and pathogen-infected cells for destruction. It depends on specialized white blood cells called lymphocytes and includes T-cells (produced from lymphocytes that matured in the thymus gland) and B-cells (produced from lymphocytes that matured in the bone marrow).

The two complementary components of the specific immune response are the cell-mediated response and the antibody-mediated response (Figure 5). The cell-mediated response involves T-cells and is responsible for directly destroying body cells that are infected with a virus or have become cancerous, or for activating other immune cells to be more efficient microbe killers. The antibody-mediated response involves both T-cells and B-cells and is critical for the destruction of invading pathogens as well as the elimination of toxins.

Both the cell-mediated and antibody-mediated responses are initiated after a particular type of phagocytic cell, a macrophage, engulfs a pathogen. Macrophages digest the pathogen and then display antigens from the pathogen on their surface. Antigens are specific molecules, such as the proteins on the surface of pathogens, that elicit an immune response. This display helps the macrophages stimulate specific helper T-cells to release signal molecules called lymphokines. The lymphokines, in turn, stimulate the cell-mediated and antibody-mediated responses.

The cell-mediated response occurs when the lymphokines released from the helper T-cells stimulate other cell types to participate in the immune response. Lymphokine-stimulated killer T-cells attach to the pathogen-infected cells and destroy them, whereas lymphokine-activated phagocytic cells produce more toxic molecules that can kill the pathogen directly.

The antibody-mediated response occurs when the lymphokines activate specific B-cells to produce antibodies (proteins that specifically recognize and bind to antigens). These antibodies attach to antigens on the surface of the pathogens and signal attack by phagocytic cells and complement system. Other B-cells go on to become memory B-cells, which respond quickly by producing more antibodies upon subsequent infection.

Immunity. When a host encounters an antigen that triggers a specific immune response for the second or later time, the memory lymphocytes recognize it and quickly begin growing and dividing, as well as producing high levels of lymphokines and antibodies. Because memory cells are present, this response happens much more quickly than in the initial encounter with the antigen. This rapid response explains why hosts are immune to developing many diseases a second time: The immune response occurs so quickly in a second encounter with the pathogen that the pathogen does not have enough time to reproduce to levels that result in disease before the host's body has destroyed it. The memory response also explains the effectiveness of vaccination for preventing even the first occurrence of many diseases.

Vaccination. A vaccine is either a killed or weakened (attenuated) strain of a particular pathogen, or a solution containing critical antigens from the

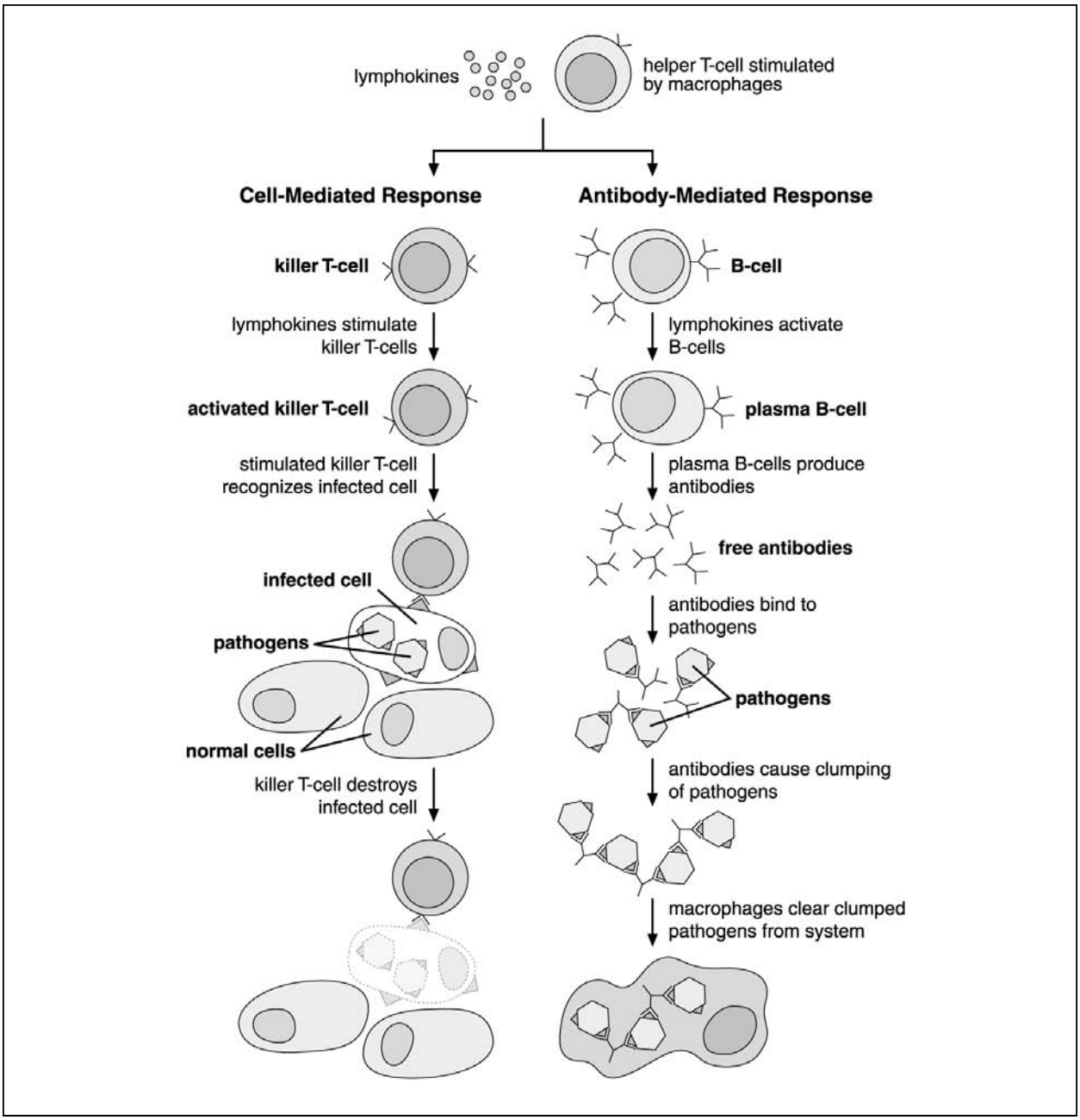


Figure 5 This diagram provides an overview of specific immunity.

pathogen. The body's immune system will respond to these vaccines as if they contain the actual pathogen, even though the vaccine is not capable of causing the disease. As a result of the specific immune response, memory lymphocytes will be present that respond rapidly when the actual pathogen is encountered. The resulting rapid activation of immune cells prevents disease.

Currently new types of vaccines, the DNA vaccines, are in early stage trials. These vaccines contain genes that encode proteins from pathogens. When these genes are inserted into host cells and are expressed in the form of pathogen proteins, an immune reaction may result.

The ultimate effectiveness of vaccination—eradication of the infectious agent—has been achieved only for smallpox. The World Health Organization has identified the polio and measles viruses among the next targets for global eradication.

For a variety of reasons, many diseases are not easily prevented by vaccination. Antibody response is generally the simplest to induce by vaccination, but some pathogens have ways to evade the immune response. Intracellular pathogens (such as viruses and some bacterial and protozoan pathogens) are not directly affected by antibodies because antibodies cannot pass inside cells. Moreover, during the disease process, some pathogens acquire an external coat composed of host-derived material while others disguise themselves by making molecules that resemble host molecules. Thus, the host's immune system does not identify them as foreign invaders. Still other pathogens mutate quickly, producing variants of their antigens that are not recognized by the host's immune system, even though the host survived a previous encounter with that pathogen. Cold and influenza viruses are examples of rapidly mutating pathogens. Scientists are working to improve vaccines against these pathogens.

Public Health Measures to Prevent Infectious Diseases

Developed countries have regulations that help protect the general public from infectious diseases. Public health measures typically involve eliminating the pathogen from its reservoir or from its route of transmission. Those measures include ensuring a safe water supply, effectively managing sewage treatment and disposal, and initiating food safety, animal control, and vaccination programs.

Safe water. Many pathogens that cause gastrointestinal diseases (for example, those that cause cholera and typhoid fever) are transmitted via water. Travelers to developing countries are frequently advised to be immunized against these diseases. This is generally unnecessary in the United States and other developed countries because the water used for washing, drinking, and preparing food is purified before it goes into homes. Purification methods include settling, filtration, and chlorination. The water for homes that use well water or springs is usually safe if guidelines about distance from sewage disposal facilities are followed; however, this water should be checked periodically. When breakdowns in a purification system occur, or when a system is overwhelmed (for example, due to unusual flooding), drinking water may not be safe and should be boiled or treated with chlorine before it is ingested.

Because gastrointestinal pathogens typically leave the body in the feces, public water must be guarded against contamination from sewage. Municipal water is usually tested for the presence of coliform organisms (nonpathogenic microorganisms that are part of the normal flora of the gastrointestinal tract) as indicators of sewage contamination. This procedure is necessary because when the water contains pathogens and is potentially dangerous, the pathogenic organisms are usually present in such small numbers that they are hard to detect.

Sewage treatment and disposal. Sewage includes wash water, water from toilets, and storm run-off. These fluids may carry the pathogens for many waterborne diseases, including giardiasis and hepatitis A; therefore, to ensure public safety the U.S. government (and the governments of other developed countries) requires that sewage be treated to eliminate pathogens. The minimal acceptable level of treatment involves collection and sedimentation of sewage waters, separating solid matter (sludge) from the liquid (effluent) portion of sewage. The effluent is chlorinated to kill pathogens before it is released to rivers or lakes. The sludge is burned or dumped.

More advanced methods of treatment use a secondary treatment following this primary treatment. The effluent is transferred to tanks containing a population of microorganisms that decompose more than 90 percent of the organic wastes and eliminate pathogens by competition (this is another example of the important role of microorganisms in *preventing* disease). The resulting effluent is chlorinated before it is released to the environment. Some sewage treatment plants include a tertiary treatment that involves additional chemicals that also eliminate pathogens.

Food safety programs. The United States has many standards, inspection plans, and regulations about food preparation, handling, and distribution. Meat-packing facilities are inspected regularly to detect and eliminate diseased animals, ensure that standards for processes such as meat cutting and refrigeration are observed, and detect residues from pesticides and antibiotics as well as contamination by bacteria and other parasites. Restaurants and supermarkets are similarly inspected. Milk is pasteurized and dated for sale and is analyzed periodically for contamination. Industry standards for canning and preserving foods are maintained through periodic quality control checks and, if contamination is found in representatives of any batches, public health officials recall the entire batch and alert the public through the media.

Animal control programs. Animals are carriers of many diseases that also affect humans. Inspecting domestic herd animals for tuberculosis (due to the bacterium *Mycobacterium bovis*) and brucellosis (a disease that causes spontaneous abortion in domestic herd animals and abscesses of the liver, spleen, bone marrow, and lymph nodes in humans) has helped eliminate the threat of passing the pathogens for those diseases to humans in contaminated milk and meat. Before their pets can be licensed, dog owners must show proof of rabies vaccination. Because most cases of rabies among people in the United States are due to bites from wild and stray animals, health officials are mandated to impound and destroy these animals. Many diseases, including bubonic plague, are spread by rodents, and rat control, especially in urban areas, is a major component of public health efforts. Insects also transmit many diseases (a notable example is malaria). The spread of insect-borne diseases can be controlled by eliminating breeding areas for insects (for example, draining areas where stagnant water collects) and using pesticides. Many imported animals must be tested for specific diseases to prevent the introduction of those diseases into the country.

Vaccination programs. Most states now require that parents or guardians show proof of vaccination before their children can be enrolled in day-care facilities or public schools, although some states allow certain exemptions, including exemptions based on religious beliefs. The value of immunization for an *individual's health* is obvious; however, it is also important for *public health*. If a certain proportion of a population (called the **threshold proportion**) is immune to a disease, the pathogen that causes that disease will be unable to reproduce itself at a high enough level to maintain itself in the population. This is because once the infected host recovers or dies, there will not be enough new, susceptible hosts for the pathogen to infect. Eventually, the pathogen cannot spread any further and could be eliminated from the population. Even if elimination of the pathogen does not occur, there will be relatively few cases of the related disease and epidemics of the disease in the population will be avoided. This phenomenon is called **herd immunity**.

The threshold proportion varies depending on the disease and other conditions in the relevant population. Vaccination programs led by public health officials aim to achieve the immunization of at least the threshold number of individuals for the population.

Public health organizations. Cities and other local areas have public health agencies that enforce regulations, provide public health services such as vaccination programs, and monitor and report the incidence of particular diseases to state and federal

Figure 6 Vaccination programs are important components of public health systems.

agencies. State public health agencies are affiliated with laboratories and staff epidemiologists for investigating disease cases.

All of these agencies report data to the U.S. Public Health Service. NIH, the funding agency of this module, began in 1887 as the Laboratory of Hygiene; NIH is one of eight health agencies of the U.S. Public Health Service. It supports health-related research aimed at understanding, preventing, treating, and controlling infectious and other diseases of humankind. The Public Health Service also operates the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, and the Food and Drug Administration (FDA). CDC staff investigate disease outbreaks, publish a summary of current epidemiological reports, and sponsor a variety of education programs, research projects, and reference laboratories. FDA monitors the safety of our food, medicines, and many other products that we use daily. Finally, the World Health Organization (WHO) provides international surveillance and control of disease. Among other efforts, WHO coordinates multinational vaccination campaigns.

Treatment of Infectious Diseases

While literally meaning "destroyer of life," the term "antibiotic" has become the most commonly used word to refer to a chemical substance used to treat bacterial infections. The term "antimicrobial" has a somewhat broader connotation, generally referring to anything that inhibits the growth of microbes. Technically, the term antimicrobial does not encompass the "antihelminthic" drugs because worms are not microscopically small. Antimicrobials can be either microbistatic (inhibiting the replication of the microbe) or microbicidal (actually killing the target microorganism). In the former case, a combination of therapy and immunity may be required to finally terminate the infection.

Treatment of bacterial diseases. Because bacteria are prokaryotes, it has been relatively easy to find and develop antibacterial drugs that have minimal side effects. These drugs target structural features and metabolic characteristics of prokaryotes that are significantly different from those in eukaryotic cells. Drugs used to treat bacterial diseases can be grouped into categories based on their modes of action. In general, these drugs inhibit cell wall synthesis, protein synthesis, nucleic acid synthesis, or other enzyme-catalyzed reactions.

The penicillins and cephalosporins all interfere with the synthesis of the peptidoglycan layer in prokaryotic cell walls. Because eukaryotes have neither the peptidoglycan components nor the enzymes that synthesize them, these drugs do not affect the host cells. A second class of drugs, including chloramphenicol, the tetracyclines, and erythromycin, bind to prokaryotic ribosomes and inhibit protein synthesis. Prokaryotic ribosomes are structurally different from eukaryotic ribosomes, so these drugs have minimal effect on eukaryotic cells. Nevertheless, some of them may be toxic to some human tissues when they are used in high doses or for prolonged periods of time.

Rifampicin is one of the antibiotics frequently used for treating tuberculosis. This drug inhibits prokaryotic RNA synthesis. DNA synthesis in prokaryotes may be inhibited by the fluoroquinolones. In contrast, the sulfonamides stop bacterial infections by inhibiting other enzymes. Sulfonamides interfere with the synthesis of folic acid, a vitamin necessary for nucleic acid synthesis. Most bacteria must synthesize their own folic acid because their membranes are impermeable to external folic acid. Mammalian cells are not affected by sulfonamides because they are unable to make their own folic acid and have evolved mechanisms for transporting external folic acid across their membranes.

Treatment of viral diseases. In general, drugs that effectively inhibit viral infections are highly toxic to host cells because viruses use the host's metabolic enzymes in their reproduction. For this reason, most illnesses due to viruses are treated symptomatically until the host's immune system controls and eliminates the pathogen (or the host dies). Antiviral drugs that are used typically target virus-specific enzymes involved in viral nucleic acid synthesis. One of the most familiar of these drugs is acyclovir, which is used to treat outbreaks of genital herpes. Amantadine is an antiviral drug sometimes used to prevent or moderate influenza among those at high risk of severe illness from the disease.

In addition to antiviral drugs that inhibit the replication of the HIV genome (such as AZT), AIDS patients today are also prescribed proteases that interfere with the packaging of the HIV genome into virus particles.

Treatment of fungal and parasitic diseases. The development of drugs to treat fungal, protozoan, and helminthic diseases is challenging because agents that kill or inhibit the growth of these eukaryotic organisms are also highly toxic to mammalian cells. Because fungi and protozoa are rapidly proliferating cells, drugs against these organisms tend to target key components of their replicative or biosynthetic pathways. Common antifungals inhibit sterol syntheses (the azole derivatives) or disrupt the cell membrane (polyenes like amphotericin B). Most antihelminthic drugs target adult worms, which are no longer growing and do not replicate. These drugs are often aimed at inhibiting fundamental processes, such as energy production and muscle function (for example, the benzimidazoles and avermectins), or at targets involved in egg production or larval development.

Malaria, a protozoan disease, was successfully treated for many years with chloroquine. In recent decades, *Plasmodium* species that are resistant to this drug have appeared and spread to areas where malaria is a common threat. In those areas, a combination of the drugs sulfonamide and pyrimethamine is frequently used to treat the disease.

Resistance to antimicrobial agents. One of the ongoing problems scientists and medical workers face in the fight against infectious diseases is the development of resistance to the agents used to control them. The phenomenon of resistance has been known since almost the beginning of antibiotic use. For example, penicillin was introduced for clinical use in treating bacterial infections in the 1940s. As early as 1943, Alexander Fleming, the discoverer of penicillin, observed that some bacteria were resistant to the drug and warned that indiscriminate use of penicillin would lead to the proliferation of resistant pathogenic bacteria. By 1946, medical staff at a London hospital estimated that 14 percent of the staphylococcal strains isolated from their patients were resistant to penicillin. Today, more than 90 percent of these bacteria are resistant. In an environment of widespread penicillin use, selection for resistant bacteria occurred; that is, the pathogenic organisms evolved.

The same process has occurred for many other antimicrobial drugs. Alarmingly, many pathogens are simultaneously acquiring resistance to multiple drugs. For example, some strains of *Mycobacterium tuberculosis* are resistant to all of the currently available drugs used for treatment.

Mechanisms of antimicrobial resistance. Antibiotic resistance appears as a result of changes in genes or the acquisition of genes that allow the pathogen to evade the action of antimicrobial drugs. Resistance mechanisms include structural changes in or around the target molecule that inhibit the drugs' ability to bind to it; reduced permeability of the cell membrane to the drug, actively pumping the drug out of the cell after it has entered; and production of enzymes that inactivate the antibiotic after it has been taken up by the cell. Microbes that produce larger than normal amounts of the target molecule may be "less susceptible" (as opposed to resistant) to a drug, meaning it takes a higher drug level to adversely affect that microbe.

Transfer of antimicrobial-resistance genes. Bacteria have many methods for developing resistance. Antibiotic resistance initially arises as mutations to existing genes; however, many (probably most) bacteria *acquire* these genes rather than experience the mutation themselves. Resistance genes are transferred to other members of the same species and across species by a variety of bacterial genetic exchange mechanisms. Many gram-negative bacteria, including *Escherichia coli* and *Salmonella* species, can transfer extra-chromosomal genetic material called plasmids via the process of *conjugation*. Bacteria endowed with the plasmids have numerous pili along their surfaces; one of these extends to a plasmid-lacking bacterium as a conjugation tube. The plasmid then replicates, and one copy travels through the conjugation tube into the recipient bacterium. One large class of plasmids is called resistance plasmids because they carry genes that confer antibiotic resistance. Many resistance plasmids carry genes for resistance to multiple antibiotics;

thus, one conjugation event can simultaneously transfer resistance to several antibiotics.

Some species of bacteria are capable of taking up free-floating bits of DNA from their environments in a process known as *bacterial transformation*. If they take up a DNA fragment containing an antibiotic resistance gene, they may become resistant to that antibiotic. Another mechanism of genetic exchange in bacteria is *transduction*. Bacteria are subject to viral infection. When a bacteria cell is infected, the virus takes over the cell's metabolism, directing synthesis of its genetic material and production of the components of the viral particle. Simultaneously, the host bacterial DNA is degraded. In the last stage of virus production, its genetic material is encapsulated in a protein coat. Occasionally, a piece of the host bacterial DNA may be packaged in a viral particle. The resulting "transducing particle," like a normal viral particle, has the ability to attach to a recipient bacterium and transfer its genetic material into the cell. However, in this case, the transferred genetic material may be a bacterial gene that provides resistance to an antibiotic.

Finally, many transposons carry antibiotic-resistance genes. Transposons are sequences of DNA that are capable of inserting themselves randomly into genomes. Because they do not appear to rely on specific genetic sequences of the target insertion site, they can readily move across species.

Although mutations that result in antibiotic resistance and, less so, bacterial genetic exchange, are rare events, they need occur only once. In an environment of heavy antibiotic use, the forces of natural selection will favor the propagation of resistant variants of a pathogen. The human body is a rich environment for the growth of large numbers of bacteria and for the interaction of a variety of pathogenic and nonpathogenic bacteria. Thus, there is optimal opportunity for rare mutational and genetic exchange events.

Other pathogens have more limited options for drug resistance. Strains of pathogens develop that are naturally less susceptible to a particular drug due to a normally occurring mutation. In the face of continuing drug use, this strain rapidly grows out of the population being spread through the usual transmission process. Malaria, a protozoan disease, was successfully treated for many years with chloroquine, a drug that was widely available over the counter in regions where malaria was a problem. In recent decades, *Plasmodium* strains that are resistant to this drug have appeared and spread throughout Africa, South America, and Southeast Asia.

Emerging and Re-emerging Infectious Diseases

Fifty years ago many people believed the age-old battle of humans against infectious disease was virtually over, with humankind the winners. The events of the past two decades have shown the foolhardiness of that position. At least a dozen "new" diseases have been identified (such as AIDS, Legionnaire disease, and hantavirus pulmonary syndrome), and traditional diseases that appeared to be "on their way out" (such as malaria and tuberculosis) are resurging. Globally, infectious diseases remain the leading cause of death, and they are the third leading cause of death in the United States. Clearly, the battle has not been won.

Emerging infectious diseases are diseases that (1) have not occurred in humans before (this type of emergence is difficult to establish and is probably rare); (2) have occurred previously but affected only small numbers of people in isolated places (AIDS and Ebola hemorrhagic fever are examples); or (3) have occurred throughout human history but have only recently been recognized as distinct diseases due to an infectious agent (Lyme disease and gastric ulcers are examples). Figure 7 lists several examples of infectious diseases that have emerged in the last three decades.

A review of Figure 7 reveals that environmental changes are related to the emergence of many infectious diseases. For example, Lyme disease, hantavirus pulmonary syndrome (HPS), and Lassa fever all emerged when humans began encountering the insect vector (for Lyme disease) or rodent host (for HPS and Lassa fever) of the causative agents in greater numbers than ever before. Factors related to the emergence of infectious diseases such as Legionnaire disease and hemolytic uremic syndrome include changing

Figure 7 Examples of Emerging Infectious Diseases

Disease	Infectious Agent	Year Recognized*	Contributing Factors
Lassa fever	*Arenaviridae* family (virus)	1969	urbanization and other conditions that favor the rodent host; nosocomial transmission
Ebola hemorrhagic fever	*Filoviridae* family (virus)	1977	unknown natural reservoir; nosocomial transmission
Legionnaire disease	*Legionella pneumophila* (bacterium)	1977	cooling and plumbing systems
hemolytic uremic syndrome	*Escherichia coli* 0157:H7 (bacterium)	1982	mass food production systems
Lyme borreliosis	*Borrelia burgdorferi* (bacterium)	1982	conditions favoring the tick vector and deer, such as reforestation near homes
AIDS	human immunodeficiency virus	1983	migration to cities, global travel, transfusions, organ transplants, intravenous drug use, multiple sexual partners
gastric ulcers	*Helicobacter pylori* (bacterium)	1983	newly recognized as due to infectious agent
cholera	*Vibrio cholerae* 0139 (bacterium)	1992	evolution of new strain of bacteria combining increased virulence and long-term survival in the environment
hantavirus pulmonary syndrome	*Bunyaviridae* family (virus)	1993	environmental changes favoring contact with rodent hosts
pandemic influenza	*Orthomyxoviridae* family (virus)	new viral strains emerge periodically	pig-duck agriculture (possibly)

Sources: Morse, S.S. 1995. Factors in the emergence of infectious diseases. *Emerging Infectious Diseases* [Serial online], 1(1). Available http://www.cdc.gov/ncidod/EID/index.htm. June 1999; Satcher, D. 1995. Emerging infections: Getting ahead of the curve. *Emerging Infectious Diseases* [Serial online], 1(1). Available http://www.cdc.gov/ncidod/EID/index.htm. June 1999; Morse, S.S. (Ed.). 1993. Examining the origins of emerging viruses. *Emerging viruses*. New York: Oxford University Press; ProMED. 1994. About ProMED. Available http://www.fas.org/promed/about/index.html, June 1999.

*Year infectious agent was identified.

technologies: air conditioning systems for the former disease and mass food production for the latter.

Re-emerging infectious diseases are diseases that once were major health problems globally or in a particular country, and then declined dramatically, but are again becoming health problems for a significant proportion of the population (malaria and tuberculosis are examples). Many specialists in infectious diseases include re-emerging diseases as a subcategory of emerging diseases. Figure 8 lists examples of re-emerging infectious diseases.

A review of Figure 8 reveals some explanations for the re-emergence of infectious diseases. Tuberculosis has re-emerged due to evolution of the causative bacteria. The pathogen has acquired resistance to the antibiotics used to treat tuberculosis (either through mutation or genetic exchange) and the long-term use of antibiotics (both within one individual and across the population) has selected for the pathogen's proliferation. Malaria has also become drug resistant, and the vector mosquito has acquired resistance to pesticides as well. The re-emergence of diseases such

Figure 8 Examples of Re-emerging Infectious Diseases

Disease	Infectious Agent	Contributing Factors
cryptosporidiosis	*Cryptosporidium parvum* (protozoa)	inadequate control in water supply; international travel; increased use of child-care facilities
diphtheria	*Corynebacterium diptheriae* (bacterium)	interruption of immunization program due to political changes
malaria	*Plasmodium* species (protozoon)	drug resistance; favorable conditions for mosquito vector
meningitis, necrotizing fasciitis (flesh-eating disease), toxic shock syndrome, and other diseases	Group A *Streptococcus* (bacterium)	uncertain
pertussis (whooping cough)	*Bordetella pertussis* (bacterium)	refusal to vaccinate based on fears the vaccine is not safe; other possible factors: decreased vaccine efficacy or waning immunity among vaccinated adults
rabies	*Rhabdovirus* group (virus)	breakdown in public health measures; changes in land use; travel
rubeola (measles)*	*Morbillivirus* genus (virus)	failure to vaccinate; failure to receive second dose of vaccine
schistosomiasis	*Schistosoma* species (helminth)	dam construction; ecological changes favoring snail host
tuberculosis	*Mycobacterium tuberculosis* (bacterium)	antibiotic-resistant pathogens; immunocompromised populations (malnourished, HIV-infected, poverty-stricken)
yellow fever	*Flavivirus* group (virus)	insecticide resistance; urbanization; civil strife

Sources: Krause, R.M. 1992. The origin of plagues: Old and new. *Science, 257*: 1073-1078; Measles—United States, 1997. April 17, 1998. *Morbidity and Mortality Weekly Report, 47*(14): 273-276; Pertussis vaccination: Use of acellular pertussis vaccines among infants and young children. 1997, March 28. *Morbidity and Mortality Weekly Report, 46*(RR-7); ProMED. 1994. About ProMED. Available from http://www.fas.org/promed/about/index.html. June 1999.

*Following the initial decline of measles cases after the licensing of the vaccine in 1963, there was a resurgence of measles—to some 50,000 cases—from 1989 to 1991. Since then, the incidence of measles has declined again, to an all-time low of 138 cases in 1997.

as diphtheria and whooping cough (pertussis) is related to inadequate vaccination of the population. When the proportion of immune individuals in a population drops below a particular threshold, introduction of the pathogen into the population leads to an outbreak of the disease.

Despite the challenges of emerging and re-emerging infectious diseases, the results of basic research, such as that sponsored by NIH, show that there is reason for hope. AIDS was first described in 1981, and it took two years to identify the retrovirus that causes AIDS, which was named the human immunodeficiency virus. In contrast, less than four months elapsed between the description of hantavirus pulmonary syndrome (HPS) in 1993 and the identification of the previously unknown viral agent, now called Sin Nombre virus. One difference between these two cases is that the years that inter-

vened between the advent of AIDS and the advent of HPS saw the development of polymerase chain reaction, a powerful new research technique that allows rapid identification of causative agents. Recommendations for avoiding and/or treating of new infectious diseases become possible when new techniques, developed through basic research, are applied to the problem of disease emergence.

Other examples of the benefits of basic research include the development of HIV protease inhibitors by researchers funded by NIH and others. These drugs, when used in combination with other anti-HIV drugs, are responsible for the dramatic decrease in deaths from AIDS in the United States. One active area of research at NIH is the development of new types of vaccines based on our new understanding of the immune system. In addition, basic research on the immune system and host pathogen interactions has revealed new points at which vaccines could work to prevent diseases.

Finally, basic research on the ecology of disease organisms—their reservoirs, modes of transmission, and vectors, if any—reveals points at which preventive measures can be used to interrupt this cycle and prevent the spread of disease. For example, research supported by NIAID delineated the mechanism of Lyme disease transmission and how disease results: The tick vector was identified and the life cycle of the causative bacterium was traced through deer and rodent hosts. Understanding this ecology has led to predictions about the regions where and years when the threat of Lyme disease is greatest, as well as recommendations to the public for avoiding infection. These examples and others demonstrate that investment in basic research has great long-term payoffs in the battle against infectious diseases.

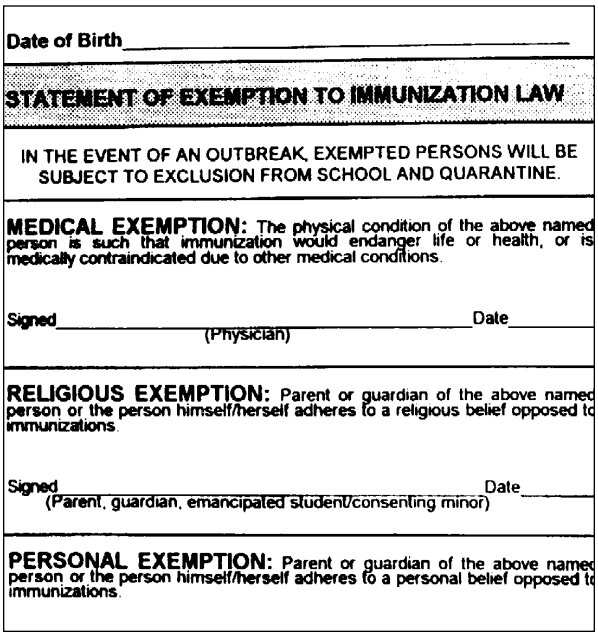
Infectious Diseases and Society

What are the implications of using science to improve personal and public health in a pluralist society? As noted earlier, one of the objectives of this module is to convey to students the relationship between basic biomedical research and the improvement of personal and public health. One way to address this question is by attending to the ethical and public policy issues raised by our understanding and treatment of infectious diseases.

Ethics is the study of good and bad, right and wrong. It has to do with the actions and character of individuals, families, communities, institutions, and societies. During the last two and one-half millennia, Western philosophy has developed a variety of powerful methods and a reliable set of concepts and technical terms for studying and talking about the ethical life. Generally speaking, we apply the terms "right" and "good" to those actions and qualities that foster the interests of individuals, families, communities, institutions, and society. Here, an "interest" refers to a participant's share or participation in a situation. The terms "wrong" or "bad" apply to those actions and qualities that impair interests.

Ethical considerations are complex, multifaceted, and raise many questions. Often, there are competing, well-reasoned answers to questions about what is right and wrong, and good and bad about an individual's or group's conduct or actions. Thus, although science has developed vaccines against many diseases, and public health laws encourage their widespread use, individuals are permitted (in most, but not all, states) to choose not to be vaccinated.

Figure 9 Most states allow exemptions to immunization law.



Date of Birth_____

STATEMENT OF EXEMPTION TO IMMUNIZATION LAW

IN THE EVENT OF AN OUTBREAK, EXEMPTED PERSONS WILL BE SUBJECT TO EXCLUSION FROM SCHOOL AND QUARANTINE.

MEDICAL EXEMPTION: The physical condition of the above named person is such that immunization would endanger life or health, or is medically contraindicated due to other medical conditions.

Signed_____ Date_____
(Physician)

RELIGIOUS EXEMPTION: Parent or guardian of the above named person or the person himself/herself adheres to a religious belief opposed to immunizations.

Signed_____ Date_____
(Parent, guardian, emancipated student/consenting minor)

PERSONAL EXEMPTION: Parent or guardian of the above named person or the person himself/herself adheres to a personal belief opposed to immunizations.

Typically, answers to these questions all involve an appeal to values. A **value** is something that has significance or worth in a given situation. One of the exciting events to witness in any discussion in ethics in a pluralist society is the varying ways in which the individuals involved assign value to things, persons, and states of affairs. Examples of values that students may appeal to in discussions of ethical issues include autonomy, freedom, privacy, protecting another from harm, promoting another's good, justice, fairness, economic stability, relationships, scientific knowledge, and technological progress.

Acknowledging the complex, multifaceted nature of ethical discussions is not to suggest that "anything goes." Experts generally agree on the following features of ethics. First, ethics is a process of rational inquiry. It involves posing clearly formulated questions and seeking well-reasoned answers to those questions. For example, developing countries suffer particularly severely from many infectious diseases because conditions of crowding and poor sanitation are ideal for the growth and spread of pathogens. The same is true for many inner city environments. These places provide a constant reservoir of disease-causing agents. We can ask questions about what constitutes an appropriate ethical standard for allocating health care funds for curtailing the spread of infectious diseases. Should we expend public research dollars to develop drugs whose cost will be out of reach for developing countries or those in the inner cities? Is there any legal and ethical way for the United States to prevent over-the-counter sales of antibiotics in other countries, a practice that may enhance the evolution of antibiotic resistant pathogens? Well-reasoned answers to ethical questions constitute **arguments**. Ethical analysis and argument, then, result from successful ethical inquiry.

Second, ethics requires a solid foundation of information and rigorous interpretation of that information. For example, one must have a solid understanding of infectious disease to discuss the ethics of requiring immunizations and reporting of infectious diseases. Ethics is not strictly a theoretical discipline but is concerned in vital ways with practical matters. This is especially true in a pluralist society.

Third, because tradeoffs among interests are complex, constantly changing, and sometimes uncertain, discussions of ethical questions often lead to very different answers to questions about what is right and wrong and good and bad. For example, we acknowledge that individuals have a right to privacy regarding their infectious disease status. Yet, some argue that AIDS patients who knowingly infect others may have their right to privacy overridden so that partners may be notified of the risk of contracting AIDS.

It is our hope that completing the activities in this module will help students see how understanding science can help individuals and society make reasoned decisions about issues relating to infectious diseases and health. Science provides evidence that can be used to support ways of understanding and treating human disease, illness, deformity, and dysfunction. But the relationships between scientific information and human choices, and between choices and behaviors, are not linear. Human choice allows individuals to choose against sound knowledge, and choice does not necessarily lead to particular actions.

Nevertheless, it is increasingly difficult for most of us to deny the claims of science. We are continually presented with great amounts of relevant scientific and medical knowledge that is publicly accessible. As a consequence, we can think about the relationships among knowledge, choice, behavior, and human welfare in the following ways:

knowledge (what is and is not known) + choice = power

power + behavior = increased human welfare (that is, personal and public health)

One of the goals of this module is to encourage students to think in terms of these relationships, now and as they grow older.

Glossary

acquired immune deficiency syndrome (AIDS): Infectious disease syndrome that is caused by the human immunodeficiency virus (HIV). Characterized by the loss of a normal immune response and increased susceptibility to opportunistic infections and some cancers.

acquired immunity: Specific immunity that develops after exposure to a particular antigen or after antibodies are transferred from one individual to another.

acyclovir: Synthetic drug with antiviral activity against herpes simplex virus. Often used to treat genital herpes.

aerobe: Organism that can grow in the presence of atmospheric oxygen.

airborne transmission: Transmission of an infectious organism in which the organism is truly suspended in the air and travels a meter or more from the source to the host. Chicken pox, flu, measles, and polio are examples of diseases that are caused by airborne agents.

allergen: Substance that can induce an allergic reaction or specific susceptibility.

amantadine: Antiviral compound sometimes used to treat influenza type A infections.

amebiasis: Infection with amoebae. Usually refers to an infection by *Entamoeba histolytica*. Symptoms are highly variable, ranging from an asymptomatic infection to severe dysentery.

amphotericin B: Antibiotic used to treat systemic fungal infections and also used topically to treat candidiasis.

anaerobe: Organism that can grow in the absence of atmospheric oxygen.

anthrax: Infectious disease of animals caused by ingesting the spores of *Bacillus anthracis*. Can occur in humans.

antibiotic: Microbial product, or its derivative, that kills or inhibits the growth of susceptible microorganisms.

antibody: Glycoprotein produced in response to an antigen. Antibodies have the ability to combine with the antigen that stimulated their production.

antibody-mediated immunity: Immunity that results from the presence of antibodies in blood and lymph.

antigen: Foreign (nonself) substance to which lymphocytes respond.

antimicrobial agent: Agent that kills or inhibits the growth of microorganisms.

antiseptic: Chemical applied to tissue to prevent infection by killing or inhibiting the growth of pathogens.

antitoxin: Antibody to a microbial toxin. An antitoxin binds specifically with the toxin, neutralizing it.

arenavirus: Type of RNA virus. Lassa fever is caused by an arenavirus.

autogenous infection: Infection that results from a patient's own microflora.

B-cell: Type of lymphocyte derived from bone marrow stem cells that matures into an immunologically competent cell under the influence of the bone marrow. Following interaction with an antigen, a B-cell becomes a plasma cell, which synthesizes antibodies.

bacillus: Rod-shaped bacterium.

bactericide: Agent that kills bacteria.

binary fission: Asexual reproduction in which a cell separates into two cells.

biologic transmission: Disease transmission in which an infectious organism undergoes some morphologic or physiologic change during its passage through the vector.

botulism: Form of food poisoning caused by a neurotoxin produced by *Clostridium botulinum*. Sometimes found in improperly canned or preserved food.

broad-spectrum drug: Chemotherapeutic agent that is effective across a wide range of different types of pathogens.

candidiasis: Infection caused by a fungus of the genus *Candida*. Typically involves the skin.

carrier: Infected individual who is a potential source of infection for other people.

cell-mediated immunity: Immunity that results from T-cells contacting foreign or infected cells and destroying them.

chemotherapeutic agent: Compound used in the treatment of disease that kills or inhibits the growth of microorganisms and does so at concentrations low enough to avoid doing damage to the host.

chicken pox: Highly contagious skin disease caused by the varicella-zoster virus. Acquired by droplet inhalation into the respiratory system.

cholera: Infectious disease caused by *Vibrio cholerae*.

coccus: Bacterium that is roughly spherical in shape.

common cold: Acute, self-limiting, and highly contagious viral infection of the upper respiratory tract.

communicable disease: Disease associated with an agent that can be transmitted from one host to another.

complement system: Group of circulating plasma proteins that plays a major role in an animal's immune response.

compromised host: Host with lowered resistance to infection and disease for any reason (for example, malnutrition, illness, trauma, or immunosuppression).

conjugation: Form of gene transfer and recombination in bacteria that requires direct cell-to-cell contact.

conjugative plasmid: Plasmid that carries the genes for sex pili and can transfer copies of itself to other bacteria during conjugation.

contact transmission: Transmission of an infectious agent by direct contact of the source or its reservoir with the host.

Creutzfeldt-Jakob disease: Chronic, progressive, fatal disease of the central nervous system caused by a prion.

diphtheria: Acute, highly contagious childhood disease caused by *Corynebacterium diphtheriae*.

disinfectant: Agent that kills, inhibits, or removes microorganisms that may cause disease.

DPT (diphtheria-pertussis-tetanus) vaccine: Vaccine containing three antigens that is used to immunize people against diphtheria, whooping cough, and tetanus.

endemic disease: Disease that is commonly or constantly present in a population, usually at a relatively constant low level.

epidemic: Sudden increase in occurrence of a disease above the normal level in a particular population.

epidemiologist: Person who specializes in epidemiology.

epidemiology: Study of the factors determining and influencing the frequency and distribution of disease, injury, and disability in a population.

eukaryotic cell: Cell that has its genetic material (DNA) enclosed by a nuclear membrane.

facultative anaerobe: Microorganism that does not require atmospheric oxygen, but grows better in its presence.

fungicide: Agent that kills fungi.

genital herpes: Sexually transmitted disease caused by the herpes simplex type II virus.

giardiasis: Intestinal disease caused by the protozoon *Giardia lamblia*.

Gram stain: Differential staining procedure that allows categorization of bacteria into two groups (gram-positive and gram-negative) based on their ability to retain crystal violet when decolorized with an organic solvent such as ethanol.

hantavirus: Type of RNA virus. Hantavirus pulmonary syndrome and Korean hemorrhagic fever are caused by viruses in the genus *Hantavirus*.

harborage transmission: Disease transmission in which an infectious agent does not undergo morphologic or physiologic change during its time inside the vector.

hepatitis A (infectious hepatitis): Type of hepatitis that is transmitted by fecal-oral contamination. It affects mostly children and young adults, especially under conditions of overcrowding and poor sanitation. Caused by the hepatitis A virus.

hepatitis B (serum hepatitis): Type of hepatitis caused by the hepatitis B virus (HBV). Transmitted through body fluids.

herd immunity: Resistance of a population to spread of an infectious organism due to the immunity of a high proportion of the population.

host: Body of an organism that harbors another organism. The host provides a microenvironment that supports the growth and reproduction of the parasitic organism.

human immunodeficiency virus (HIV): Retrovirus that is associated with the onset of AIDS.

immune: Protected against a particular disease by either nonspecific or specific immune defenses.

immune response: Response of the body to contact with an antigen that leads to the formation of antibodies and sensitized lymphocytes. Designed to render harmless the antigen and the pathogen producing it.

immunity: General ability of a host to resist developing a particular disease.

immunology: Science concerned with understanding the immune system and the many factors that are involved with producing both acquired and innate immunity.

index case: First disease case in an epidemic within a population.

infection: Invasion of a host by an agent, with subsequent establishment and multiplication of the agent. An infection may or may not lead to disease.

infectious agent: Living or quasi-living organism or particle that causes an infectious disease. Bacteria, viruses, fungi, protozoa, helminths, and prions are infectious agents.

infectious disease: Change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its products.

inflammation: Localized protective response to tissue injury or destruction. In an acute form, it is characterized by pain, heat, redness, and swelling in the injured area.

influenza (flu): Acute viral infection of the respiratory tract caused by one of three strains of influenza virus (A, B, and C).

intermediate host: Host that serves as a temporary but essential environment for the completion of a parasite's life cycle.

Koch's postulates: Set of rules for proving that a microorganism causes a specific disease.

Koplik's spot: Lesion of the oral cavity caused by the measles virus.

Legionnaire disease: Pulmonary form of disease caused by infection with *Legionella pneumophila*.

Lyme disease: Tick-borne disease caused by the spirochete *Borrelia burgdorferi*.

lymphocyte: Type of white blood cell. Lymphocytes transmit chemical signals that help coordinate the immune system.

malaria: Infectious disease caused by the protozoon *Plasmodium*. Characterized by fever and chills that occur at regular intervals.

measles: Highly contagious skin disease caused by a virus in family *Paramyxoviridae*. The virus enters the body through the respiratory tract or the conjunctiva. Measles is endemic throughout the world.

microbiota (microbial flora): Microorganisms that are normally associated with a particular tissue or organ.

morbidity rate: Number of individuals who become ill with a particular disease within a susceptible population during a specified time period.

mortality rate: Ratio of the number of deaths from a particular disease to the total number of cases of the disease.

nonspecific immunity: General defense mechanisms that provide animals with protection from infection and disease but are not targeted at a particular pathogen.

nosocomial infection: Infection produced by a pathogenic agent that a patient acquires during hospitalization or treatment inside another health care facility.

opportunistic organism: Organism that is usually harmless, but can be pathogenic in a compromised host.

pandemic: Increase in the occurrence of a disease in a large and geographically widespread population. Sometimes called a worldwide epidemic.

parasite: Organism that lives on or within another organism (the host). The relationship benefits the parasite and harms the host.

pasteurization: Process of heating milk and other liquids to destroy microorganisms that can cause spoiling or disease.

pathogen: Disease-producing agent.

pathogenicity: Ability to cause disease.

penicillins: Group of antibiotics that are often used to treat infections by gram-positive bacteria.

peptidoglycan: Large polymer that provides much of the strength and rigidity of bacterial cell walls.

period of infectivity: Time during which the source of an infectious agent is disseminating the agent (is infectious).

plague: Acute, infectious disease with a high mortality rate; caused by *Yersinia pestis*.

plasmid: Circular, double-stranded DNA molecule that can exist and replicate independently of the host cell chromosome or be integrated with it. Although a plasmid is stably inherited, it is not required for bacterial cell growth and reproduction.

poliomyelitis: Acute, contagious viral disease of the central nervous system that can lead to paralysis.

population: Group of organisms of the same species.

prevalence rate: Total number of people infected at one time in a population, regardless of when the disease began.

prion: Infectious particle that is responsible for certain slow-acting diseases such as scrapie in sheep and goats, and Creutzfeldt-Jakob disease in humans. Prions have a protein component, but scientists have not yet detected a nucleic acid component.

prokaryotic cell: Cell that lacks a membrane-delimited nucleus and other membrane-bound organelles. Bacteria are prokaryotic cells.

rabies: Acute infectious disease of the central nervous system caused by an RNA virus of the rhabdovirus group.

reservoir: Site, alternate host, or carrier that harbors pathogenic organisms and serves as a source from which other individuals can be infected.

retrovirus: RNA virus that carries the enzyme reverse transcriptase and forms a DNA copy of its genome during its reproductive cycle.

schistosomiasis: Helminth infection acquired from contact with water containing infected snails.

smallpox: Highly contagious, often fatal disease caused by a poxvirus. Smallpox has been eradicated throughout the world.

source: Location or object from which a pathogen is immediately transmitted to a host.

specific immune response: Collection of several immunological events in which lymphocytes recognize the presence of a particular antigen and act to eliminate it.

spirillum: Rigid, spiral-shaped bacterium.

spirochete: Flexible, spiral-shaped bacterium.

sporadic disease: Disease that occurs occasionally and at random intervals in a population.

superinfection: Bacterial or fungal infection that is resistant to the drug(s) being used to treat it.

T-cell: Lymphocyte derived from bone marrow stem cells that matures into an immunologically competent cell under the influence of the thymus. Involved in cell-mediated immune reactions.

TB skin test: Tuberculin hypersensitivity test to detect a current or past infection with *Mycobacterium tuberculosis*.

tetanus: Often fatal disease caused by the anaerobic, spore-forming bacterium *Clostridium tetani*. Characterized by muscle spasms and convulsions.

toxin: Microbial product or component that at low concentrations can injure a cell or organism.

transduction: Transfer of genes between bacteria by bacteriophages.

transformation: Mode of gene transfer in bacteria in which a piece of DNA in the environment is taken up by a bacterium and integrated into the bacterium's genome.

transposon: DNA segment that carries the genes required for transposition and can move from one place to another in the genome. Often carries genes unrelated to transposition as well.

tuberculosis: Infectious disease resulting from infection by a species of *Mycobacterium*. Infection is usually by inhalation, and the disease usually affects the lungs, although it can occur elsewhere in the body.

vaccination: Administration of a vaccine to stimulate an immune response.

vaccine: Preparation of killed microorganisms; living, weakened (attenuated) microorganisms; inactive or attenuated virus particles; inactivated bacterial toxins; or components (protein, carbohydrate, or nucleic acid) of the microorganism that is administered to stimulate an immune response. Vaccines protect an individual against the pathogenic agent or substance in the future.

vector: Living organism that transfers an infective agent from one host to another.

vector-borne transmission: Transmission of an infectious pathogen between hosts by way of a vector.

virulence: Degree or intensity of pathogenicity of an organism as indicated by mortality rate from the related disease and/or ability to invade tissues and cause disease.

virus: Infectious agent composed of a protein coat and a single type of nucleic acid. Lacks an independent metabolism and reproduces only within a host cell.

whooping cough (pertussis): Infectious disease of the respiratory tract caused by *Bordetella pertussis*.

APPENDIX E.3: BACTERIAL, VIRAL, FUNGAL, AND PARASITE SAFETY CLASSIFICATIONS AND LANL CURRENTLY PROPOSED AND CDC SELECT AGENTS

Table E.3-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Acinetobacter	*spp.*					
Acinetobacter	*baumannii*					2
Acinetobacter	*lwoffi*					
Actinobacillus	*actinomycetem-comiana*					2 implied
Actinobacillus	*spp.*					2
Actinomadura	*madurae*					
Actinomadura	*pelletieri*					
Actinomyces	*bovis*					
Actinomyces	*gerencseriae*					
Actinomyces	*israelii*					
Actinomyces	*naeslundii*					
Actinomyces	*pyogenes*					2
Actinomyces	*spp.*					
Aeromonas	*hydrophilia*					2
Aeromonas	*punctata*					
Aeromonas	*spp.*					
Afpia	*spp.*					
Amycolata	*autotrophica*					2
Arachnia	*propionica*					
Arcanobacterium	*haemolyticum*					2
Archanobacterium	*equi*					
Arizona	*hinshawii*					2
Bacillus	*anthracis*	✸	✸	2/3 (I/E)	A	2
Bacillus	*cereus*					
Bacillus	*subtilis*					1
Bacillus	*licheniformis*					1
Bacillus	*thuringiensis*					
Bacteroides	*fragilis*					
Bacteroides	*spp.*					

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[2] LANL proposed list is from PC 2001b
[3] Select agent list is from 42 CFR 72
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[5] Risk Grouping from CDC 2000a
[6] NIH Risk Groups (RG) are from NIH 2001
RG 1 not associated with disease in healthy human adults
RG 2 associated with human disease that is rarely serious and prophylactic intervention ***often*** available
RG 3 associated with human disease that is serious or lethal and prophylactic intervention ***may be*** available
RG 4 associated with human disease that is serious or lethal and prophylactic intervention ***not usually*** available
I/E Requires import and/or export permit from CDC and/or Deparment of Commerce or I/E
AP - animal pathogen
* activities with high droplet or aerosol production potential
✸ applicable organism

Table E.3-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Bartonella	*bacilliformis*					3 implied
Bartonella	*elizabethae*					3 implied
Bartonella	*spp.*					3
Bartonella	*henselae*					2
Bartonella	*quintana*					2
Bartonella	*vinsonii*					2
Bordetella	*spp.*					2
Bordetella	*bronchiseptica*					2 implied
Bordetella	*parapertussis*					2 implied
Bordetella	*pertussis*	✸		2		2
Borrelia	*burgdorferi*					2
Borrelia	*duttoni*					
Borrelia	*recurrentis*					2
Borrelia	*spp.*					
Borrelia	*vincenti*					
Brucella	*abortus*	✸	✸	3 (I/E)	B	3
Brucella	*canis*		✸	3 (I/E)	B	3
Brucella	*melitensis*	✸	✸	3 (I/E)	B	3
Brucella	*ovis*				B	3 implied
Brucella	*spp.* (except *B. ovis*)			3 (I/E)	B	3
Brucella	*suis*	✸	✸	3 (I/E)	B	3
Burkholderia	*spp.*					
Burkholderia	*mallei*	✸	✸	2/3* implied (I/E)	B	3
Burkholderia	*pseudomallei*	✸	✸	2/3* (I/E)		3
Calymmatobacterium	*granulomatis*	✸				
Campylobacter	*coli*	✸		2		2
Campylobacter	*fetus* (*ssp. fetus*)	✸		2		2
Campylobacter	*jejuni*	✸		2		2

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Table E.3-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Campylobacter	*laridis*	✸				
Campylobacter	*spp.*	✸		2 implied		
Campylobacter	*sputorum*					
Capnocytophaga	*spp.*					
Cardiobacterum	*hominis*					
Chlamydia	*pneumoniae*			2/3*		2
Chlamydia	*psittaci*			2/3*		2
Chlamydia	*spp.* (*C. pneumoniae*)			2/3* implied		3
Chlamydia	*trachomatis*			2/3*		2
Citrobacter	*spp.*					
Clostridium	*botulinum*	✸	✸	2/3*	A	2
Clostridium	*chauvoei*					2
Clostridium	*difficile*					
Clostridium	*equi*					
Clostridium	*haemolyticum*					2
Clostridium	*histolyticum*					2
Clostridium	*novyi*					2
Clostridium	*perfringens*				B	
Clostridium	*septicum*					2
Clostridium	*sordelli*					
Clostridium	*spp.*					
Clostridium	*tetani*	✸		2		2
Corynebacterium	*bovis*					
Corynebacterium	*diphtheriae*			2		2
Corynebacterium	*matruchotii*					
Corynebacterium	*minutissimum*					
Corynebacterium	*pseudotuberculosis*					2
Corynebacterium	*renale*					2
Corynebacterium	*spp.*					

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[2] LANL proposed list is from PC 2001b
[3] Select agent list is from 42 CFR 72
[4] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
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I/E Requires import and/or export permit from CDC and/or Deparment of Commerce or I/E
AP - animal pathogen
* activities with high droplet or aerosol production potential
✸ applicable organism

Table E.3-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Corynebacterium	*ulcerans*					
Coxiella	*burnetii*		✸	3 (I/E)	B	3
Dermatophilus	*congolensis*					2
Edwardsiella	*tarda*					2
Eikenella	*corrodens*					
Enterobacter	*aerogenes/cloacae*					
Enterobacter	*spp.*					
Enterococcus	*spp.*					
Erlichia	*sennetsu*					
Erlichia	*spp.*					
Erysipelothrix	*rhusiopathiae*					2
Erysipelothrix	*spp.*					
Escherichia	*coli* (pathogenic strains)			2	B	2
Escherichia	*coli K12* (genetically crippled)					1
Flavobacterium	*meningosepticum*					
Flavobacterium	*spp.*					
Fluoribacter	*bozemanae*					
Francisella	*novocida*					
Francisella	*tularensis* (Type A)		✸	2/3	A	3
Francisella	*tularensis* (Type B)		✸	2/3	A	3
Fusobacterium	*necrophorum*					
Fusobacterium	*spp.*					
Gardnerella	*vaginalis*					
Haemophilus	*ducreyi*					2
Haemophilus	*influenzae*					2
Haemophilus	*spp.*					
Hartmanella	*spp.*					
Helicobacter	*pylori*	✸		2		2
Herellea	*vaginicola*					

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[2] LANL proposed list is from PC 2001b

[3] Select agent list is from 42 CFR 72

[4] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC

[5] Risk Grouping from CDC 2000a

[6] NIH Risk Groups (RG) are from NIH 2001

RG 1 not associated with disease in healthy human adults

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I/E Requires import and/or export permit from CDC and/or Deparment of Commerce or I/E

AP - animal pathogen

* activities with high droplet or aerosol production potential

✸ applicable organism

Table E.3-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Kingella	*kingae*					
Klebsiella	*oxytoca*					1
Klebsiella	*pneumoniae*					2
Klebsiella	*spp.*					2
Lactobacillus	*spp.*					
Legionella	*pneumophila*	✸		2/3*		2
Legionella	*spp.*			2/3*		2
Legionella	*like organisms*			2/3*		
Leptospira	*interrogans*			2 (I/E)		2
Listeria	*ivanovii*			2 implied (I/E)		2 implied
Listeria	*monocytogenes*			2 (I/E)		2 implied
Listeria	*spp.*			2 implied (I/E)		2
Mima	*polymorpha*					
Moraxella	*spp.*					2
Morganella	*morganii*					
Mycobacterium	*africanum*				C	2 implied
Mycobacterium	*asiaticum*			2		2
Mycobacterium	*avium-intracelluare*			2		2
Mycobacterium	*bovis*			2/3 (I/E)	C	3
Mycobacterium	*chelonei*			2		2
Mycobacterium	*fortuitum*			2		2
Mycobacterium	*kansasii*			2		2
Mycobacterium	*leprae*			2		2
Mycobacterium	*malmoense*			2		2
Mycobacterium	*marinum*			2		2
Mycobacterium	*microti*					2 implied
Mycobacterium	*paratuberculosis*			2		2
Mycobacterium	*scrofulaceum*			2		2

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Table E.3-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Mycobacterium	*simiae*			2		2
Mycobacterium	*spp.* (except *M. tuberculosis* complex)			2		
Mycobacterium	*szulgai*			2		2
Mycobacterium	*tuberculosis*	✸		3	C	3
Mycobacterium	*ulcerans*			2		2
Mycobacterium	*xenopi*			2		2
Mycoplasma	*hominis*					2 implied
Mycoplasma	*mycoides*					Restricted AP
Mycoplasma	*pneumoniae*					2 implied
Mycoplasma	*agalactiae*					Restricted AP
Mycoplasma	*spp. (except M. mycoides & M. agalactiae)*					2
Neisseria	*gonorrhoeae*	✸		2/3*		2
Neisseria	*meningitidis*	✸		2/3*		2
Neisseria	*spp.*			2/3* implied		
Nocardia	*asteroides*					2
Nocardia	*brasiliensis*					2
Nocardia	*caviae*					
Nocardia	*farcinica*					
Nocardia	*nova*					
Nocardia	*spp.*					
Nocardia	*transvalensis*					2
Nocarida	*otitidis-caviarum*					2
Pasteurella	*haemolytica*					
Pasteurella	*multocida*					3
Pasteurella	*pneumotropica*					
Pasteurella	*spp. (virulent strains)*					3

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Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Peptostreptococcus	*anaerobius*					
Plesiomonas	*shigelloides*					
Porphyromonas	*spp.*					
Prevotella	*spp.*					
Proteus	*mirabilis*					
Proteus	*penneri*					
Proteus	*spp.*					
Proteus	*vulgaris*					
Providencia	*alcalifaciens*					
Providencia	*rettgeri*					
Providencia	*spp.*					
Pseudomonas	*aeruginosa*					
Pseudomonas	*spp.*					
Rhodococcus	*equi*					2
Rickettsia	*(vole)*					
Rickettsia	*akari*			2/3 (I/E)		3
Rickettsia	*australis*			2/3 (I/E)		3
Rickettsia	*canada*					3
Rickettsia	*conorii*			2/3 (I/E)		3
Rickettsia	*japonicum*			2/3 (I/E)		
Rickettsia	*montana*					
Rickettsia	*mooseri*			2/3 (I/E)		3
Rickettsia	*parkeri*					
Rickettsia	*prowazekii*		✸	2/3 (I/E)		3
Rickettsia	*rhipicephali*					
Rickettsia	*rickettsii*		✸	2/3 (I/E)		3
Rickettsia	*sennetsu*					
Rickettsia	*sibirica*			2/3 (I/E)		3
Rickettsia	*spp.*					

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Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Rickettsia	*tsutsugamushi*			2/3 (I/E)		3
Rickettsia	*typhi (mooseri)*			2/3 (I/E)		3
Salmonella	*arizonae*			2	B	2
Salmonella	*cholerasuis*			2	B	2
Salmonella	*enteritidis*			2	B	2
Salmonella	*gallinarum-pullorum*			2	B	2
Salmonella	*meleagridis*			2	B	2
Salmonella	*paratyphi* (Type A, B, C)			2	B	2
Salmonella	*spp.*			2	B	2 implied
Salmonella	*typhi*	✸		2/3* (I/E)	B	2
Salmonella	*typhimurium*			2	B	2
Serpulina	*spp.*					
Serratia	*marcescens*					
Serretia	*liquefaciens*					
Shigella	*boydii*	✸		2 (I/E) implied		2
Shigella	*dysenteriae* (Type 1)	✸		2 (I/E) implied	B	2
Shigella	*flexneri*	✸		2 (I/E)		2
Shigella	*sonnei*	✸		2 (I/E) implied		2
Shigella	*spp.*	✸		2 (I/E)		2 implied
Sphaerophorus	*necrophorus*					2
Staphylococcus	*aureus*				B	2
Staphylococcus	*epidermidis*				B	
Streptobacillus	*moniliformis*					2
Streptobacillus	*spp.*					
Streptococcus	*agalactiae*					2 implied
Streptococcus	*pneumoniae*					2
Streptococcus	*pyogenes*					2

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Table E.3-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Streptococcus	*spp.*					2
Streptococcus	*suis*					
Treponema	*carateum*					2
Treponema	*pallidum*			2		2
Treponema	*pertenue*					
Treponema	*spp.*					
Treponema	*vincentii*					
Ureaplasma	*urealyticum*					
Vibrio	*cholerae*			2 (I/E)	B	2
Vibrio	*parahaemolyticus*			2 (I/E)		2
Vibrio	*spp.*			2 (I/E) implied		2 implied
Vibrio	*vulnificus*					2
Yersinia	*enterocolitica*					2
Yersinia	*pestis*	✸	✸	2/3* (I/E)	A	3
Yersinia	*pseudotuberculosis*					
Yersinia	*spp.* (except *Y. pestis*)					

[1] Basic genus and specie list is from ABSA 1998 with some additions.
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✸ applicable organism

Table E.3-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Adenoviridae	Adenovirus (human, all types)					2
Arenaviruses	Flexal		*			3
Arenaviruses	Guanarito		*	4 (E)	A	4
Arenaviruses	Junin virus		*	V2 (E), 3/4 (E)	A	V3, 4
Arenaviruses	Lassa fever virus		*	4 (E)	A	4
Arenaviruses	Lymphocytic choriomeningitis (neurotropic virus)			2/3* (E)	A	3
Arenaviruses	Lymphocytic choriomeningitis (non-neurotropic virus)			2/3* (E)		2
Arenaviruses	Machupo virus		*	4 (E)	A	4
Arenaviruses	Mopeia virus (and other Tacaribe viruses)			3		BMBL
Arenaviruses	Sabia		*	4 (E)	A	4
Arenaviruses	Tacaribe complex			2		2
Astroviridae	Astroviridae					
Bunyaviridae	Bunyaviridae (others known to be pathogenic)					
Bunyaviridae/ Bunyavirus Group	Bunyamwera virus			2		2
Bunyaviridae/ Bunyavirus Group	Bunyavirus					
Bunyaviridae/ Bunyavirus Group	California encephalitis virus			2		BMBL
Bunyaviridae/ Bunyavirus Group	Oropouche virus			3		BMBL
Bunyaviridae/ Bunyavirus Group	Tensaw virus			2		BMBL
Bunyaviridae/ Hantaviruses	Black Creek Canal	*	*	2/3 implied (E)	C	3
Bunyaviridae/ Hantaviruses	El Moro Canyon	*	*	2/3 implied (E)	C	3
Bunyaviridae/ Hantaviruses	Hantaan (Korean haemorrhagic fever)	*	*	2/3 (E)	C	3
Bunyaviridae/ Hantaviruses	Hantaviruses (others known)	*	*	2/3* (E)	C	3
Bunyaviridae/ Hantaviruses	Prospect Hill virus	*	*	2/3 implied (E)	C	3
Bunyaviridae/ Hantaviruses	Puumala virus	*	*	2/3 (E)	C	3
Bunyaviridae/ Hantaviruses	Seoul virus	*	*	2/3 (E)	C	3
Bunyaviridae/ Hantaviruses	Sin nombre virus	*	*	2/3 (E)	C	3
Bunyaviridae/ Nairovirus	Nairobi Sheep Disease			3 (I), R		BMBL
Bunyaviridae/ Nairoviruses	Congo Crimean haemorrhagic fever (Tick-borne encephalitis virus)		*	4 (E)	C	4
Bunyaviridae/ Nairoviruses	Hazara virus			2		BMBL
Bunyaviridae/ Phleboviruses	Rift Valley Fever		*	V2 (E), 3 (I/E)		V2, 3
Bunyaviridae/ Phleboviruses	Sandfly fever virus			2		BMBL
Bunyaviridae/ Phleboviruses	Toscana virus			2		BMBL
Bunyaviridae/ Phleboviruses	Zinga (See Rift Valley Fever)			V2 (E), 3 (E)		

[1] Basic name and viral group list is from ABSA 1998 with some additions.
[2] LANL proposed disease list is from PC 2001b
[3] Select agent list is from 42 CFR 72
[4] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
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[6] NIH Risk Groups (RG) are from NIH 2001
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RG 3 associated with human disease that is serious or lethal and prophylactic intervention ***may be*** available
RG 4 associated with human disease that is serious or lethal and prophylactic intervention ***not usually*** available
E -- Requires export permit from CDC and/or Deparment of Commerce or USDA
I -- Requires import permit from CDC and/or Deparment of Commerce or USDA
R -- is for restricted authorization to use either by the CDC or USDA
V -- is for vaccine
* activities with high droplet or aerosol production potential

Table E.3-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Calciviridae	Calciviridae (others known)					2
Calciviridae	Hepatitis E virus	*		2		2
Calciviridae	Norwalk virus					2
Coronaviridae	Coronavirus					2
Filoviridae	Ebola virus		*	4 (E)	A	4
Filoviridae	Marburg virus		*	4 (E)	A	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Absettarov (Tick-borne encephalitis virus)		*	3/4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Central European Tick-borne encephalitis virus		*	4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Dengue virus			2		2
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Hanzalova (Tick-borne encephalitis virus)		*	3/4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Hypr (Tick-borne encephalitis virus)		*	3/4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Kokobera			2		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Kumlinge (Tick-borne encephalitis virus)		*	3/4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Kunjin			2		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Kyasanur Forest (Tick-borne encephalitis virus)		*	4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Looping ill (Tick-borne encephalitis virus)		*	3 (I)	C	BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Murray Valley encephalitis (Australian encephalitis)			3		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Omsk (hemorrhagic fever), (Tick-borne encephalitis virus)		*	4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Powassan			3		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Rocio			3		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Russian spring-summer encephalitis (Tick-borne encephalitis virus)		*	4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Sammarez Reef			3		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	St. Louis encephalitis			3		3
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Tick-borne		*		C	BMBL

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Table E.3-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Wesselsbron virus			3 (I)		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	West Nile fever virus			3 (E)		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Yellow fever virus (vaccine strain 17D)			V2 (E)		2
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Yellow fever virus (wild type)		*	3 (E)	C	3
Flaviviridae/Flavivirus (Grp B Arbovirus)	Japanese B encephalitis			3 (E)		3
Flaviviridae/Flavivirus (Grp B Arbovirus)	Japanese encephalitis, Nakayama			3 (E)		BMBL
Flavivirus	Flaviviruses (others known to be pathogenic)					BMBL
Hepadnaviridae	Hepatitis B virus	*		2		2
Hepadnaviridae	Hepatitis D (Delta) virus (b)	*		2		2
Herpesviridae	Herpesviruses (unassigned, HHV 7, HHV8)	*		2 implied		BMBL
Herpesviridae	Human B lympho-tropic virus					2 (types 6 and 7)
Herpesviridae	Rhadinovirus (except H.ateles,H. saimiri)					
Herpesviridae / Gamma-herpesvirinae	Gammaherpes					
Herpesviridae/ Alphaherpesviridae	Pseudorabies virus					
Herpesviridae/ Alpha-herpesviridae	Herpes simplex viruses	*		2		2 (types 1 and 2)
Herpesviridae/ Alpha-herpesviridae	Herpesvirus simiae (B virus)	*		2/3/4		4
Herpesviridae/ Alpha-herpesviridae	Herpesvirus zoster (Varicella)	*		2		2
Herpesviridae/ Animal virus vector	Herpesvirus saimiri (Genus Rhadinovirus)	*		2 implied		1
Herpesviridae/ Animal virus vector	Marek's disease virus					1
Herpesviridae/ Animal virus vector	Murine cytomegalovirus					1
Herpesviridae/ Animal virus vector	Thetalymphocryptovirus					
Herpesviridae/ Betaherpesviridae	Cytomegalovirus (CMV) (Genus Lymphocryptovirus)			2		2
Herpesviridae/ Gamma-herpesviridae	Epstein-Barr virus (EBV)			2		2

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Table E.3-2. Viral Microorganisms and Their Safety Classifications

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Herpesviridae/ Rhadinovirus	Herpes saimiri	*				1
Herpesviridae/ Rhadinovirus	Herpesvirus ateles	*				1
Herpesviridae/ Rhadinovirus	Rhadinovirus (except H. ateles and H. saimiri)					BMBL
Orthomyxoviridae	Influenza virus (Types A-C)	*		2 (I)		2
Orthomyxoviridae	Influenza virus (vaccine strain)	*		1		BMBL
Orthomyxoviridae	Orthomyxoviridae (Tick-borne encephalitis virus)		*	4	C	BMBL
Orthopoxvirus	Ectromelia (mousepox)					
Papovaviridae	Papillomaviruses (human)					2
Papovaviridae	Polyomavirus (BK and JC viruses)					1
Papovaviridae/ Animal virus vector	Simian virus 40 (SV40)					1
Papovavirus/ Animal virus vector	Shope papilloma virus					1
Papovavirus/Animal virus vector	Bovine papilloma virus					1
Paramyxoviridae	Subsclerosing pancencephalitis					
Paramyxoviridae/ Morbillivirus	Hendra and Hendra-like viruses			3+/4 (I/E)		4
Paramyxoviridae/ Morbillivirus	Measles virus					2
Paramyxoviridae/ Morbillivirus	Morbillivirus (except Rinderpest)					
Paramyxoviridae/ Paramyxovirus	Mumps virus					2
Paramyxoviridae/ Paramyxovirus	Newcastle Disease virus					2
Paramyxoviridae/ Paramyxovirus	Parainfluenza virus (Type 3, SF4 strain)					
Paramyxoviridae/ Paramyxovirus	Parainfluenza viruses					2 (Types 1-4)
Paramyxoviridae/ Pneumovirus	Respiratory syncytial virus					2
Paramyxoviruses/ Parainfluenza viruses	Sendai virus (murine parainfluenza virus type 1)					
Parvoviridae	Parvovirus (human)					2 (B19)
Picornaviridae	Acute haemorrhagic conjunctivitis virus (AHC)					
Picornaviridae	Aphthovirus					
Picornaviridae	Cardiovirus					
Picornaviridae/ Rhinoviruses	Rhinovirus					2
Picornoviridae/ Enterovirus	Coxsackie					2 (Types A and B)
Picornoviridae/ Enterovirus	Echoviruses					2
Picornoviridae/ Enterovirus	Entero					
Picornoviridae/ Enterovirus	Polioviruses	*		2/3		2
Picornoviridae/ Hepatovirus	Hepatitis A virus (human enterovirus type 72)	*		2		2

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Table E.3-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Poxviridae	Alastrim			2 implied (E)		R
Poxviridae	Buffalopox virus: 2 viruses (1a vaccinia variant)			2 implied (E)		2
Poxviridae	Camel pox virus			2 implied (E)		2
Poxviridae	Cowpox virus			2 (E)		2
Poxviridae	Elephantpox virus (variant of cowpox)			2 (E)		2
Poxviridae	Milker's node virus			2 implied (E)		2
Poxviridae	Molluscum contagiosum virus			2 implied (E)		2
Poxviridae	Paravaccinia virus			2 implied (E)		2
Poxviridae	Rabbitpox virus (vaccinia variant)			2 (E)		2
Poxviridae	Tanapox			2 (E)		2
Poxviridae	Variola (major and minor) virus		✸	R	A	R
Poxviridae	Whitepox (Variola)			R	A	R
Poxviridae	Yabapox virus (Tana and Yaba)			2 (E)		
Poxviridae/ Orthopoxvirus	Monkeypox virus			2 (E)		3
Poxviridae/ Orthopoxvirus	Orthopoxviruses (other pathogenic, not in RG 2 or 4)			2 implied (E)		2
Poxviridae/ Orthopoxvirus	Vaccinia virus			2 (E)		2
Poxviridae/ Parapoxvirus	Orf virus			2 implied		2
Reoviridae	Coltiviruses					2 (incl. Colorado Tick Fever)
Reoviridae	Orbiviruses					2
Reoviridae	Reoviruses					2
Reoviridae	Rotavirus (human)					2
Retroviridae	Lentivirinae (except HIV-1 and HI)	✸		2/3* implied		
Retroviridae	Simian sarcoma virus (SSV-1)			2/3* implied		
Retroviridae/ Lentiviridae	Human Immunodeficiency virus (HIV Types 1 and 2, Oncornavirus C)	✸		2/3*		3 (Types 1 and 2)
Retroviridae/ Lentiviridae	Simian immunodeficiency virus			2/3*		3
Retroviridae/ Oncovirinae	Oncornavirus B			2/3* implied		
Retroviridae/ Oncovirinae	Oncornavirus C (except HTLV I and II)			2/3* implied		
Retroviridae/ Oncovirinae/ Genus Oncornavirus C	Human T-cell lymphotropic viruses (HTLV)			2/3* implied		3 (Types 1 and 2)
Rhabdoviridae	Flanders-Hart Park virus (see Zinsser, pg 777)			2		BMBL
Rhabdoviridae	Hart Park virus (see Zinsser, pg 777)			2		BMBL
Rhabdoviridae	Vesicular stomatitis virus	✸		2/3 (I/E) some R		2 (lab adapted strains), 3
Rhabdoviridae/ Lyssavirus	Rabies virus			2 /3*		2

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Table E.3-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Togaviridae/ Alphavirus (Grp A Arbovirus)	Alphaviruses (others known)					
Togaviridae/ Alphavirus (Grp A Arbovirus)	Barmah Forest			2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Bebaru virus			2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Chikungunya virus			V2 (E), 3 (E)		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Eastern equine encephalomyelitis (EEE)		✸	2 (I)	B	2
Togaviridae/ Alphavirus (Grp A Arbovirus)	Everglade virus			3		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Mayaro virus			3		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Mucambo virus			3		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Ndumu			3		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	O'Nyong-Nyong virus			2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Ross River virus			2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Semliki Forest virus			3		3
Togaviridae/ Alphavirus (Grp A Arbovirus)	Sindbis virus			2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Tonate virus			3/4 (E), some R		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Venezuelan equine encephalomyelitis			V2 (E), 3 (I/E)	B	V2, 3
Togaviridae/ Alphavirus (Grp A Arbovirus)	Western equine encephalomyelitis			2 (I)	B	2
Togaviridae/ Pestivirus (Canada)	Hepatitis C	✸		2		2
Togaviridae/ Rubivirus	Rubivirus (Rubella)					2
Toroviridae	Toroviridae					
Unclassified viruses	Hepatitis (bloodborne viruses not yet identified)	✸		2 implied		2 implied
Unconventional agents, prions	Bovine spongiform encephalopathy (BSE)			2* (I)		
Unconventional agents, prions	Chronic wasting disease (CWD)			2		
Unconventional agents, prions	Creutzfeldt-Jacob disese			3		3
Unconventional agents, prions	Exotic ungulate encephalopathy (EUE)			2		

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Table E.3-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Current LANL proposed[2]	Select Agents[3]	CDC Biosafety Level[4]	CDC Risk Group[5]	NIH Risk Group[6]
Unconventional agents, prions	Feline spongiform encephalopathy (FSE)			2		
Unconventional agents, prions	Gatal familial insomnia (FFI)			3		
Unconventional agents, prions	Gerstmann-Straussler-Scheinker syndrome			3*		3 implied
Unconventional agents, prions	Kuru			3*		3
Unconventional agents, prions	Scrapie			2* implied		
Unconventional agents, prions	Transmissible mink encephalopathy (TME)			2		
Viral vector/Animal retrovirus	Avian leukosis virus (ALV)					1
Viral vector/Animal retrovirus	Avian sarcoma virus					1
Viral vector/Animal retrovirus	Bovine immunodeficiency virus (BIV)					
Viral vector/Animal retrovirus	Bovine leukemia virus (BLV)					1
Viral vector/Animal retrovirus	Feline leukemia virus (FeLV)					1
Viral vector/Animal retrovirus	Feline sarcoma virus (FeSV)					1
Viral vector/Animal retrovirus	Gibbon leukemia virus (GaLV)					1
Viral vector/Animal retrovirus	Mason-Pfizer monkey virus					1
Viral vector/Animal retrovirus	Mouse mammary tumor virus					1
Viral vector/Animal retrovirus	Murine leukemia virus					1
Viral vector/Animal retrovirus	Murine sarcoma virus					1
Viral vector/Animal retrovirus	Rat leukemia virus					1
Viral vector/Animal virus	Baculovirus					
Viral vector/Animal virus	Chick embryo lethal orphan (CELO)					
Viral vector/Animal virus	Dog sarcoma					
Viral vector/Animal virus	Guinea pig herpes					
Viral vector/Animal virus	Hamster leukemia					
Viral vector/Animal virus	Lucke (frog) virus					
X-Arboviruses	Aino			3		BMBL
X-Arboviruses	Akabane			3		BMBL
X-Arboviruses	Araguari			3		BMBL
X-Arboviruses	Batama			2		BMBL
X-Arboviruses	Batken			3		BMBL
X-Arboviruses	Bhanja			3		BMBL
X-Arboviruses	Bimbo			3		BMBL
X-Arboviruses	Bluetongue			2 (E)		BMBL
X-Arboviruses	Bobaya			3		BMBL
X-Arboviruses	Bobia			3		BMBL
X-Arboviruses	Buenaventura			3		BMBL
X-Arboviruses	Cabassou			3		BMBL
X-Arboviruses	Cache valley			2		BMBL
X-Arboviruses	Chim			3		BMBL
X-Arboviruses	Cocal			3		BMBL
X-Arboviruses	Dhori			3		BMBL
X-Arboviruses	Dugbe			3		BMBL

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X-Arboviruses	Ganjam (E permit)					
X-Arboviruses	Garba			3		BMBL
X-Arboviruses	Germiston			3		BMBL
X-Arboviruses	Getah			3		BMBL
X-Arboviruses	Gordil			3		BMBL
X-Arboviruses	Guaratuba			2		BMBL
X-Arboviruses	Ibaraki			3		BMBL
X-Arboviruses	Inhangapi			3		BMBL
X-Arboviruses	Inini			3		BMBL
X-Arboviruses	Israel Turkey Mening.			3		BMBL
X-Arboviruses	Issyk-Kul			3		BMBL
X-Arboviruses	Itaituba			3		BMBL
X-Arboviruses	Kairi			3		BMBL
X-Arboviruses	Khasan			3		BMBL
X-Arboviruses	Koutango			3		BMBL
X-Arboviruses	Kyzylagach			3		BMBL
X-Arboviruses	LaCrosse virus			2		BMBL
X-Arboviruses	Langat virus			2		BMBL
X-Arboviruses	Middelburg			3		BMBL
X-Arboviruses	Nariva, Negishi			3		BMBL
X-Arboviruses	New Minto			3		BMBL
X-Arboviruses	Nodamura			3		BMBL
X-Arboviruses	Northway			3		BMBL
X-Arboviruses	Ouango			3		BMBL
X-Arboviruses	Oubangui			3		BMBL
X-Arboviruses	Paramushir			3		BMBL
X-Arboviruses	Piry			3 (I)		BMBL
X-Arboviruses	Razdan			3		BMBL
X-Arboviruses	Rochambeau			3		BMBL
X-Arboviruses	Sagiyama			3		BMBL
X-Arboviruses	Salanga			3		BMBL
X-Arboviruses	Santa Rosa			3		BMBL
X-Arboviruses	Saumarex Reef			3		BMBL
X-Arboviruses	Sepik			3		BMBL
X-Arboviruses	Slovakia			3		BMBL
X-Arboviruses	Spondweni			3		BMBL
X-Arboviruses	Tamdy			3		BMBL
X-Arboviruses	Telok Forest			3		BMBL
X-Arboviruses	Tlacotalpan			3		BMBL
X-Arboviruses	Tocio					BMBL
X-Arboviruses	Turlock virus			2		BMBL
	Nipah virus				C	
	Hemorrhagic fever agents and viruses undefined					4

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Table E.3-3. Fungi and their Safety Classifications

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Absidia	*corymbifera*				
Absidia	*ramosa*				
Ajellomyces	*capsulatus*				
Ajellomyces	*dermatitidis*				
Aspergillus	*flavus*				
Aspergillus	*fumigatus*				
Aspergillus	*spp*				
Blastomyces	*dermatitidis*		2		2
Candida	*albicans*				
Candida	*spp*				
Cladosporium	*bantianum*		2		2
Cladosporium	*carrionii*				
Cladosporium	*trichoides*		2		2 (Xylo-hypha)
Cladophialopora	*bantians*		2		
Coccidioides	*immitis*		2, 3 arthro-conidia; cont. soil		3 (soil, sporul. cultures)
Cryptococcus	*neoformans*		2		2
Dactylaria	*gallopava*		2		2 (Ochro-conis)
Dermatophilus	*congolensis*				
Emmonsia	*parva*				
Epidermophyton	*floccosum*		2, implied		2, implied
Epidermophyton	*spp*		2		2
Exophiala	*dermatitidis*		2 (Wan-giella)		2 (Wan-giella)
Filobasidiella	*bacillispora*				
Filobasidiella	*neoformans*				
Fonsecaea	*compacta*				
Fonsecaea	*pedrosoi*		2		2
Geotrichum	*spp*				
Histoplasma	*capsulatum*		3 (capsulatum)		3 (capsulatum and duboisii)
Histoplasma	*farcinimosum*				
Histoplasma	*spp.*				
Loboa	*lobai*				
Madurella	*grisea*				
Madurella	*mycetomatis*				

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[2] Select agent list is from 42 CFR 72

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[4] Risk Grouping from CDC 2000a

[5] NIH Risk Groups (RG) are from NIH 2001
RG 1 not associated with disease in healthy human adults
RG 2 associated with human disease that is rarely serious and prophylactic intervention often available
RG 3 associated with human disease that is serious or lethal and prophylactic intervention may be available
RG 4 associated with human disease that is serious or lethal and prophylactic intervention not usually available

Table E.3-3. Fungi and their Safety Classifications

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Microsporum	*spp*		2		2
Mucor	*spp*				
Neotestudina	*rosatii*				
Ochroconis	*gallopavum*		2		
Paracoccidioides	*brasiliensis*				2
Penicillium	*marneffei*		2		2
Phialophora	*compacta*				
Phialophora	*pedrosoi*				
Ramichlorisium	*mackenzieim*		2		
Rhinocladiella	*compacta*				
Rhinocladiella	*pedrosoi*				
Rhizopus	*cohnii*				
Rhizopus	*microspous*				
Sporothrix	*schenckii*		2		2
Stachybotrus	*atra*		2		
Trichophyton	*rubrum*		2, implied		2, implied
Trichophyton	*spp*		2		2
Trichosporon	*spp*				
Xylohypha	*bantania*				
Zymonema	*dermatitidis*				

[1] Basic genus and specie list is from ABSA 1998 with some additions.

[2] Select agent list is from 42 CFR 72

[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC

[4] Risk Grouping from CDC 2000a

[5] NIH Risk Groups (RG) are from NIH 2001
RG 1 not associated with disease in healthy human adults
RG 2 associated with human disease that is rarely serious and prophylactic intervention often available
RG 3 associated with human disease that is serious or lethal and prophylactic intervention may be available
RG 4 associated with human disease that is serious or lethal and prophylactic intervention not usually available

Table E.3-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Acanthamoeba	*castellani*	Protozoa		2		
Acanthamoeba	*spp*	Protozoa		2		
Acanthocheilonema	*spp*	Helminth, Nematode				
Ancylostoma	*duodenale*	Helminth, Nematode		2 implied		2
Ancylostoma	*spp*	Helminth, Nematode		2 implied		2
Ancylstoma	*ceylanicum*	Helminth, Nematode		2 implied		2
Angiostrongylus	*cantonensis*	Helminth, Nematode				
Angiostrongylus	*costaricensis*	Helminth, Nematode				
Angiostrongylus	*spp*	Helminth, Nematode				
Ascaris	*lumbricoides*	Helminth, Nematode		2 implied		2
Ascaris	*spp*	Helminth, Nematode		2		2
Ascaris	*suum*	Helminth, Nematode		2 implied		2
Babesia	*divergens*	Protozoa		2 implied		2
Babesia	*microti*	Protozoa		2 implied		2
Babesia	*spp*	Protozoa		2		2
Balamuthia	*spp.*	Protozoa		2		
Balantidium	*coli*	Protozoa				
Balantidium	*spp*	Protozoa				
Brugia	*malayi*	Helminth, Nematode		2 implied		2
Brugia	*pahangi*	Helminth, Nematode		2 implied		2
Brugia	*spp*	Helminth, Nematode		2 implied		2

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Table E.3-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Brugia	*timori*	Helminth, Nematode				2
Capillaria	*philippinensis*	Helminth, Nematode				
Capillaria	*spp*	Helminth, Nematode				
Clonorchis	*sinensis*	Helminth, Trematode				
Clonorchis	*spp*	Helminth, Trematode				
Clonorchis	*viverrini*	Helminth, Trematode				
Coccidia	*spp*	Protozoa		2		2
Cyclospora	*cayetanensis*					
Cryptosporidium	*parvum*	Protozoa		2 implied		2
Cryptosporidium	*spp*	Protozoa		2		2
Cysticercus	*cellulosae*	Helminth, Cestode larva		2		2
Cysticercus	*spp*	Helminth, Cestode		2		2
Dicrocoelium	*spp*	Helminths, Trematode				
Dipetalonema	*perstans*	Helminth, Nematode				
Dipetalonema	*spp*	Helminth, Nematode				
Dipetalonema	*streptocerca*	Helminth, Nematode				
Diphyllobothrium	*latum*	Helminth, Cestode				
Diphyllobothrium	*spp*	Helminth, Cestode				
Dipylidium	*spp*	Helminth, Cestoda				

[1] Basic genus and specie list is from ABSA 1998 with some additions.

[2] Select agent list is from 42 CFR 72

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Table E.3-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Dracunculus	*medinensis*	Helminth, Nematode				
Dracunculus	*spp*	Helminth, Nematode				
Echinococcus	*granulosis*	Helminth, Cestode		2 implied		2
Echinococcus	*multilocularis*	Helminth, Cestode		2 implied		2
Echinococcus	*spp*	Helminth, Cestode		2		2
Echinococcus	*vogeli*	Helminth, Cestode		2 implied		2
Entamoeba	*histolytica*	Protozoa		2		2
Enterobius	*spp*	Helminth, Nematode		2		2
Fasciola	*gigantica*	Helminth, Trematode		2 implied		2
Fasciola	*Hepatica*	Helminth, Trematode		2 implied		2
Fasciola	*spp*	Helminth, Trematode		2 (metacercariae)		2
Fasciolopsis	*buski*	Helminth, Trematode				
Fasciolopsis	*spp*	Helminth, Trematode				
Giardia	*lamblia*	Protozoa		2 implied		2
Giardia	*spp*	Protozoa		2		2
Hartmanella	*spp*	Protozoa				
Heterophyes	*spp*	Helminth, Trematode		2		2
Hymenolepis	*diminuta*	Helminth, Cestode				2
Hymenolepis	*nana*	Helminth, Cestode		2		2

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Table E.3-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Hymenolepis	*spp*	Helminth, Cestode		2		2
Isospora	*spp*	Protozoa		2 implied, Coccidia		2
Leishmania	*braziliensis*	Protozoa		2 implied		2
Leishmania	*donovani*	Protozoa		2 implied		2
Leishmania	*ethiopica*	Protozoa		2 implied		2
Leishmania	*major*	Protozoa		2 implied		2
Leishmania	*mexicana*	Protozoa		2 implied		2
Leishmania	*peruviania*	Protozoa		2 implied		2
Leishmania	*spp.*	Protozoa		2		2
Leishmania	*tropica*	Protozoa		2 implied		2
Linguatula	*spp*	Arthropod				
Loa	*loa*	Helminth, Nematode		2 implied		2
Loa	*spp*	Helminth, Nematode		2 implied		2
Macracanthorhynchus	*spp*	Acanthocephala				
Mansonella	*ozzardi*	Helminth, Nematode				
Mansonella	*perstans*	Helminth, Nematode				
Microsporidium	*spp.*	Protozoa		2 implied		2
Naegleria	*fowleri*	Protozoa		2		2
Naegleria	*gruberi*	Protozoa		1		1
Naegleria	*spp*	Protozoa		2		1 or 2
Necator	*americanus*	Helminth, Nematode		2		2
Necator	*spp*	Helminth, Nematode		2		2
Onchocerca	*spp*	Helminth, Nematode		2 implied		2
Onchocerca	*volvulus*	Helminth, Nematode		2 implied		2

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Table E.3-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Opisthorchis	*felineus*	Helminth, Trematode				
Opisthorchis	*spp*	Helminth, Trematode				
Paragonimus	*spp*	Helminth, Trematode				
Paragonimus	*westermanii*	Helminth, Trematode				
Piroplasma	*spp*	Protozoa				
Plasmodium	*cynomologi*	Protozoa		2		2
Plasmodium	*falciparum*	Protozoa		2 implied		2
Plasmodium	*malariae*	Protozoa		2 implied		2
Plasmodium	*ovale*	PRotozoa		2 implied		2
Plasmodium	*simian parasites*	Protozoa		2 implied		2
Plasmodium	*spp*	Protozoa		2		2
Plasmodium	*vivax*	Protozoa		2 implied		2
Pneumocystis	*carinii*	Protozoa				
Sarcocystis	*spp*	Protozoa		2		2
Sarcocystis	*sui hominis*	Helminth, Cestode larva		2 implied		
Schistosoma	*haematobium*	Helminth, Trematode		2 implied		2
Schistosoma	*intercalatum*	Helminth, Trematode		2 implied		2
Schistosoma	*japonicum*	Helminth, Trematode		2 implied		2
Schistosoma	*mansoni*	Helminth, Trematode		2 implied		2
Schistosoma	*mekongi*	Helminth, Trematode		2 implied		2
Schistosoma	*spp*	Helminth, Trematode		2		2
Strongyloides	*spp*	Helminth, Nematode		2		2

[1] Basic genus and specie list is from ABSA 1998 with some additions.

[2] Select agent list is from 42 CFR 72

[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC

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Table E.3-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Strongyloides	*stercoralis*	Helminth, Nematode		2 implied		2
Taenia	*saginata*	Helminth, Cestode				
Taenia	*solium*	Helminth, Cestode		2		2
Taenia	*spp*	Helminth, Cestode				2
Toxascaris	*spp*	Helminth, Nematode				
Toxocara	*canis*	Helminth, Nematode				2
Toxocara	*spp*	Helminth, Nematode				2
Toxoplasma	*gondii*	Protozoa		2 implied		2
Toxoplasma	*spp*	Protozoa		2		2
Trichinella	*spiralis*	Helminth, Nematode				2
Trichomonas	*vaginalis*	Protozoa				
Trichostrongylus	*spp*	Helminth, Nematode				
Trichuris	*trichiura*	Helminth, Nematode				
Trypanosoma	*brucei brucei*	Protozoa		2 implied		2
Trypanosoma	*brucei gambiense*	Protozoa		2 implied		2
Trypanosoma	*brucei rhodensiense*	Protozoa		2 implied		2
Trypanosoma	*cruzi*	Protozoa		2 implied		2
Trypanosoma	*spp*	Protozoa		2		2
Wuchereria	*bancroftii*	Helminth, Nematode		2 implied		2
Wuchereria	*spp*	Helminth, Nematode		2		2

[1] Basic genus and specie list is from ABSA 1998 with some additions.

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APPENDIX F: ABNORMAL EVENTS INFORMATION

Information derived for this analysis comes from publicly available literature with much of the data coming from the U.S. Army due to its premier role in the United States biological defense program which has been in existence for decades. This program, the U.S. Army Biological Defense Research Program (BDRP), is a research, development, test and evaluation (RDT&E) program conducted by the U.S. Department of Defense, with the Department of the Army (DA) serving as the executive agent. This program is conducted in accordance with 32 CFR 627 and under that scope (32 CFR 627.3) applies to all elements of the Army to include its contractors and subcontractors who use, produce, store, handle, or ship etiologic agents in support of the BDRP regardless of the source of the agent(s). This regulation essentially codifies the guidance of the CDC in their BMBL (CDC 1999). This DA program has management responsibility for (1) the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), which is the lead laboratory in medical defense against biological warfare threats; (2) the U.S. Army Chemical Research, Development, and Engineering Command (CRDEC), which manages and conducts research, development, and engineering activities to provide non-medical defense against biological warfare threats; and (3) the U.S. Army Dugway Proving Ground (DPG), which is a major range and test facility supporting all Department of Defense components and housing the Baker Laboratory Complex.

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F.1 Potential Risk to Workers -- Laboratory-Acquired Infection

"The actual risk of a laboratory-acquired infection is difficult to measure because there is no systematic reporting system at the state, federal, or professional society level that monitors the number of laboratory workers and infections associated with the workplace (Sewell 1995)."

The potential for acquiring an infectious disease while working in a microbiological laboratory is significantly less than the occupational – related risks for healthcare workers. Indeed, the risk is very small if the appropriate microbiological facilities and containment devices are available, correct procedures and techniques are used, and adequate protective barriers are in place. These cautionary any measures are needed because the quantities of microorganisms necessary for an infectious dose can be as little as one organism (Sewell 1995). Below, the historical perspective shows that in the early 1900s laboratory-acquired infections were common and pervasive throughout medical care facilities and laboratories. However, control of infection in laboratories has achieved a high level of sophistication to the point where virtually no reports of infection occur in biosafety laboratories in the United States today.

Historical Perspective In the last half of the 20th century the observations of physicians Oliver Wendell Holmes and Ignaz Semmelweis showed there was a connection between healthcare workers not washing their hands and patients acquiring certain diseases (Noskin and Peterson 2001). This started the concept of infection control which has subsequently driven equipment and facility design as well as the development of standardized procedures (CDC 1999; Collins and Kennedy 1999; Fleming 1995; and Sewell 1995).

Since the early 1900s, various individuals conducted surveys or reported the connection between healthcare and laboratory workers contracting infectious diseases (CDC 1999; Collins 2000; Collins and Kennedy 1999; Pike 1979, 1976; Pike et al. 1965; Sewell 1995; and Sulkin and Pike 1951, 1949). The data they present are essentially published anecdotal reports, selected outbreaks with a specific microorganism, retrospective questionnaire-based surveys, and information presented at meetings related to laboratory-acquired infections and biosafety. (Sewell 1995). These reports did result in the recognition that at least one primary route of transmission was aerosol, which in turn led to the development of the BSC. The consequence of using BSCs in laboratories was the later shift in focus from bacteria and rickettsia as the chief laboratory-associated infections evolved to viruses. This is because the BSCs significantly reduced aerosol-induced infections to laboratory workers which were largely bacteria and rickettsia while the viruses are bloodborne and transmitted through contact (Sewell 1995).

During 1949 to 1974, the results of 3,921 infection reports were published in Health Laboratory Science journal (Pike 1976). As expected, bacterial infections were predominant with 1,669 cases (42.5 percent), followed by viral with 1,049 (26.7 percent), rickettsial with 573 (14.6 percent), fungal with 353 (9 percent), chlamydial with 128 (3.3 percent), parasitic with 115 (2.9 percent), and unspecified cases with 34 reports (0.9 percent). The bacterial infections were caused by various *Brucella* species, *Salmonella typhi, Franciscella tularensis*, and *Mycobacterium tuberculosis*. Also, 90 viral infections were described with 36 percent caused by

the hepatitus virus and Venezuelan equine encephalitis virus. The rickettsia infections were due largely to *Coxiella burnetii* (Q fever) and the fungal infections were mostly due to *Histoplasma capsulatum* and *Coccidioides immitis*. It was noted in these reports that after 1955 the total number and frequency of bacterial, chlamydial, and rickettsial infections declined dramatically (Pike 1976).

Since the 1970s, when CDC issued their *Classification of Etiologic Agents on the Basis of Hazard*, (CDC 1974), which was essentially equivalent to the *NIH Guidelines for Research Involving Recombinant DNA* (NIH 2001), there has been both a reduction in surveys and analysis while reports of laboratory-acquired infection dropped in the United States. The BSLs established by the HHS, Public Health Service, CDC, and NIH in their BMBL (now in its fourth edition [CDC 1999]) have been commonly accepted by most laboratories since the 1980s and are required of those handling select agents covered under 42 CFR 72. The knowledge, the techniques, and the equipment to prevent most laboratory infections are available (Pike 1979). There is some indication that this is true when one reviews the admittedly anecdotal literature from more recent periods. "Some laboratory-acquired infections are now history (Collins and Kennedy 1999). For example, since 1991…no new reports have been found of tularaemia, plague, leptospirosis, cholera and typhoid fever, nor of the many rarer viral infections." A recent bibliographic database (Collins 2000) starting with reports at the turn of the century and covering up through August 7, 2000, reveals substantial reductions of laboratory-acquired infections reported in the 1990s. There is a particularly notable lack of reported cases in the literature relating to laboratory-acquired infections in the United States during the last ten years.

The experience of the U.S. Army at their BDRP facilities over several decades provides further insight to the potential for laboratory-acquired infection. The DA program underwent a programmatic NEPA evaluation in 1989, the *Final Programmatic Environmental Impact Statement Biological Defense Research Program* (PEIS) (DA 1989). Since 1976, there have been no occurrences of overt disease in laboratory workers handling infectious organisms within the DA BSL-3 facilities, although in 1980, one focal infection with *F. tularensis* occurred at the site of a puncture wound (DA 1989)." There were also no deaths since 1964 (DA 1989). The PEIS (DA 1989) also estimated laboratory-acquired infection rates for their USAMRIID facility for different biocontainment levels (roughly equivalent to the CDC BSL levels) over different periods of time. For their BSL-3 equivalent laboratory operations from 1960 to 1962 they estimated there were six laboratory-acquired infections for a rate of 2 per million man-hours worked. For their BSL-4 equivalent laboratory operations from 1960 to 1969, they estimated seven laboratory-acquired infections for a rate of 1 per million man-hours worked. These infections included subclinical infections and mild illnesses where hospitalization was not required (DA 1989).

Overall, the PEIS estimated the rate of public infection from USAMRIID as less than 0.001 per 1,000,000 person-years and the risk of death to a laboratory worker (for the defensive period 1970 to 1989) as 0.005 per 1,000,000 person-years (DA 1989). For the Offensive or Weapons Period (1954 to 1964) the values were about 5 orders of magnitude higher.

Routes of Exposure. The recognized routes of exposure for laboratory workers to contract infectious diseases is ingestion, inoculation, contamination of skin and mucous membranes, and inhalation (Sewell 1995). Today, many of these routes have limited potential because of facility design, equipment, and procedures. For example, some of the ingestion pathways are from mouth pipetting, contamination of articles or fingers placed in mouth, and consumption of food in the workplace. Due to the common acceptance of standard microbiological practices (CDC 1999) none of these should occur now. The primary routes of exposure remain inoculation which occurs largely from the accidental needlestick, and inhalation from the numerous laboratory procedures which generate aerosols (Sewell 1995). Procedures which produce aerosols include, spontaneous discharge from a microbiological loop, the streaking of media, preparing microscopic slides, cooling a loop in culture media, and heating a loop in an open flame. Other devices often found in microbiological laboratories that can produce aerosols are centrifuges, blenders, homogenizers, shakers, sonicators, and mixers.

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F.2 Potential Risk to Non-Workers from Contact with Biosafety Laboratory Workers

One concern that members of the public may have is the potential for the proposed biosafety laboratory workers to inadvertently transmit diseases to other workers, family members, or the general public. As described in Appendix E.2, in the article on *Understanding Emerging and Re-emerging Infectious Diseases* (NIH 1999), infectious agents may be transmitted through a variety of direct (communicable from one host to another) and indirect contact with an infected individual. It is through understanding the infectious cycle of the respective microorganism that is critical in identifying the potential for transmission and means of mitigation. Some organisms require a vector, such as a flea, tick, or rodent, to transmit the infectious agent from one person to another. Other infectious microorganisms are directly contagious from one person to another. "Organisms that survive primarily or entirely in the human host and are spread through sexual contact, droplet nuclei, and close physical contact can be readily carried to any part of the world. For example, AIDS, tuberculosis, measles, pertussis, diptheria, and hepatitis B are easily spread…Organisms that have animal hosts, environmental limitations, arthropod vectors, or complicated life cycles become successively more difficult to "transplant"…Epidemics of dengue fever and yellow fever cannot appear in a geographic area unless competent mosquito vectors are present. Schistosomiasis cannot spread in an environment unless a suitable snail intermediate host exists in that region. " (Wilson 1995). "What is carried by humans…? Pathogens in or on body, microbiologic flora, vectors on body, immunologic sequelae of past infections, genetic makeup, cultural preferences, customs, behavioral patterns, technology, and luggage and whatever it contains" (Wilson 1995). More discussion on this issue is presented in Section 4.1.1, Human Health Chapter 4.

The tools to deal with transmission issues are vaccines and drugs, and vector-control methods such as pesticides. Of course, the primary means of defense is to limit all contact with infectious organisms and insure that they are destroyed or inactivated when they are on environmental surface or disposed in waste while still in the laboratory.

Historical Perspective. The literature is confusing with regard to the transmission of infectious agents between laboratory workers and the outside. Unfortunately, some of these infections have been transmitted from those workers to members of their families and to others outside the laboratory (Collins and Kennedy 1999). No specific statistical information was readily available on this subject. The only information specific to this is found in the information from the DA and the CDC.

According to the U.S. Army PEIS for the BDRP, there have never been any occurrences of infections in non-laboratory workers or in the general community arising from organisms handled in their BSL-3 or BSL-4 equivalent facilities associated with the BDRP (DA 1989). Similarly, discussion with the CDC in Atlanta about their BSL-3 and BSL-4 laboratories revealed that they have never had a documented case of a laboratory worker's family members or other members of the public acquiring a disease associated with their laboratory operations (PC 2001a).

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F.3 Accidents

Accidents associated with microbiological laboratories are generally thought of in terms of what might be considered routine accidents that have a reasonable probability of occurrence, but a very low consequence. These accidents would be leaking specimen/sample containers, spills involving broken glass or other containers, spillage and breakage in BSCs and centrifuge accidents (Collins and Kennedy 1999). Many of the laboratory-acquired infections may have resulted from these types of routine minor accidents. A literature search and discussions with laboratory regulators (such as the CDC, NIH, and the U.S. Army) revealed no examples of infectious materials released due to catastrophic accidents involving microbiological laboratories. In referring to these events the Army states that "The likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable. No such event has occurred in the more than 50 years in which the military has been conducting biological defense activities (DA 1989)." Transportation-related accidents are considered separately in this EA (see Appendix G).

Historical Perspective. Researchers and preparers of infection incident summaries compiled information on accidents related to laboratory operations and specifically laboratory-acquired infections relating to accidents. In the review of 3,921 laboratory infections reported, 59 percent occurred in research laboratories (Pike 1976). About 70 percent of these resulted from working directly with infectious agents, some involving infectious aerosols (13 percent), and some from accidents (18 percent) (Sewell 1995). Overall, accidents were the second greatest source (initiator) of infections. Seventy percent of them were due to accidental inoculation (over 40 percent) with the remaining due to splashes and spills (about 30 percent). Another potential aerosol-producing accident, centrifuge accidents, results in relatively few laboratory-acquired infections, but a single incident often exposes several individuals (Sewell 1995).

The U.S. Army's extensive experience (DA 1989) can be helpful in evaluating the potential for accidents involving infectious agents. The PEIS states "there have been laboratory accidents that resulted in potential exposures; however, prior immunization or immediate treatment with the appropriate therapy has averted the possible development of clinical disease…(DA 1989). The outstanding safety record (no illness resulting from laboratory exposure to agents or toxins in the last 10 years) at USAMRIID…and DPG…is indicative of how safely research with hazardous infectious organisms can be conducted. They additionally state that 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 (DA 1989). The Army further noted that during its many years of operations at Fort Detrick, they did not cause a single case of infection in the surrounding community.

Accident Scenarios from other NEPA Documents. Various NEPA accident scenarios have been postulated for infectious agents in BSL-3 laboratories (BMI 1993; DA 1989, 1992, 1996). Three of these NEPA documents present an accident analysis which are termed as maximum credible events (MCE). The analysis of MCEs are required under the U.S. Army regulations (32 CFR 627). The documents described the MCEs as realistic events that have some probability of

occurrence and resulting in maximum potential consequences. Two of these documents are EAs for relatively small operations (BMI 1993 and DA 1996). The other two are EISs, one for a military installation (DA 1992) and the other a PEIS for the entire U.S. Army BDRP (DA 1989). Each accident approach is described briefly, except for the PEIS accident which is described in more detail.

The first, scenario for a BSL-3 facility in Ohio (BMI 1993), involved an accident that resulted in an release of exotoxin from the common soil pathogen, *Clostridium botulinum*. Three different toxins were planned for use in the facility (botulinum, ricin, and *Staphylococcal* enterotoxin B), but botulinum toxin was chosen because it was determined to be the most toxic of the three. The scenario involved the release of an aerosol equivalent in amount to one of their standard tests in the interior of a Class III BSC followed by release through the cabinet filtration system. The BSC exhausts through two HEPA filters in series with each removing 99.97 percent of the aerosol. The EA analysis also considered an accident relating to microorganism handling in which the organisms were not contained within a BSC as not being a credible accident since the only open culture handling, including packaging and un-packaging, is done inside their BSCs. They similarly discounted fire, explosion, loss of ventilation control, airplane crash, earthquake, and flooding as also not being credible events to initiate accidents. They determined that there was no effect on humans due to the release which was several orders of magnitude lower than the no-effect dose (BMI 1993).

The second EA involves the Armed Forces Institute of Pathology (AFIP) at Fort Detrick in Frederick, MD (DA 1996). This facility handles primarily *Brucella spp*. bacteria, which are normally transmitted by direct contact with the secretions of body fluids, aborted fetuses of infected animals, and by ingesting contaminated meat. Brucella is virulent (readily able to cause disease) and the infective dose can result from less than 10 microorganisms (DA 1996). While not explicitly stated an accident analysis was not performed for the EA since the anecdotal information suggests there should be no reasonable probability of an accident event. Only one presumptive case of Brucellosis infection is identified in a worker (blood test suggested exposure but culturing could not prove the presence of the organism) but did not result in development of the disease. No incidence of secondary transmission of disease to those outside of the AFIP laboratory has been reported (DA 1996).

The third NEPA document is the EIS for the Life Sciences Test Facility at the Dugway Proving Grounds (DA 1992). This document reviewed accident scenarios and identified those considered by the DA to be reasonably foreseeable. The review covered two intentional release scenarios, ten accidental release scenarios, and six unexpected external event scenarios. The only scenario determined to be reasonably foreseeable was laboratory-acquired infection. This facility is also part of the Army's BDRP and is also discussed in the PEIS.

In the fourth NEPA document the DA considered an MCE analogous to a "worst case analysis" in Appendix A9 of the PEIS (DA 1989). However, the PEIS states:

"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…For the purpose of perspective and information, this appendix also presents estimates of the extent of potential impacts, under various conditions, resulting from the 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 the primary site boundaries…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."

The MCE bioagent accident from the PEIS (DA 1989), Appendix A9 is presented as follows:

Initial conditions:

- A typical BSL-3 equivalent laboratory exists at USAMRIID and is designed to exceed CDC guidelines.
- A centrifuge, the key piece of equipment in this scenario, is in a room and not in a BSC.
- The size of the room is 1,080 ft^3 (30,240 liters), but since the room is under negative pressure and air flow is continuous, the volume of the duct from the room leading to the filter is also included (608 ft^3 or 17,024 liters) for a total volume of 1,688 ft^3 (47, 264 liters).
- The BSL-3 equivalent laboratory centrifuge room exhausts air via two filters in series, which are conservatively estimated to have a 95 percent particulate removal efficiency, and air then exits through a roof stack.
- The only micro organism handled in the laboratory is a Rickettsial organism, *Coxiella burnetii,* which causes Q-fever, this organism is hardy and withstands laboratory manipulation with little or no loss in viability, is highly stable in aerosols and dies at a rate of about one percent per minute over a wide range of humidities (30 to 85 percent relative humidity) and temperature (0 to 30 ^oC). It is extremely infectious in a small particle aerosol.
- A single worker is working with one liter of *Coxiella burnetii* slurry.
- The worker places 165-milliliters of slurry into each of six 250 milliliter polypropylene centrifuge tubes AND fails to insert O-rings or tighten the centrifuge caps which are screw-on.

Accident scenario:

The centrifuge is turned on at 10,000 revolutions per minute for 30 minutes

- All six tubes leak
  - *Some slurry leaks into the rotor*
  - *Some slurry leaks into centrifuge compartment*
  - *Most of the slurry remains in the tubes*
  - *Most of the slurry that leaked into covered rotor is not aerosoloized (99 percent)*
  - *Only a fraction of the slurry that leaked into the centrifuge cabinet is aerosolized and 90 percent of that settles as droplets inside the chamber*
- A few minutes after the centrifuge stops the worker opens the centrifuge and reaches in to remove the rotor
  - *He notices leak.*
  - *He gets assistance of two co-workers to help him manage the spill.*
  - *Four more workers enter the laboratory not knowing of the accident.*
  - *All seven workers may have been exposed to a dose of organisms sufficient to cause infection in unimmunized individuals.*
- The slurry is thixotropic (much like egg white) but due to centrifuging has a reduced viscosity (20 to 25 centipoise) containing about 20 percent dry solids.
- The 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) representing the maximum infectivity for man is determined to conservatively be 0.1 percent.

Result to the Workers:

- The accident immediately produces 9.9×10^9 airborne human infective doses at a 50 percent rate for contracting the disease (HID_{50}) contained in a 3x3x3 foot area above and around the centrifuge (756 liters)
- There are 1.3×10^3 HID_{50} per liter of air in the seconds after the lid was opened
- The centrifuge operator, exited by the accident was breathing 15 liters of air per minute and was in the confined aerosol for no more than 5 minutes and could have inhaled about 100,000 HID_{50}
- The two co-workers coming to the operator's assistance were exposed to only a slightly less dose than the centrifuge operator
- The other four workers were exposed for less than 1 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}

Result to the General Population and Surrounding Environment:

- The quantity of human infective doses, by simple Gaussian plume dispersion models, is expected to be dissipated to:
  - *Less than 1 HID50 in 1 liter (L) of air at a distance of less than 2 m from the stack,*
  - *Less than 0.1 HID50 in 1 L of air at a distance of 16 m from the stack, and*
  - *less than 0.01 HID50 in 1 L of air at a distance of 38 m from the stack.*

Of the rickettsial agents, *Coxiella burnetii* probably represents the greatest risk of laboratory infection, according to the CDC. The organism is highly infectious and remarkably resistant to drying and environmental conditions. The infectious dose of virulent Phase I organisms in laboratory animals has been calculated to be as small as a single organism. The estimated HID (25-50) (inhalation) for Q fever is 10 organisms…Q fever is the second most commonly reported laboratory associated-infection (CDC 1999). The CDC and the WHO identify Q fever as a disease most commonly contracted occupationally by those working with livestock handling and processing, and those in laboratory and veterinary practice (CDC 2001b; WHO 1999).

Men who were previously vaccinated and then exposed to aerosols of 150 or 150,000 infectious doses of virulent *Coxiella burnetii* did not consistently become ill (Benenson 1959). Therefore, since the centrifuge operator would have been vaccinated as a requirement of employment, it is questionable whether he would contract the illness. Antibiotic treatment (doxycycline), soon after exposure, significantly decreases the chances of developing symptoms of the disease (Benenson 1959).

The DA conclusion for their MCE showed that the only worker to conceivably contract the illness as a consequence of the accident would be the centrifuge worker, and even that individual would likely not become ill. The second MCE described in the PEIS (DA 1989) using a biological toxin is not relevant to this EA and is therefore not discussed.

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APPENDIX G.1: TRANSPORTATION ACCIDENT INFORMATION AND DATA ANALYSIS

"Every year, more than 40,000 Americans die and several hundred thousand are injured in transportation-related incidents, mainly from motor vehicle accidents. A small number of these fatalities and injuries result from the unintentional release of hazardous materials during the transport. For example, during each of the past 15 years, approximately 10 people died as a result of fires that occurred in gasoline-truck accidents, with truck drivers accounting for approximately 7 of the 10 deaths…For most hazardous materials…estimating the fatality and injury risks associated with their transportation is more difficult. Approximately 100,000 shipments of chlorine occur each year…since 1985, only one fatality and a handful of injuries have occurred as a result of accidents involving the transportation of chlorine in the United States." (Brown et al. 2000)

These comments from a National Transportation Risk Assessment study are indicative of the problem of trying to develop probabilities for risk associated with accidents that have a low frequency of occurrence. Their study (Brown et al. 2000) did not deal with infectious substances because their focus was on what constitutes at least 90 percent of the transportation risk from toxic-by-inhalation (TIH) materials and that did not include infectious substances.

Infectious substances (etiologic agents) in transit are covered under the U.S. DOT regulations (49 CFR 171, 172, 173, and 178) for the safe transportation of hazardous materials. Regulation 49 CFR 171.15 deals with tracking the suspected release of hazardous materials during transportation. One subpart of that regulation (49 CFR 171.15(a)3) covers "fire, breakage, spillage, or suspected contamination occurs involving shipment of infectious substances (etiologic agents)." Another subpart of that regulation (49 CFR 171.16) provides instructions for the hazardous materials incident reports. Information about shipments and incidents associated with them are maintained and reported by the Office of Hazardous Materials Safety, Research and Special Programs Administration and is developed from documentation developed under 49 CFR 171.15 and 171.16 and reported on Incident Report Form 5800.a. Summarized data are available from the world-wide-web at http:/hazmat.dot.gov/spills.htm. The "Hazardous Materials Shipments" (October 1998) documents the most recent analysis of statistics available from the same website. More recent statistical information providing extensive details on hazardous materials shipments is also available on the web from the Hazardous Materials Information System (HMIS).

The general population risk per year (1994 to 1998) from hazardous materials transportation is 1 in 8,129,000 or 0.11 fatalities per million shipments (DOT 2001a). This risk is dominated by the transportation of six TIH materials including chlorine, ammonia, sulfur dioxide, hydrogen fluoride, fuming sulfuric acid, and fuming nitric acid; and liquefied petroleum, gas, gasoline, and explosives. In comparison, the general population risk per year for a motor vehicle accident is 1 in 6,300 or 1.7 deaths per 100 million vehicle miles, and the general population risk per year for

commercial air carrier accident is 1 in 1,568,000 or 0.7 deaths per 100 million aircraft miles or 0.19 deaths per million departures (DOT 2001a).

The number of hazardous materials shipments is about 800,000 per day with at least 10,000 involving waste hazardous materials identified generally as medical wastes and various other hazardous materials. While only about 43 percent of all hazardous materials tonnage is transported by truck, they account for approximately 94 percent of the individual number of shipments. For the hazardous materials category, which includes infectious substances, 80.27 percent of the shipments are carried by truck with the remaining 19.73 percent transported by rail (DOT 1998).

There are an estimated 4,300 non-hospital waste generating facilities (i.e., laboratories) that are potential generators of medical waste and other kinds of infectious substances including diagnostic specimens. These facilities generate 73,037 tons per year of infectious medical waste and ship about 200 tons per day (DOT 1998).

Statistical information covering the period from 1995 to 1999 was extracted from the HMIS database and is included in Appendix G.2. These data provide information on the number of incidents, major injuries, minor injuries, and deaths from the infectious substances class and separately from the "all hazardous materials classes." These data show that infectious substance incidents are too few to even be ranked (NL=not listed) except for minor injuries in 1999. The number of annual infectious substance incidents from 1995 through 1999 is, respectively, 2, 3, 9, 10, and 166. While low and insignificant in comparison to the "all hazardous materials class" (less than one percent), it is unknown why there is an increase trend. The only injuries related to infectious materials incidents occurred in 1999 with three minor injuries.

The remainder of the data includes "all hazardous materials classes." The percentages of incidents for highway, railway, transportation phase, result, community site, and land use site remained relative constant for the period from 1995 through 1999. For the 5-year period, human error leads the mode or cause for both highway (about 85 percent) and railway (about 60 percent) incidents, but highway incidents make up 85 percent of all modes of accidents for this class. Similarly, unloading accounts for a nearly constant 56 percent of all incidents in the transportation phase. As for the impact or result, spillage accounts for 95 percent of all incidents over the 5-year period. As may be expected since the accidents occur largely when unloading, it is nearly an even split between urban and suburban, and between industrial and commercial with all at about 30 to 50 percent.

New Mexico has consistently about 1 percent or less of all hazardous materials incidents each year while the neighboring states of Arizona and Colorado each are only slightly higher and range from 1 to 3 percent each year. Texas has also stayed rather consistent at 7 to 8 percent of all incidents. There is an apparent increase in hazardous materials incidents overall in the United States which rose from 14,700 in 1995 to 17,069 in 1999.

APPENDIX G.2: TRANSPORTATION STATISTICAL INFORMATION FROM THE DOT HAZARDOUS MATERIALS INFORMATION SYSTEM

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1995		Incidents	Numbers				Percentages			
			Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Infectious Substance Class									
Class	Number	2	0	0	0	0			
Commodity Summary	Rank	NL	NL	NL	NL				

All Hazardous Materials Classes

1995		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Mode or Cause Highway	Human Error	10911	10	212	1	85	53	77	14
	Package Failure	1528	6	38	0	12	32	14	0
	Vehicular Accident or Derailment	244	1	13	6	2	5	5	86
	Other	81	2	14	0	1	11	5	0
	Subtotal	12764	19	277	7	87			
Mode or Cause Railway	Human Error	636	4	19	0	55	50	30	0
	Package Failure	454	3	37	0	39	38	59	0
	Vehicular Accident or Derailment	50	1	3	0	4	13	5	0
	Other	13	0	4	0	1	0	6	0
	Subtotal	1153	8	63	0	8			

1995		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Transportation Phase	En Route	2573	14	151	6	17	47	41	86
	Loading	2541	2	51	1	17	7	14	14
	Unloading	8618	9	148	0	58	30	40	0
	Temporary Storage	787	5	19	0	5	17	5	0
	Unreported	224	0	1	0	2	0	0	0
	Subtotal	14743	30	370	7	100			
Result	Vapor (Gas) Dispersion	430	8	89	3	3	19	18	12
	Material Entered Waterway or Sewer	16	0	0	1	0	0	0	4
	Spillage	14716	30	370	7	96	70	76	28
	Fire	45	4	11	7	0	9	2	28
	Explosion	14	0	8	5	0	0	2	20
	Environmental Damage	43	0	4	2	0	0	1	8
	None	20	0	0	0	0	0	0	0
	Other	109	1	2	0	1	2	0	0
	Subtotal	15393	43	484	25	104			
Community Type at Site	Urban	5806	8	147	4	39	27	40	57
	Suburban	6263	10	116	1	42	33	31	14
	Rural	2431	11	100	2	16	37	27	29
	Unreported	243	1	7	0	2	3	2	0
	Subtotal	14743	30	370	7	100			

1995		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Land Use at Site	Industrial	7701	10	160	1	52	33	43	14
	Commercial	6252	16	163	4	42	53	44	57
	Residential	237	2	18	0	2	7	5	0
	Agricultural	115	1	4	0	1	3	1	0
	Undeveloped	253	1	20	2	2	3	5	29
	Unreported	185	0	5	0	1	0	1	0
	Subtotal	14743	30	370	7	100			

Total Incidents	United States	14743	
	Arizona	130	1
	Colorado	345	2
	New Mexico	138	1
	Texas	1071	7

NOTE: Due to multiple classes being involved in a single incident, the total in one category may not match the total in another.

1996		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
	Infectious Substance Class	**Numbers**				**Percentages**			
Class	Number	3	0	0	0	0			
Commodity Summary	Rank	NL	NL	NL	NL				

All Hazardous Materials Classes

1996		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Mode or Cause Highway	Human Error	9929	13	131	1	83	36	73	13
	Package Failure	1538	8	37	0	13	22	21	0
	Vehicular Accident or Derailment	289	12	10	5	2	33	6	63
	Other	160	3	2	2	1	8	1	25
	Subtotal	11916	36	180	8	85			
Mode or Cause Railway	Human Error	602	2	30	0	54	18	3	0
	Package Failure	436	2	43	0	39	18	5	0
	Vehicular Accident or Derailment	43	2	840	2	4	18	92	100
	Other	31	5	2	0	3	45	0	0
	Subtotal	1112	11	915	2	8			

1996		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Transportation Phase	En Route	2622	20	933	117	19	43	83	98
	Loading	2619	5	26	1	19	11	2	1
	Unloading	7806	16	155	2	56	34	14	2
	Temporary Storage	765	6	12	0	5	13	1	0
	Unreported	138	0	2	0	1	0	0	0
	Subtotal	13950	47	1128	120	100			
Result	Vapor (Gas) Dispersion	479	12	838	3	3	15	40	1
	Material Entered Waterway or Sewer	44	2	3	2	0	2	0	1
	Spillage	13928	42	1126	119	95	52	53	48
	Fire	58	12	52	117	0	15	2	47
	Explosion	18	7	54	5	0	9	3	2
	Environmental Damage	69	6	31	4	0	7	1	2
	None	23	0	1	0	0	0	0	0
	Other	114	0	6	0	1	0	0	0
	Subtotal	14733	81	2111	250	106			
Community Type at Site	Urban	5792	14	114	0	42	30	10	0
	Suburban	5438	16	116	1	39	34	10	1
	Rural	2381	16	896	118	17	34	79	98
	Unreported	339	1	2	1	2	2	0	1
	Subtotal	13950	47	1128	120	100			

1996		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Land Use at Site	Industrial	7229	21	154	3	52	45	14	3
	Commercial	5810	12	107	2	42	26	9	2
	Residential	254	3	5	0	2	6	0	0
	Agricultural	150	4	8	2	1	9	1	2
	Undeveloped	262	7	853	113	2	15	76	94
	Unreported	245	0	1	0	2	0	0	0
	Subtotal	13950	47	1128	120	100			

Total Incidents	United States	13951	
	Arizona	224	2
	Colorado	408	3
	New Mexico	137	1
	Texas	1004	7

NOTE: Due to multiple classes being involved in a single incident, the total in one category may not match the total in another.

1997		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
	Infectious Substance Class	**Numbers**				**Percentages**			
Class	Number	9	0	0	0	0			
Commodity Summary	Rank	NL	NL	NL	NL				

All Hazardous Materials Classes

1997									
Mode or Cause Highway	Human Error	9920	11	74	0	84	26	65	0
	Package Failure	1523	30	28	1	13	71	25	8
	Vehicular Accident or Derailment	258	1	10	10	2	2	9	83
	Other	161	0	2	1	1	0	2	8
	Subtotal	11862	42	114	12	85			
Mode or Cause Railway	Human Error	573	0	24	0	52	0	55	0
	Package Failure	449	1	14	0	41	100	32	0
	Vehicular Accident or Derailment	52	0	5	0	5	0	11	0
	Other	28	0	1	0	3	0	2	0
	Subtotal	1102	1	44	0	8			

1997		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Transportation Phase	En Route	2623	4	73	10	19	9	40	83
	Loading	2596	2	18	0	19	5	10	0
	Unloading	7786	37	74	2	56	86	41	17
	Temporary Storage	796	0	16	0	6	0	9	0
	Unreported	195	0	1	0	1	0	1	0
	Subtotal	13996	43	182	12	100			

Result									
	Vapor (Gas) Dispersion	568	5	32	3	4	9	15	10
	Material Entered Waterway or Sewer	30	0	2	0	0	0	1	0
	Spillage	13795	42	172	11	94	76	79	38
	Fire	63	7	5	11	0	13	2	38
	Explosion	15	1	3	4	0	2	1	14
	Environmental Damage	57	0	0	0	0	0	0	0
	None	51	0	0	0	0	0	0	0
	Other	92	0	4	0	1	0	2	0
	Subtotal	14671	55	218	29	105			

Community Type at Site									
	Urban	5526	3	66	4	39	7	36	33
	Suburban	5777	30	62	2	41	70	34	17
	Rural	2153	9	47	5	15	21	26	42
	Unreported	540	1	7	1	4	2	4	8
	Subtotal	13996	43	182	12	100			

1997		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Land Use at Site	Industrial	7089	31	89	0	51	72	49	0
	Commercial	5754	10	71	7	41	23	39	58
	Residential	251	1	5	3	2	2	3	25
	Agricultural	137	0	5	0	1	0	3	0
	Undeveloped	261	0	6	2	2	0	3	17
	Unreported	504	1	6	0	4	2	3	0
	Subtotal	13996	43	182	12	100			

Total Incidents	United States	13998	
	Arizona	333	2
	Colorado	312	2
	New Mexico	176	1
	Texas	1009	7

NOTE: Due to multiple classes being involved in a single incident, the total in one category may not match the total in another.

1998		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
	Infectious Substance Class	**Numbers**				**Percentages**			
Class	Number	10	0	0	0	0			
Commodity Summary	Rank	NL	NL	NL	NL				

All Hazardous Materials Classes

1998		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Mode or Cause Highway	Human Error	11236	9	107	5	87	50	79	38
	Package Failure	1342	4	21	0	10	22	16	0
	Vehicular Accident or Derailment	263	4	7	8	2	22	5	62
	Other	128	1	0	0	1	6	0	0
	Subtotal	12969	18	135	13	84			
Mode or Cause Railway	Human Error	607	2	6	0	61	50	33	0
	Package Failure	309	1	9	0	31	25	50	0
	Vehicular Accident or Derailment	51	1	3	0	5	25	17	0
	Other	23	0	0	0	2	0	0	0
	Subtotal	990	4	18	0	6			

1998		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Transportation Phase	En Route	2959	9	47	8	19	39	27	62
	Loading	2810	2	20	0	18	9	11	0
	Unloading	8334	11	92	5	54	48	53	38
	Temporary Storage	935	1	11	0	6	4	6	0
	Unreported	313	0	4	0	2	0	2	0
	Subtotal	15351	23	174	13	100			
Result	Vapor (Gas) Dispersion	685	4	33	1	4	14	17	3
	Material Entered Waterway or Sewer	39	1	2	8	0	3	1	21
	Spillage	14852	19	150	13	94	66	76	34
	Fire	56	4	6	11	0	14	3	29
	Explosion	13	0	3	5	0	0	2	13
	Environmental Damage	52	1	4	0	0	3	2	0
	None	33	0	0	0	0	0	0	0
	Other	57	0	0	0	0	0	0	0
	Subtotal	15787	29	198	38	103			
Community Type at Site	Urban	6809	5	68	5	44	22	39	38
	Suburban	5704	11	65	4	37	48	37	31
	Rural	2168	7	34	4	14	30	20	31
	Unreported	676	0	7	0	4	0	4	0
	Subtotal	15357	23	174	13	100			

1998		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Land Use at Site	Industrial	6576	10	68	0	43	43	39	0
	Commercial	7594	10	79	8	49	43	45	62
	Residential	227	0	8	2	1	0	5	15
	Agricultural	92	2	5	0	1	9	3	0
	Undeveloped	220	1	10	3	1	4	6	23
	Unreported	642	0	4	0	4	0	2	0
	Subtotal	15351	23	174	13	100			

Total Incidents	United States	15350	
	Arizona	209	1
	Colorado	261	2
	New Mexico	117	1
	Texas	1188	8

NOTE: Due to multiple classes being involved in a single incident, the total in one category may not match the total in another.

All Hazardous Materials Classes

1999	Infectious Substance Class	Numbers				Percentages			
		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Class	Number	166	0	3	0	1			
Commodity Summary	Rank	NL	NL	19	NL				

1999		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Mode or Cause Highway	Human Error	12644	19	137	2	88	53	78	29
	Package Failure	1328	11	30	0	9	31	17	0
	Vehicular Accident or Derailment	229	5	8	5	2	14	5	71
	Other	224	1	1	0	2	3	1	0
	Subtotal	14425	36	176	7	85			
Mode or Cause Railway	Human Error	690	1	19	0	65	33	59	0
	Package Failure	290	2	12	0	27	67	38	0
	Vehicular Accident or Derailment	57	0	0	0	5	0	0	0
	Other	23	0	1	0	2	0	3	0
	Subtotal	1060	3	32	0	6			

1999		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Transportation Phase	En Route	2909	15	59	5	17	38	27	71
	Loading	2723	6	44	0	16	15	20	0
	Unloading	9658	15	95	2	57	38	43	29
	Temporary Storage	974	3	19	0	6	8	9	0
	Unreported	805	0	4	0	5	0	2	0
	Subtotal	17069	39	221	7	100			

Result									
	Vapor (Gas) Dispersion	632	8	64	2	4	16	23	15
	Material Entered Waterway or Sewer	20	0	3	0	0	0	1	0
	Spillage	16608	29	197	2	95	58	72	15
	Fire	49	8	8	6	0	16	3	46
	Explosion	11	3	1	1	0	6	0	8
	Environmental Damage	61	2	0	2	0	4	0	15
	None	76	0	2	0	0	0	1	0
	Other	41	0	10	0	0	0	4	0
	Subtotal	17498	50	275	13	103			

Community Type at Site									
	Urban	8304	14	81	2	49	36	37	29
	Suburban	5867	14	99	3	34	36	45	43
	Rural	2308	11	33	2	14	28	15	29
	Unreported	590	0	8	0	3	0	4	0
	Subtotal	17069	39	221	7	100			

1999		Incidents	Major Injuries	Minor Injuries	Deaths	Incidents	Major Injuries	Minor Injuries	Deaths
Land Use at Site	Industrial	7178	15	78	2	42	44	36	29
	Commercial	8796	15	120	2	51	44	55	29
	Residential	310	0	6	0	2	0	3	0
	Agricultural	65	1	2	0	0	3	1	0
	Undeveloped	200	3	7	2	1	9	3	29
	Unreported	534	0	5	1	3	0	2	14
	Subtotal	17083	34	218	7	100			

Total Incidents	United States	17069	
	Arizona	302	2
	Colorado	221	1
	New Mexico	109	1
	Texas	1365	8

NOTE: Due to multiple classes being involved in a single incident, the total in one category may not match the total in another.