DOE/EA-1442

Environmental Assessment for The Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California

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Department of Energy
National Nuclear Security Administration
Oakland Operations Office

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 Lawrence Livermore National Laboratory (LLNL) in support of these missions requires work with infectious agents, including those historically used for bioweapons. The laboratory's pioneering work on biological agent (bioagent) detection and counter-terrorism technologies, and basic research understanding of emerging and re-emerging natural diseases are key elements of the LLNL efforts to support the NNSA mission. As a result, the need to conduct research with infective agents in a secure environment at LLNL and within NNSA is growing rapidly.

DOE does not currently operate any microbiological laboratory facility beyond Biosafety Level (BSL)-2. Much of the proposed work must be performed with BSL-3 containment and protection. BSL-3 facilities provide for environmentally safe and physically secure manipulation and storage of infectious microorganisms, many of which are potential bioweapon agents. NNSA's BSL-3 work would require efficient high-quality sample processing, and, for scientific and security reasons, assurance of sample security and integrity. These requirements also necessitate that cross-contamination and degradation of samples be minimized by reducing excessive handling and transportation. The few offsite commercial or governmental BSL-3 facilities currently available 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 LLNL's existing onsite facilities, expertise, and capabilities, and ensure the necessary quality, integrity, and security of microbiological work, NNSA needs BSL-3 laboratory capability at LLNL.

The Proposed Action and alternatives differ mainly in how the facility would be constructed. In all of the alternatives, the BSL-3 facility would be designed and operated in accordance with guidance for 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 proposed BSL-3 facility. The proposed facility would have the unique capability within DOE/NNSA to perform aerosol studies to include challenges of rodents using infectious agents or biologically derived toxins (biotoxins). Sample shipments would be received only in compliance with all established shipping guidelines and requirements. The samples would be stored in the BSL-3 laboratory within a locked labeled 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, and other applicable federal, state, and local regulations.

The Proposed Action is to assemble on-site an approximately 1,500 ft^2, one-story permanent prefabricated BSL-3 laboratory facility which would have three individual BSL-3 laboratory rooms (one capable of handling rodents), a mechanical room, clothes-change and shower rooms, and small storage space. The building footprint would take less than one-quarter acre. It is estimated that the operational design life of the proposed building would be at least 30 years.

Under the Remodel/Upgrade Alternative, NNSA would create a single BSL-3 laboratory from an existing BSL-2 laboratory at LLNL. This would require substantial building modification and probable disruption of other on-going work in the facility. This alternative has the lowest waste generation during construction and operation since it is only a single laboratory while the other two options consist of three laboratories each. This alternative would be in accordance with NNSA's purpose and need for action. Being only a single BSL-3 laboratory, it would be self-limiting to the amount of research that could be conducted.

The Construct On-Site Alternative would meet NNSA's purpose and need for action. This alternative does not differ significantly from the Proposed Action for operation and decontamination and decommissioning with one exception. The longer time it takes to construct the facility under this alternative affects the duration of noise, dust, and truck traffic and disruption of workers in adjacent buildings. This longer period also means it would be months longer before the facility would be operational.

Under the No Action Alternative, NNSA would not construct or place a BSL-3 facility at LLNL. In this event, NNSA would continue to have its BSL-3 laboratory needs met by using existing or new BSL-3 laboratories located offsite from LLNL. 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 would be minor and would not differ greatly between the Proposed Action and alternatives. 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 LLNL'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 B). As such, the potential human health effects from these events are discussed as Abnormal Events and Accidents. No cases of illness would be expected to result from implementing the Proposed Action as a result of an abnormal event or accident.

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ACRONYMS AND ABBREVIATIONS

AAA	American Antiquities Act
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
ABSA	American Biological Safety Association
ACGIH	American Conference of Governmental Industrial Hygienists
AFIP	Armed Forces Institute of Pathology
AIDS	Acquired Immune Deficiency Syndrome
ANSI	American National Standards Institute
BA	Biological Assessment
BASIS	Biological Aerosol Sentry and Information System
BBRP	LLNL Biology and Biotechnology Research Program
BDRP	Biological Defense Research Program
BLS	Bureau of Labor Statistics
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BMI	Battelle Memorial Institute
BMP	Best Management Practice
BSC	Biological Safety Cabinet
BSL	Biological Safety Level
BWC	Biological Weapons Convention
CAA	Clean Air Act
CBNP	Chemical and Biological National Security Program
CDC	Centers for Disease Control and Prevention
CDF	California Department of Finance
CEQ	Council on Environmental Quality
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
CFR	Code of Federal Regulations
CRDEC	Chemical Research Development and Engineering Command
D&D	Decontamination and Decommissioning
DA	Department of the Army
dB	decibel (a measure of noise level)
dBA	A-weighted decibel
DHS	California Department of Health Services
DNA	Deoxyribonucleic Acid
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
DOP	Dioctyl phthalate
DOT	U.S. Department of Transportation
DPG	Dugway Proving Ground
EA	Environmental Assessment
EIR	Environmental Impact Report
EIS	Environmental Impact Statement
EIS/EIR	Environmental Impact Statement/Environmental Impact Report
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ESA	Endangered Species Act

FDA	Food and Drug Administration
FEIS	Final Environmental Impact Statement
FONSI	Finding of No Significant Impact
FY	Fiscal Year
GSA	General Services Administration
HAP	Hazardous Air Pollutant
HEPA	High Efficiency Particulate Air-Purifying
HHS	US Department of Health and Human Services
HID	Human Infective Dose
HID_{50}	Human Infective Dose - 50 percent
HMIS	Hazardous Material Information System
HRSA	HHS, Health Resources and Services Administration
HVAC	Heating, ventilation, and air conditioning
IACUC	LLNL Institutional Animal Care and Use Committee
IATA	International Air Transport Association
IBC	Institutional Biosafety Committee
ID_{50}	Infective Dose - 50 percent
ISMS	Integrated Safety Management System
JH	Johns Hopkins
kW	Kilowatt
LAA	Laboratory Animal Allergy
LANL	Los Alamos National Laboratory
LBOC	LLNL Biosafety Operations Committee
LD_{50}	Lethal dose at 50 percent mortality
LLNL	Lawrence Livermore National Laboratory
LR/SAT	Laboratory Registration/Select Agent Transfer
LWRP	Livermore Water Reclamation Plant
MCE	Maximum Credible Event
MMWR	Morbidity and Mortality Weekly Report
NAAQS	National Ambient Air Quality Standards
NAI	Nonproliferation, Arms Control, and International Security
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NHPA	National Historic Preservation Act
NIH	National Institutes of Health
NNSA	National Nuclear Security Administration
NSC	National Safety Council
ORPS	Occurrence Report Processing System
OSHA	Occupational Safety and Health Administration
PEIS	Programmatic Environmental Impact Statement
PM	Particulate Matter
PPE	Personal Protective Equipment
RCRA	Resource Conservation and Recovery Act
RDT&E	Research Development Testing and Evaluation
RG	Risk Group
RNA	Ribonucleic Acid

SA	Supplement Analysis
SNL	Sandia National Laboratories
SNL/CA	Sandia National Laboratory, California
SNL/NM	Sandia National Laboratory, New Mexico
SOP	Standard Operating Procedure
SSH	Suppression Subtractive Hybridization
SWPP	Storm Water Pollution Prevention
TLV	Threshold Limit Value
UC	University of California
USAMRIID	United States Army Medical Research Institute for Infectious Diseases
USC	United States Code
USDA	United States Department of Agriculture
USFWS	United State Fish and Wildlife Service
USPS	United States Postal Service
VEE	Venezuelan Equine Encephalomyelitis
WMD	Weapons of Mass Destruction
WHO	World Health Organization

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)

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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 (CEQ) 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 (FONSI). 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 Lawrence Livermore National Laboratory (LLNL), Livermore, CA (Figure 1-1). LLNL 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 LLNL; (4) analyze the potential indirect, direct, and cumulative impacts to the existing environment from implementation of the Proposed Action and other reasonable alternatives; and (5) compare the impacts 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 LLNL.

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 LLNL. 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.

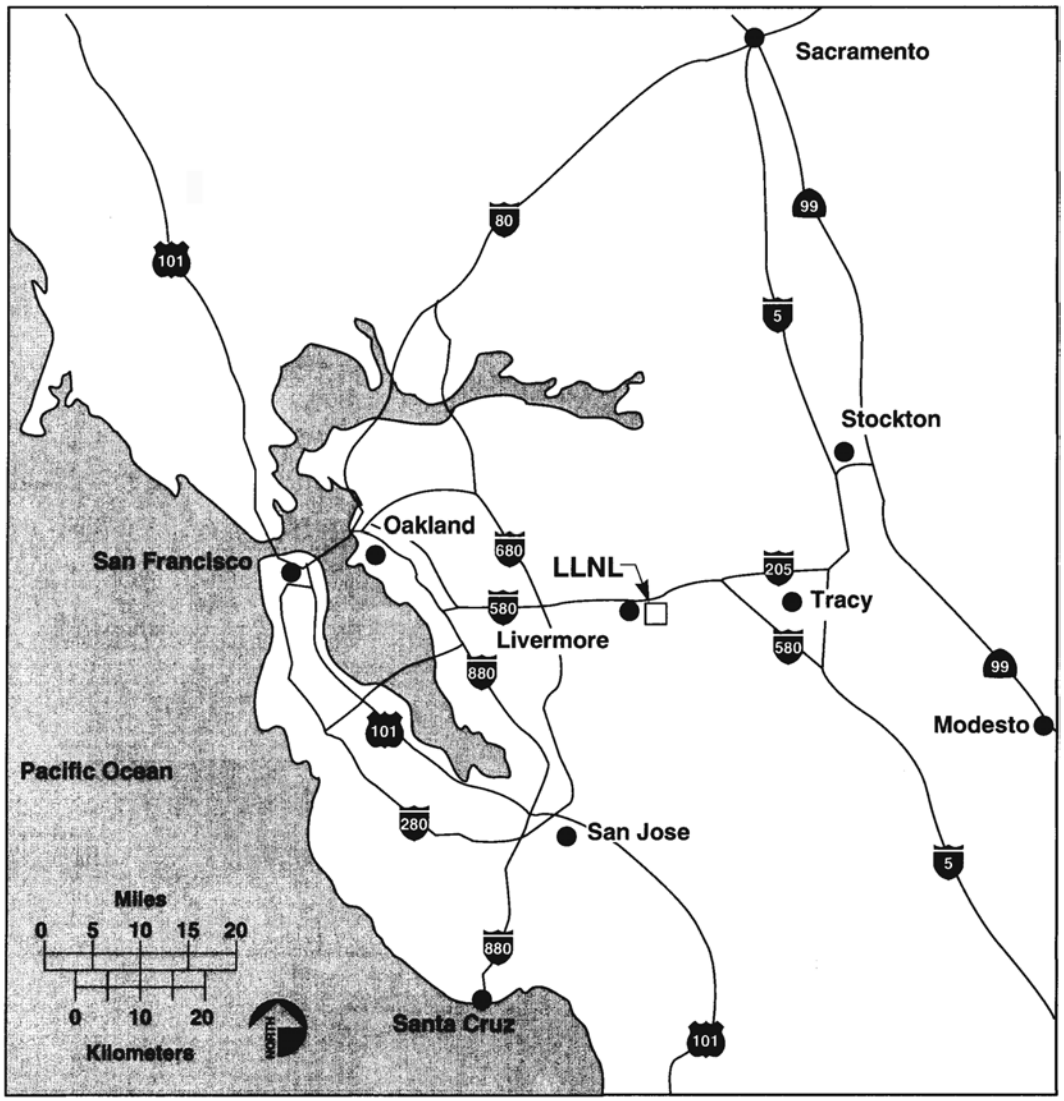


Figure 1-1. Location of Lawrence Livermore National Laboratory (LLNL)

1.2 BACKGROUND

The LLNL Livermore site lies just outside the boundary of Livermore, California. It occupies a total area of approximately 1.3 sq miles (821 acres), and is about 40 miles east of San Francisco at the southeast end of the Livermore Valley in southern Alameda County, California. The City of Livermore's central business district is located about 3 miles to the west. Figure 1-1 and Figure 1-2 show the regional location of the LLNL Livermore site and its location with respect to the City of Livermore. Lawrence Livermore National Laboratory (LLNL) is a U.S. Department of Energy national laboratory operated by the University of California (UC). LLNL was founded in September 1952 as a second nuclear weapons design laboratory to promote innovation in the design of our nation's nuclear stockpile through creative science and engineering. LLNL has also become one of the world's premier scientific centers, where cutting-edge science and engineering in the interest of national security is used to break new ground in other areas of national importance, including energy, biomedicine, and environmental science.

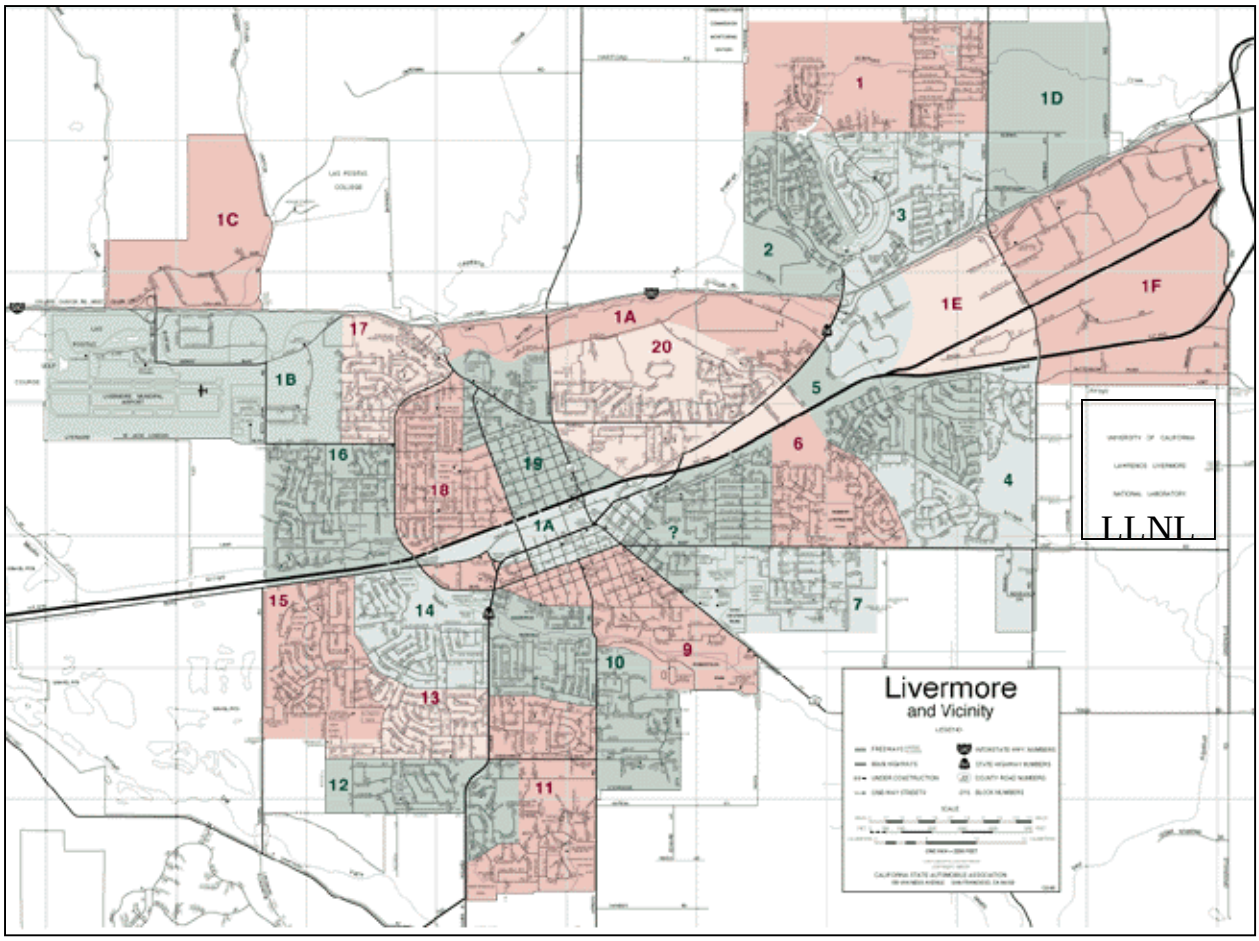


Figure 1-2. Location of LLNL with respect to the City of Livermore, CA

Current NNSA mission-support work at LLNL includes research and development work performed for a variety of programs within the NNSA, other DOE programs, 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 LLNL 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 (WMD); and (6) To support United States leadership in science and technology" (50 USC Chapter 41, § 2401(b)). Work conducted at LLNL provides support to these NNSA missions, with a special focus on national security.

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

The DOE Chemical and Biological National Security Program (CBNP) was initiated in fiscal year (FY) 1997 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 against the people and economy of the United States of America as well as the threat against democracy and freedom. The CBNP was established in response to the *Defense Against Weapons of Mass Destruction Act* passed by Congress in 1996 (50 USC § 2301).

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, computations, 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 joining 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.

LLNL has been assigned research and development activities in support of these NNSA responsibilities. The LLNL Biology and Biotechnology Research Program (BBRP) has been assigned the primary responsibility for conducting work related to biological science research including work with national health security issues and emerging diseases. Program objectives include understanding genetic and biochemical causes of disease, countering biological terrorism, bioengineering research, and developing and applying computational biology capabilities. Most of the on-site work is conducted in the Building 360 Complex area (Figure 1-3). Current research performed at this complex includes structural, molecular, and cellular biology, biophysics, biochemistry, and genetics research.

The BBRP work in the biosciences arena at LLNL has been ongoing for more than 40 years, and is conducted according to the accepted national standards for biosafety level (BSL)-1 and -2 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 -1, -2, and -3 and specific information and requirements for work in microbiological laboratories are provided in Appendix A of this EA. In addition, prior to commencement of any

[3] DNA is the polymeric deoxyribonucleic acid that determines the hereditary information in cells.

Figure 1-3. Map of LLNL showing the location of the Building 360 Complex Area (within the dashed line)

LLNL experiments involving biological agents[4], work is reviewed and must be approved by the LLNL Laboratory Biosafety Operation Committee (LBOC). Certain projects must also be reviewed and approved by the LLNL Institutional Biosafety Committee (IBC), which is made up of LLNL staff members, UC and community health care providers, a DOE Federal member, and at least two members of the public. The IBC typically meets in the Building 361 Complex several times per year, depending on demand. 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. 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

[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.

manipulated at BSL-2 are not known to be transmissible, person-to-person by the airborne pathway. Examples of diseases include Hepatitis, 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, are 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.

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 about 250 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 university research and development laboratories. Requirements of operating a BSL-3 facility (CDC 1999) are detailed in Appendix A.

Current research and technology development work conducted at LLNL targets both the reduction of the national threat from terrorism using biological weapons and enhances the Nation's public health capabilities. For example, in support of these responsibilities LLNL has developed the Biological Aerosol Sentry and Information System (BASIS) for early detection and rapid response to biological attack, conducts "expression studies" of *Yersinia pestis*, the causative bacterial agent in plague to understand the mechanisms of virulence, and performs "suppression subtractive hybridization" (SSH) to study the fundamental biology of microbes through DNA segmentation and similar-strain comparison. This current research and technology development work is focused on the development of scientific tools to identify and understand the pathogens of medical, environmental, and forensic importance.

The importance of work performed for NNSA in bioscience research and development in support of its national security WMD nonproliferation 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 LLNL in bioscience research is limited to BSL-2. Pending and future 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. DOE does not currently have under its administrative control within the DOE complex any microbiological laboratory facility capability beyond BSL-2, but BSL-3 facilities are proposed both at LLNL (as outlined in this EA) and at Los Alamos National Laboratory (LANL) (DOE 2002).

Additional information regarding the DOE and NNSA mission areas of work conducted at LLNL is presented in the *Final Environmental Impact Statement and Environmental Impact Report for*

Continued Operations of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore, August 1992 (DOE/EIS-0157) (DOE 1992) and its associated Supplement Analysis (SA) (DOE 1999) .

1.3 PURPOSE AND NEED FOR AGENCY ACTION

DOE conducts bioscience work in support of its biology and biotechnology research programs, work for other agencies, and work 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."

In order to meet the NNSA mission requirements, it is necessary to expand some existing capabilities to test the understanding and effectiveness of research on infectious agents and biotoxins, particularly those associated with potential bioweapons threats. Efficient execution of the NNSA mission therefore, also requires the capability to handle operations involving small-animal (rodent) challenges of bioagents (and possibly biotoxins) and the ability to produce small amounts of biological material (enzymes, DNA, ribonucleic acid[6] [RNA], etc.) using infectious agents and genetically modified agents under conditions that would require management of the facility at the BSL-3 level.

This capability does not currently reside within DOE/NNSA facilities, but some of the research is carried out for the LLNL Nonproliferation, Arms Control, and International Security (NAI) Directorate primarily by the BBRP using external (private-sector and University) laboratories to conduct the BSL-3 level components of the research. 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 be minimized by reducing excessive handling and transportation. The several key off-site BSL-3 facilities that conduct work for LLNL in support of NNSA, are often heavily committed to other projects or tailored to work with microorganisms not of specific interest to NNSA. This has especially become an issue since September 11, 2001. Because of this these laboratories are unlikely to be able to provide the quick response that may be necessary to support the NNSA need.

An on-site BSL-3 facility would provide safe and secure manipulation and storage of infectious microorganisms at a time when these issues are imperative to national security. In order to more effectively utilize and capitalize on existing onsite facilities and capabilities at LLNL, including informatics and DNA sequencing capability, and to ensure the quality, timeliness, integrity and security of microbiological work, NNSA needs BSL-3 laboratory capability within the boundaries of this national laboratory.

1.4 PUBLIC INVOLVEMENT

The Draft EA was originally made available for public comment from July 24th through August 23rd of 2002. The comment period was extended on August 21st through September 7th, 2002.

[6] Ribonucleic acid or RNA is a generic term for a group of natural polymers present in all living cells directly involved with protein synthesis.

1.5 COMMENT SUMMARIES AND NNSA RESPONSES

The full text of the comments received by NNSA on the draft EA by stakeholders and members of the public are included in Appendix C-2 of this EA. Where comments were duplicated, as in the presentation of form-type letters, only one is shown in its entirety. Many of the topics generated from public responses are of broad interest or concern and were categorized into twelve general issues which comprise the twelve sections in Appendix C-1. Comments and concerns voiced by the commentors were addressed through changes made to the document text to the extent practicable. Changes to the Final EA from the draft EA are identified by a sidebar (a vertical line in the margin next to the text which had some change). Some commentors raised issues that are not pertinent to the NEPA review. These were also addressed to the extent practicable. The following general issues are discussed in the appendix:

1. NEPA Compliance: Documentation/Review Level
2. Safety of Laboratory Operations
3. Defensive vs. Offensive-oriented Research
4. Compliance with the Biological Weapons Convention
5. Public Health and Safety, and Worker Safety Issues
6. Accident Analysis
7. Threat of Terrorist Attack/Sabotage
8. Transportation Safety
9. Purpose and Need
10. Adequacy of Alternatives Analysis
11. Waste Disposal
12. Timeline for the BSL-3 Facility

2.0 DESCRIPTION OF PROPOSED ACTION AND 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 LLNL

NNSA proposes to construct and operate a BSL-3 facility at LLNL for the purpose of conducting biological research projects involving indigenous or exotic agents which may cause serious or potentially lethal or debilitating effects on humans, plants, and animal hosts, therefore, potentially impacting human health as well as agriculture, food, and other industries. LLNL's existing BSL-2 laboratory capability which cannot be used to perform this work is primarily located in the Building 360 Complex area (see Figure 1-3). As proposed, the BSL-3 facility would be an essential component for future advanced biological sciences research and development performed by LLNL's staff but would not replace the other biological laboratory capabilities at LLNL. The BBRP would continue to support current biological sciences

initiatives at LLNL through the existing BSL-2 laboratories. The proposed facility (Figure 2-1) would be a permanent modular unit that would be constructed off-site and assembled on-site near the northwest corner of Building 361. It would have the same life expectancy as a facility constructed on-site.

The construction would be permanent and meet applicable building code, and required structural, seismic, plumbing, electrical, and fire standards. The proposed facility would include three BSL-3 laboratory rooms, one of which would be capable of holding rodents. The building would include clothes-change and shower rooms, a mechanical room, and some storage space, but no office space. When complete, the BSL-3 facility would be about 1,500 ft^2 (135 m^2) in size and would normally be occupied by no more than 6 workers. As currently projected, these staff members would come from the adjacent Building 360 Complex laboratory facilities (Figure 2-1) with no requirement for permanent relocation. Any additional staffing needed to support BSL-2 work previously done by workers who would be performing BSL-3 work 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. During the operational life of the building, the performance of routine maintenance actions would be expected. At the end of the facility's useful life, final decontamination and demolition would be performed as needed.

2.1.1 Proposed BSL-3 Facility Location and Construction Measures

The proposed location is in the current parking area and access-drive directly adjacent to (east of) building B-365 and northeast of the intersection of Fifth Street and West Inner Loop (see

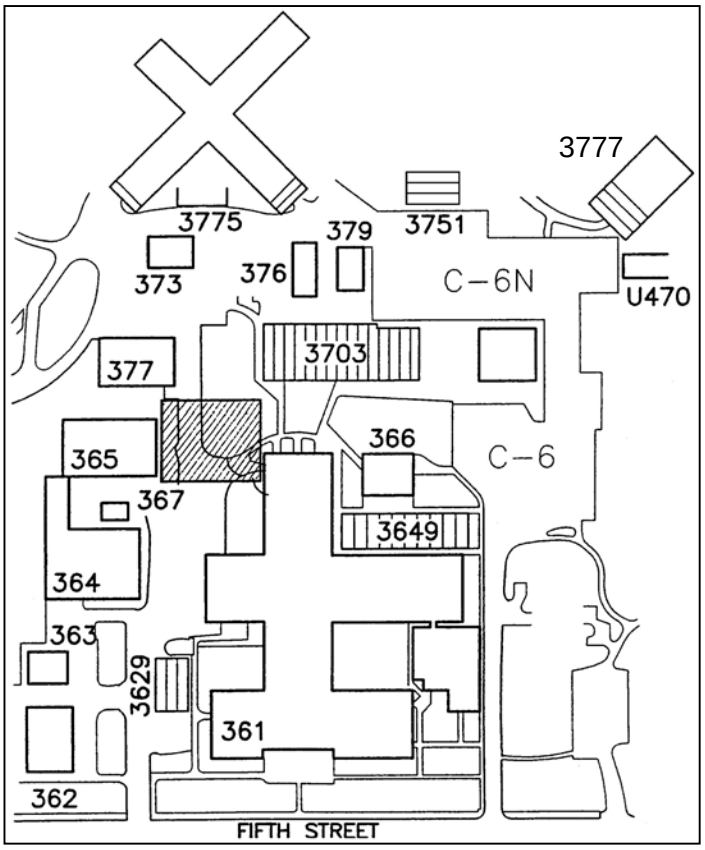


Figure 2-1. Map of the Building 360 Complex Area showing the location of the proposed BSL-3 facility (cross-hatched area)

Figure 2-1). Approximately 20 parking spaces of the paved current parking area would become permanently unavailable for use due to the footprint of the building and it may be necessary to redirect part of the parking access driveway.

The footprint of the proposed building would be less than one-quarter of an acre. Utilities necessary for construction and operation of the BSL-3 facility would be available within 50 ft (15 m) of the proposed construction site facility. These include potable water, natural gas, steam, sewer, electricity, and telephone service. Some minor trenching (at depths less than about 4 ft [1.3 m]) would be required to bring those utilities to the site.

Construction Measures: As noted above, the project construction site would be at a location that has previously been cleared of buildings or structures and is 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 a solid waste management unit.

The BSL-3 facility building would be designed in accordance with guidance for BSL-3 laboratories established by the CDC and NIH (CDC 1999, NIH 2001). The CDC, which is part

of the Department of Health and Human Services, provides guidelines for the operation of BSL-3 facilities, registers facilities that will access, use and transfer select agents, and then periodically inspects these facilities during operation. DOE Order O420.1 (DOE 1996b) which addresses natural phenomena hazard mitigation for non-nuclear facilities would be considered in preparing the final design criteria for seismic, wind and flooding events.

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 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. Where possible, the finished landscaping of the involved construction area would utilize non-potable water, reused and recycled materials, and native plant species.

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 or paleontological significance were encountered during construction, activities would cease until their significance was determined and appropriate subsequent actions taken in accordance with the National Historic Preservation Act (NHPA, 16 USC 470) or the American Antiquities Act (AAA, 16 USC 430). Standard dust suppression methods (such as water spraying) would be used onsite, if needed, to minimize the generation of dust during all phases of construction activities.

All construction work would be planned and managed to ensure that standard worker safety goals would be met. All work would be performed in accordance with good management practices, with regulations promulgated by the Occupational Safety and Health Administration (OSHA, 29 CFR 1910 and 29 CFR 1926), in accordance with various DOE orders involving worker and site safety practices, and in accordance with the LLNL Environment, Health and Safety Manual (LLNL 2001c). 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 any excavated soil and surface water discharge during construction of the BSL-3 facility. After the facility is constructed, mounds of loose soil would be tested for previous contaminants, removed from the area, and either reused or disposed of appropriately.

During site preparation and construction, noise levels (for short time periods) would be consistent with those expected from the construction of single-story frame non-residential structures using metal studs and cross members. The use of welding equipment, air compressors, riveting tools, and heavy equipment is reported to range from 65 to 125 dBA[7] continuous or

[7] 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)

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 and heavy machinery (such as front-end loaders, 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 overnight. If needed, temporary task lighting would be used. Wastes generated by site preparation and construction activities would be expected to be nonhazardous.

Construction of the BSL-3 facility is estimated to start in FY 2003 and take several months to complete. Construction materials would be procured primarily from local California suppliers. Construction workers would be drawn from local communities or would be derived from the current in-house LLNL staff.

2.1.2 BSL-3 Facility Description and Operations

Facility Description: The proposed BSL-3 facility would be a one-story building with about 1,500 ft^2 (135 m^2) of floor space (Figure 2-2) housing three BSL-3 laboratories (one with rodent handling and maintenance capability), showers, sinks, lavatories, and mechanical and electrical equipment areas. The BSL-3 facility would most likely be constructed using concrete footing and stem walls with concrete slab-on-grade floors. 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 such laboratories. 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, to aid in maintaining appropriate ventilation system air pressures, and to keep pests out. Laboratory furniture would be capable of supporting anticipated loading and use, and 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 with disinfectants.

Each of the three BSL-3 laboratories would have at least one Class II Type B biological safety cabinet[8] (BSCs) (Figure 2-3). Class II BSCs provide their own airflow, have High Efficiency Particulate Air-Purifying (HEPA)[9] filtration internally within the cabinet and would be designed to provide personal, environmental, and test material protection. Exhaust air from the BSCs would exit the room via the fixed-duct connection to HEPA filters in the mechanical rooms, then outside the building. All BSC air would be 100 percent exhausted to the outside through the building heating, ventilation, and air conditioning (HVAC) and HEPA filtration system (air exhausted from BSCs is doubly-filtered). Class II Type B BSCs are designed to operate at a

[8] A BSC (biosafety cabinet) is a specialized type of hood and is the primary means of containment for working safely with infectious microorganisms.

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

minimum inward flow of a 100 linear ft per min (30.5 linear m per min) at the face opening (CDC 2000b). BSCs would be located away from doors, room supply louvers, and heavily

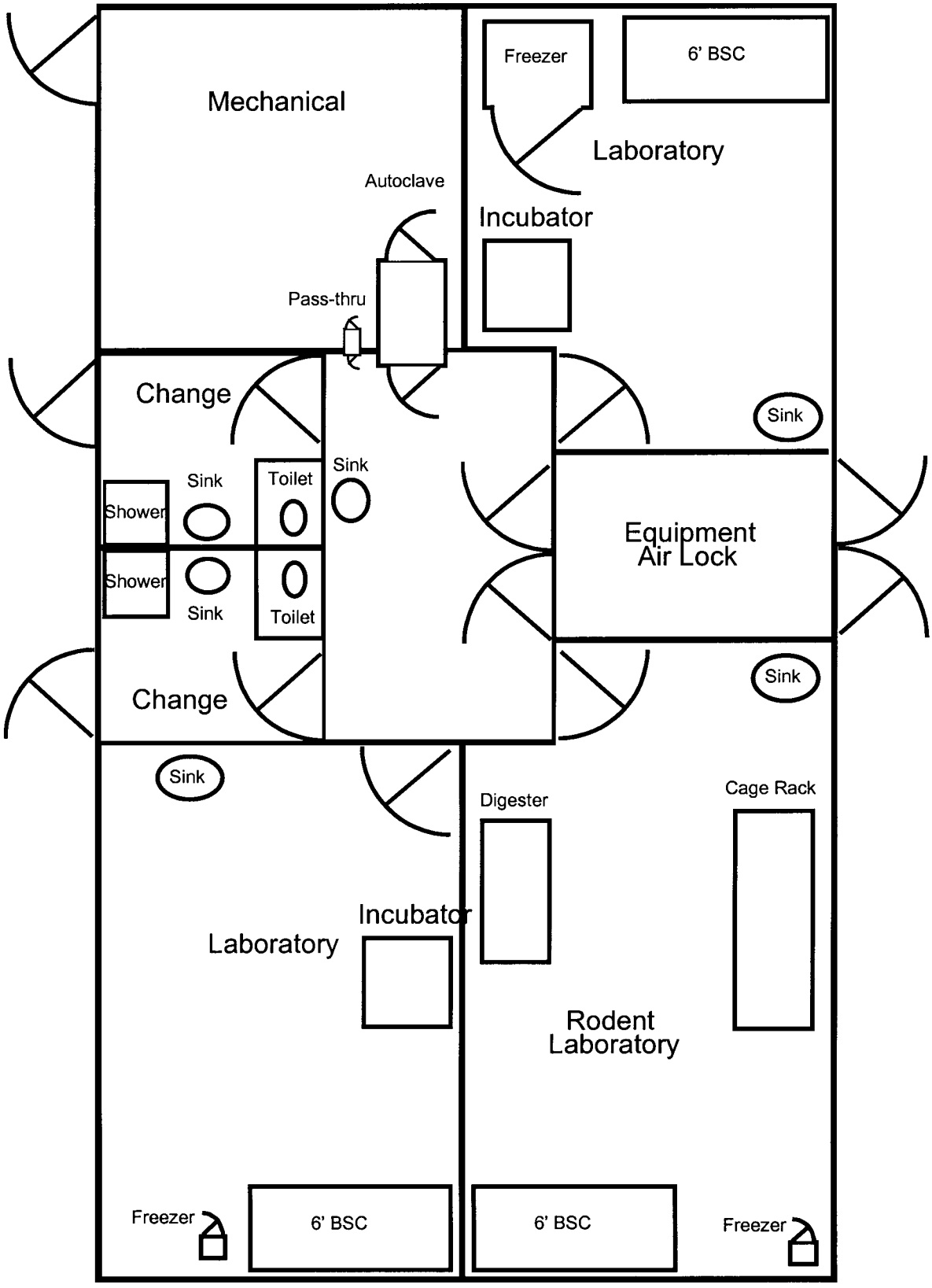


Figure 2-2. Conceptual floor plan for the proposed BSL-3 facility at LLNL (not to scale)

Figure 2-3. Photo of a Baker SterilchemGard III™ - Class II Type B3 BSC[10]

traveled laboratory areas. BSC interiors would be cleaned by use of appropriate methods and could include ultraviolet light or chemical disinfection. BSCs would be tested and certified annually and after installation, repair, or relocation in accordance with CDC guidance (CDC 2000b).

No windows would be installed in the BSL laboratory's exterior walls. Non-opening observation windows would be placed on interior doors. Centrifuges or other equipment that have the potential to produce aerosols would be operated in BSCs or with appropriate combinations of personal protective equipment (PPE), physical containment, or control devices. Vacuums would be provided to critical work areas using portable vacuum pumps properly fitted with traps and HEPA filtration.

Each laboratory would also contain at least one refrigerator or freezer. Biological materials would be stored either in regular refrigerators for short-term use or in ultra-low temperature mechanical freezers operating between –50 and –85^{o}C for long-term sample storage or archiving.

The BSL-3 laboratory used for rodent handling would have a tissue digestor for the purpose of sterilizing all animal tissues at the conclusion of each study involving small rodents. Figure 2-4 shows an example of a tissue digestor unit that could be used. The digestor would use an alkaline hydrolysis process at an elevated temperature to convert all of the organic material (as well as infectious microorganisms) into a sterile aqueous solution of small peptides, amino acids, sugars, and soaps. The alkali would be used up in the process. Aside from the aqueous solution, the only byproducts would be mineral (ash) components of the bones and teeth.

The BSL-3 laboratory used for rodent testing would also contain an rodent caging system similar to that shown in Figure 2-5. These ventilated cages would be pressurized with HEPA-filtered air, thus reducing both ammonia and carbon dioxide. The negative pressurization would provide

[10] The use of a tradename does not constitute an endorsement nor does it indicate that the product would be purchased. This is only shown to be representative of the type of equipment that would be used.

Figure 2-4 Photo of a Waste Reduction Inc. ™ small-capacity tissue digestor[11]

continuous quarantine status, protecting personnel and preventing contact with the other rodents in the cage rack. A maximum of 100 rodents, mainly mice (some rats and possibly guinea pigs), would be used at any one time. Once a rodent would be used in testing it would never leave the cage except for cage-cleaning and inspection which would occur only in the confines of the BSCs. Once removed from a cage the rodents would only be placed back into a clean cage. The dirty cage and its contents would be autoclaved[12] prior to reuse. All rodents used would be supplied by the already-existing rodent quarantine facility located and operated in an adjacent building. The cage rack would be restrained from toppling over by resisting about 1g of lateral acceleration. Cage latches have been tested to 2g's of pull force.

Figure 2-5. Photo of an Allentown Caging Equipment Co.™ BioContainment Unit for small animals[10]

[11] The use of a tradename does not constitute an endorsement nor does it indicate that the product would be purchased. This is only shown to be representative of the type of equipment that would be used.
[12] An autoclave is an apparatus using superheated steam under pressure to kill or sterilize microorganisms

Some rodents would be exposed to infectious agents in the BSC through inhalation via a device known as a collision nebulizer. This device creates aerosol particles of known size (depending upon the specific nozzle used) to which rodents would be exposed through a nose-piece. The nebulizer consists of a 32-ounce Pyrex™ glass liquid storage container with a "T-shaped" stainless steel aerosol jetting-device operated by compressed air. The device would only be used in the BSC and would be chemically disinfected in place after use. Once exposed, the rodent would (while still in the BSC) be placed directly into a clean cage and placed back into the ventilated cage rack for observation.

Physical security of the facility building would be implemented commensurate with the level of work being performed. The facility safeguards would be based upon a security analysis conducted during the project planning stage. As in all facilities managed at LLNL, security in the proposed facility would be maintained by limiting access to only authorized DOE-badged personnel. Employee qualifications and training requirements are described in CDC-NIH guidelines (CDC 1999) along with a discussion of 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 LLNL'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 discharged from the floor drains to a retention tank system, for containment, characterization, and disinfection as needed, prior to discharge to the sanitary sewer system.

Dual HEPA filter banks in the building exhaust system would filter all room air one-time-through and provide secondary filtration for exit air from the BSCs. Filter banks could be switched or alternated to permit disinfection and filter replacement. Routine maintenance of the filter banks would be conducted by certified technicians, including replacement of the filters. Replaced filters would be chemically sterilized prior to disposal. There would be only one electrical room with access for maintenance 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 through the change rooms which would serve as self-closing double-door access.

The air-handling systems, including the heating, ventilation and air conditioning (HVAC) systems, would be designed in accordance with CDC guidelines to provide for individual temperature and ventilation control zones as required in the BSL-3 laboratories and support areas. A ducted exhaust HVAC system would draw air into the BSL-3 laboratories from the adjoining areas toward and through the BSL-3 laboratories areas with no recirculation from the BSL laboratories to other areas of the building. The BSL-3 laboratories would be under the most negative pressure with respect to all other areas of the building. Air discharged from the BSL-3 facility would be dispersed well above the roofline and away from adjacent building air intake ducts. 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. Operation of all equipment would be designed to avoid interference with the air balance of the BSCs or the designed airflow of the building.

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 would be supplied with backup power from an adjacent 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.

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.

All research-related biological waste from the BSL-3 laboratory would undergo either autoclaving or chemical disinfection. These wastes would be discharged from laboratory sinks, floor drains, or the tissue digestor and would be held and disinfected in retention tanks before being discharged into the sanitary sewer system. Tap water entering the BSL-3 laboratories through spigots in the sinks or shower heads would have backflow preventers to protect the potable water distribution system from contamination. Biological cultures could be disposed of in the sinks after undergoing treatment with chemical disinfectants for an appropriate amount of time.

The electrical requirements for the BSL-3 facility would be about 60 kilowatts (kW); the building would be attached to an adjacent building which has 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.

Parking would be in nearby common-use lots with handicapped-accessible parking near the building entry (ANSI 1998).

Operations: The BSL-3 facility would be operated according to all guidance and requirements established by the CDC and NIH (CDC 1999), DOE, and LLNL. Prior to operating the facility using select agents, the facility would be registered with a unique registration number obtained 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 LLNL's Facility Responsible Official. LLNL would be required in accordance with the Integrated Safety Management System (ISMS) to participate in and follow the requirements of the CDC LR/SAT Program for handling of select agents[13] and must follow the provisions that apply to 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

[13] 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.

disposal requirements; and (6) research and clinical exemptions (42 CFR 72). No select agents would be handled in the proposed BSL-3 laboratories without first obtaining IBC approval in accordance with ISMS and secondly prior registration and approval from CDC. 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. Operation of the proposed facility would also involve handling of microorganisms that are regulated by the U.S. Department of Agriculture (USDA) and require BSL-3 containment.

Microorganisms expected to be cultured (i.e., viable organisms) at the BSL-3 facility in the near term would be, but not limited to, the select agents *Bacillus anthracis*, *Yersinia pestis*, *Clostridium botulinum*, *Coccidioides immitis*, *Brucella spp.*, *Francisella tularensis*, *and Rickettsia spp.* (see Appendix A). The facility may be used to handle small amounts of biotoxins which are generally handled at the biosafety level established for the microorganisms that produce them. The CDC and NIH guidances and requirements also extend to handling genetically modified microorganisms. All research in microbiology laboratories that involves altering microbial genomes follows standard procedures approved by NIH (NIH 2001). It is possible that 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. LLNL 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 and authorized by LLNL management in strict accordance with the following:

- Biological Weapons Convention Treaty (BWC 1972) permits defensive research for the purpose of developing vaccines and protective equipment.
- 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).
- The LLNL Biosafety Operations Committee (LBOC), a diversified group of LLNL operational-level researchers and representatives from all LLNL-affected institutional and regulatory compliance organizations who are responsible for the first-level reviews of projects/microorganisms and provide recommendations to the IBC.
- The LLNL Institutional Biosafety Committee (IBC) who reviews and approves each project such as those involving recombinant DNA or pathogenic organisms and toxins before such work can be undertaken at LLNL.
- When completed,[14] LLNL safety and security documentation (Facility Safety Basis, Facility Safety Plans, Hazard Control Plans, Human Pathogens Exposure Program, and

[14] 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.

security assessments) would provide the key documentation framework for operation of the BSL-3 facility.

- The BSL-3 facility would undergo a readiness review prior to startup to ensure that the infrastructure for safe operation is implemented and that the health and safety of workers, public, and the environment is protected.

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, LLNL, and currently applicable BMBL requirements (according to Work Smart Standards) would be certified as having been met before operations would begin at the proposed BSL-3 facility. 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).

Appropriate PPE used by employees entering the laboratories would include eye protection, gloves (in some cases the worker would be double-gloved), and disposable closed-front gown or clothing (including disposable booties and disposable cap). Air-purifying respirators might be worn as an additional safety measure for some tasks. Workers' hands would be 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 if deemed necessary. 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 test tubes or culture dishes may be needed for some minor amount of 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 would be handling so that appropriate staging of work could occur. Open cultures would only be handled in BSCs. BSCs would be at negative pressure with respect to the room and the rest of the building. Airflow 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 also be tested for normal immunocompetancy[15], and would have medical treatment readily available in the event of an accidental exposure.

No radiological material would be used or stored in the BSL-3 facility. A pest program would be in place to control vector populations.

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

One of the three BSL-3 laboratories would have rodent handling capability (<100 rodents). The rodents (mice, rats, and possibly guinea pigs) would be in the BSL-3 facility only when part of a research study. These rodents would be cared for in accordance with federal regulations and guidelines. LLNL adopted the requirements of the Animal Welfare Act of 1968 (7 USC 2131-2157, as amended) and voluntarily adheres to the guidelines for the use of vertebrate animals in research established by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. These requirements are administered by the LLNL Associate Director for the BBRP and are implemented by the LLNL Institutional Animal Care and Use Committee (IACUC).

Rodents would be held in quarantine in another Building 360 Complex laboratory for at least 30 days prior to use in a BSL-3 laboratory. They would be maintained in enclosed cages that would individually be connected to the building exhaust air duct. All rodent studies would occur only in the BSL-3 BSCs. Rodents are routinely transferred from dirty to clean cages in the BSCs. Used cages would be closed, autoclaved without dumping the litter, then further cleaned and disinfected prior to reuse. Rodent studies could involve intravenous injections and therefore the laboratories would have sharps, sharps containers, and a "needlestick" program that would be developed at the outset and would focus on ensuring workers do not accidentally inject themselves (autoinjection). All rodents brought into the proposed facility would be euthanized for the purpose of post-mortem medical examination (necropsy). All necropsied rodents and rodent tissues would be sterilized in a tissue digester located in the rodent BSL-3 laboratory.

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 by experiment-specific procedures under IBC approval. Less than 1 liter of cultured microorganisms in their stationary growth phase (maximum cell density of about 10^8 cells per ml) would be the maximum quantity handled in any BSL laboratory at any point in time. This 1-liter quantity would only be removed from the BSC in 250 ml double-contained plastic containers with safety-caps. No open cultures (where the free liquid surface is exposed directly to the ambient air) would be allowed outside of the BSC.

Seed cultures or samples would be provided by commercial suppliers, research collaborators, or other parties associated with the LLNL projects. These may contain either previously identified or unidentified organisms. Identification provides diagnostic, reference, or verification of strains[16] of microorganisms present. Diagnostic and reference strains, which may include the geographic source of the sample, contribute to the understanding of the microorganism's original source and 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, determination of antibiotic resistance, and contamination or infection of others.

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

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

Sample Arrival at the LLNL BSL-3 Facility for Processing: Sample shipments would only be received at the BSL-3 facility operating within the parameters specified in all established guidelines and requirements. If the samples would be select agents, they would only be accepted when the CDC form (EA-101) has been completed per regulations, the registration verified, and the requesting facility responsible official notified in advance of shipment according to CDC registration requirements. Biological materials or infectious agents could only be shipped to LLNL by commercial package delivery services, the U.S. Postal Service (USPS), other authorized entity, or delivered to the receiving area from an origination point within LLNL by a designated LLNL employee acting as a courier (39 CFR 111; 42 CFR 72; 49 CFR 171-178). 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 one-fifth of a teaspoon in volume). Smaller samples could be shipped that would be microliters in size; the maximum probable sample size would be 15 milliliters.

The protocol for receiving and handling of samples (such as soil) would be worked out prior to receipt and reviewed and approved by the IBC. 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 LLNL-requesting-facility responsible official a 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 incoming packages (regardless of origination point) containing infectious agents would have to have been packaged in DOT-approved packages (42 CFR 72) (see Figure 2-6). 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 LLNL receiving site would be followed.

Biological shipments to and from LLNL could initially be as much as ten times the current levels (4 in and 2 out per month now) of shipments to existing LLNL biological research laboratories. Once the facility became fully operational and "stocks" of needed materials 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. External packaging material from packages received at the facility would be inspected, removed, auto-claved, and disposed of according to LLNL waste handling procedures. 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

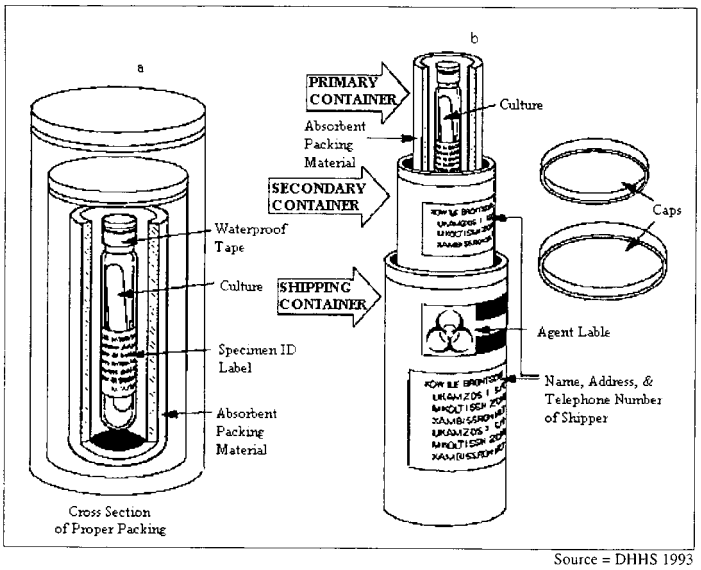


Figure 2-6. Example of a Primary Shipping Package.

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 LLNL Shipping and Receiving in various fresh, frozen, or "fixed" (for example, in formaldehyde) forms including aqueous liquids, solids, or as material contained in bodily fluids. 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).

Upon arrival at LLNL Shipping and Receiving, these sample containers would be examined for damage, logged in, and taken to the BSL-3 laboratory for removal of the external packaging material. Damaged packages would be handled in accordance with procedures for BSL-3 laboratories (to be developed once the project obtains approval). The removed packaging would then be autoclaved and disposed as solid waste. 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 any 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 LLNL in a safe and secure manner in accordance with applicable NNSA and LLNL 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). All preparations and manipulations of cultures or samples would only occur within a fully operating BSC. When the external packaging materials were removed, they would be autoclaved within the facility and disposed of according to LLNL's solid waste handling procedures (LLNL 1994).

Culture of Samples in a BSL-3 Laboratory: For culturing, the samples or seed cultures would be removed from their primary containers in a BSC, and 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[17] 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 the chemical known as phenol. The lysed or killed cells and the culture media could be processed into biological material that would later be analyzed by various research methods at various LLNL research laboratories, and potentially at other laboratories off-site. Following incubation (hours to days), all cultured materials would be cleaned up within one work-shift (8 hours). Many cultures would be archived in small quantity and maintained in the ultra-freezers in each laboratory.

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. Sanitary waste from portable toilets used during construction would be removed by commercial vendors and be disposed of in a sanitary sewer system offsite from LLNL in accordance with the permit requirements applicable to the commercial vendors.

During operation of the BSL-3 laboratories, the disinfection after each use of the interior working surfaces of the BSCs 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. 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 electronically to insure its effectiveness. This method is the same waste management method used by hospitals and similar facilities to sterilize their waste. Solid waste landfills may accept autoclaved or chemically sterilized wastes for disposal depending on their individual waste acceptance criteria and operating permit requirements. Alternatively, LLNL could contract to send sterilized wastes produced by the proposed BSL-3 facility to a licensed commercial incinerator located offsite for waste disposal.

Laboratory research experiments would be expected to generate about 22 lbs (9.9 kg) of lab trash (gloves, pipette tips, culture tubes, tissues, etc.) per week or about 1,144 lbs per yr (515 kg per

[17] 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.

yr). Other "solid waste" (note-paper, etc.) generated in the non-laboratory portions of the facility would raise the total solid waste production to less than 2,000 lbs per yr (900 kg per yr).

Sanitary liquid waste also would be generated from the proposed BSL-3 facility. Sanitary waste would be generated from research activities and 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 can be disposed in the laboratory sinks after first being treated with disinfectants. Waste generated from research is projected to be about 3 gal per wk (11 liters per wk) or 156 gal per yr (590 liters per yr), and could be disposed in the sanitary sewer system. An additional 40 gal per day (152 liters per day) or 10,000 gal per yr (37,900 liters per yr) can be produced by toilets and showers, although it shouldn't be considered a net increase since the BSL-3 facility workers are already working in adjacent BSL-2 buildings with toilets and showers.

No hazardous waste and no radiological waste would be generated by the facility.

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. HAPs are limited to 10 tons per yr individually.

All hazardous chemicals used in the proposed facility (such as: formaldehyde, chloroform, phenol, ethyl alcohol, isopropyl alcohol, amyl alcohol, and sodium hypochlorite) would not become waste for this facility. Only small quantities of these chemicals (sufficient for daily activities) would be present in the facility at any time due to a lack of storage space in the facility. These chemicals would either be used up in process (becoming non-hazardous) or would leave the facility as a stabilizing or sterilizing chemical for samples being sent to other laboratories. About 30 lbs per month (14 kg per month) or 360 lbs per yr (168 kg per yr) of sodium hydroxide or potassium hydroxide would also be used for rodent tissue digestion/sterilization. These chemicals would be used up in the digestion process. Waste fluid generation may need pH adjustment prior to discharge to the sanitary sewer system if it is too alkaline to meet discharge standards.

For any chemical disinfectant used by the BSL-3 facility, quantities used annually would not exceed reportable quantity volumes. 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 a local landfill.

2.1.3 BSL-3 Facility Decontamination and Decommissioning

It is estimated that the operational design life of the proposed building would be at least 30 years. Decontamination and either demolition, removal, or reuse of the facility would likely occur. After decontamination (which would include disinfection of certain parts of the facility) the building could be disassembled and disposed of through the existing LLNL program for disposition of excess government property. This could ultimately require that the facility's modular components be moved offsite from LLNL. Alternately, the facility could be demolished and disposed of in a solid waste landfill offsite. Another alternative would be the reuse of the facility, either in whole or in part by other LLNL users, since BSL-2 laboratory space is traditionally in short supply at LLNL. Additional NEPA compliance review would be required when the decontamination and future-use options were ripe for review/decision.

The ultimate decontamination and decommissioning (D&D) of the BSL-3 facility would involve only the normal deconstruction and disposal of construction debris. This facility would undergo a final fumigation and testing to insure that microbes were not lingering in the remnants of the building. The building would not contain any radioactive or hazardous components.

2.2 ALTERNATIVE ACTION TO REMODEL/UPGRADE A SINGLE-ROOM LABORATORY IN BUILDING B-365 TO BSL-3

It is expected that the cost of upgrading an old facility, such as a laboratory room in LLNL building B-365 (Figure 2-1) would approach or exceed the cost of constructing a new facility with the same single-laboratory capabilities. The initial problem of upgrading is the need for physical isolation of the laboratory space. Since the facility was not originally intended for this purpose it would not lend itself directly to physical isolation. The most significant retrofits in terms of cost and time would involve HVAC systems; HEPA filtration' fumigation systems; and sealing of walls, floors, ceilings, plumbing and electrical conduits. Often a new room inside the room must be installed to insure complete sealing of entrance/exit points around all the normal breaches, such as wall electrical outlets. The "remodel" option also often has problems; for example, with: sanitary sewer drainage (where this lab is located relative to others in the same building); HVAC pressure balancing (effects from other room doors opening/closing and BSCs); addition of HEPA filter banks for disinfection without shutdown of system; and location of exhaust stacks relative to other existing intakes.

This option is not necessarily a cost-effective one, but it can and has been done by the CDC in Atlanta, GA. Discussion with personnel from the CDC (PC 2001a, 2001b) suggest that their biggest problems come from retrofit laboratories. The CDC personnel would not recommend this alternative.

2.3 ALTERNATIVE ACTION TO CONSTRUCT AND OPERATE AN ON-SITE-CONSTRUCTED BSL-3 FACILITY

An alternative to a modular construction would be on-site construction. The only appreciable difference in the installation of a modular assembly constructed off-site and the on-site construction option is the duration of the construction phase and the associated noise, traffic, and movement of building materials. The installation of a modular assembly on-site takes a matter of weeks while the on-site construction takes months and is more disruptive for a longer period. Once constructed, there is no appreciable operational difference between them. The operational and D&D phases would, for all intents and purposes, be the same as for the proposed action.

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. This alternative 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 have to continue to rely on meeting its BSL-3 laboratory needs by exporting work and staff to existing or new BSL-3 laboratories located offsite from LLNL. It is expected that while the potential tasking of LLNL by DOE and through work-for-others would grow, no new workers would be hired within the BBRP at LLNL since the only need to hire additional staff under this option would be to be able to export staff and equipment to offsite laboratories as workloads increase rather than to conduct the research on-site with currently existing staff assets which should remain sufficient for the foreseeable future. Also, 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 at LLNL.

2.5 ALTERNATIVES CONSIDERED BUT ELIMINATED FROM FURTHER ANALYSIS

Additional alternatives were considered but have been dismissed from detailed analysis in this document.

2.5.1 Construction and Operation of the Proposed BSL-3 Facility at Another Mainsite LLNL Location

The LLNL mainsite is very space-limited. There are few remaining open areas available for new construction, and none in the near vicinity of the BBRP complex. However, any location other than the proposed location would be, at a minimum, a logistical problem. First, it is expected that the researchers and staff who would be working in the proposed BSL-3 facility would have offices and regular work assignments in buildings adjacent to the proposed facility location in the Building 360 Complex under the preferred alternative. This is also where the rodent colony and quarantine areas are located, as are all the supplies for the proposed building including. From a safety perspective, the LLNL Biosafety Officer and the most highly trained and experienced staff would also be located in the buildings immediately adjacent to the currently proposed building location. A remote location would be a safety and security risk that is unnecessary. This

alternative was dismissed from further consideration in this NEPA analysis although it would meet the Agency's purpose and need for action.

2.5.2 Construction and Operation of the Proposed BSL-3 Facility at Site 300

The same issues apply to Site 300 as they do for another mainsite LLNL location (section 2.5.1), although the significance of the safety issues and issues related to ground transport of infectious agents and toxins between the two sites are greater. This alternative also was dismissed from further consideration in this NEPA analysis although it would meet the Agency's purpose and need for action.

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

The NNSA supports three national security laboratories: Los Alamos National Laboratory, at Los Alamos, New Mexico, 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 proposed BSL-3 facility at either SNL or LANL to the exclusion of LLNL 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, however, meet the purpose and need for NNSA to conduct future BSL-3 level work at LLNL in support of its assigned national NNSA security –and science mission responsibilities.

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 under conditions that would meet the necessary national security requirements needed. However, it would not allow the work to be performed as quickly or efficiently as may be needed in all cases. LLNL has qualified and experienced personnel and a sophisticated existing biological infrastructure in the BBRP. Placing the BSL-3 laboratory at another NNSA laboratory would require significant duplication of this capability. Also, none of the existing or proposed (DOE 2002) NNSA locations, which are all now operating at the BSL-2 level, have or would have the capability to conduct aerosol challenges of rodents.

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 LLNL.

2.6 RELATED ACTIONS

There are no known related actions.

3.0 AFFECTED ENVIRONMENT

The *Final Environmental Impact Statement and Environmental Impact Report for the Continued Operation of Lawrence Livermore and Sandia National Laboratories, Livermore, August 1992* (LLNL FEIS/EIR) (DOE 1992) and its associated Supplement Analysis (SA) (DOE 1999) provide a detailed discussion of the affected environment at LLNL. 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 from the LLNL FEIS and SA or includes by reference the information presented in that document.

This section 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 section or eliminated from detailed discussion, as shown in Table 3-1 in Section 3.2.

3.1 REGIONAL AND LOCAL SETTING

The LLNL Livermore site occupies a total area of approximately 3.3 km^2 (821 acres) at the southeast end of the Livermore Valley, located about 80 km (50 miles) east of San Francisco, in southern Alameda County, California. The Livermore Valley is characterized by nearly level, shallow-to-deep soils that vary in texture from clays to sandy clay loams or mixed gravels. The valley forms an irregularly shaped lowland area about 16 miles long east-to-west and 7 to 10 miles wide north-to-south. The floor of the valley slopes to the west at about 20 ft per mi (4 m per km). The soils tend to be high in sodium, calcium, magnesium, iron, chlorides, and sulfur, and low in organic matter, nitrates, phosphates, and potassium. The characteristics of the soil series found at the Livermore site are hard when dry and plastic when wet; the soils have high permeability and high water-retention capacity. Since the Livermore site is nearly flat, there would be no areas of potential slope instability in the location of the proposed project.

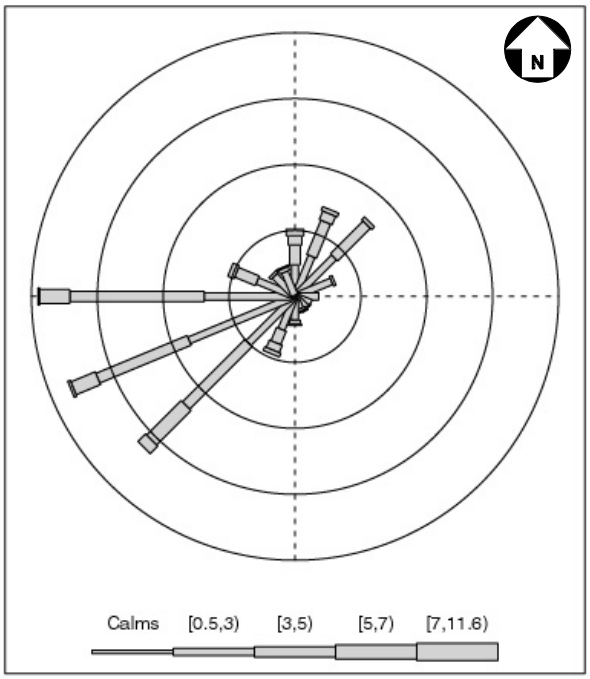
3.1.1 Climate and Meteorology

The Livermore Valley is characterized by mild, rainy winters and warm, dry summers. The mean annual temperature for the 30-yr period from 1950 through 1980 is 14.5°C (58.1°F) with daily extremes ranging from -8°C (18°F) to 45°C (113° F).

Both rainfall and wind exhibit strong seasonal patterns. Most of the annual rainfall, which averages 36 cm (14 in.), occurs between October and April and is associated with migratory, low-pressure systems from the Gulf of Alaska. Prevailing winds are from the west and southwest from April through September. During the wet season, northeasterly and north-northeasterly winds that are associated with post-frontal, anti-cyclonic flow are also common. Figures 3-1 and 3-2 show the day and nightime wind roses for LLNL for the five-year period from January 1997 through January 2002.

Calms: 1.6%

Daytime



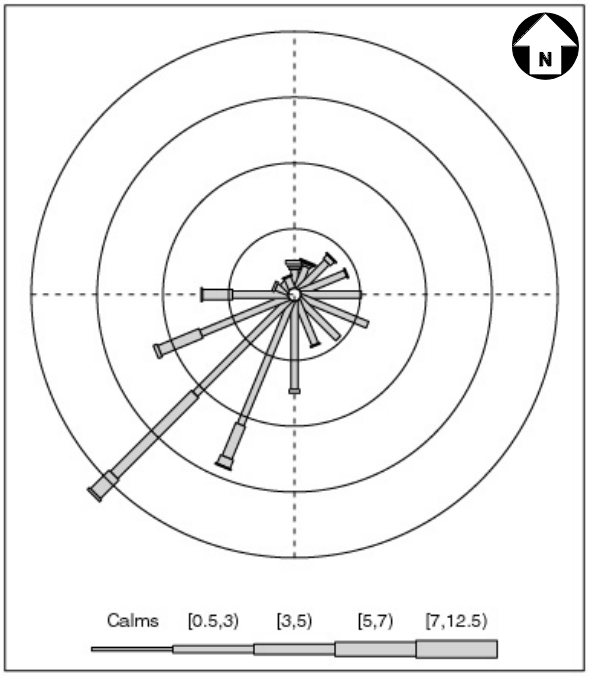
Circles are 5% 10% 15% 20%

Speeds are Calms [0.5,3) [3,5) [5,7) [7,12.5)

Figure 3-1. 5-Yr daytime wind rose for LLNL

Calms: 7.8%

Nighttime



Circles are 5% 10% 15% 20%

Speeds are Calms [0.5,3) [3,5) [5,7) [7,12.5)

Figure 3-2. 5-Yr nighttime wind rose for LLNL

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 applicable or not (EA section is not applicable, NA, and a brief explanation of why not) and where they are discussed if they have a direct bearing on the analysis.

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

Resource Category	Applicability	BSL-3 EA Section
Ecological Resources	Yes	3.3.1
Human Health	Yes	3.3.2
Air Quality	Yes	3.3.3
Noise	Yes	3.3.4
Waste Management	Yes	3.3.5
Geology/Soils/Seismology	Yes	3.3.6
Socioeconomics	The projected financial expenditures for the proposed construction project would be too small to have any perceptible affect on the local environment. No net increase in the number of workers would be anticipated.	NA
Visual Resources	This facility would be consistent in architectural style with, and in the midst of, a number of larger buildings. No visual issues would be perceived.	NA
Transportation	The number of LLNL material shipments associated with operating the proposed facility would be imperceptible to LLNL and there would be no net change in the number of individuals working in the Building 360 Complex area.	NA
Utilities/Infrastructure	The small size of the proposed facility and its intended location show that there would be no appreciable impact to utilities and infrastructures.	NA
Cultural Resources	No prehistoric or historic cultural properties greater than 100 yrs old are located at or adjacent to this site (DOE 1992).	NA
Environmental Justice	There would be no disproportionately high or adverse human health or environmental effects on minority or low-income populations (DOE 1992) as a result of operating an on-site BSL-3 facility in addition to the current BSL-2 facilities.	NA
Environmental Restoration	There are no potential release sites at or adjacent to the proposed location (DOE 1992).	NA

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

Resource Category	Applicability	BSL-3 EA Section
Floodplains/Wetlands	The proposed facility is not within the 100-yr floodplain nor are there wetlands at or adjacent to it (DOE 1992).	NA
Land Use	The area surrounding the proposed site 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 (DOE 1992).	NA
Water Quality/Hydrology	There would be no effect on surface water or groundwater quality and no perceptible increase in potable water use. There are no NPDES outfalls at the proposed facility location (DOE 1992).	NA

3.3 ENVIRONMENTAL RESOURCES POTENTIALLY AFFECTED

3.3.1 Ecological Resources

The Livermore site is a developed area that provides only marginal wildlife habitat because of the high degree of human activity and the few areas of undisturbed vegetation. Of the 3.3 km^2 (821 acres) comprising the Livermore site, 2.6 km^2 (640 acres) are developed. Annual wild oat along with non-grass annuals and perennials now dominate the grassy areas of the site. The common plant species are ripgut brome (*Bromus diandrus*), slender oat (*Avena barbata*), star thistle (*Centaurea solstitialis*), Russian thistle (*Salsola kali*), turkey mullein (*Eremocarpus setigerus*), alfalfa (*Medicago sativa*), sweet fennel (*Foeniculum vulgare*), California sagebrush (*Artemisia California*), and Italian ryegrass (*Lolium multiflorum*).

The LLNL Livermore site hosts numerous birds, reptiles, and amphibians, with a minimum of 3 species of amphibians and reptiles, 10 species of mammals, and 31 species of birds. Jackrabbits are the most common wild mammal present; gophers, snakes, and field mice can be found in the undeveloped areas of the Livermore site.

Resource surveys of LLNL Livermore, California, were conducted in 1986 (Orloff 1986), and a biological assessment (BA) in 1991 pursuant to the U.S. Endangered Species Act and the State of California Endangered Species Act addressed the status of threatened, endangered, and other species of concern (referred to as sensitive species) that may occur or are known to occur in these areas. Although several listed and proposed endangered and threatened species of plants and animals may occur in the general area of the LLNL Livermore site, the U.S. Fish and Wildlife Service (USFWS) determined that, to the best of its knowledge, these species were not known to occur within the boundaries and proposed future growth areas of these sites at that time (U.S. Fish and Wildlife Service 1991). Since that time, one State-protected bird species, the White-tailed kite (*Elanus leucurus*), has been found to nest along the eastern and northern tree line of the site, in spite of normal daily traffic and routine maintenance activities; also, one state species of special concern, the Burrowing Owl (*Athene cunicularia*), had been found in the north

buffer zone of the LLNL Livermore Site in the mid-1990s. Additionally, the Federally threatened California red-legged frog (*Rana aurora draytonii*) has been found in the Arroyo Los Positas (along the northern buffer zone). A BA was completed in 1997 and amended in 1998 to account for potential impacts to the frog from routine maintenance activities at the LLNL site. In 2001, a narrow strip along the northern and eastern edges of the site were designated as a portion of the federal critical habitat for the frog. The proposed BSL-3 facility would not be located in or near these natural resource-sensitive areas.

Although not usually considered as such, soils are also an ecological resource (Burden and Sims 1999). Soils are known to naturally contain a diversity of numbers and types of microorganisms. The range is substantial as it depends upon the environmental conditions, which dictate the bacteria and fungi microflora (plant microorganisms) that can survive. Infectious microorganisms can also be found naturally in soils. Some of these may be handled in the proposed BSL-3 laboratories (e.g., *Bacillus spp.* and *Clostridium spp.*).

3.3.2 Human Health

In 2000 there were approximately 1.3 million people living in Alameda County (HRSA 2000), in which Livermore is located, and about 6.9 million people living within a 50-mile radius of LLNL (LLNL 2001b). Health of individuals living here is favorable (better) relative to California peer counties and the U.S. as a whole (HRSA 2000). Infectious diseases are not common in the county. In fact, over the three year period of 1996, 1997, and 1998, most of the infectious diseases were diarrheal (63 cases from *Escherichia coli*, 809 cases from *Salmonella spp*. and 441 cases from *Shigella spp*.) associated with either unclean water or improper hygiene and food handling (HRSA 2000). There were also 472 cases of viral hepatitis A (infectious hepatitis), 21 cases of viral hepatitis B (serum hepatitis), 8 cases of the measles virus (Rubeola), and 109 cases of pertussis (whooping cough) reported to Alameda County Health officials (HRSA 2000).

Statewide there are appreciably more cases of infectious diseases. Table 3-2 shows the cases and deaths associated with selected notifiable diseases in the State of California for a four-year period (CDF 2001). These statistics show, for example, that while there were no cases of anthrax for the reported years, there were a few cases of plague (unspecified), psittacosis, Q-fever, brucellosis, tularemia, and typhus, along with a number of more common diseases. Although not on the table, there were 9 hantavirus cases in 1999. Acquired immune deficiency syndrome (AIDS) and venereal diseases are some of the most prevalent infectious diseases in California.

3.3.3 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. Criteria pollutant emissions data for LLNL have not changed appreciably

TABLE 3-2. CASES AND DEATHS, SELECTED NOTIFIABLE DISEASES CALIFORNIA, SELECTED YEARS

T.C.D. 10th Edition		1990		1997		1998		1999	
		Cases	Deaths a/	Cases	Deaths a/	Cases	Deaths a/	Cases	Deaths a/
B20-B24	AIDS	8,827	5,041	6,774	1,857	5,786	1,432	5,358	1,558
A06	Amoebiasis	1,638	2	933	1	700	1	599	---
A22	Anthrax	---	---	---	---	---	---	---	---
A05.1	Botulism	36	---	48	1	51	---	65	3
A23	Brucellosis	26	---	30	1	12	---	18	---
P01.9, P35.8 *	Chickenpox (Varicella-Zoster)	904	32	n/r	23	n/r	22	n/r	---
B38 *	Coccidioidomycosis	441	23	704	50	719	36	939	28
A93.2	Colorado Tick Fever	---	---	---	---	1	---	---	---
P39.1	Conjunctivitis of the Newborn	25	---	23	---	25	---	21	---
	Diarrhea of the Newborn h/	---	---	---	---	---	---	---	---
A36	Diphtheria	---	---	---	1	---	---	---	---
	Encephalitis, Viral	125	17	76	17	79	14	108	---
	Food & Waterborne Illness	1,079	---	1,951	2	3,968	1	3,617	---
P35.0	Rubella-Congenital	8	6	3	1	---	2	2	---
B15-B19 *	Hepatitis, Viral	10,594	265	8,658	704	6,210	860	4,961	248
B15	A (Infectious)	6,408	15	6,422	21	4,178	10	3,439	20
B16	B (Serum)	2,940	145	1,658	186	1,445	222	1,234	58
B17.1, B17.8 *	Non-A, Non-B b/	623	---	467	467	464	595	191	131
B17.0	D	8	105	8	30	6	33	10	---
B19	Unspecified	615	---	103	---	117	---	87	9
A30	Leprosy	79	---	40	1	38	---	36	---
A27	Leptospirosis	3	1	12	---	2	---	1	---
B50-B54	Malaria	328	---	406	---	217	---	218	---
B05	Measles: Indigenous	12,719	39	22	---	6	---	14	---
	Measles: Imported	91	---	8	---	4	---	4	---
A87 *	Meningitis, Viral	1,525	7	2,307	3	3,040	4	1,544	4
A39	Meningococcal Inf.: d/	426	---	402	41	319	28	304	30
A39.2-A39.4 *	Meningococcemia	---	46	156	21	132	12	125	13
A39.0 *	Meningitis	---	---	215	12	153	13	154	10
B26	Mumps	571	1	151	---	110	1	95	---
A37.0 *	Pertussis	467	---	483	---	1,085	---	1,144	---
A20	Plague	---	---	2	---	1	---	---	---
A80	Poliomyelitis	---	---	2	---	1	---	1	---
A70	Psittacosis	8	---	8	---	6	---	3	---
A78	Q Fever	2	1	9	---	4	---	3	---
A82	Rabies, Human	---	---	---	---	---	---	---	---
A68	Relapsing Fever	10	---	7	---	7	---	8	---
100-102 *	Rheumatic Fever	25	11	11	12	5	15	10	2
A77.0	Rocky Mt. Spotted Fever	1	---	2	---	1	---	1	---
A01.1-A01.4, A02 *	Salmonella	5,725	8	5,993	6	4,724	6	4,208	4
A03	Shigellosis	5,703	4	3,221	1	3,033	---	2,364	---
A49.1 *	Streptococcal Infections c/	6	2	---	45	---	46	1	12
A33-A35 *	Tetanus	7	2	11	1	8	---	16	1
B75	Trichinosis	1	---	1	---	3	---	2	---
A16-A19 *	Tuberculosis	4,889	211	4,043	194	3,857	165	3,608	139
A21	Tularemia	---	---	4	---	3	---	3	---
A01.0	Typhoid Fever	149	---	83	---	83	---	73	---
A75 *	Typhus Fever	3	---	16	---	12	---	11	---
A50-A64 *	Venereal Disease e/	137,544	10	90,507	5	98,954	6	106,575	5
A57	Chancroid	159	---	13	---	14	---	6	---
	Chlamydia trachomatis g/	66,213	---	68,599	---	76,401	---	85,022	---
A54 *	Gonococcal Infections	54,076	1	18,002	1	19,555	---	18,656	2

TABLE 3-2. CASES AND DEATHS, SELECTED NOTIFIABLE DISEASES CALIFORNIA, SELECTED YEARS

T.C.D. 10th Edition		1990		1997		1998		1999	
		Cases	Deaths a/	Cases	Deaths a/	Cases	Deaths a/	Cases	Deaths a/
A58	Granuloma Inguinale	7	---	n/r	---	n/r	---	n/r	---
A55	Lymphogranuloma venereum	24	---	n/r	---	n/r	---	n/r	---
A50-A53	Syphilis, Total f/	17,065	9	3,893	4	2,984	6	2,891	3
A51 *	Primary	2,220	---	165	1	123	---	105	---
	Secondary	2,274	---	221	---	202	---	179	---

* The Tenth Revision of the International Classification of Diseases (ICD-10) codes may not be comparable to the Ninth Revision (ICD-9) codes. Caution should be used when looking at the number of deaths by year.

a/ Deaths shown above may not agree with deaths shown in vital statistics tables because some diseases are not listed separately in the International Classification of Diseases List of Causes of Death on which the vital statistics tables are based, or because the definitions of some of the diseases used in the International List differ from the definitions used for morbidity purposes.

b/ Non-A, Non-B is a new category added in 1982 by the Center for Disease Control, Atlanta, Georgia.

c/ Respiratory infections not included after 1988. After May 1989, cases reported only in foodhandlers, dairy workers and outbreaks.

d/ Prior subcategories combined for reporting beginning with 1993.

e/ Does not include NGU or PID.

f/ Also includes congenital, early latent, late and late latent syphilis.

g/ Chlamydia became a reportable disease in mid-1989; 1990 is considered the first full report year.

h/ Outbreak related cases only.

n/r No longer reportable.

Source: Department of Health Services, http://www.dhs.cahwnet.gov/
Cases--Communicable Disease Control Division, Office of Statistics and Surveillance, (916) 323-9808
Deaths--Office of Vital Records and Statistics, Vital Statistics Section, (916) 445-6355

since the 1992 FEIS (DOE 1992) with the exception that the Laboratory now lies within a federal non-attainment area for ozone. None of the criteria pollutants emitted from LLNL, when combined with existing background pollutant levels, substantially contributes to existing or new degradations of air quality in the Bay Area.

3.3.4 Noise

Noise levels to protect worker hearing at LLNL are based on DOE orders (DOE 1984), OSHA regulations (29 CFR 1910.95), and recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH 2000). 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. Noise levels that affect residential receptors are normally 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 normally require a city or county permit.

Noise levels at the proposed BSL-3 facility would be generated primarily by vehicle traffic and facility HVAC systems except during facility construction. Ambient noise measurements for typical lightly industrialized areas are around 50 dBA during morning and evening rush hours dropping a few dBA during nighttime hours. These levels 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. Noise levels for heavy construction equipment can be more than 20 dBA higher than typical light industrialized areas depending upon the proximity to the source of the noise and the type of equipment being used.

3.3.5 Waste Management

LLNL 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 at LLNL. The quantity of solid waste expected to be generated by construction activities, relative to LLNL-wide waste generation, is negligible and no hazardous waste generation is projected; therefore, neither will be further evaluated.

Sanitary Liquid Waste. Sanitary liquid waste from LLNL is discharged by sewer to the City of Livermore Water Reclamation Plant (LWRP) in accordance with procedures specified in the LLNL ES&H Manual (LLNL 2001c). All discharges are continuously monitored with a radiation detector, an industrial pH probe, and an x-ray fluorescence unit for most regulated metals prior to discharge off-site. Discharges are regulated by the federal government under the Clean Water Act (also known as the Federal Water Pollution Control Act of 1972, 40 CFR 403). The State of California regulates these discharges under Title 22 of the California Code of Regulations, and the City of Livermore imposes restrictions under the LLNL Wastewater Discharge Permit which is issued under Livermore's municipal code. Discharge limits for non-radioactive parameters include 11 inorganic elements/constituents plus pH (acidity), total toxic organics, volatile halogenated solvents, total identifiable chlorinated hydrocarbons (pesticides), oil and grease, and polychlorinated biphenyls. Although no discharge limits currently exist for infectious materials which are commonly discharged by healthcare and veterinary facilities and laboratories or homes, liquid waste as generated from the proposed BSL-3 laboratory operations would be discharged to a retention tank system, for containment, characterization, and disinfection as needed, prior to discharge to the sanitary sewer system.

3.3.6 Geology/Soils/Seismology

The LLNL Livermore site is located in a region that has experienced earthquakes within historical times. The effect of seismic activity is likely to be confined to ground shaking with no surface displacement (DOE 1992). Active faults considered capable of causing strong ground motion at the Livermore site have been identified, and the potential impact on Livermore operations assessed (DOE 1992). A maximum ground surface acceleration for the LLNL site of 0.6 g (1.0 g represents acceleration due to gravity) has an annual probability of exceedence of 10^{-3} (Kennedy *et al.* 1990). Figure 3-3 shows the active faults in the Livermore Region. None are in proximity to the location of the proposed facility.

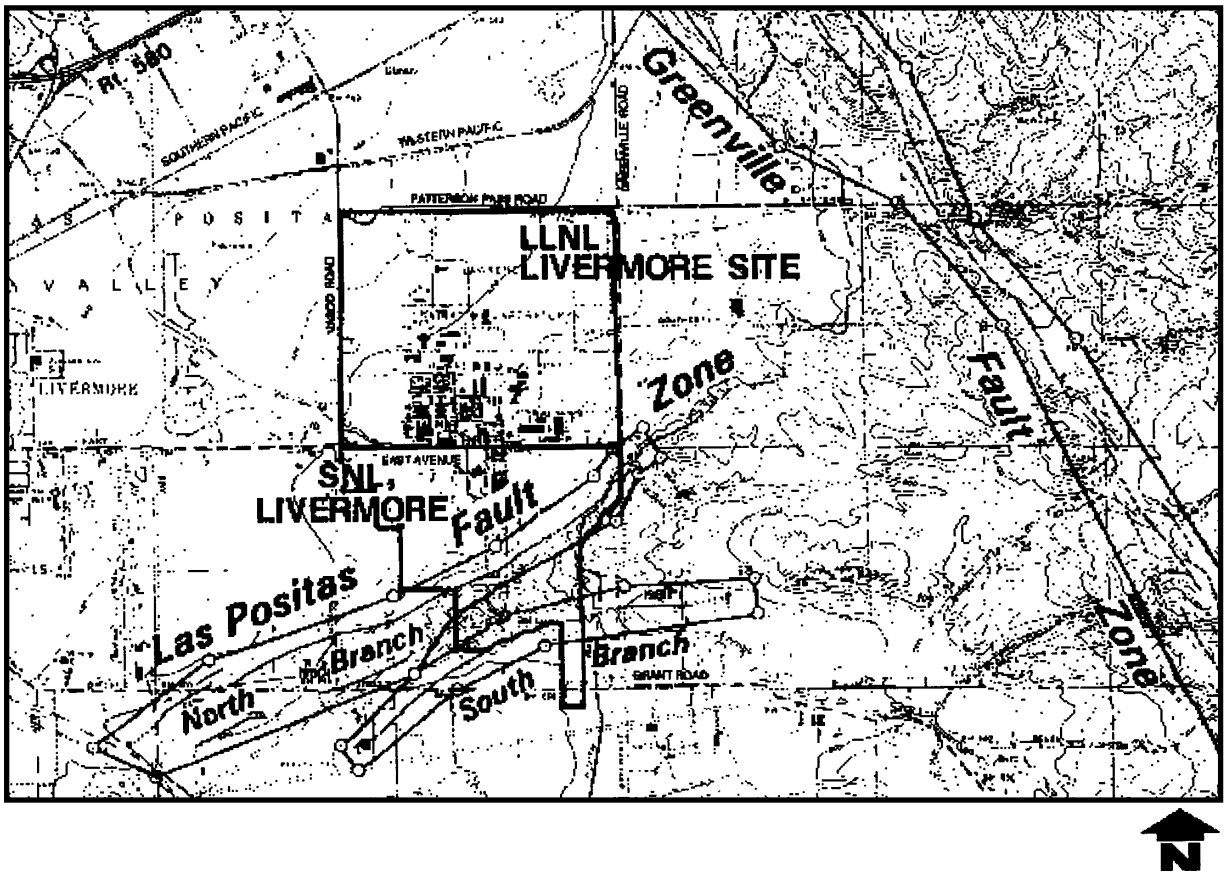


Figure 3-3. Map showing active faults in the Livermore region (DOE 1992)

4.0 ENVIRONMENTAL CONSEQUENCES

This section evaluates the environmental consequences of the Proposed Action, Alternative Actions and the No Action alternative. Except for the No Action Alternative, this evaluation covers site preparation, construction, operation, abnormal events (accidents), and decontamination and decommissioning. The consequences of the Proposed Action and the Alternative to Construct On-site would be the same except for those related to construction. The Remodel/ Upgrade Alternative would have no site preparation, so the discussion covers construction, operation, and D&D. The abnormal event (accident) issues are the same for all alternatives since the work in all alternatives would be done in an individual laboratory conforming to CDC/NIH guidelines for design and operation of a BSL-3 laboratory.

4.1 ENVIRONMENTAL CONSEQUENCES OF THE PROPOSED ACTION

4.1.1 Ecological Resources

As stated in Section 3.3.1, no threatened or endangered species habitat or buffer areas would be located at or adjacent to the proposed BSL-3 laboratory facility.

Site Preparation and Construction. Less than one-quarter acre of previously disturbed land would be used for site preparation, utility installation, and other construction activities. It would be expected that continuous and impact noise (described in Section 4.1.4) could have temporary effects to non-sensitive wildlife species in the immediate site location area. However, these minor effects would not be long term.

Site preparation and construction would have some effect upon the resulting soil characteristics. A small portion of some shallow soil horizons would be removed where they would be under foundation footings and other parts of the building's base. Soil microflora would be disturbed but only for the duration of soil-intrusive activity.

Operation. The operation of the proposed BSL-3 facility would have little if any effects on 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 City of Livermore Water Reclamation Plant (LWRP) 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 4.1.2, Human Health). This process is the same as for healthcare and veterinary facilities and laboratories in the area.

The second relates to emergency response operations. There is a potential for microorganisms to be introduced into the environment if they were not contained within the laboratory during a fire-response or natural phenomena event (e.g., seismic). However, even if they should escape containment, a number of environmental factors should effectively kill microorganisms in the vegetative state. These are enumerated in Section 4.1.2. 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).

Decontamination and decommissioning. Other than the effect of noise at the localized site area from D&D activities (building demolition), there would be no effect on ecological resources.

4.1.2 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 LLNL. The effects would be very localized and would 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 officially-sponsored site visitors to a number of common hazards including, for example:

- Biological hazards (e.g., snake bites, poison ivy, and insect stings);
- Electrical hazards (temporary electrical drops, excavations in areas with underground utilities, heavy-equipment lifting with nearby overhead utilities);
- Fire and explosion hazards (portable gasoline containers for generators and other gasoline-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 1997, 1998).

UC workers at LLNL 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. LLNL workers are currently involved in similar activities on site. Because of the expected limited involvement of LLNL workers in the construction of the new buildings, only minor effects to these workers are anticipated. The Proposed Action is expected to have no substantial effect on the health of any non-LLNL construction workers under normal operation conditions. 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 several months to complete. Appropriate personal protection measures would be a routine part of the construction activities (such as gloves, hard hats, steel-toed boots, eye shields, and ear plugs or covers).

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 LLNL. While the most obvious potential concern of operating a BSL-3 laboratory involves handling of infectious organisms (listed in the tables in

Appendix A), 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 stored in the facility at any one time would be just a few liters each of chemical disinfectants (such as sodium hypochlorite or potassium hypochlorite) and biologic stabilizers (phenol). Chemicals such as paraformaldehyde would not be stored in the facility but brought in only when required for fumigation (the facility has a minimal amount of storage space). The hazardous chemicals used and stored would be tracked using ChemTrack (LLNL's computerized chemical inventory system) and handled according to the BBRP directives (LLNL 2000a), the Building 360 Complex directives for Biohazardous Operations (LLNL 2001a), and the LLNL Chemical Hygiene Plan for Laboratories (LLNL, 2001c). Use of biotoxins are discussed later in this section.

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 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 laboratory-acquired infections associated with operations in CDC-registered laboratories since the implementation of CDC-developed guidelines issued in 1974 (See Appendix A). 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 1990s. There is a notable lack of reported cases in the literature relating to laboratory-acquired infections in the United States particularly in the last 10 years.

The experience of the U.S. Department of the Army (DA) at its 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). Up to time of that publishing, there were 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)." Since then there was one incident in 2000 (CDC 2000c) where a worker was exposed to *Burkholderia mallei* the causative agent of human glanders. The individual was hospitalized and shortly recovered. 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 LLNL spans a period of many years. Based on information provided by the LLNL BBRP Assurance and Facility Manager, LLNL has operated BSL-1- and BSL-2-equivalent laboratories for at least the last 20 years without any infections associated with their operation (PC 2002). Also, there were no unintentional releases to the environment or to the public associated with the LLNL biological research laboratories. Additionally, the LLNL BBRP Assurance and Facility Manager reviewed available Occurrence Reporting and Processing System (ORPS) Reports (from the past 10 years). These reports include information on workers at BSL-1 and -2 laboratories at LLNL. The result of this review was that there have been no incidences of laboratory-acquired infections recorded for LLNL workers (PC 2002). Based on extensive experience with the safe handling of biological materials at LLNL and the Department of the Army, it is projected that the National Defense-related and scientific research to be conducted at the proposed BSL-3 facility would not result in significant impacts from normal operations to workers or the public.

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 (Appendix B). 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 are based upon historical published accounts (anecdotal information) over many decades of experience in medical and bacteriological laboratories (CDC 1999) (see Appendix B).

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,[18] vector-borne transmission,[19] vehicle-borne transmission,[20] airborne transmission[21], and water-borne transmission.[22]

[18] 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).

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[23] 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 sterilization by autoclave or chemical disinfection. The guidelines established by the CDC and NIH, which would be followed within the proposed BSL-3 facility, are designed to reduce this potential method of transmission. This would substantially reduce 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. HEPA filters are rated as 99.97 percent efficient at a most-penetrating "design point" of 0.3 microns[24] diameter as tested by dioctyl phthalate (DOP) particles (NSC 1996). This means that HEPA filters are designed to remove at least 99.97 percent of all the particulates that hit the filters, even in the most-penetrating sizes of 0.1 to 0.4 microns. The remaining particles (less than 0.03 percent) can penetrate or pass through the filters. The number of viable vegetative microorganisms after HEPA filtration would be negligible. Filters are made from randomly laid non-woven natural or synthetic fiber materials made into a flat sheet that is pleated and placed

[19] 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 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).

[20] 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).

[21] 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).

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

[23] 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).

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

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 remove most all particles below 0.1 micron (NSC 1996). A "most-penetrating particle size" exists between 0.1 and 0.4 microns which is the reason for testing and certifying HEPA filters for particle removal at 0.3 microns (NSC 1996). The DOP test is highly conservative relative to microorganisms that may have sticky cell-walls and/or protuberances such as, flagella and pili (protein fibers 0.5 to 20 microns in length) which help them adhere to other cells. Bacterial spores are larger than their vegetative cells and have charged surfaces that promote attraction to other surfaces. Being sticky or with charges on their surfaces promotes their capture by the HEPA filter.

NNSA acknowledged in the LLNL Supplement Analysis for Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore (March 1999, DOE/EIS-0157-SA-01) the issue of reduced removal efficiency of HEPA filters for particles in the size range from 0.1 micron to 0.3 microns. The study which provided this information was from a dissertation written by Ronald C. Scripsick (Los Alamos National Laboratory Report, LA-12797-T, 1994). Even though the most-penetrating particle size in his study was slightly smaller than the HEPA filter "most-penetrating design point" of 0.3 microns, his results still showed a 99.97% removal efficiency or higher in the range from 0.148 to 0.196 microns.

HEPA filters at the LLNL BSL-3 facility (including those in the BSCs) would be tested annually and replaced as necessary. 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 and naturally 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 California-adopted uniform plumbing code requirements would prevent microbes within the facility from migrating back through the water supply piping to the public. Water exiting through the sink

drains would be diverted to a retention tank where it would be disinfected before being sent to the sewer system and the LWRP facility.

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 content meets this requirement.

Animal Handling Operations. Appendix B presents some background information on laboratory-acquired infection due to animal handling. The most common effect is for the animal handlers to develop allergies to the hair, dander, urine, and possibly serum of rats or mice. This is, however, very controllable with adherence to standard operating procedures, maintenance of a high standard of quality for anything entering the cages, utilization of cages designed for high standards of ventilation and cleanliness, and a good overall design for the rodent facility. The proposed facility would use a state-of-the-art ventilated caging system similar to the one shown in Section 2. These systems have high rates of exchange air, are designed for easy cleaning, and are HEPA-exhausted for worker protection and for research quality maintenance. Also, once exposed to a pathogen or toxin, the rodents would not leave the cages except inside a BSC. Following proper recognized procedures would help to insure that workers aren't exposed to pathogens from the rodents.

When handling human pathogens or zoonotic disease-causing agents (capable of being exchanged between humans and other animals) workers would use personal protective equipment (PPE) and would be either immunized and/or would have medical treatment available (prophylaxis) for the specific pathogen. Human pathogens for which there is no immunization or prophylaxis would not be handled in the proposed BSL-3 laboratory in accordance with the BMBL guidelines.

Historically the greatest opportunity for contracting a disease from the animals is through an inadvertent needlestick (autoinjection) or from bites and scratches. These can be averted by adhering to standard operating procedures (SOPs) and safety procedures using safety equipment that virtually eliminates these occurrences. These SOPs would be in place, along with the use of appropriate equipment in the proposed BSL-3 facility, prior to operation.

Rodent Challenge Studies.

Activities planned for the proposed action include aerosol-studies using rodents (mice, rats, and possibly guinea pigs). These studies would only be done inside a BSC that meets all currently applicable BMBL requirements (according to WorkSmart Standards) for the materials involved. One possible aerosol-challenge device, a collision nebulizer, would have its reservoir filled while in the BSC from other containers. The rodent would be challenged with the aerosol and the rodent would be placed into a clean cage. The nebulizer would be cleaned and chemically disinfected while still in the BSC. Procedures would be written and adhered to that would insure the device could not be removed from the BSC and be capable of generating an aerosol. Compressed air is necessary for generating the aerosol and it would be immediately disconnected

at the end of the process of challenging the rodent. After removal from the BSC, the device and all its parts would be put into an autoclave to insure sterilization.

Biotoxin Research.

The handling and use of a biologically-derived toxin is essentially the same as the handling of a hazardous chemical. As explained in Appendix B, there are three routes of exposure, but the most likely route of exposure would be the inadvertent needlestick. The probability of being exposed to a biotoxin if appropriate safeguarding and other safety procedures are followed would be extremely low. The Proposed Action facility would have appropriate procedures in place prior to operation of the facility.

Decontamination and Decommissioning. When the time comes for D&D of this facility, there would be no pathogens or toxins in the facility after it has been treated with chemical disinfectants and fumigated. Therefore there would be no human health effects related to biological materials expected from D&D activities. Also, no human health effects would be expected due to the deconstruction activities themselves since OSHA and EPA-type health, safety, and environmental protection procedures to control dust and noise would mitigate these potential issues.

4.1.3 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 on ambient 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, cranes, and those involved in waste disposal actions would also produce temporary and localized emissions of other air pollutants. Mobile sources, such as construction and waste transport vehicles, would produce other air pollutants (such as sulfur oxide), but the quantities would be minimal relative to the amount of mobile sources already in the area Air District.

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' commutes to and from work. Almost all of the workers are already working in adjacent buildings, so there would be no net effect to air quality from the travel of these individuals. Even the addition of a few new workers (if needed) would not produce a substantial contribution to air emissions. Since vehicle use would not change substantially as a result of operating the new facility, emissions from automobiles would not noticeably increase within the Building 360 Complex Area.

The emergency generator designated for the proposed BSL-3 facility is already operational at an adjacent building and therefore would not add to air emissions. No additional emergency generators, boilers, or other fuel-burning equipment would be added as a consequence of building and operating the proposed BSL-3 facility.

Periodic use of disinfecting gases could be part of the routine operation of the facility. These gases or vapors, such as formaldehyde (from paraformaldehyde) would not affect the local air quality since they would be inactivated at the end of each use. Effects of these gases, if any, would be temporary and localized and would dissipate very quickly. HEPA filtration of all laboratory exhausts removes virtually all biological particles and therefore there would be no incremental increase due to BSL-3 laboratory operation.

Decontamination and Decommissioning. Air emissions from D&D activities would consist of particulate dust emission due to demolition activities (controlled by water application) and mobile emissions due to trucks hauling building debris to the local landfill. These trips to the landfill would be minimal due to the small size of the building.

4.1.4 Noise

Site Preparation and Construction. It is possible 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 and only in the immediate vicinity of the site preparation and construction activity. Members of the public would not be exposed during the daytime or nighttime to noise levels exceeding city planning and zoning code standards (ambient noise level greater than 75 dBA beyond the boundaries of the site, nor greater than 60 dBA at the boundary of a residential district) (City of Livermore 2000). This is predicated on the distance of the proposed facility being about one-half mile to the nearest residence (near West Gate, Figure 1-3).

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; Magreb 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 LLNL action level of 80 dBA for steady-state noise. Sound levels would be expected to dissipate to background levels well short of the LLNL boundaries.

The additional construction-worker personal vehicular traffic would not be expected to increase the present noise level produced by vehicular traffic on Vasco and Greenville Roads and East Avenue 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.

Operation. The expected noise levels during operation of the proposed BSL-3 facility would be consistent with those of other existing LLNL bench-top research laboratory facilities. 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 ambient noise level greater than 75 dBA beyond the boundaries of the site, nor greater than 60 dBA at the boundary of a residential district (City of Livermore 2000).

Decontamination and Decommissioning. While there might be more trips from heavy equipment (dump trucks) during this phase of activity, the noise levels and extent of noise to the LLNL boundaries would be no more than that for site preparation and construction, or from other routine site infrastructure maintenance and construction activities.

4.1.5 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 LLNL facility (2,363 tons in 2000, LLNL 2001b). 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 tearing up of associated parking area. This solid waste would probably be disposed at the Altamont Landfill (Alameda County Landfill). Additionally, the project could generate very minor amounts of excess uncontaminated soil from excavation activities. The soil could be stockpiled at an approved soil material management area for future use or disposal.

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 sanitary sewer waste production associated with the operation of the facility would be minimal (on the order of 10,000 gal per yr or 37,900 liters per yr) with respect to the total waste volumes generated by the entire LLNL facility (256,000 gal per day or 970,000 liters per day in 2000) (LLNL 2001b) and negligible with respect to the City of Livermore's sewer system discharge (6.5 million gal per day or 25 million liters per day in 2000) (LLNL 2001b). Retention tanks would be used to capture research-related biological liquid waste to ensure disinfection is adequate prior to discharge to the sanitary sewer system. There would be no need for waste accumulation areas since no hazardous waste would be produced (hazardous chemicals would be used up in process or leave the building as a stabilizing product for microorganisms and biological material).

Decontamination and Decommissioning. At the conclusion of operations, the building would be fumigated and surfaces would likely be washed down with dilute concentrations of household bleach to kill any pathogens. No appreciable hazardous waste would be generated from this operation. D&D of this facility would mainly generate solid waste which would be comprised almost entirely of construction debris. Construction debris is comprised primarily of wood, concrete, gypsum wall board, metal, asphalt, paper and plastic and would be typical of waste expected to be generated during demolition of any laboratory or light-industrial facility. This solid waste would probably be disposed at the Altamont Landfill (Alameda County Landfill).

4.1.6 Geology/Soils/Seismology

Site Preparation and Construction. Except for the temporary disturbance of up to a depth of a few feet on parts of one-quarter acre of land during site preparation and construction, there would be a negligible effect upon geology, soils, or seismicity. Soil erosion prevention measures (application of the SWPP Plan for mainsite LLNL activities) 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 areas not covered by the building footprint or by parking areas would be reseeded.

Operation. There would be no effect from the proposed BSL-3 facility operation on geology, soils, or seismicity. Soils surfaces not covered by the building footprint or not paved would be landscaped to control erosion from stormwater runoff.

Decontamination and Decommissioning. Except for the temporary disturbance of portions of up to one-quarter acre of land during building demolition, there would be a negligible effect upon geology, soils, or seismicity. As noted above, soil erosion prevention measures would be in place during this phase to minimize erosion from stormwater. Also, dust suppression measures would be employed to minimize wind erosion. Once demolished, the building debris would be removed and the site would be stabilized for water and wind erosion.

4.2 ANALYSIS OF ABNORMAL EVENTS AND ACCIDENT SCENARIOS

4.2.1 Site Preparation and Construction

The site preparation and construction part of Section 4.1.2 deals with routine injury and illness related to nonresidential building construction. Routine accidents are those that commonly occur on construction sites (for example, slips, trips and falls). Because they are routine, they are not considered abnormal events, nor do they take into consideration accidents with more substantial consequences, such as those resulting from catastrophic events. The Proposed Action facility has the potential to be affected by earth movements due to earthquakes. The maximum predicted ground surface acceleration of 0.6 g has an annual probability of exceedance of 10^{-3}. This magnitude of earthquake could cause damage to the proposed one-story building during construction and could injure construction workers by physical mass-movement. However, no RCRA-regulated hazardous materials or pathogens would be present during construction, and therefore no exposures to these materials would result to workers or the public from a seismic event. Once constructed, the facility would be capable of withstanding the predicted g-force (i.e., Performance Category-2, LLNL 2001c).

4.2.2 Operation

This section evaluates potential abnormal event scenarios for operation of the BSL-3 facility that have 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 involving similar laboratory activities. 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, needlesticks. 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, and the potential for transportation accidents.

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. 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 B, Section B.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 its 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 appears to be much lower today in large part due to decreased laboratory activity levels since 1968, and in part due to greatly improved preventive measures.

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 rarely occur and the primary route of exposure is through autoinnoculation by the unintentional injection or needle-stick (Sewell 1995). Needles would be used in the proposed BSL-3 facility. Broken glass with sharp edges could result from accidents with (infrequently used) glassware. Broken glass, needlesticks or even scalpels present a low likelihood of exposure but are obvious when they happen and can be promptly treated with antibiotics, antiviral drugs, or other appropriate medical strategies. The potential for accidental laboratory-acquired infection by these means would be reduced to the improbable level of occurrence.

The Laboratory Release Accident Scenario. The potentially hazardous material to be handled in the proposed facility would consist of infectious microorganisms in containers holding liquid suspensions or on semi-solid media. Accident scenarios usually envisioned for DOE facilities would normally be seen to exacerbate or enhance a release or spread of the hazardous materials, but for the BSL-3 facility would potentially render these materials innocuous (heat, fire, sunlight, and wind). These would be avoided when working 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 radiological or chemical accident analyses, were viewed as having the potential to actually reduce the consequences of microbiological material 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 hypothetical centrifuge-accident analysis of a *Coxiella burnetti* release from the proposed BSL-3 facility structure described later in this section. The probability of catastrophic events (due to earthquake) is already very low. The low probability of an earthquake capable of rupturing the facility containment, coupled with an additionally low probability of such an event occurring during a daytime activity where microorganism containment would be vulnerable, also makes it an unlikely event. The proposed laboratory hypothetical centrifuge accident-release scenario, which itself is very unlikely due to the simultaneous occurrence of several events/conditions that must be combined to produce a release, bounds the catastrophic release scenario. Appendix B provides background information on microbiological accidents.

The BSL-3 facility would have only a few operations or activities that would hypothetically place up to 1 liter 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) would be 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. 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, the first being 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 B 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. 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 LLNL. The reason this accident analysis should be considered relevant to the proposed BSL-3 facility at LLNL is because the PEIS analyzed BSL-3 facilities with engineering and operating characteristics similar to those proposed for LLNL, such as similar HVAC system designs for negative pressure and air turnover; the facilities having 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 DA's accident analysis modeling and the conditions at the proposed LLNL 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 scenario assumes to have essentially non-windy site conditions and nearby non-involved facility workers and members of the public. The LLNL site is usually windy and members of the public would usually be a minimum of one-half mile away. The differences in the DA's modeling assumptions and the conditions at LLNL result in the accident analysis being much more conservative for LLNL conditions than the analysis modeled at the DA site. Therefore, the effects of such a scenario, if it were to actually occur, would be much less adverse at LLNL 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 other environmental conditions. The estimated human infective dose (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 animal prions and human parasites are Risk Group 1 or Risk Group 2 microorganisms. Only one fungus identified by the CDC requires BSL-3 and all the rest only require BSL-2 or below (CDC 1999). Many viruses require BSL-3 procedures and

equipment 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 procedures and equipment.

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 immunocompetency 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 also considered a critical biological agent[25] (CDC 2000a).

The scenario for the MCE (detailed in Appendix B) 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 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 co-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 only 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 for 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 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.

[25] 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.

This hypothetical accident can be used as a bounding accident analysis for the Proposed Action LLNL BSL-3 facility. However, it is exceedingly conservative. From a slightly more realistic perspective, there are some aspects of this accident scenario that would significantly lessen the possible outcome to the point that it would not produce even one HID_{50} at the end of the stack in the case of the proposed facility at LLNL. Some of these are:

- Cultures in a centrifuge in their stationary phase (with 10^8 cells per ml) would quickly pack to the bottom of the centrifuge tube and the upper liquid phase that would become aerosolized would have very few cells (depending upon when the accident occurred in the cycle) – therefore the concentration of cells in the aerosol would likely be many orders of magnitude below that used for the analysis (extremely conservative).
- At LLNL (and most small BSL-3 laboratories) normally only two workers would be allowed in a BSL-3 laboratory at a time for safety reasons.
- In an emergency response mode, the responder would enter only after ascertaining the risk and donning appropriate personal protective equipment.
- The worker(s) would have the appropriate prophylaxis available or immunization prior to working in the laboratory and would not become symptomatic.
- If all the room air were doubly HEPA-filtered with each at a minimum of 95 percent efficiency, the overall filtration would be 99.75 percent efficiency (passing through the first filter with 95 percent efficiency would leave 5 percent to pass through and the second filter would remove 95 percent of the 5 percent – resulting in 99.75 percent overall removal efficiency).
- HEPA filtration is rated at 99.97 percent efficient at the most penetrating design point of 0.3 microns using the DOP standard for calibration and measurement which is a uniform size, shape, and non-charged. Removal efficiency is not based upon size alone because there are several physical processes which actually cause the particulate removal. Penetration of larger- or smaller-sized particulates than 0.1 to 0.3 microns (the most penetrating size range) is negligible (less than 0.03 percent). Actual microbes, especially wet, have biofilms on their surfaces, are not uniform in size or shape, agglomerate together, and would not likely penetrate even at 95 percent efficiency because of their physical characteristics.
- The hypothetical accident results of even these extremely small effects rely on compounding of several independent actions whose combined probability of sequential occurrence would be extremely low (o-rings are not inserted, caps not screwed on properly, all six tubes leak, the worker opens the lid not realizing the tubes leaked, the worker gets two other workers to come over and look, and four more enter not knowing what has happened).
- The aerosol efficiency of 0.1% assumed for the scenario is at least one order of magnitude higher than would be likely in a real situation.
- The modeling assumptions (as described in Appendix B) are for the most stable open-terrain conditions and LLNL is both urban and non-open due to the predominance of buildings and trees which increase turbulence and tortuosity (i.e., mixing) and settling.

- Increases in wind speed over the modeled rate of 4.5 mph would increase aerosol dilution while humidity (not considered by the model) enhances the settling of particulates and would also decrease airborne concentrations.
- The normal high rate of air-changes for a laboratory like this would not generate a single "concentrated slug" of aerosolized material to exit the building as proposed in the model.
- Last, but not least, Risk Group 3 agents (those handled in BSL-3 laboratories) are associated with serious or lethal human diseases for which preventative or therapeutic intervention may be available (high individual risk but low community risk).

The conclusion is that members of the public would have a very low likelihood of being exposed to even a small fraction of one HID_{50}. At LLNL, the nearest member of the public is about one-half mile away. Adverse health effects to uninvolved workers in adjacent buildings or 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). 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). Information extracted from the DOT Hazardous Materials Information System (HMIS) database (DOT 2001b) on infectious substances transportation from 1995 to 1999 show that infectious substance incidents are too few to even be ranked. There is, however, an apparent national increase in overall 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 federal 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. LLNL has never had a biological-material transportation incident (PC 2002).

4.3 REMODEL/UPGRADE ALTERNATIVE

Construction: This alternative would mainly be disruptive to the other workers in the building being remodeled or upgraded. The first step would be deconstruction of the identified laboratory. The laboratory room would first be stripped to the bare walls, floor and ceiling. Ducting, plumbing and electrical work would be done next, then new walls would be installed that could be made seamless. This work would be noisy, but periodic exceedance of the OSHA standard would be infrequent, depending upon the specific task. This activity could interrupt research in adjacent laboratories due to the additional dust, vibration, and the effect on electrical or "plumbed" service being periodically shut off. The most difficult task would be air-balancing of the BSC and the effects of activities in the adjacent laboratories.

Operations. The effects of operation would be the same as for the Proposed Action.

Decontamination and Decommissioning. The effects of D&D would be the same as for the Proposed Action.

4.4 CONSTRUCT ON-SITE ALTERNATIVE

Site Preparation and Construction. The difference between this alternative and the Proposed Action is the time it would take to construct the facility at the proposed LLNL site. This alternative would mainly be more disruptive to workers in the adjacent buildings for a longer time (many months).

Operations. The effects of operation would be the same as for the Proposed Action.

Decontamination and Decommissioning. The effects of D&D would be the same as for the Proposed Action.

4.5 ENVIRONMENTAL CONSEQUENCES OF THE NO ACTION ALTERNATIVE

Under this alternative, LLNL would continue contracting with other laboratories for services or laboratory space for the work proposed for the BSL-3 laboratory. This would represent no change in the level of operations at LLNL, even though mission requirements can be expected to continue to grow. 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.

While not considered a "resource area" for analysis of impacts, continuing problems with the quality and security of data produced by outside laboratories could adversely affect the ability of LLNL to conduct high-quality, efficient research on BSL-3 organisms and may additionally adversely affect 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 Building 360 Complex Area and adjacent lands.

LLNL Operations at the Building 360 Complex Area. No new types of operations and very few, if any, new personnel would be introduced into LLNL as a result of the Proposed Action. Land use within the Building 360 Complex Area would remain unchanged. Local traffic congestion would be unaffected by the Proposed Action since there would be no net increase expected in the number of workers for the Complex Area.

Due to the small size of the proposed facility the projected quantities of water, wastewater, and energy consumption would be insignificant relative to that used by LLNL. All workers in the proposed facility would likely be relocated from adjacent buildings and the net increases due to the new facility in these areas would be expected to be very minor.

Parking availability in the Building 360 Complex Area would change from the current configuration due to the effects of removal of parking spaces to erect the proposed new facility. However, since adjacent parking lots are existing and readily available, the Proposed Action would not significantly alter the general employee parking space availability at LLNL.

The overall visual quality within the Building 360 Complex Area would not change significantly because the new construction is in the middle of and directly adjacent to several older buildings. The minor negative effects on viewsheds of LLNL-area development and the slightly increased lighting in the night sky would be considered a minor regional effect. The Proposed Action is not expected to be a major contributor to this effect; 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.

Implementing the Proposed Action would generate noise primarily during the daytime hours during initial construction activities and during D&D. This noise generation would be mostly confined to the immediate Building 360 Complex Area and would be mostly heard only by the involved workers.

Alameda County, the City of Livermore, and LLNL have historically been in a non-attainment area for air quality with regards to criteria pollutants; but, visibility has always been excellent. Implementation of the Proposed Action is expected to have an insignificant impact on the overall air quality of the valley.

As stated in Table 3-1 (Section 3.2), there would be no Environmental Justice issues associated with the proposed facility since there would be no disproportionately higher adverse human health or environmental effects on low income or minority populations.

6.0 AGENCIES AND PERSONS CONSULTED

In the process of preparing material for 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 project-specific consultation with the U.S. Fish and Wildlife Service was conducted in compliance with the *Endangered Species Act (ESA)*, as the Proposed Action and alternatives would not be expected to affect either individuals of threatened or endangered species or their critical habitat. Recent sitewide consultations under Section 7 of the ESA were conducted by the DOE in 1997 and 1998 concerning maintenance activities at LLNL. No consultation with the State Historic Preservation Office was conducted in compliance with the *National Historic Preservation Act* (16 U.S.C. § 470, 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).

7 U.S.C. § 2131-2157: Title 7 U.S. Code Section 2131-2157, "Animal Welfare Act," as Amended.

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 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).

16 U.S.C. § 430: Title 16 U.S. Code Section 430, "American Antiquities Act," as Amended.

16 U.S.C. § 470: Title 16 U.S. Code Section 470, "National Historical Preservation Act," as Amended (and 36 CFR 800.5).

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.

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APPENDIX A: CDC GUIDANCE AND INFORMATION ON MICROORGANISMS

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." (BMBL Dedication, CDC 1999)

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.

CDC 1999; Centers for Disease Control and Prevention, "Biosafety in Microbiological and Biomedical Laboratories," report by the Centers for Disease Control and Prevention and the National Institutes of Health, 4th Edition, Washington D.C. (April 1999).

Laboratory Biosafety Level Criteria

The essential elements of the four biosafety levels for activities involving infectious microorganisms and laboratory animals are summarized in Tables of 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 covered 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 of 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 Class 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.

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 LLNL 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, then the CDC would consider this strain to

be exempt from this regulation. If the strain of the select agent LLNL would be working with does not meet the above criteria, then it would still considered a select agent and would not be exempt from the regulation. In this case, LLNL 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.

A.3: BACKGROUND INFORMATION ON UNDERSTANDING INFECTIOUS MICROORGANISMS AND THE LLNL 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. 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 CFR 171-178).

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 at the end of Appendix A. 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 at the end of Appendix A 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 their entirety in this EA due to their large size.

LLNL Proposed Action Microorganisms. LLNL 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 at the end of Appendix A. Only by prior approval of the LLNL 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].

[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.

LLNL has an immediate interest in any organism or toxin identified as a "select agent" by the CDC. Also of interest are Dengue virus, West Nile fever virus, and Wheat rust (*Tilletia spp*. fungi). The tables at the end of this appendix include all of the select agents and many additional microorganisms.

These microorganisms could be processed a number of ways, for example:

- Selective culturing[5]
- Sample amplification[6]
- Chemical separation of parts (e.g., DNA, RNA, protein expression)
- Centrifugation[7]
- Freezing
- Decontamination by autoclaving[8]
- Decontamination by chemical disinfection

[2] Proteins are building blocks of cells and are used for support, storage, transport of substances, and defense against invaders.
[3] Attenuatedorganisms that have been deactivated by various means so that they have very limited growth potential or pathogenicity.
[4] A vegetative form is one that is capable of actively growing.
[5] Selective culturing uses nutrients and environmental controls to enhance the growth of some microorganisms relative to others which might also be present.
[6] Amplification is the process to rapidly and significantly increase the number of microorganisms in a sample.
[7] Centrifugation is the process of spinning a sample at a high rate of revolution to cause a separation of materials based upon their density.
[8] Autoclaving is the process of using steam under pressure for a sufficient time to produce sterilization of materials.

Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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.*				
Bartonella	*bacilliformis*				3 implied
Bartonella	*elizabethae*				3 implied
Bartonella	*spp.*				3

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AP - animal pathogen
* activities with high droplet or aerosol production potential
✸ applicable organism

Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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
Campylobacter	*laridis*				
Campylobacter	*spp.*		2 implied		
Campylobacter	*sputorum*				
Capnocytophaga	*spp.*				
Cardiobacterum	*hominis*				
Chlamydia	*pneumoniae*		2/3*		2
Chlamydia	*psittaci*		2/3*		2

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Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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.*				
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

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Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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*				
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*				

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Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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
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*				

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Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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
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

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Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Rickettsia	*rhipicephali*				
Rickettsia	*rickettsii*	✸	2/3 (I/E)		3
Rickettsia	*sennetsu*				
Rickettsia	*sibirica*		2/3 (I/E)		3
Rickettsia	*spp.*				
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
Streptococcus	*spp.*				2

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Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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*)				

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Table A-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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)		
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

[1] Basic name and viral group list is from ABSA 1998 with some additions.
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E -- Requires export permit from CDC and/or Department of Commerce or USDA
I -- Requires import permit from CDC and/or Department 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 A-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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
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				

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Table A-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Herpesviridae/ Betaherpesviridae	Cytomegalovirus (CMV) (Genus Lymphocryptovirus)		2		2
Herpesviridae/ Gamma-herpesviridae	Epstein-Barr virus (EBV)		2		2
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
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

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Table A-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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
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

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Table A-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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		
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

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Table A-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
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
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 A-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)
Claduphialopora	*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*				
Microsporum	*spp*		2		2
Mucor	*spp*				
Neotestudina	*rosatii*				

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Table A-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]
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*				

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Table A-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
Brugia	*timori*	Helminth, Nematode				2
Capillaria	*philippinensis*	Helminth, Nematode				

[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 A-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]
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				
Dracunculus	*medinensis*	Helminth, Nematode				
Dracunculus	*spp*	Helminth, Nematode				
Echinococcus	*granulosis*	Helminth, Cestode		2 implied		2
Echinococcus	*multilocularis*	Helminth, Cestode		2 implied		2

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[2] Select agent list is from 42 CFR 72

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Table A-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]
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
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

[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 A-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]
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
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

[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 A-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]
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
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				

[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 A-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]
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.

[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

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APPENDIX C: **Public Comments**

C.1 Response to Public Comment Letters/Email Messages

1. NEPA COMPLIANCE: DOCUMENTATION/REVIEW LEVEL.

Several commentors expressed the opinion that a BSL-3 facility at LLNL would allow for experiments with a broad spectrum of biotoxins and biological materials/agents. They believed that this would be a new program for DOE and LLNL that, if inadequately analyzed before proceeding, could endanger the workers and the community. Commentors indicated that the draft EA provided only boilerplate assertions that the risks would be negligible, and relies on adherence to procedures, some of which DOE laboratories have not followed in the past according to the commentors. Consequently, they believe that a further environmental review in the form of a project-specific Environmental Impact Statement (EIS) should be conducted. Some of the same commentors were of the opinion that the proposed project represents an integrated new program area for the DOE, and as such, a Programmatic EIS (PEIS) should be prepared to review the effects of undertaking work in this "new" mission area. Several commentors expressed the opinion that the purpose and need for the proposed action at LLNL is without precedent, and the commentors called for a complete NEPA review (PEIS) of the NNSA Chemical and Biological National Security Program (CBNP) which some referred to as the "Chemical and Biological Nonproliferation Program."

Response
LLNL has been a national focus of bioscience research for almost four decades. Bioscience researchers at LLNL already safely conduct research at BSL-1 and BSL-2 levels in disease susceptibility, prevention, diagnosis, treatment, and rehabilitation and in support of National Institutes of Health (NIH), DOE, and NNSA mission requirements, LLNL already works on research aimed at detection and identification of biological warfare agents. The Biology and Biotechnology Research Program (BBRP) at LLNL also contributes to a number of high-profile national-level efforts in both health-related bioscience research and in developing defenses against the potential use of biological-warfare agents against either our civilian population or military forces. This work involves close cooperation with other national laboratories, DOE, and other agencies (e.g., health, military, and law enforcement). Currently, research conducted at the existing LLNL BSL-2 laboratories involves anthrax (Bacillus anthracis) and plague (Yersinia pestis). This research includes supporting development of tests for quick identification of plague based on a DNA signature and the development of decontamination reagents. Operation of a BSL-3 facility would not constitute a new or unique role for LLNL, would not be inconsistent with existing DOE mission work, and would not be unique or without precedent.

The EA analysis considered effects relating to human health, ecological resources, air quality, noise, waste management, soils, geology, and seismology. Effects to these resource areas were minor in nature. Human health effects are expected to be no different from those at other U.S. Centers for Disease Control and Prevention (CDC)-registered laboratories operated according to CDC and NIH guidelines. Those laboratories experience very infrequent worker accidents

with minor or no consequences to workers and members of the public. Socioeconomics, visual resources, transportation, utilities and infrastructure, cultural resources, environmental justice, and environmental restoration resources were identified as being unaffected by the construction and operation of the BSL-3 facility; or as being minimally affected and inherently mitigated by the project design; or as being minimally affected and temporary and intermittent in nature. Because the potential effects of the project are not significant in terms of context and intensity, the NNSA has concluded that the potential project effects do not require preparation of a project-specific EIS.

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 (CEQ's) NEPA Implementing Regulations (40 CFR 1508.18(b)(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 regulations speak to the scope of NEPA EISs (40 CFR 1508.25(a)(1)) and to connected actions such as those that "automatically trigger other actions which may require EISs"; "cannot or will not proceed unless other actions are taken previously or simultaneously"; or "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 individual studies and research projects have been conducted over the years both for the benefit of 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 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 and 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, in as much 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 the 1996 Congressional passage of the Defense Against Weapons of Mass Destruction Act, which authorized the DOE to establish a Chemical and Biological Weapons Nonproliferation Program (now known as the Chemical and Biological National Security 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 CEQ'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 CEQ'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 meet NNSA's NEPA compliance requirements with regard to the construction and operation of the proposed BSL-3 facility at LLNL.

2. SAFETY OF LABORATORY OPERATIONS

Several commentors expressed the general opinion that LLNL has a history of leaks, spills, fires, explosions and accidents. They indicated that this information concerning operational history is relevant but is not included in the draft EA on DOE's response to build and operate a BSL-3 facility. Commentors also stated that the CDC is more qualified than LLNL and they should be handling the BSL-3 research. Commentors expressed the opinion that issues of safety of lab operations are especially important in light of the February 2001 DOE Office of Inspector General (IG) report entitled "Inspection of Department of Energy Activities Involving Biological Select Agents." Some commentors also felt that it is "a huge leap between BSL-2 and 3 facilities" and that "safety measures and procedures… are vastly different, as are the risks." Another commentor stated in reference to the IBC that "there is no indication whether there will be a process to guarantee full public scrutiny of committee deliberations."

Response

Since it was founded in 1952, LLNL has been managed by the University of California. While mistakes, accidents, leaks, and spills will inevitably occur, LLNL is committed to providing employees and the community with a safe and healthy environment. LLNL has had an infrequent history of incidents and none has resulted in a significant impact to the public or the environment. In 2000, DOE's Integrated Safety Management System (ISMS) was implemented at LLNL, resulting in better safety practices and greater safety awareness. A DOE Verification Team inspected safety procedures at 25 facilities across the Laboratory, reviewed over 700 supporting documents, and determined that LLNL effectively implemented ISMS. The response to comment 11 (Waste Disposal) below discusses LLNL's compliance with permit limits for discharges into the sanitary sewer (between 99 and 100 percent compliance from 1996 to 2000) and LLNL's record of inspections for compliance with the California Medical Waste Management Act. As discussed in Section 4.1.2 of the Draft EA, LLNL has operated BSL-1- and BSL-2-equivalent laboratories for the last 20 years without any infections associated with their operations and no unintentional releases to the environment or to the public.

The CDC, which is part of the Department of Health and Human Services, provides guidelines for the operation of BSL-3 facilities, registers facilities that will access, use and transfer select agents, and then periodically inspects these facilities during operation. The CDC through the Antiterrorism and Effective Death Penalty Act of 1966 (See Appendix A-2) controls the transfer and receipt of select agents. As described in Appendix A-1, each successive CDC-defined

biosafety level builds upon the previous level practices, safety equipment (primary barriers), and facility requirements (secondary barriers). These practices go, for example, from limited access to controlled access, decontamination of only "needed waste" to all waste, and defining medical surveillance requirements to requiring specific baseline serum. Safety equipment requirements for BSL-2 and BSL-3 laboratories are the same, except that in a BSL-2 facility the biosafety cabinets (BSC) are required only for manipulations of agents that cause splashes or aerosols of infectious materials. In a BSL-3 facility all open manipulations are conducted in a BSC. BSL-3 laboratories within facilities need physical separation of areas, self-closing double-door access, and controls on ventilation systems that do not permit air recirculation and have negative airflow into BSL-3 laboratories. BSL-2 laboratories do not have these requirements. Therefore, the engineering controls built into a BSL-3 facility are significant, but there is not a huge technological difference between a BSL-2 facility and a BSL-3 facility. LLNL institutionally uses the same types of facility controls in its other facilities.

CDC laboratories perform work that is different from the research work performed at LLNL. The CDC contracts with DOE and NNSA facilities, as well as with other government and private facilities (due to their capabilities), to perform much of its needed research work, rather than duplicating the research expertise of these agencies within the Department of Health and Human Services. While it is the opinion of some commentors that only the CDC should perform this work, this is neither cost effective nor practical. (Safety measures are discussed further under the response to comment topic 5).

The IG report cited by the commentors (DOE/IG-0492 dated February 2001) states at the beginning of the 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", 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 is conducted. At the time of the IG inspection, LLNL had already incorporated the provisions of the CDC/NIH Guidelines into its work standards for operation of its BSL-2-level facilities and was compliant with its provisions. The IG report had no adverse findings with regard to LLNL activities involving operation with biological select agents. DOEs operating contract with the University of California (UC) also requires that LLNL implement the CDC/NIH Guidelines through their Work Smart Standards and their ES&H Manual.

The currently established Institutional Biosafety Committee (IBC) will have authority over approving projects conducted at the proposed BSL-3 facility at LLNL, as it does for current BSL-1 and BSL-2 operations at LLNL. (The role of the IBC is discussed further under the response to comment topic 4 below.) NNSA will maintain strict adherence to the CDC and NIH guidelines

for operating a facility of this nature. DOE oversight actions would also continue to be responsive to the recommendations made by the IG report.

(Additional responses related to safety are discussed under comment topic 5 and security measures are addressed in comment topic 7 below.)

3. DEFENSIVE- VS. OFFENSIVE-ORIENTED RESEARCH

Several commentors expressed their concerns about siting a BSL-3 facility at a nuclear weapons design lab. The commentors questioned how the DOE would prove that this new work with bio-agents is defensive and would not be used in the future for the manufacture of biological weaponry. The commentors expressed their opinions that the proposed culture of some organisms (*Brucella spp.*, *Coccidiodes immitis*) suggests the potential development of agents that could aid U.S. offensive military operations. Commentors also expressed concerns about collocating a BSL-3 facility close to the existing LLNL Environmental Microbial Biotechnology Facility (EMBF), suggesting that it implied existence of future operation of an offensive biological weapons program at LLNL. The commentors were of the opinion that, since the EMBF is a biological fermentor with a capacity in excess of 1500 liters, the facility could be used for industrial-scale production of biological select agents with weapons applications. Commentors cited the proposed production of up to one liter of biological agent at the BSL-3 facility as excessive for defensive research purposes, suggesting that gram or sub-gram quantities of any agent are sufficient for such research. The proposed rodent aerosol challenge tests prompted commentors to infer that this would necessitate weaponization of agents and could pose increased dangers to workers and the public. It was the commentors' opinion that the Draft EA failed to address the risks posed by the aerosolizing, or as the commentor alleges: "weaponization." Another commentor stated that the proposed facility is not a small facility based upon CDC definitions (42CFR72.6(j)). One commentor expressed the opinion that, in addition to a Programmatic NEPA review of DOE's biological warfare defense research, a Nonproliferation Impact review should be conducted.

Response
NNSA acknowledges that many people are opposed to the research, development, and testing of nuclear weapons, weapons research, and testing using live microorganisms. However, Congress directs DOE and NNSA with regards to the missions, and work performed at their facilities must support congressionally mandated missions. Similarly, the Department of Defense (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 discussed in the response to comment topic 1 above, defensive biological research is ongoing at LLNL, is performed in support of DOE and NNSA mission requirements, and would not be inconsistent with existing DOE mission work.

NNSA also acknowledges that certain individuals might see the proposed BSL-3 facility as adding to the perception that the U.S. plans to prepare bioweapons for development of an offensive capability. However, the U.S. is a signatory to the Biological and Toxins Weapons Convention Treaty and has agreed that this nation shall not perform the actual development and production of bioweapons. Additionally, all such U.S. offensive capabilities were destroyed and

offensive-oriented research was halted after the 1969 Presidential decision. Nonetheless, if the U.S. were indeed now planning a major departure in its 33-year-old policy on offensive capabilities, such work would require a facility with different functional capability and of a larger size than the proposed three-laboratory room BSL-3 facility. The microbiological research sample preparation equipment being proposed for the LLNL BSL-3 laboratory would not be the correct type needed to support a bioweapons production facility. Unlike the proposed BSL-3 facility at LLNL, a bioweapons production laboratory would require much more floor space to accommodate a sizeable worker staff and multiple pieces of specialized equipment. DOE does not now, and does not propose to, conduct research or engage in preparation or production of biological materials or toxins for potentially offensive use or purposes at LLNL and it would not be allowed under the Biological Weapons Convention.

It is true that a number of organisms that could potentially be used in research at the proposed BSL-3 facility, including the organisms mentioned by the commentor, could have offensive uses. But research currently being conducted by LLNL and proposed research in a BSL-3 facility would be for defensive purposes. For example, work conducted at LLNL by the Biology and Biotechnology Research Program (BBRP) in 2001 was focused on two areas: advanced detection systems to provide early warning of an attack; to identify the populations at risk, contaminated areas, and facilitate prompt treatment; and to develop DNA signatures and biological forensics technologies to identify the agent, its geographical origin, and/or the initial source of infection. The proposed BSL-3 facility is limited to quantities less than 10 liters (working with over10 liters of culture quantities defines the NIH threshold for a "large-scale research or production" facility). The proposed BSL-3 facility and its operation would be limited to less than 1 liter of cultured microorganisms as the maximum quantity handled in any BSL-3 laboratory room at any point in time. Some research that the proposed facility would conduct requires growth media of up to "liter-size" quantities in order to have sufficient material from which to extract enough genetic material to conduct certain types of genetic research such as that involving messenger RNA. Additionally, organisms such as Coccidiodes immitis, already being investigated by LLNL, are locally important (Valley fever or San Joaquin fever) and research on this is public health related and extremely important to California and the nation at large. DOE believes that work conducted in the facility will not lead to proliferation of offensive biological weapons capabilities and that the EA makes it clear that the proposed facility is not designed as a production facility for offensive research or weapons production. With regard to the additional need for a "Nonproliferation Impact Review" the NNSA is of the opinion that none is required. While NNSA will ensure that the proposed facility would comply with the BWC there is no formal process requiring a "Nonproliferation Impact Review" per se and therefore none would be implemented by the NNSA.

There is no affiliation between the EMBF's 1500-liter fermentor and the proposed BSL-3 facility. The EMBF was established for the investigation, development, and growth of microorganisms that have environmental remediation applications. The facility can also be used for other biotechnological studies, such as the production of microbial pharmaceuticals and food additives. However, the facility is not suited for activities involving pathogenic organisms. BSL-3 facility protocols and engineering and design requirements in conformance with CDC guidance are quite stringent (CDC Biosafety Level Criteria are included in Appendix A-1 to this EA). The EMBF is <u>not designed</u> to meet these BSL-3 criteria, is not being proposed for

operation at the BSL-3 level, and would not be easy to retrofit to meet these criteria. Also, as noted earlier, all biological work conducted at LLNL must be reviewed by the Laboratory Biosafety Operations Committee (LBOC) and, when involving pathogenic organisms specifically, reviewed and approved by the IBC. Work that is not in conformance with federal regulations, CDC/NIH Guidelines, DOE Orders, and LLNL directives cannot be performed because it would not be approved by the IBC and would not be in conformance with provisions of the U.C. contract with DOE.

The term "weaponization" in reference to biological agents can be broadly defined as "the design, and production and storage in large quantity, of biological agents and their delivery systems for military purposes." This is not being done at LLNL, and is not a part of a DOE proposal. Aerosol challenges do not imply "weaponization". An aerosol challenge is the method used to test a rodent by inhalation. The route of pathogen exposure affects the timing for onset of symptoms and it is the inhalation pathway that is one of the quickest. Aerosol challenge allows for testing of detection assays, treatment regimens, and medical intervention approaches as a consequence of inhalation exposures to pathogens. Nebulizers used for challenging test animals are frequently employed in private industry, including in the research and development of cosmetic products. The research proposed for the BSL-3 facility would involve growing and culturing agents, and in some cases challenging rodents by means of administering agents with a nebulizer. Again, no technology is being proposed, developed, or adapted at LLNL for the purpose of "weaponizing" agents.

4. COMPLIANCE WITH BIOLOGICAL WEAPONS CONVENTION

A commentor expressed concern that the proposed work would undermine the Biological Weapons Convention and be viewed with suspicion by the world community. Additionally, the commentor remarked that the draft EA gives no indication of how BWC compliance would be instituted. Several commentors were of the opinion that the draft EA does not provide a process to guarantee public scrutiny of the LLNL biosafety committee deliberations and decision making.

Response
U.S. participation in the Biological Weapons Convention is discussed under topic 3 above.

The proposed BSL-3 facility would be operated according to all guidance and requirements established by such agencies as the CDC, NIH, USDA, DOE and LLNL. Specific guidance references are detailed in Section 2.1.2 of this EA. NIH guidelines require that an IBC be appointed by an institution to provide local and institutional oversight and approval of potentially hazardous lines of biological research (NIH 2001). Section IV-B-2 of the NIH guidelines establishes procedures that the IBC shall follow in its role of review and approval responsibility. These guidelines include review and approval of applications, proposals, and activities; and making available to the public, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies must make available to the public. As detailed in this EA and in the NIH guidelines, at least two members of the IBC are not affiliated with LLNL and they represent the interest of the surrounding community with respect to health and protection of the environment. These IBC members may

be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns of the community. Since the IBC is ultimately responsible for ensuring that research conducted at, or sponsored by, LLNL is in compliance with applicable guidelines or regulations, this ensures that the public will be involved in approval of BSL-3 research and review of safety and compliance protocol as it does now for certain BSL-2-level projects. It is possible that some specific project information will be subject to DOE security and classification restrictions, and will consequently not be made available to the public. All proposed microbiological research projects at LLNL, even projects with classified portions, will undergo review and approval by the IBC.

The IBC was established at LLNL in 1991 to ensure compliance with recognized guidelines and regulations concerning research with recombinant DNA or human, animal, and plant pathogens. In 1998, the IBC registered LLNL under the Laboratory Registration and Select Agent Transfer Program of CDC. As currently practiced at LLNL, the IBC must approve all research in the cited subject areas prior to commencement.

5. PUBLIC HEALTH AND SAFETY, AND WORKER SAFETY ISSUES

Comments regarding the issue of public health and safety ranged from general opposition to a BSL-3 facility at LLNL to specific concerns about the potential for accidents and the implementation of procedural safeguards. One commentor remarked that there was no evidence that LLNL conducted a preliminary hazards analysis for the proposed facility and another commentor stated that it was inappropriate to allow biological warfare agent research so close to a major population center. Commentors also expressed the opinion that anticipated work with genetically modified organisms would pose unique or unknown risks to the general public, emergency personnel, and regional medical workers. Commentors expressed concern about how LLNL would respond in the event of an accident at the BSL-3 and how the lab would notify the public and provide information on emergency response actions during an accident.

One commentor remarked that the Draft EA failed to address the effect that a release or exposure could have on the way a region functions. The commentor cited the anthrax attacks of 2001 as an example of the difficulties of determining the nature and extent of a hazard and the potential for entire facilities to close down, despite a relatively small number of casualties. One commentor stated an opinion that the immunization status of laboratory workers represents critical information that should be available to all employees of LLNL and residents of the area.

Response

A Preliminary Authorization Basis Document (analogous to a preliminary hazard analysis) would be completed and approved by NNSA prior to the facility being constructed. A Final Authorization Basis Document (analogous to a final hazard analysis) will be completed and approved by NNSA prior to the facility becoming operational. As for emergency response, the scope and extent of emergency planning and preparedness at LLNL are based on, and commensurate with, the hazards and potential consequences associated with a facility and its operation. The Laboratory uses an emergency management system (known as the Incident Command System) that is capable of responding to and mitigating the consequences resulting

from operational emergencies. Under this system LLNL coordinates with Livermore Police and Fire Departments who in turn notify the public during emergencies. The emergency management system also incorporates provisions and procedures for dialogue with and involvement of local area law enforcement, fire, emergency response agencies if necessary. Emergency response procedures are documented in the LLNL Environment, Safety & Health (ES&H) Manual. The requirements in the ES&H Manual are based on the Work Smart Standards (WSS) identified for the specific work and associated hazards and LLNL best practices that management has determined are requirements. The WSS set was derived from statutes, regulations, DOE Orders, and national and internally developed consensus standards. The ES&H Manual also describes the implementation of the ES&H management commitments made in the Laboratory's Integrated Safety Management System Description. Adherence to the requirements and processes described in the ES&H Manual ensures that safety documents across the Laboratory are developed and updated in a consistent manner.

NNSA is confident that the proposed BSL-3 facility at LLNL can be operated safely and securely.

The day-to-day functions of the proposed BSL-3 facility, and potential increase in the number of biological material shipments to and from the proposed BSL-3 facility do not portend a significant increase in the possibility of human health risks to workers or the public beyond those related to LLNL's current ongoing, routine, BSL-2-level activities.

The safe operation of over 250 BSL-3 facilities within the U.S. substantiates the analysis presented in this EA with regards to this issue. There are on the order of 40 BSL-3 facilities currently operating under the control of the University of California. Several of these are nearby at the UC San Francisco and UC Davis campuses. Representatives of the CDC are authorized to periodically inspect all BSL-3 facilities. When operational, CDC and NNSA would regularly inspect the BSL-3 facility at LLNL.

In reference to the immunization status of workers at LLNL, the information would be made available to proper authorities, such as the CDC. The immunization status of individual workers is part of their personal medical records and, as such, cannot be released to the general public. However, to reiterate from the EA (Section 2.1.2, Operations, pg 18), "Workers would be offered appropriate immunizations for the microorganisms being handled." Information about what immunizations are being offered to BSL-3 laboratory workers would be available from the regular meeting minute records of the IBC, as that pertains to controlling risk associated with proposed research. In the event of unusual epidemiological occurrences involving communicable diseases, information about the medical condition of affected workers would be made readily available to CDC and other authorized public health officials.

6. ACCIDENT ANALYSIS

Several commentors expressed the opinion that the Draft EA lacks a comprehensive analysis of earthquakes, and should address local and regional fault zones. Commentors called for a more thorough analysis of release possibilities and outcomes from seismic risks, as well as other natural disasters. One commentor expressed concern about the vulnerability of a prefabricated building versus that of a conventionally constructed building.

Several commentors pointed out that a 50-mile radius around LLNL embraces more than 7 million people as opposed to the 1.3 million stated in the Draft EA. Given the density and proximity of nearby populations, the commentors were of the opinion that the Draft EA lacked appropriate modeling for accidental releases. Commentors questioned the appropriateness of using accident scenario data related to operation of the U.S. Army Biological Defense Research Program (BDPR) or that of the existing BSL-2 labs operated by LLNL. The commentors stated that the U.S. Army has a long history of operating a BSL-3 facility, and neither DOE nor LLNL has comparable experience.

Commentors expressed the opinion that the Draft EA understated the potential risks of worker exposure, as well as subsequent potential risks of off-site transmission of diseases. Further, several commentors remarked that the process of aerosolizing agents could substantially increase the risk of release and exposure, especially in light of the quantity (up to one liter) of medium containing pathogens that would be permitted. Commentors were of the opinion that the Draft EA does not address the potential for failure of filter systems and called for a more complete analysis of the potential for HEPA filter failure. These commentors alleged that DOE has a poor record of maintenance with regard to operating HEPA filters in some of its nuclear facilities. Further, the commentors state that the Draft EA makes claims for the protective qualities of HEPA filters that exceed the documented record, citing DOE reports that the efficiency of HEPA filters for capture of particles in the 0.1 micron size range is less than the efficiency for the 0.3 micron-sized particles discussed in the Draft EA.

Response

The BSL-3 facility would incorporate design considerations for the occurrence of natural phenomena as appropriate for the LLNL site. The facility would be designed to the latest Performance Category 2 (PC-2) requirements of DOE Standard 1020-2002. Specifically, the seismic design would conform to the 2000 International Building Code, Seismic Use Group III, Criteria 2/3, MCE Ground Motion with an Importance Factor of 1.5. It would be operated under the requirements of LLNL ES&H Manual, Volume II, Part 10, Supplement 27.02, Earthquakes. According to Supplement 27.02, all structures over 5 feet in height must be seismically secured. Furthermore, incompatible materials must be segregated to mitigate spills that could cause chemical or biological releases, as well as fires or explosions due to chemical incompatibility.

In order to obtain a significant margin of safety a peak wind gust of 91 mph would be used as the design wind load, although it is an extremely unlikely event. Flooding is not a design consideration at the LLNL site, per the DOE's Final Environmental Impact Statement and Environmental Impact Report for the Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore [DOE, 1992]. Prefabricated modular units, if used for the proposed BSL-3 facility, would be required to be constructed to standards equal to those for a permanent on-site constructed facility, including earthquake and ground motion standards.

The 2000 U.S. Census reports that Alameda County has a population of approximately 1.4 million people (Health Resources and Human Services [HRSA] 2000). The 2000 LLNL Environmental Report (LLNL 2001b) states that there are 6.9 million residents within an 80-km

(approximately 50-miles) radius of the LLNL site. The EA will be changed to add the population of the 50-mile radius from LLNL.

The U.S. Army has been doing biological defense work for years, operating under the same safety protocol and CDC and NIH-developed guidelines as would be applicable at the proposed LLNL BSL-3 facility. This EA describes the Army's extensive experience working with hazardous infectious organisms and references their outstanding safety record to provide a perspective on the adequacy of following these guidelines in the safe operation of its facilities. The DOE has also been involved in biological defense research at LLNL and other facilities for years and has extensive BSL-2 facility experience. The BLS-2 laboratory staff at these facilities have safely handled many of the same agents that are proposed for handling in BSL-3 facilities. Highly trained individuals would operate the laboratory with modern equipment and in accordance with established nationally recognized guidelines and comprehensive oversight. Since 2000, LLNL researchers have safely worked with a number of strains of anthrax and plague at the BSL-2 level. The work has been conducted safely and in full compliance with all applicable security, health, and other administrative requirements and guidelines. NNSA is confident that DOE and LLNL have comprehensive and appropriate experience and trained personnel to safely operate the BSL-3 facility, and that potential risks to workers and non-workers have been adequately addressed in this EA.

The accident analysis scenario presented in the EA addresses the potential effects associated with an accident in which potential highly infectious cells would be disbursed into the environment from the proposed facility during its operation. Analysis of historical data related to the operation of other similar federal and industrial facilities shows that a significant release beyond the facility building is extremely unlikely to occur. The only releases that are probable would be contained within the building, which is a facility specifically designed for decontamination. Any accidental releases, if they occurred, would impact only a small area of the lab, which could easily be decontaminated. The likelihood of a wide area, city or population, effect should be considered improbable. The nature of the agents, dose/response potential, dispersion, the limited quantities involved, and the design of the building and safety protocols preclude a large-scale or widespread release potential. As described in the Draft EA, human pathogens for which there is no immunization or medical treatment available would not be handled in the proposed BSL-3 laboratory, in accordance with Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines.

In June 1999, LLNL imposed lifespan limits on HEPA filters, found in UCRL-AR-133354 Rev 1, "HEPA Filter and In-place Leak Testing Standard", of 10 years from date of manufacture if the filter is in a dry location or five years from date of manufacture or testing if it is where the filter could become wet, such as during a fire suppression system discharge. The HEPA filter installation proposed for the LLNL BSL-3 facility would be in accordance with accepted good practice for biological safety as specified in the nationally accepted criteria for biological safety, the Centers for Disease Control and Prevention/National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories (CDC 1999). Testing of HEPA filters in biological safety cabinets is part of the BSC certification and would be done in accordance with the National Sanitation Foundation (NSF International) Standard 49 as noted by the CDC (CDC

2000b). Performance testing of the HEPA filters would be conducted by NSF-accredited field certifiers.

NNSA acknowledged in the LLNL Supplement Analysis for Continued Operation of Lawrence Livermore National Laboratory and Sandia National Laboratories, Livermore (March 1999, DOE/EIS-0157-SA-01) the issue of reduced removal efficiency of HEPA filters for particles in the size range from 0.1 micron to 0.3 microns. The study which provided this information was from a dissertation written by Ronald C. Scripsick (Los Alamos National Laboratory Report, LA-12797-T, 1994). Even though the most penetrating particle size in his study was slightly smaller than the HEPA filter "most penetrating design point" of 0.3 microns, his results still showed a 99.97% removal efficiency or higher in the range from 0.148 to 0.196 microns. These removal efficiencies are higher than the removal efficiencies used for the accident scenario in this EA and therefore the scenario conclusions are unaffected by recognizing a smaller most penetrating particle size.

7. THREAT OF TERRORIST ATTACK/SABOTAGE

Commentors expressed a general opinion that the Draft EA does not adequately address external or internal security issues, citing that no security analysis is included in the document. Concerns included the potential for unauthorized access, the potential for removal of biological agents by a BSL-3 worker or other person, and the potential for a deliberate release of biological agents and subsequent risk to the surrounding community.

Commentors stated that the Draft EA does not address the possibility of terrorist attack, and in light of the September 11, 2001 events and anthrax mailings, consideration of terrorism and internal threats must be included in the NEPA analysis for the BSL-3 facility. One commentor stated an opinion that LLNL already represents a terrorist target and the addition of a BSL-3 facility, which the world may believe is for offensive research purposes, will exacerbate the threat of terrorism.

Response
As stated in the EA, physical security and safeguards would be based upon a security analysis conducted during the appropriate project planning stage. As in all facilities managed at LLNL, access is limited to only authorized DOE-badged personnel or under DOE-approved escort procedures. Safeguards would also be consistent with CDC/NIH guidelines. It would be imprudent to describe the specific security protocols in a public NEPA document as the commentor suggests. This is due in part to the relative high-security of the overall LLNL operations, and also to the limited and synoptic availability of significant quantities of viable pathogens due to the facility being focused on genetic research (on the parts of the microorganisms). Added to this is the extremely limited potential for a release of microorganisms from the multiple levels of bio-containment within the building. The level of security at LLNL and the uncertainty of available and viable microorganisms would preclude it from being a desirable or likely target for removal or theft of biological agents.

There are at least two reasons why the potential results of terrorist attacks are not currently included in NEPA analyses, nor are they anticipated for inclusion in detail in these analytical

documents in the near future. The first reason is that NEPA accident risk analysis is done for "reasonably foreseeable" accident events. While terrorist events are possible, these are not reasonably foreseeable accident events in the sense that a probability of occurrence could be determined for a NEPA analysis. This is not to say that NNSA would not evaluate possible terrorist actions and work to mitigate them. On the contrary, NNSA continuously strives to assess and remove potential threat opportunities. Secondly, regardless of the initiating event (whether naturally occurring, human-error, or malicious intent), the NEPA accident analysis scenario presented in this EA in which the rickettsia microorganism, C. burnetii, is accidentally released into the environment from the proposed facility is bounding in.

Terrorist attacks come under the realm of security and therefore are appropriately evaluated in a separate risk assessment. That risk assessment would determine what security measures would be taken to protect the facility. This assessment document and its details are not available for public review since this would defeat the purpose by making all security measures public knowledge. Terrorists could then use this information to better plan for future attacks—something that no one wishes to facilitate.

8. TRANSPORTATION SAFETY

One commentor expressed concern about the safety of biological material shipments, especially traveling through the USPS, to and from the facility. The commentor stated that the EA does not adequately analyze the possibility of a shipment of pathogens being intercepted.

Response

The volume of shipments of microorganisms into the proposed BSL-3 facility would 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 existing and ongoing LLNL bioscience and health technology research. Shipments out of the facility would also represent only a slight increase over existing levels of biological shipments. Both incoming and outgoing shipments are typically of milliliter- or micro liter-size samples packaged inside several layers of containment, per Department of Transportation (DOT) shipping requirements. The packaged samples are shipped via federal and commercial or private couriers and are tracked in accordance with nationally-accepted DOT and CDC requirements. Any increase in incidence of shipping accidents due to the incremental increase in the number of shipments to and from LLNL as a result of implementing the proposed BSL-3 facility would be negligible given the volume of mail and packages transported by these transport services. Similarly, any increase in vulnerability of biological agent shipments to terrorist seizure resulting from the incremental increase in shipments to or from LLNL would be negligible given the volume of mail and packages transported by these national-scale operations.

The EA notes that the shipment of samples to and from LLNL would involve materials packaged in accordance with DOT standards. The packaging required by DOT has already undergone extensive drop, crush, and other accident-condition testing, before DOT determined the safe and appropriate transport and packaging requirements for these types of samples. Using DOT standards for packaging and/or using couriers that transport the shipments according to DOT requirements does not result in an obligation by DOE to perform a unique NEPA review for

transport of its materials through common carriers. 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. Federal and commercial carriers have 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 in large numbers every day. Any increase in the risk of accident or terrorist attack because of shipments associated with the proposed BSL-3 facility at LLNL would be negligible.

9. PURPOSE AND NEED

A commentor expressed the opinion that the proposed action is not sufficiently justified in the "purpose and need" secton of the Draft EA. The commentor suggested that the DOE should look comprehensively at existing BSL-3 facilities and capabilities, so as not to duplicate capabilities by constructing a BSL-3 facility at LLNL. For example, the commentor questioned why the Draft EA did not discuss in more detail the option to conduct all the necessary BSL-3-level work at a BSL-3 facility currently used by LLNL (such as the CDC facility in Fort Collins) for its current projects. Additionally, commentors were of the opinion that the DOE is required to analyze whether the proposed Los Alamos National Laboratory (LANL) BSL-3 facility would provide an alternative to construction of the proposed facility at LLNL. Commentors questioned why it is necessary to have two BSL-3 facilities under the jurisdiction of the DOE, when BSL-3-level research could be done at one facility.

Response
LLNL conducts its own specific research, including understanding genetic and biochemical causes of disease, projects for countering biological terrorism, bioengineering research, and developing and applying computational biology capabilities. Many of these are unique to LLNL. Currently, DOE and NNSA research projects requiring BSL-3 sample preparation are contracted to universities or private sector laboratories. This procedure has increasingly become difficult and represents a barrier to continued efficient research for several reasons. Government and private sector projects requiring BSL-3-level facilities are on the rise, resulting in the existing laboratories being unable to accept as much outside work such as that represented by NNSA's/DOE's projects. Information security also needs to be carefully considered, since information associated with some samples requires a very high degree of physical security, which is not uniformly available through the use of contractor facilities. Additionally, scheduling difficulties at contract laboratories could seriously limit or compromise timely research projects. Quality assurance documentation, including chain of custody issues related to federal projects, are also essential to verifying data and interpreting results. It is critical to the research being conducted that the quality and security of samples not be compromised. If the DOE hopes to further the Nation's ability to detect and isolate microorganisms and treat victims of bioterrorism, enhanced capabilities are necessary at the location-centers for such research. For the reasons described above, the integrity of the research dictates that the BSL-3 facilities be under the direction of DOE, and the individual

National Laboratory. It is not possible to continue conduct of all the BSL-3-level research in a timely, efficient, cost-effective, or security-controlled manner at another laboratory.

Although construction of the LANL BSL-3 facility recently began, it is not operational and won't be until it has met all readiness requirements. In addition, the research currently conducted at LLNL is different from that at LANL, and it is likely that each facility will continue to have separate areas of expertise. LLNL and LANL staff members would continue to collaborate on technical matters relating to their separate research and development efforts, as they have been doing in the past. For these reasons, DOE and NNSA believe that it is not duplicative to have two BSL-3 facilities under the jurisdiction of the DOE.

10. ADEQUACY OF ALTERNATIVES ANALYSIS

A commentor expressed the opinion that the discussion of alternatives in the Draft EA is deficient, stressing that a careful analysis of alternatives is essential due to the risks of placing such a laboratory in a densely populated urban area. According to the commentor, the EA addresses only various ways to construct a BSL-3 facility at LLNL but does not compare other possibilities for accomplishing the mission, such as using other existing facilities, using government facilities to be constructed in the near future, or constructing a BSL-3 facility at another DOE site.

Response
The Draft EA presents a discussion of three different alternatives for construction and operation of a BSL-3 Facility at another National Security Laboratory or at the other locations at the Livermore Site or at Site 300 (Sections 2.5 through 2.5.3). The discussion of these alternative indicates that they do not meet the NNSA's purpose and need. Accordingly, these alternatives were not analyzed further in the EA.

The response to topic 5 above reviews the accident scenario and potential for risk to the local community. The response to topic 9 above addresses the need for a BSL-3 facility under the jurisdiction of DOE at LLNL, and discusses why the use of existing facilities located off-site (including potential BSL-3 facilities at other DOE sites) does not meet this need.

11. WASTE DISPOSAL

Commentors stated that although the Draft EA indicates that the proposed facility would direct 10,000 gallons of wastewater to the city sewage system, the EA does not adequately describe a monitoring system for the wastewater. Commentors questioned how LLNL would detect a "release" and how it would be prevented from being released into the city sewage treatment. The commentors expressed the opinion that since LLNL has had releases of toxic metals, radionuclides, and hazardous materials, a more thorough analysis of these issues should be undertaken.

One commentor remarked that the Draft EA was not clear on whether liquid waste materials generated from laboratory operations would be discharged directly to the sanitary sewer or first to retention tanks. The commentor points out that page 34 in the Draft EA states that liquid

waste from the proposed facility operations would be discharged to a retention tank system, but page 45 states that there would be no retention tanks. The commentor also noted that discharge of waste from improperly characterized retention tanks to the sewer system has been a problem in the past at LLNL with radioactive and hazardous wastes, and suggested that discharge of toxins or pathogens to the sewer system is a possibility.

Similar comments were also raised concerning solid waste disposal. Commentors raised concerns about which area landfills would be used for non-hazardous solid waste and what analytical methods LLNL would employ to ensure that hazardous and infectious agents are not sent to the landfills.

Response

As described in the LLNL Environmental Report 2000 (LLNL 2001b) made widely available to the public, LLNL achieved greater than 99% compliance with Livermore Water Reclamation Plant (LWRP) permit limits covering discharges into the sanitary sewer during 2000. During 2000, only three notices of violation were written (two for metals and one for cyanide) and no sewer releases exceeded discharge limits for radioactive materials. LLNL achieved between 99 percent and 100 percent compliance with permit discharge limits for 1996 through 2000.

All LLNL medical waste management operations comply with the California Medical Waste Management Act, which establishes a comprehensive program for regulating the management, transport, and treatment of medical wastes that contain substances that may potentially infect humans. In September 2000, an Alameda County Department of Environmental Health (ACDEH) inspection of the Biology and Biotechnology Research Program (BBRP) found no compliance issues or violations (LLNL 2001b). The Annual LLNL Environmental Reports for 1997-1999 state that inspections of LLNL's medical waste generator and treatment facilities also resulted in no compliance issues or violations. In 1996 the Alameda County Environmental Health Services Inspector issued only one report of violation for storage of medical waste (cotton swabs, bandages, and gauze pads) longer than 7days above 0^{o} C. Immediately after the violation was received, a LLNL self-assessment of medical waste compliance was conducted, additional training was provided, and revised medical-waste management procedures were implemented.

Sanitary liquid waste would be generated from the proposed BSL-3 facility from research activities and from toilets, showers, and sinks. Soluble or liquid waste material generated from laboratory operations are expected to be about 3 gallons per week and would be treated with disinfectants prior to disposal in the laboratory sinks. As stated in the EA, no discharge limits currently exist for infectious materials that are commonly discharged by healthcare and veterinary facilities and laboratories or homes. However, liquid waste generated from the proposed BSL-3 operations would be discharged to a retention tank system for characterization and disinfection as needed prior to discharge to the sanitary sewer system. The incorrect statement on page 45 (no retention tanks) of the Draft EA has been removed. Discharge guidelines, monitoring, and applicable regulatory requirements and restrictions are described in Section 3.3.5 of the EA.

As described in Section 2.1.2 of the EA, all waste generated in the laboratories of the BSL-3 facility (including sample packaging, culture materials, petri dishes, personal protective equipment, and associated process wastes) would leave the laboratories only after decontamination in the autoclave and/or after being chemically sterilized. Waste sterilization and quality assurance procedures for the autoclave are detailed in the EA. Live pathogen agents are not sent to landfills. No toxic metals, hazardous wastes, radiological waste, or hazardous chemical waste would be generated by the facility. Solid waste generated from the proposed facility would be sent to area landfills in the same manner as other BBRP and LLNL-produced solid waste. Any biological shipments sent from LLNL to other researchers or the CDC are decontaminated prior to shipment, as described in the EA.

12. TIMELINE FOR THE BSL-3 FACILITY

Commentors expressed the opinion that the timeline for construction of the LLNL BSL-3 facility, stated in the Draft EA as "…estimated to start in FY 2002 and take approximately 6 months to complete", indicates that the DOE is not serious about a good-faith NEPA review nor public involvement in decision-making. The commentor states that the 6-month construction period suggests that DOE has already decided to use a prefabricated building and the construction timeframe indicates a foregone conclusion and not a decision that is dependant on the NEPA review process.

Response
The proposed action in the Draft EA (a permanent modular unit constructed off-site and assembled on-site) is clearly described as the preferred alternative. CEQ and DOE NEPA regulations call for an EA to describe the Agency's preferred alternative, but this does not suggest that DOE has chosen this alternative, begun implementation of the alternative, or in any other way predetermined the results of the NEPA review process. The same is true for the projected construction schedule noted in the proposed action in the Draft EA. The dates and completion schedule outlined in the Draft EA were proposed schedules for the preferred alternative provided for illustrative purposes for the preferred alternative. Revised projected schedules for project completion are included in the Final EA.

C.2 Public Comment Letters/Email Messages

Table C-1 lists all the public comments received for this EA. Many were form-type email and letter submissions (identified by an asterisk in the first column on the table). Following the table are the letters and emails submitted. Only one of the form-type emails is shown.

TABLE C-1. LIST OF PUBLIC COMMENT LETTERS/EMAIL MESSAGES RECEIVED

E-mail/ Ltr	Name	E-mail Address	Address
e-mail*	Louise Aldrich & Helen Callbeck	aldrich@igc.org	57 Meadow Dr., San Rafael, CA 94903
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letter*	Joann Frisch		852 Sungold Cir., Livermore, CA 94551
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TABLE C-1. LIST OF PUBLIC COMMENT LETTERS/EMAIL MESSAGES RECEIVED

E-mail/ Ltr	Name	E-mail Address	Address
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letter	Andrew M. Lichterman		1504 Franklin St. Suite #202, Oakland, CA 94612
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e-mail*	John Michael	chefjemichel@yahoo.com	205 Washington St. #17, Grass Valley, CA 95945
e-mail*	Barry Miller	bamiller@igc.org	214 S. 9th St., Olean, NY 14760
letter*	Leroy Moore		3360 14th St., Boulder, CO 80304
letter*	Patricia Moore		23 Diamond Dr., Livermore, CA 94550
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e-mail*	Dale Nesbitt	dnesbitt@idiom.com	1712 Marin Ave., Berkeley, CA 94707
letter	Nuclear Watch of New Mexico		551 W. Cordova Rd. #808, Santa Fe, NM 87505
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* Form-type letter

-----Original Message-----
From: Mike Donly [mailto:mtdonly@worldnet.att.net]
Sent: Sunday, September 01, 2002 1:52 PM
To: rich.mortensen@oak.doe.gov
Subject: draft EA

I don't want my tax dollars used for a BSL-3 facility run by the DOE. Why isn't the CDC handling this research? They appear to be more qualified than the Livermore Lab. Your safety record should eliminate you from the list of potential facilities for this research.

What a sad day it is for this once great country.

Michael Donly

Structural Engineer

-----Original Message-----
From: RFORSBERG@aol.com [mailto:RFORSBERG@aol.com]
Sent: Saturday, September 07, 2002 2:01 PM
To: rich.mortensen@oak.doe.gov
Subject: comment on DOE/EA-1442

Mr. Richard Mortensen
DOE NEPA Document Manager
US DOE, Livermore Site Office, M/S L-293
PO Box 808
Livermore, CA 94551

Dear Mr. Mortensen:

I am writing to comment on the Environmental Assessment (DOE/EA-1442) for the construction and operation of a Biosafety Level 3 (BSL-3) facility at the Department of Energy's (DOE) Lawrence Livermore National Laboratory (LLNL).

A BSL-3 facility would allow LLNL to experiment with a broad spectrum of bio-toxins and biological agents including anthrax, bubonic plague, botulism, small pox and even genetically modified lethal bio-warfare agents. This is a new program that, if inadequately analyzed before proceeding, could endanger workers and the community. Thus, it is important that further environmental review in the form of a project specific Environmental Impact Statement (EIS) be conducted.

The Livermore Lab has a history of leaks, spills, fires, explosions and accidents. In recent years, these have included, but are not limited to, a chlorine gas leak that forced an evacuation, a filter shredding accident that contaminated workers with curium, numerous inadvertent releases to the sanitary sewer and an explosion that sent one employee to the hospital. Radioactive and toxic contaminants have found their way from DOE operations at LLNL into the air, groundwater and soil on-site and off-site, and have jeopardized the health of workers and surrounding communities.

This operational history, which was not included in the draft EA, is relevant to the proposal to site a BSL-3 facility at Livermore; certainly as relevant as the operational history of non-DOE facilities that is outlined in the draft EA. Clearly, a proposal to allow the use of potentially deadly bio-agents and bio-toxins at a facility with such a spotty safety record requires a comprehensive analysis of the risks and thorough environmental review. The EA lacks the level of analysis necessary to inform decision-making.

For 50 years Livermore Lab has been one of the nation's two primary nuclear weapon design labs, along with Los Alamos National Lab, in New Mexico. A BSL-3 facility is also proposed at Los Alamos. Yet, in both EA's, the DOE states that it has no BSL-3 facility, omitting mention that the agency is planning multiple facilities. In fact, DOE is moving forward with an integrated, new program area -- researching bio-warfare agents. It is essential that a Programmatic EIS be prepared to adequately review the programmatic, cumulative and integrated effects of undertaking this new mission area. Further, a full analysis of alternatives, which is central to a PEIS, is absent from the draft EA.

Constructing and operating a BSL-3 facility represents a new direction and program for DOE and LLNL; one that could have serious health and environmental consequences. Therefore, this proposal to create a BSL-3 facility at LLNL merits both a programmatic and project specific EIS. It is in the context of a full environmental review that the specific questions I have raised (and others) could best be answered.

Thank you for the opportunity to comment on the draft Environmental Assessment. Please inform me in writing of any decisions DOE makes regarding the BSL-3 facility at LLNL and its environmental review process.

Sincerely,

Rev. Robert Forsberg
Presbytery of San Francisco
1280 Laguna St. #10J
San Francisco CA 94115-4265

-----Original Message-----
From: George Franklin [mailto:george@groundworknews.org]
Sent: Friday, September 06, 2002 9:22 PM
To: rich.mortensen@oak.doe.gov
Subject: No Bio-warfare at LLNL

Dear Mr. Mortensen,

please do not allow Livermore Laboratory to engage in biological-warfare research. This Lab has a terrible history of heeding the welfare of the surrounding communities, which grow denser every year.

It is entirely inappropriate to allow Livermore Lab to conduct such research in a major population center.

Thank you for your attention to this matter,

George Franklin
San Francisco, CA

311 Douglass Street
San Francisco, CA 94114
September 7, 2002

Mr. Richard Mortensen
DOE NEPA Document Manager
US DOE, Livermore Site Office, M/S L-293
PO Box 808
Livermore, CA 94551

Dear Mr. Mortensen:

I am writing on behalf of the SF-Bay Area Chapter of Physicians for Social Responsibility, representing over 1,500 members throughout the SF-Bay Area, to comment on the Environmental Assessment (DOE/EA-1442)
For the construction and operation of a Biosafety Level 3 (BSL-3) facility At the Department of Energy's (DOE) Lawrence Livermore National Laboratory(LLNL). As an organization dedicated to ending the dangers posed by the proliferation of all weapons of mass destruction, including biological weapons, and to the protection of public health, we have a number of significant concerns about the plans for establishing a BSL-3 facility in LLNL, and about the planned proliferation of similar operations throughout the DOE complex.

Need for Programmatic and Project-Specific EIS

The plans for building and operating a BSL-3 facility at LLNL need to be examined in the context of DOE's overall plans to develop a new integrated program through multiple facilities on researching bio-warfare agents, putatively for defensive purposes. We believe that it is imperative that a Programmatic and Project-Specific EIS be prepared to adequately review the integrated and cumulative effects of undertaking this new mission area, particularly as regards potential weapons proliferation and health risks. In addition, a full analysis of alternatives, which is absent from the draft EA, but central to a PEIS is needed.

Proliferation Issues

PSR is particularly concerned that the planned work involving numerous pathogenic organisms, including genetically-modified varieties, would tend to severely undermine the internationally sanctioned, primary-prevention-based "alternative" to the proliferation of, and dangers posed by biological weapons-—the Biological Weapons Convention(BWC). This is especially disturbing given the continued rejection by the U.S. government of global efforts to develop strong inspection and verification protocols for the BWC. Given that DOE encouraged U.S. government leaders to scuttle the draft international agreement of 2001, the fact that high-level research on biological agents will be performed secretly in weapons facilities such as LLNL will likely be viewed with suspicion by the world community, encouraging a global biological weapons race. In this regard, it is instructive to recall the September 2001 *New York Times* reports of U.S. plans to work with genetically-modified anthrax, and of the prototype germ warfare facility developed at the Nevada Test Site, that raised widespread concerns about possible U.S. violations of the BWC.

The draft EA for the LLNL facility raises similar concerns. On page 17 of the main document, it is mentioned that viable organisms expected to be used "would be, but not limited to the select agents *Bacillus anthracis, Yersinia*

pestis, Clostridium botulinum, Coccidiodes immitis, Brucella spp., Franciscella tularensis, and *Rickettsia spp*," and that it "is possible that the facility would receive genetically altered microorganisms." Although the EA states that all work with infectious microorganisms must be in strict accordance with the BWC, there is no detailed indication of how such compliance would be instituted, either at LLNL or DOE-wide.

Given the universally appreciated ambiguity of much "biodefense" work, as regards offensive potential, it is important that the specific nature of any review process regarding these issues be spelled-out, and made completely transparent. Although the draft EA says that a LLNL biosafety committee will review experiments, there is no indication whether there will be a process to guarantee full public scrutiny of committee deliberations.

These issues are particularly important given that the proposed facility, will work with a large number of potential biowarfare agents, while being located close to a large and modern bioreactor facility (EMBF) that reportedly has a capacity in excess of 1,600 liters, as well as equipment that can prepare large amounts of microbes for field release. Given such capabilities, it is hard to distinguish the putative defensive nature of the program from an offensive weapons program able to produce bioweapons in disturbing quantities. These concerns are underscored by the fact that the EA indicates that BW agent cultures may be produced in quantities of up to one liter, that portend considerable doses. For example, if such a volume of Coxiella burnetti were produced at EA-indicated concentrations of 10^8 organisms per ml, it would provide enough organisms to theoretically produce ten billion human infections. Since gram or sub-gram quantities of any agent is considered sufficient for defensive research, it is important to confirm if LLNL indeed plans to produce liter volumes of pathogens, and for what reason.

Of the organisms mentioned in the EA for consideration of being cultured in the near future, some (*Brucella spp.*, *Coccidiodes immitis*) are considered incapacitating, rather than deadly agents, raising additional concerns about the presumed defensive nature of the work, in contrast to the potential development of agents that could aid U.S. offensive military operations.

Public Health Issues

The EA's description of planned aerosol challenge tests on rodents, which will likely necessitate weaponization of agents. Such operations would apparently require specialized equipment and would pose increased dangers from accidents to lab workers and the general public, issues not addressed adequately in the EA. Inadvertent exposure to pathogens has been documented, as indicated by the case of the researcher at Fort Detrick who a few years ago came down with a case of glanders, a disease that is considered a potential biowarfare agent. The researcher had spent considerable time in his community before the diagnosis was made, a fact missing in the EA reference. There is considerable potential danger posed by the anticipated work with organisms genetically-modified to increase lethality or confer resistance to countermeasures, and only one release could be disastrous for millions of people.

Issues of safety of lab operations are especially important in light of the report released in February 2001 the by the DOE Office of Inspector General entitled "Inspection of Department of Energy Activities

Involving Biological Select Agents." The report indicated in the section "Results of Inspection," the report indicated that "[T]he 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."

These potential dangers need to be considered in the context of LLNL's well-documented history of leaks, spills, fires, explosions and accidents. In recent years, these have included a filter shredding accident that contaminated workers with curium, a chlorine gas leak that forced an evacuation, many inadvertent releases to the sanitary sewer, as well as an explosion that sent one employee to the hospital. Radioactive and toxic contaminants have migrated from DOE Operations at LLNL into the air, groundwater and soil both on-site and off-site, jeopardized the health of workers and surrounding communities. This history should be incorporated into the EA. The draft EA also needs to bring its estimate of what population could be affected by accidents in line with standard DOE/LLNL considerations of a 50-mile radius around LLNL embracing more than 7 million people, as opposed to the 1.3 million stated in the document.

Given this large at-risk population, the draft EA needs a more thorough examination of the potential impact of earthquakes and other natural disasters. Although it is asserted that quakes, fires and other natural disasters may effectively kill airborne agents this assessment may underestimate the potential survival and distribution of hardy organisms, such as anthrax or fungal spores, not to mention whatever might be bioengineered for such capability.

In conclusion, there are far better, and safer ways to protect our nation, and the world from biological weapons, and all infectious disease, than the development of a national network of facilities conducting ambiguous research with extremely lethal agents. Such facilities, including the proposed one at LLNL will likely encourage increased proliferation of deadly technologies that instead require effective primary prevention. Central to such preventive efforts should be a national commitment to a significantly strengthened Biological Weapons Convention.

Respectfully submitted,

Robert M. Gould, MD
President
SF-Bay Area Chapter
Physicians for Social Reponsibility

Phone (W) 408-972-7299
Fax (W) 408-972-6429
rmgould1@yahoo.com

-----Original Message-----
From: Edward Hammond [mailto:hammond@sunshine-project.org]
Sent: Friday, September 06, 2002 12:46 PM
To: rich.mortensen@oak.doe.gov
Subject: Comments on Proposed LLNL BL-3 Laboratory
Importance: High

6 September 2002

Mr. Richard Mortensen, Document Manager
LLNL BSL-3 EA
Lawrence Livermore National Laboratory
P.O. Box 808
Livermore CA 94551

Dear Mr. Mortensen,

This electronic mail contains Sunshine Project comments on the Draft Environmental Assessment for the proposed BL-3 facility at LLNL (DOE/EA-1442).

The Sunshine Project is an international non-governmental organization with offices in Austin, Texas and Hamburg, Germany. The Sunshine Project works against the hostile use of biotechnology, using research, publications, and advocacy to strengthen the global consensus against biological warfare and to ensure that international treaties effectively prevent development and use of biological weapons. The Sunshine Project is a federally recognized charity in Germany and the United States (501(c)3 non-profit organization). The Sunshine Project does not accept funding from the US government or from any military source.

I will send a paper copy of these comments to you by mail today. I would appreciate your acknowledgement of receipt of this e-mail.

Comments

1. The proposed BL3 laboratory is to be located in alarmingly close proximity to the EMBF, a modern and very large bioreactor facility with a capacity in excess of 1,600 liters. EMBF also contains equipment for preparing large masses of microbes for field release. Indeed, this is its purpose, and the LLNL website boasts of this dual-use capability. The facility has already produced biodegradant organisms with bioweapons potential. The position of director of this facility demands a high security clearance, an unusual requirement for a facility whose stated purpose is to produce organisms for

bioremediation.

The proposed BL3 laboratory will work with a large number of BW pathogens. It will be modern, expert staffed, and militarily associated. The overlay of this proposed facility and the EMBF amounts to an unmistakable signature of an offensive biological weapons program capable of production of weaponized pathogens in quantities sufficient for theater scale use.

The collocation of these facilities is extremely ill advised. Both domestically and internationally, this will raise deep suspicions about BW-related activities at LLNL, particularly considering the United States' rejection of a verification system to the Biological and Toxin Weapons Convention (BTWC) and DOE's encouragement of US policymakers to scuttle the draft agreement. These suspicions will be enhanced by LLNL's mission to produce weapons of mass destruction and will be detrimental to US foreign policy and the worldwide prohibition on biological weapons.

2. The draft EA indicates that, within the proposed BL3 facility, BW agent cultures may be produced in quantities of up to one liter. It is extraordinarily difficult to envisage a legitimate prophylactic use for this quantity of BW pathogen. For example, the Rickettsia Coxiella burnetti, causative agent of Q fever, is apparently among those agents to be cultured at the proposed facility. The human inhalational infectious dose of Q fever is considered to be 10 organisms. The draft EA states that the proposed facility will produce up to one liter of agent at 10(8) organisms per milliliter. Distributed under ideal circumstances, the agent contained in one liter of LLNL Q fever culture (100 billion organisms) is theoretically capable of producing 10 billion human infections. That is an inhalational dose for every human being on the planet, with inoculations left over for many of the world's cows, sheep, and goats. Similar calculations may be made with other agents.

Production of gram or sub-gram quantities of any agent is sufficient for defensive research. For what justifiable and legal purpose does LLNL anticipate production of liter batches of BW agent? Such large-scale production will draw suspicion from other countries and increases health risks to surrounding communities. In addition, the draft EA indicates that such quantities of agent may be removed from the proposed facility. For what defensive and legal purpose would LLNL produce and distribute such large quantities of pathogenic agent?

3. The immunization status of laboratory workers is critical information for tracking the suspected release of pathogens, whether

accidental or deliberate. The draft EA indicates that BL3 lab workers would be offered appropriate immunizations. Will the complete vaccination status of all laboratory workers be available to all employees of LLNL, residents of Livermore and surrounding communities, and state and local health officials? The absence of such transparency will impede investigation of possible agent leaks and sour relations between LLNL and surrounding communities in the event of unusual epidemiological events involving communicable diseases.

4. The draft EA indicates that aerosol challenge tests on rodents are planned for the proposed facility. In order for this type of testing to yield useful information for a biological defense program, the challenge agents must be prepared in a manner to simulate warfare conditions and technologies used by potential enemies. In other words, the challenge tests will require agent weaponization. Preparing such agents will require specialized equipment beyond a collision nebulizer, such as grinding (to reduce particle size) and drying equipment. This equipment is not mentioned in the EA, much less the enhanced dangers posed by weaponized agent. The operation of this equipment poses health risks to laboratory workers and the surrounding community because it is designed to render the agents more infectious and pervasive in an open environment. Accidents performing these procedures are particularly dangerous. The draft EA is therefore deficient in failing to address risks posed by weaponized agents and the weaponization of agents.

5. The draft EA claims "An on-site BSL-3 facility would provide safe and secure manipulation and storage of infectious agents at a time when these issues are imperative to national security". It is accurate to state that biodefense has risen in national priorities, considering the anthrax attacks of 2001, and particularly that are likely to have been perpetrated by a US biodefense worker. The EA's justification, however, nonsensically mixes "issues" with "facility". The heightened national interest in biodefense, in itself, is not a justification for facility at LLNL. Indeed, with the US biodefense program already posing a concrete threat to domestic security and dwarfing all other biodefense programs in the world in size and scope, the emergence of biodefense as a national policy priority issue signals the need for reconsideration of the wisdom of many US biodefense activities, rather than the mindless proliferation of laboratories handling extremely dangerous agents. Clearly, with other NNSA labs proposed, a large NIAID lab construction program, renewed USDA biodefense work, and US Army biodefense expansion, the claimed benefits of this proposed lab must be weighed not only against its risks; but must be justified vis-à-vis the numerous other

similar facilities that exist, or are proposed, at DOE and other sites. This will require a DOE programmatic EIS of biodefense expansion with an interagency element to ensure that risks are not being multiplied by construction of duplicative facilities by multiple governmental agencies, with each facility posing threats.

6. The draft EA indicates that a LLNL biosafety committee will review experiments. Does this committee operate under full public scrutiny? Are all records of the committee public? Are all of its meetings open to public participation? The inclusion of "members of the public" on the committee cannot be equated with public access and participation in its decisionmaking. All documentation of experiments requiring approval by the biosafety committee, and particularly those involving genetic modification of any agent, must be available to the public.

7. The draft EA refers to "pending" work on BW agents at LLNL (as opposed to future work). What is this work, which has been defined, and why is it not discussed in more detail in the draft EA? Identification of this work by appending the relevant project documents to the EA would enable better public understanding of LLNL activities. LLNL here has the opportunity to discuss planned activities and to establish clear and open lines of communication with the public regarding its biodefense research; but is choosing not to. This may be interpreted as a disturbing indication that LLNL intends to keep the public in the dark as to the activities conducted in the proposed lab.

8. The draft EA mentions a number of organisms likely to be cultured in "the near term" (p. 17.). Of these, two - Coccidioides immitis (causative agent of valley fever, not to be confused with Rift Valley Fever) and Brucella spp. (causative agents of brucellosis) - are regarded as incapacitating, rather than lethal, biological weapons and are unusual choices for BW research with a defensive intent, particularly at a DOE facility.

Both brucellosis and valley fever incapacitate their victims; but are readily treatable and rarely fatal. Brucella is only known to have been weaponized by the United States and the former Soviet Union. Brucella is thought to have been the first agent weaponized by the US offensive bioweapons program, which has long experience with the agent and the illnesses caused. Brucellosis, while serious, is only fatal in approximately 5% of untreated cases. Similar to Brucellosis, up to 95% of the victims of valley fever spontaneously recover. Again like brucella, valley fever is not generally human-to-human transmissible. There is no record of valley fever ever having been

weaponized by any state.

Incapacitating agents - particularly those with a long incubation period, such as Brucella - are very unlikely to be used against the United States. A terrorist - or state - posing a biological threat to the United States will opt for lethal agents. By contrast, a large, technologically advanced, and well-armed country, such as the United States, is far more likely to choose incapacitating BW as a weapon, in order to weaken civilian and military populations prior to an invasion. Because incapacitating agents pose a minor security threat to the US, there is no apparent defensive purpose of research with these agents at this proposed facility.

Thank you very much for attention in this important matter. I look forward to receiving LLNL's response as soon as possible.

Sincerely,

Edward Hammond
Director

RECEIVED 8/20/02

Dear Sir:

We've recently learned of live strains of virus & germs coming to the Livermore Lab. We are completely opposed to this. We have enough of these labs already. How about looking for ways to advance & evolve all people in ways of peace instead of subjugation & threats?

Sincerely,

Carl & Wendy Hassell
Tracy

ALAMEDA COUNTY FLOOD CONTROL AND WATER CONSERVATION DISTRICT
5997 PARKSIDE DRIVE ♦ PLEASANTON, CALIFORNIA 94588-5127 ♦ PHONE (925) 484-2600 FAX (925) 462-3914

August 23, 2002

8/26: LEFT VM RE: RECEIPT OF COMMENTS AND EXTENSION OF COMMENT PERIOD TO 9/7.

Mr. Richard Mortensen, DOE NEPA Document Manager
United States Department of Energy
Livermore Site Office, L293
P.O. Box 808
Livermore, CA 94551

Re: Draft Environmental Assessment for Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory

Dear Mr. Mortensen:

Zone 7 has completed its review of the referenced NEPA document. Our understanding is that the proposed project consists of the construction and operation of a 1,500 square-foot laboratory facility within the Lawrence Livermore National Laboratory (LLNL) site. The site for this facility is approximately 0.25 acres. It currently consists of paved parking and a road in the vicinity of Building 360 complex.

Our comments are made in the context of Zone 7's responsibilities within its service area to provide wholesale treated water, untreated water for agriculture and irrigated turf, stream management and flood protection, and groundwater management. Zone 7 does not have any existing or planned flood control facilities nor water production/transmission in the project vicinity.

The draft environmental assessment states that wastewaters generated by this facility will be disposed of to the City of Livermore's sanitary sewer system. Municipal sewer systems typically have leaking pipe joints. Also, the City of Livermore recycles a portion of its treated wastewater for turf and landscape irrigation over the Valley's main groundwater basin, and it may also someday store recycled wastewater in one of Zone 7's Chain of Lakes. Our primary concern for this project is that infectious materials, biotoxins, or pharmaceuticals might reach the groundwater through one of the above pathways. Our comments have been organized to follow the order of the draft environmental assessment, as follows:

1. Page 8, Proposed BSL-3 Facility Location and Construction Measures

   This paragraph mentions that the proposed project would be within an existing paved parking area. If construction is contained to the existing paved parking area, a drainage fee for Zone 7's Special Drainage Area (SDA) 7-1 may not be required, since no impervious area would be created. However, if the construction does create new impervious area, it will be subject to SDA 7-1 drainage fees.

2. Pages 22 and 23, Waste Generation at the BSL-3 Facility

   The first paragraph on page 23, states that "soluble or liquid waste materials generated from laboratory operations can be disposed of in the laboratory sinks after first being treated with disinfectants." Please confirm that simple disinfection will be adequate for all constituents of concern. Will disinfection always be performed?

3. Page 34, Sanitary Liquid Waste and Page 45, Waste Management

This paragraph states that "...liquid wastes as generated from the proposed BSL-3 laboratory operations would be discharged to a retention tank system, for containment, characterization, and disinfection as needed, prior discharge to the sanitary sewer system." Whereas the second paragraph on page 45 states that "There would be no retention tanks or need for waste accumulation areas since no hazardous waste would be produced..." These statements need clarification.

If the liquids are going to go to a retention tank for "containment, characterization, and disinfection as needed" please provide some discussion as to the process which determines whether disinfection is needed. The sentence on page 34 that states "...no discharge limits currently exist for infectious materials which are commonly discharged by healthcare and veterinary facilities and laboratories or homes" does not justify ignoring the need for monitoring, but instead, might point to possible flaws in the existing regulations. Are the potential discharges from a BSL-3 facility the same as those for healthcare and veterinary facilities and laboratories or homes?

4. Pages 39-41, Potential Pathways for Infectious Agents to Escape BSL-3 Containment, Water-borne Transmission

In the paragraph on Water-borne Transmission, page 41, it states "Water exiting through the sink drains would be disinfected, if necessary, and would be diluted by mixing with sanitary wastewater in the sewer system and at the LWRP facility." As mentioned above, what determines whether disinfection will be needed? Will disinfection and dilution be effective for all of the potential constituents of concern? What is the potential for discharge of pharmaceutical pollutants? What is the potential for discharge of resistant strains of bacteria and viruses?

Please feel free to call me at (925)-484-2600, ext. 400, or Jack Fong at ext. 245 if you have any questions or comments.

Sincerely,

Jack Horen for

Jim Horen
Principal Engineer
Advance Planning Section

JH:JF:jr

cc: Ed Cummings
John Mahoney
Yan Kee Chan
Dave Lunn
Diana Gaines
Matt Katen
Jack Fong

P:\Advplan\LLNL-BiosafetyFacility.doc

-----Original Message-----
From: marylia@earthlink.net [mailto:marylia@earthlink.net]
Sent: Saturday, September 07, 2002 11:58 AM
To: rich.mortensen@oak.doe.gov
Subject: Add'l comment on DOE/EA-1442

September 7, 2002

Mr. Richard Mortensen
DOE NEPA Document Manager
US DOE, Livermore Site Office, M/S L-293
PO Box 808
Livermore, CA 94551

Dear Mr. Mortensen:

I am writing to supplement my earlier comment on the Environmental Assessment (DOE/EA-1442) for the construction and operation of a Biosafety Level 3 (BSL-3) facility at the Department of Energy's (DOE) Lawrence Livermore National Laboratory (LLNL).

Tri-Valley CAREs (Communities Against a Radioactive Environment) is a Livermore-based non-profit organization founded in 1983 by residents of the Tri-Valley area living in the shadow of the Livermore Lab. The group seeks to monitor activities at the Livermore Lab, safeguard community health and the environment, effect conversion of LLNL's mission from weapons of mass destruction to peaceful purposes and involve the public in decision-making on nuclear weapons and related policy issues. It is on behalf of the organization's board and members that I submit comments on this draft EA.

1. The draft EA was released with a 30 day public comment period and no address, email or fax number anywhere in document telling interested members of the public where or how to submit comments. Upon receiving written and phone requests for a 30-day extension -- including from Tri-Valley CAREs -- DOE decided to extend the public comment period by 15 days. While we appreciate the extension, and the timely manner in which DOE made the decision, we note that a 15 day extension is an insufficient amount of time to permit a comprehensive review of the draft EA, its 2 appendices and other background material not included in the EA, but necessary nonetheless in order for a member of the public to comment adequately.

2. The "purpose and need" for the proposed action (i.e., construction and operation of a multi-lab BSL-3 facility at LLNL), is not sufficiently justified in the draft EA and does not meet the requirements of the National Environmental Policy Act (NEPA). Specifically, in the draft EA, the central "purpose and need" is given as:

"The several key off-site BSL-3 facilities that conduct work for LLNL in support of NNSA, are often heavily committed to other projects or tailored to work with microorganisms not of specific interest to NNSA..." (page 7), and

"The few offsite commercial of governmental BSL-3 facilities currently available are often heavily committed to other projects or tailor

their work with specific types of microorganisms... (executive summary).

It is my understanding after talking to LLNL staff and others that one of the BSL-3 facilities used by LLNL is the Centers for Disease Control and Prevention (CDC) facility in Fort Collins, Colorado. I believe that there are several other candidate (and some currently utilized) sites as well. One would, therefore, expect that the text of the draft EA would document in detail DOE's serious and good-faith attempts to negotiate a memorandum of understanding or pursue other appropriate method(s) to resolve this "presenting" issue of DOE/LLNL obtaining sufficient time and means to conduct a reasonable scope of work (e.g., development of a hand held bio-detector) at an outside facility.

Instead, outside of making the above-listed and related assertions, the draft EA is silent on this topic. There is no indication of which BSL-3 facilities LLNL and/or DOE currently use, no analysis of their capabilities, no list of alternate facilities and no record showing attempts to improve the working relationships (e.g., between two federal agencies, DOE and CDC) so DOE can better utilize outside facilities.

Moreover, a plethora of new and/or expanded facilities are being planned by an alphabet soup of federal agencies (in addition to CDC). Before DOE ventures into this new mission area (running BSL-3 facilities) it must look comprehensively at the capabilities that are already out there or are reasonably foreseeable so as not to unnecessarily duplicate capabilities by constructing a BSL-3 facility at LLNL.

Additionally, the draft EA states that "DOE does not have under its administrative control any microbiological laboratory facility capability beyond Biosafety Level (BSL)-2" (executive summary). While this is narrowly true, it overlooks the fact DOE has made a decision to go forward with a BSL-3 facility at its Los Alamos National Laboratory (LANL) in New Mexico.

Tri-Valley CAREs believes that the BSL-3 facility at LANL should not proceed without benefit of a project-specific and a Programmatic Environmental Impact Statement (EIS). However, DOE is nonetheless required by the NEPA to analyze whether the LANL BSL-3 facility would -- even in part or in tandem with other facilities -- provide an alternative to construction of the proposed BSL-3 facility at LLNL.

The draft EA lacks this or any other alternatives analysis (beyond a simple assertion that no alternative exists to the agency's proposed action).

3. The timeline for the LLNL BSL-3 facility is shocking -- and suggests that DOE is neither serious about NEPA nor public involvement in decision-making. The draft EA states: "Construction of the BSL-3 facility is estimated to start in FY 2002 and take approximately 6 months to complete" (page 11).

To begin construction in fiscal year 2002, activities would need to commence before September 30, 2002 -- a scant two weeks away. This suggest that DOE's "go - no go" decision is based on a foregone conclusion and not the NEPA process. Further, the 6 month construction period listed in the draft EA suggests that DOE has already decided to use a prefabricated building -- again in advance of conducting a good faith NEPA review.

4. The draft EA states the BSL-3 facility will increase biological

shipments in and out of LLNL as much as ten-fold (page 20) during an unspecified start up phase. Bio-agents would be permitted to arrive by mail, commercial delivery service, courier and other authorized entity. A more comprehensive analysis of accident scenarios and potential risk is called for. The draft EA, in essence, simply asserts that procedures will be followed. Analysis of the potential for terror attack during these procedures (or at any other time) is strikingly absent. Thus, there are no mitigation measures, no contingency plans listed, etc.

5. To augment my earlier comment on the lack of security measures in the draft EA, I would ask if any analysis has been done on the vulnerability (e.g., to airplane attack) of a prefabricated building vs. one constructed by conventional means from the ground up. This (and other) analyses need to be conducted before the process moves forward, not at some later date (after key decisions are already made).

6. As mentioned in my earlier comment, DOE's Livermore Lab has a history of serious pollution problems with its hazardous and radioactive materials. These problems are relevant the question of potential impacts to worker and community health due to operation of a BSL-3 facility, in part because the BSL-3 would be under the aegis of the same parent agency and operated largely by existing LLNL personnel. The following items augment the list in my prior comment. This list, prepared in 1997, is a snapshot and is neither comprehensive or exhaustive. It should, however, further demonstrate the need for more thorough NEPA analyses of potential accidents, hazards and risks at the proposed BSL-3 facility.

a) Discharges to city sewer system:

In May, 1997, the City of Livermore cited LLNL for chronic discharges of heavy metals and corrosive chemicals into the municipal sewer system. According to city officials, there had been 14 releases from LLNL above its permit limits since January, 1996, a rate of about one violation per month. A February, '97, accident involved a discharge of silver, costing $41,000. Another discharge, in March, '97, this time of lead, cost $8,000.

b) Accidents in 1997 alone:

February -- LLNL doctors cut a small hunk of plutonium-contaminated tissue out of an employee's thumb after the worker had accidentally stuck himself with a sliver of the radioactive metal during routing cleanup.

March -- Three LLNL workers were contaminated when uranium filings caught fire.

April -- It was reported that a chlorine gas leak forced about 20 workers to flee after an alarm sounded.

May -- The City of Livermore cited LLNL, again, for chronic discharges of heavy metals and corrosive chemicals.

June -- It was reported that in May, '97, two workers were contaminated with tritium (radioactive hydrogen) while packaging the radioactive waste in the Tritium Facility.

July -- On July 2, workers shredding used air filters were radioactively contaminated. One worker was contaminated with curium, an alpha emitter, on his chest, face and in his nostrils. A DOE report credited inadequate safety procedures for this accident. In another July, '97 accident a hazardous waste technician accidentally mixed nitric acid and alcohol while workers were "bulking," (i.e., pouring spent chemicals into

waste drums). This combination of chemicals could cause fire, explosion or fumes, and resulted in fumes that triggered alarms and caused 25 workers to evacuate and LLNL to suspend "bulking" for a week.

c) Noncompliance with safety procedures:

As mentioned above, on July 2, 1997, a worker at LLNL was radioactively contaminated with curium in an accident that DOE itself admitted was due to inadequate safety procedures. Also, in this instance, procedures that had been recently put into place with the state of California's guidance were apparently ignored by LLNL, which raises questions about whether LLNL really follows agreed-upon safety procedures. This is underscored by another recent LLNL report confirming that a total of 15 criticality violations (a "criticality accident" is a runaway nuclear chain reaction) occurred over a two-month period (mid-May, '97 to mid-July, '97) in LLNL's plutonium building (Building 332) -- where, again, safety procedures were ignored. The internal LLNL report on the violations reveals deep, pervasive, systemic deficiencies in management, worker understanding and employee attitudes, citing 1) inadequate training, with workers unaware of rules and some even stating that there is nothing wrong with violating rules to get a job done; and 2) ineffective management, with supervisors not recognizing the problem. It is therefore reasonable that the NEPA review in the draft EA should not rely DOE asserting that safety procedures will be followed in the proposed BSL-3 facility.

d) Notices of Deficiency and Notices of Violations from the State of California Dept. of Toxic Substances Control (DTSC):

A May 21, 1997 letter from Rick Robison, Unit Chief of DTSC's Statewide Compliance Division to Harry Galles, Head of LLNL's Environmental Protection Dept., cites the following combined waste (CW) violations: 1) possible hazardous & radioactive constituents of CW remaining on-site weren't identified; 2) waste generating processes for wastes inspected were not identified; 3) accumulation start dates of CW were not listed at Satellite Accumulation Areas; 4) the treatment process description, as well as the reason for the treatment, for CW that was treated and then sewered was not provided, nor was information provided regarding the disposition of the sludge produced by the treatment process; 5) a date of treatment was not provided; 6) no information was provided for attempts to find available treatment and/or disposal options for CW; 7) no manifest number was given for CW shipped off-site.

A May 23, 1997 Inspection Report by Barbara Barry, Hazardous Substances Scientist with DTSC's Statewide Compliance Division, refers to the May 23, 1993 Stipulation and Order #HWCA 93/94-047 signed by DTSC and LLNL for the latter's violations of the Hazardous Waste Control Law from 1989 until 1992. Ms. Barry's May 23, 1997 Inspection Report also cites later violations by LLNL, including: 1) DTSC's 8-14-92 Compliance Evaluation Inspection (CEI) report's findings of 11 violations including storage of incompatible wastes, failure to certify a repaired tank before returning it to service, having an open waste container, and failure to complete employee training; 2) DTSC's 8-6-93 CEI report's findings of 17 violations, including improper storage of incompatible wastes, incomplete inspection logs, inadequate aisle space in waste storage area, improper labeling of hazardous wastes, inadequate employee training, failure to do tank certification, storage of waste over 90 days without authorization, failure to maintain land ban notification/certification records, and falsification of records; and 3) DTSC's 6-1-94 field-issued CEI report's findings of 7 violations,

including storage of hazardous waste over 90 days without authorization or permit, failure to properly label hazardous wastes, failure to meet treatment standards, notification failures, failure to maintain inspection logs with required information, failure to inspect hazardous waste tankers each operating day, and failure to provide annual refresher employee training.

Ms. Barry's May 23, 1997 Inspection Report also describes how LLNL's Total Waste Management System (TWMS), a method of tracking waste sitewide (e.g., waste source, treatment method, treatment results, storage, discharge, movement throughout the site, ultimate destination, shipping date and manifest number) using computer and waste drum bar codes, was inoperable at the time of her inspection.

Ms. Barry's May 23, 1997 Inspection Report also cited LLNL for violating 1) 22 California Code of Regulations section 6626.23(a) (1-3); (b) and (e) for shipping CW off-site without a manifest; 2) 22 CCR 66265.71(a)(1-6) for receiving CW from Site 300 without a manifest; (3) 22 CCR 66262.34 (f) (1-3) for storing CW labeled "Radioactive Waste Only," instead of using the required hazardous waste label (the statute requires hazardous waste labels for all Resource Conservation and Recovery Act (RCRA) wastes, all mixed wastes, all California wastes and all combined wastes, in addition to any labeling required by the AEC (sic) for the radioactive portion of the waste); 4) California Health and Safety Code (CH & SC) sections 25200.5(b)(1-2) and (c), and 25201(a) for storing and treating CW's not listed on the DTSC-approved Part A permit as well as treating CW with processes not listed on the DTSC-approved Part A permit, and also for storing CW for more than 1 year without DTSC's written authorization (this latter also violates CH & SC section II part 1(a) and the Interim Status Document issued by DTSC); 5) 22 CCR 66265.13(a)(1) and (b)(1-2) for excluding from its Waste Analysis Plan (WAP) the appropriate methodolgy and parameters for making analyses of California hazardous wastes as well as RCRA hazardous wastes; and 6) 22 CCR 66265.16(a)(1-2) and (3)(A-F); (c) and (d)(3) for inadequate training procedures, in that a) LLNL's Training Plan for employees in the Hazardous Waste Management Dept. (HWMD) was below minimum requirements, and b) the WAP requires extensive lectures and practical training in sampling procedures and the handling of samples, yet none of the HWMD training descriptions referred to any practical training other than first aid and fire/earthquake training.

DTSC's 3-7-97 Notice of Deficiency re: LLNL's Part B Application for the WTSF permit, signed by Pauline Batarseh, Unit Chief of DTSC's Northern California Permitting Branch, found 160 deficiencies.

This does not complete my comments on the draft EA, but the comment deadline is at hand. Again, the comment period should have been extended for 30 days, not 15.

Thank you for this opportunity to comment on DOE/EA-1442.

Sincerely,

Marylia Kelley
Executive Director
Tri-Valley CAREs

Marylia Kelley
Executive Director,
Tri-Valley CAREs
(Communities Against a Radioactive Environment)

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Tri-Valley CAREs

Communities Against a Radioactive Environment

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Peace Justice Environment since 1983

Citizens Education Project, Salt Lake City, UT
Coalition for a Safe Lab, Hamilton, MT
Los Alamos Study Group, Santa Fe, NM
Nuclear Watch of New Mexico, Santa Fe
Physicians for Social Responsibility, SF-Bay Area CA
The Sunshine Project, Austin, Tx
Tri-Valley CAREs, Livermore, CA
Western States Legal Foundation, Oakland, CA

Non-Profit Coalition Calls for a National Reassessment of the Biodefense Building Boom

(October 14) A non-profit coalition is calling upon Congress and the public for an urgent national reassessment of America's biodefense spending. The coalition contends that the $6 billion in biodefense that Congress hastily appropriated after last fall's anthrax attacks have triggered a laboratory rat race more likely to undermine US national and environmental security than to enhance it.

The groups dedicated to research safety, arms control, and scientific responsibility do not oppose all biodefense work; but cite a range of concerns and evidence in support of their demands (see attached quotes and contact sheet). The Coalition says that unless a national reconsideration is done, competition for biodefense funding and poor planning will combine with dangerous results, including a needless proliferation of facilities handling biowarfare agents and a spread of the knowledge needed to wage biowarfare. This poses dangers to local communities, to arms control, and US national security, they claim. Instead of emphasizing biotech band aids from facilities pursuing dream vaccines and working in secret, the coalition says spending should focus on unclassified, public research to bolster local public health capabilities.

"The number of new biodefense biosafety level 3 and 4 laboratories being developed far exceeds what is prudent and necessary, and we are asking Congress to freeze biodefense laboratory construction until a cross-cutting federal review ensures that the massive new investment isn't going away, and wouldn't be better spent elsewhere," said Steve Erickson of the Citizen's Education Project in Salt Lake City. According to Edward Hammond of the Austin, TX-based Sunshine Project, "Government and academic labs are responding less to bona fide needs than the urge to build power and revenue centers for what they hope is a perpetual biodefense boom. This will result in a dangerous proliferation of bioweapons agents and the knowledge to use them."

"Too many agencies want too many facilities, likely leading to duplication and unnecessary danger.". Colin King of Nuclear Watch of New Mexico in Santa Fe, "Agencies are confusing the public by trying to gain lab approval on a one-by-one basis, obfuscating the risks and ramifications of large national programs."

The coalition is calling for programmatic environmental impact assessments and insists that Congress and the General Accounting

Office carefully examine the programs of the National Institutes of Health and the Departments of Defense, Energy, and Agriculture both individually and for their collective implications. "Congress and the GAO need to identify the pork, the overlap, the national and local dangers, and address the bigger question of whether the proposed construction of more than a dozen new (or upgraded) biodefense labs really serves America's domestic and international interests" argues Tara Dorabji of TriValley CAREs in Livermore, CA.

The coalition is currently working on biodefense lab and program expansions proposed at Lawrence Livermore National Laboratory in California, Los Alamos National Laboratory in New Mexico, Utah State University and Dugway Proving Ground in Utah, Rocky Mountain Laboratory in Montana, and the University of Texas in Galveston. Other new and upgraded BL3 and 4 labs are proposed in San Antonio and Lubbock, TX, Manhattan, KS, Albuquerque, NM, Davis, CA, Honolulu, HI, and Plum Island, NY. The National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, is promising up to a dozen "Centers of Biodefense Excellence", each with BL3 and/or 4 capacity.

Additional Information, Contacts, Quotes

The coalition members are Citizen's Education Project (Salt Lake City, UT), Coalition for a Safe Lab (Hamilton, MT), Los Alamos Study Group (Santa Fe, NM), Nuclear Watch of New Mexico (Santa Fe), The Sunshine Project (Austin, TX), Tri-Valley CAREs (Livermore, CA) and Western States Legal Foundation (Oakland, CA). Members cite a range of concerns and evidence in support of their demands, including:

Domestic Threat: The FBI's investigation of last fall's anthrax letters has determined that the attack was perpetrated with a US biodefense anthrax strain, and suggests that the author of the attacks was a biodefense insider with hands-on training courtesy of the federal government. Under current plans, thousands of new people will gain access to bioweapons agents and knowledge of their preparation and use. How is the government making sure that it isn't sowing the seeds of domestic terrorism?

Manipulation of the Facts: In California, Lawrence Livermore National Laboratory (LLNL) wants a new biodefense lab smack dab in the middle of a major nuclear weapons design facility, and right next door to a bioreactor (fermenter) facility potentially capable of producing agents on a massive scale. These issues were brushed aside in the lab's draft environmental impact assessment. LLNL claims it needs the new facility because it has insufficient access to similar labs nearby and because the Department of Energy has no BL3 capacity. "LLNL is manipulating the truth to its convenience." says Tara Dorabji of Livermore-based Tri-Valley CAREs. "First, LLNL's environmental assessment fails to give due consideration to the civilian-mission BL3 facilities already in existence. Second, LLNL conveniently ignores the fact that DOE also wants to build a BL3 facility at the Los Alamos Lab in New Mexico. And, finally, new information has surfaced showing LLNL involvement in a proposal to build BL4 and BL3 labs in nearby Davis, California."

Opaque Proposals: In Utah, the US Army's Dugway Proving Ground wants a 200% increase in its biodefense activity, including BL3 lab

upgrades and another aerosol chamber, a very controversial piece of testing equipment with many potential offensive uses. The Army has produced a huge draft environmental impact assessment (DEIS), but according to Steve Erickson of the Citizens Education Project in Salt Lake City, "The DEIS is 1000 pages long, but it's so vague that it's impossible to fairly assess what the Army wants to do. They want to conduct many more in-lab and open-air tests, but won't say with what and when or under what conditions until future plans and studies are completed and rubber-stamped by the brass. There is no independent oversight of this facility, and given its penchant for secrecy and its track record of exposing civilians and contaminating the environment with its biological, chemical, and radiological tests, Dugway can't be trusted with such blanket permission to expand programs and missions."

Poor Community Consultation: In Hamilton, Montana, the National Institutes of Health (NIH) wants to build a new BL4 facility at Rocky Mountain Labs (RML). NIH originally proposed to begin building in February 2003 with only a brief environmental assessment and a two week public comment period. Hamilton's Coalition for a Safe Lab demanded more public participation and a more thorough review of the project. NIH relented and is now conducting an Environmental Impact Statement, which will delay groundbreaking. Then, RML put together a community outreach committee; but decided the meetings would be by invitation only. The Coalition protested again. At the last minute, RML opened the meetings to the public; but still required interested people to call ahead and advise the lab that they would like to attend.

Coalition for a Safe Lab organizer Mary Wulff, says, "When we arrived for their meeting we were welcomed with the news that we needed a security escort to use the restroom. The meeting was scheduled for 2 hours. During that time we listened to NIH talk about public relations with their community, children's programs, and bus rides across the NIH campus. Ten minutes were left for our twenty community 'leaders' to comment and ask questions. Several of them didn't comment at all. Our Coalition previously presented RML with a comprehensive list of questions, which they have not yet answered. RML's assistant director said at the meeting that they definitely will not be working with smallpox or Ebola; but conflicting information was given to a Coalition by RML's biosafety committee chairman. The chairman said that if the world situation changes then 'all bets are off'. It's unfair to thrust a national facility like this on a small community, especially in the absence of a comprehensive national review."

Ephemeral Promises? In Galveston, Texas, the University of Texas (UT) is building a new BL4 lab. UT claims good community relations for the effort, which began before September 11th, 2001. UT held public meetings and in July 2001, dispelled criticism that the lab's work might be "secret or ominous" with the public declaration that "No classified research will be performed." In September 2002, the Austin-based Sunshine Project wrote the lab's Director to verify that the University of Texas stands by its no-secrets pledge, and to request the lab's biosafety committee transparency rules. The BL4 that prides itself on community relations did not reply.

Dangerous Relationships With Weaponsmaking: In New Mexico, a number of non-profit organizations are asking tough questions of Los Alamos National Laboratory (LANL), which wants to build a new BL3 facility. Greg Mello of Los Alamos Study Group in Santa Fe says "Does it really make sense to put a biodefense lab at the nation's largest facility for designing, testing, and producing weapons of mass destruction? Los Alamos has little conspicuous expertise in biology, but it does have a 60-year history of secrecy and compartmentalization devoted to weapons development. What is the rest of the world going to think? What should they think? Los Alamos is not inspectable. A decision to build a bioweapons 'defense' facility at such a place could cripple efforts to build a better nonproliferation regime for biological weapons."

New Mexico non-profits are fed up with LANL's dismal environmental and safety compliance. In August, Nuclear Watch of New Mexico filed suit in federal court, arguing that LANL and DOE have failed to take the hard look at their bioweapons research program that is required under federal law. "We hope to compel DOE to undergo a Los Alamos-specific Environmental Impact Statement, and a Programmatic EIS for the Chemical and Biological National Security Program. If we are successful, this will greatly increase public scrutiny of DOE's program, and make it more difficult for the agency to continue to avoid environmental and public health issues," said Nuclear Watch's Colin King.

Misplaced Priorities: The coalition sees overinvestment in high-tech facilities to handle pathogens as the wrong emphasis for protecting the public against biological agents - whether naturally-arising or intentionally introduced by terrorists. Dr. Robert M. Gould, President of the San Francisco Bay Area chapter of Physicians for Social Responsibility states "We need to develop a comprehensive, primary-prevention approach towards all forms of infectious disease, which means providing adequate resources to combat AIDS, antibiotic-resistant tuberculosis, as well as the rise in diseases such as malaria predicted to increase from global climate change. According to a UN report from 2000, $10 billion a year would provide enough clean water and sanitation to cut by up to one third the 4 billion cases of diarrheal disease that kill 2 million people every year."

International Ramifications: According to the coalition, the emphasis on labs doing work such as aerosol challenge tests, particularly by the Defense and Energy Departments, runs terrible risks of being misinterpreted by other countries and triggering a bioweapons research race, or even worse. Says Jackie Cabasso of Western States Legal Foundation in Oakland, CA: "With biological weapons, the line between offense and defense is exceedingly difficult to draw. In the end, secrecy is the greatest enemy of safety. Last year, the US single-handedly blew apart an international system for inspections of these kinds of laboratories, a system that would have made great strides toward ensuring that biodefense labs aren't abused for offensive purposes. Having thumbed our nose at the world, the US is now massively expanding its biodefense program, mostly in secretive facilities. Other countries are going to be suspicious. This bodes badly for the future of biological weapons control."

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Subject: LLNL bio-warfare agent facility - Sign and email this comment
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Date: Fri, 6 Sep 2002 13:23:37 -0700
MIME-Version: 1.0
X-Mailer: Internet Mail Service (5.5.2656.59)
Content-Type: multipart/alternative;
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Content-Transfer-Encoding: 7bit

Dear colleagues:

Below, please find a comment letter -- ready for you to send -- on the proposed construction and operation of a BSL level 3 bio-warfare agent facility at the Department of Energy's Livermore Lab. Type your name and address at the end of the letter and then email it by Saturday, Sept. 7 to: rich.mortensen@oak.doe.gov.

If you wish to add any additional comments, please feel free to do so. This is an extremely important issue -- as you will see from the text. Thank you in advance for sending this. --Marylia

September 6, 2002

r. Richard Mortensen
DOE NEPA Document Manager
US DOE, Livermore Site Office, M/S L-293
PO Box 808
Livermore, CA 94551

by email: rich.mortensen@oak.doe.gov

Dear Mr. Mortensen:

I am writing to comment on the Environmental Assessment (DOE/EA-1442) for he construction and operation of a Biosafety Level 3 (BSL-3) facility at he Department of Energy's (DOE) Lawrence Livermore National Laboratory (LLNL).

Need for a Full EIS

A BSL-3 facility would allow LLNL to experiment with a broad spectrum of bio-toxins and biological agents including anthrax, bubonic plague, botulism, small pox and even genetically modified lethal bio-warfare agents. This is a new program that, if inadequately analyzed before proceeding, could endanger workers and the community. Thus, it is important that further environmental review in the form of a project specific Environmental Impact Statement (EIS) be conducted.

LLNL Operation History is Relevant

The Livermore Lab has a history of leaks, spills, fires, explosions and accidents. In recent years, these have included, but are not limited to, a

chlorine gas leak that forced an evacuation, a filter shredding accident that contaminated workers with curium, numerous inadvertent releases to the sanitary sewer and an explosion that sent one employee to the hospital. Radioactive and toxic contaminants have found their way from DOE operations at LLNL into the air, groundwater and soil on-site and off-site, and have jeopardized the health of workers and surrounding communities.

This operational history, which was not included in the draft EA, is relevant to the proposal to site a BSL-3 facility at Livermore; certainly as relevant as the operational history of non-DOE facilities that is outlined in the draft EA. Clearly, a proposal to allow the use of potentially deadly bio-agents and bio-toxins at a facility with such a spotty safety record requires a comprehensive analysis of the risks and thorough environmental review. The EA lacks the level of analysis necessary to inform decision-making.

Need for Programmatic Review

For 50 years Livermore Lab has been one of the nation's two primary nuclear weapon design labs, along with Los Alamos National Lab, in New Mexico. A BSL-3 facility is also proposed at Los Alamos. Yet, in both EA's, the DOE states that it has no BSL-3 facility, omitting mention that the agency is planning multiple facilities. In fact, DOE is moving forward with an integrated, new program area -- researching bio-warfare agents. It is essential that a Programmatic EIS be prepared to adequately review the programmatic, cumulative and integrated effects of undertaking this new mission area. Further, a full analysis of alternatives, which is central to a PEIS, is absent from the draft EA.

Problems with Siting a BSL-3 at a Nuclear Weapons Design Lab
Livermore Lab claims that the proposed 1,500 square foot building housing 3 laboratories, including small animal experiments, would be used for defensive bio-research. However, the draft EA states that the Livermore BSL-3 facility would, among other things, "... produce small amounts of biological material (enzymes, DNA, ribonucleic acid [RNA], etc.) using infectious agents and genetically modified agents..."

Livermore Lab's central mission for the past 50 years has been the development of nuclear weapons of mass destruction. The processes involved in conducting the research outlined in the draft EA -- and results of this type of research (genetically modified bio-warfare agents, aerosolized agents, etc.) -- in theory could be used either offensively or defensively. How will DOE convince the world that this new work with bio-agents is strictly defensive? This is an important question that must be addressed before DOE moves ahead with BSL-3 facilities, yet the draft EA is silent on this issue.

A higher-level environmental review (i.e., EIS and PEIS) is needed to fully examine this question and to look at alternatives. For example, DOE could better-utilize existing BSL-3 facilities run by the Centers for Disease Control, which has both a civilian mission and a history of operating BSL-3 facilities.

The draft EA speaks of the inconvenience of using other BSL-3 facilities, but fails to analyze methods (e.g., a negotiated memorandum of understanding between agencies) that could mitigate the inconvenience without building a BSL-3 facility at Livermore Lab.

Lack of Modeling for Accidental Release(s)

The draft EA mentions the 1.3 million people living in Alameda County. Yet, in other documents, DOE and LLNL declare the 50-mile radius around the Lab as the affected population, more than 7 million people.

The draft EA lacks any modeling for accidental releases. How might various types of bio-agents be spread? How might infectious diseases be spread if one or more persons or animals are exposed? Shockingly, the draft EA deems public exposure as such a remote possibility that it does not merit analysis. The proximity of workers and density of nearby populations require this analysis be conducted in advance of the decision to construct and operate a BSL-3 facility.

The draft EA states that the proposed facility will have the same worker and illness rate as the US Army Biological Defense Research Program (BDPR) and laboratories and the existing (BSL-2) biological research labs operated by LLNL.

BDPR has a long history of operating a BSL-3 facility. Neither DOE nor LLNL has this experience, making the analogy ill footed. Additionally, to claim that the safety records for a BSL-2 and BSL-3 facility will be the same, grossly underestimates the huge leap between BSL-2 and 3 facilities (e.g., a flu virus in a BSL-2 vs. up to a liter of live anthrax in a BSL-3). The safety measures and procedures for the BSL-2 and BSL-3 facilities are vastly different, as are the risks. Therefore, substituting analogy for analysis -- as this draft EA does consistently -- is inappropriate.

Risks in Aerosolizing Bio-warfare Agents; Using Liter-level Quantities

The LLNL BSL-3 facility proposes to aerosolize bio-agents. This could substantially increase the risk of release and exposure. In addition, the EA states that LLNL may work with up to 1 liter at a time of a given pathogen. No reason for using these quantities was given in the draft EA. What are the requirements of a defensive bio-program that would require the use of more than gram or milligram quantities of an individual agent at a time?

Waste Water Risks

According to the draft EA, the proposed facility will produce 10,000 gallons of wastewater that will flow into the city sewage. Currently, no discharge limits exist for infectious materials. Further, the EA does not adequately describe any monitoring system for the wastewater. How will LLNL know for certain in advance that microorganisms are not being accidentally released? Will an alarm sound locally in the lab? How will LLNL stop discharge of water on site if microorganisms are being accidentally released into the city sewage treatment?

The LLNL record on inadvertent releases to the sewer system is long and frightening. Toxic metals have been released, as have numerous radionuclides and other hazardous materials. A more thorough analysis of possible accidents and mitigation measures must be undertaken before proceeding with the BSL-3.

Air Pollution Risks

The EA proposes that double HEPA filters will be used to prevent exposures via airborne pathways. LLNL has a record of negligence with regard to its HEPA filters in the plutonium facility and other key buildings. In the plutonium facility, for example, LLNL has left HEPA filters in place for up to 30 years. HEPA filters become more fragile and brittle with age.

Further, the draft EA makes claims for the protective qualities of HEPA filters that exceed the documented record. According to the reports from multiple DOE-sponsored conferences on HEPA air filtration, HEPA filters have a "valley" in their capture efficiency in the .1 micron range; specifically DOE reports state that the efficiency of HEPAs for capture of particles in the .1 micron size range is less than the efficiency for the .3 micron-sized particles. Therefore, the statement in the draft EA that the capture efficiency for .3 microns is 99.97%, and that the capture efficiency for all other particle sizes is "virtually 100%" (page 51) is optimistic at best.

A more complete analysis of the potential for HEPA filter failure and other related HEPA efficiency issues is required before moving ahead with this facility. Moreover, a more comprehensive assessment of the overall potential for airborne release is clearly needed as well.

Solid Waste Issues

According to the draft EA, solid waste may be disposed of in a landfill, instead of first undergoing treatment at a commercial, off-site facility. Is disposal of the waste in the Altamont dump a consideration? Other area landfills? The BSL-3 facility is expected to generate 1,144 - 2,000 pounds of solid waste annually. By what analytical method(s) will the Lab ensure that hazardous and infectious agents aren't in any of those thousands of pounds of waste? The draft EA does not adequately describe detection methods -- or contingency measures.

Security Risks

The draft EA does not adequately address security issues, externally or internally. In fact, no security analysis is included in the draft document. What is the potential for unauthorized access? For attack (e.g., from an LLNL staff, a subcontractor, a visitor [delivery personnel, for example] or outsider(s))? What is the potential for unauthorized removal of a select portion of bio-agent by a BSL-3 worker or other person? Clearly, the type of security in place will impact the potential for a deliberate release of bio-agents and thus the risk to surrounding communities.

The recent Anthrax attacks in the U.S. mail are often cited as the reason or needing this type of facility to "counter bioterrorism", yet the draft EA does not address the possibility of a terrorist attack. This is a genuine risk, and it needs to be analyzed carefully -- as it includes the potential for direct risk to the more than 7 million people living in a 50 mile radius of the facility.

Earthquake and Other Natural Disaster Risks

The draft EA lacks a comprehensive analysis of earthquakes. The document states that the BSL-3 facility will not be built on a crack. True enough, but what of the active earthquake faults in the vicinity, including the Las

Positas fault zone, located less than 200 feet from the LLNL boundary. What about the Greenville fault, considered inactive until it initiated a 5.5 quake in 1980, causing a reported $44 million in damages at LLNL? Moreover, a number of regional faults from the Hayward to the San Andreas are capable of causing damage at LLNL. A comprehensive earthquake analysis should include the potential for cracks to open up on the LLNL site as well as looking at shaking. Moreover, the fate of equipment inside the BSL-3 facility needs to be assessed in addition to the building.

Similarly, the draft EA gives equally short shrift to any analysis of other natural disasters. There are sweeping statements in the draft EA that quakes, fires and other natural disasters may effectively kill airborne agents. While this may be true in many cases, there is no assessment in the document to show that it would be true in all cases. In fact, some bio-agents allowable in a BSL-3 facility may prove quite hardy and adept at surviving in the outside environment. This is one reason these agents are considered potential bio-warfare agents. A much more careful analysis of release possibilities and outcomes than is contained in the draft EA (virtually zero) is called for.

Conclusion

Constructing and operating a BSL-3 facility represents a new direction and program for DOE and LLNL; one that could have serious health and environmental consequences. Therefore, this proposal to create a BSL-3 facility at LLNL merits both a programmatic and project specific EIS. It is in the context of a full environmental review that the specific questions I have raised (and others) could best be answered.

Thank you for the opportunity to comment on the draft Environmental Assessment. Please inform me in writing of any decisions DOE makes regarding the BSL-3 facility at LLNL and its environmental review process.

Sincerely,

Name:

Address:

Marylia Kelley
Tri-Valley CAREs
(Communities Against a Radioactive Environment)
2582 Old First Street
Livermore, CA USA 94551

<<http://www.trivalleycares.org>http://www.trivalleycares.org> - is our new web site address. Please visit us there!

(925) 443-7148 - is our phone
(925) 443-0177 - is our fax

Working for peace, justice and a healthy environment since 1983, Tri-Valley CAREs has been a member of the nation-wide Alliance for Nuclear Accountability in the U.S. since 1989, and is a co-founding member of the Abolition 2000 global network for the elimination of nuclear weapons, the

U.S. Network to Abolish Nuclear Weapons and the Back >From the Brink campaign to get nuclear weapons taken off hair-trigger alert.

nuclear watch new mexico

August 19, 2002

Mr. Richard Mortensen
DOE NEPA Document Manager
U.S. Department of Energy
Livermore Site Office
Mail Stop L-293
PO Box 808
Livermore, CA 94551-0808
rich.mortensen@oak.doe.gov

Via email

Dear Mr. Mortensen,

I am writing to you to ask that you extend the comment period for the "Draft Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California, DOE/EA-1442." As your are aware, the comment period for this Environmental Assessment (EA) is slated to end August 23, 2002. Being mindful of the intent of the National Environmental Policy Act (NEPA) and the Council on Environmental Quality (CEQ) regulations, as well as DOE's own implementing regulations, it would be in the best interest of the Agency and the public to provide the greatest possible opportunity for discourse on the proposed facility. The NEPA process is designed to provide Agencies a path for sound policy and planning decisions. It has been my experience that public input through this process has greatly aided Agencies to make wise decisions.

Though I recognize that DOE is not obligated by law to provide an extended comment period on the Draft EA, the significance of the proposed action and the great potential for public concern as a result of the unprecedented nature of the action make this a reasonable request. Furthermore, DOE did extend the comment period on the Draft EA for the proposed BSL-3 at Los Alamos National Laboratory when they realized that more time was required to discuss the proposed action. An extension of the comment period by 10-15 days could be considered reasonable.

I appreciate your consideration of this matter.

Sincerely,

Colin King
Research Director

>-----Original Message-----
>From: lacroixdn@netscape.net [mailto:lacroixdn@netscape.net]
>Sent: Friday, July 26, 2002 9:30 AM
>To: rich.mortensen@oak.doe.gov
>Subject: Pathogen facility
>
>We are opposed to the pathogen facility in Livermore. It would present a
>danger to our community and citizens. We have always been strong supporters
>of the Lab since we moved here 17 years ago. We are prepared to fight this
>and rally our friends and neighbors to prevent it.
>
>Cliff&Diann LaCroix
>2094 Vintage Lane
>Livermore, Ca 94550

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www.wslfweb.org

8/20/02: CALLED ANDREW LICHTERMAN ACKNOWLEDGING RECEIPT OF FAX.

8/21/02: CALLED AND LEFT A VM FOR ANDREW LICHTERMAN INFORMING HIM OF THE EXTENSION TO 9/7.

August 20, 2002

Mr. Richard Mortensen
DOE NEPA Document Manager
U.S. Dept. of Energy, Livermore Site Office
Mail Stop L-293
P.O. Box 808
Livermore, CA 94551

BY FAX

Dear Mr. Mortensen:

Western States Legal Foundation is a nonprofit organization that for almost two decades has monitored the impacts of the Lawrence Livermore National Laboratory and other Department of Energy weapons research facilities. We request that the comment period for the Draft Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory (DOE/EA-1442) be extended for a period of no less than thirty days. In addition, the EA did not include information regarding the appropriate point of contact for comments. Before the new comment period begins, a new notice for the availability of the EA and for the new comment period, including the point of contact to which comments should be sent should be circulated via the Federal Register, to all public agencies, organizations, and interested individuals to which the EA was circulated, and by adding the information on the point of contact and new deadline for comments to copies of the EA in DOE reading rooms.

This Environmental Assessment (EA) raises issues that are complex and technical in nature. The proposed action would make possible a significant expansion of LLNL on-site activities relevant to biological warfare defense, and as such raises new issues, including both a new set of hazards and their potential cumulative and synergistic impacts in combination with the wide variety of hazardous activities already present at the laboratory. The new facility is being built at a time when new missions in this area of research for LLNL may be defined under the proposed Department of Homeland Security. In addition, this EA is being circulated for comment during the scoping comment period for the Site Wide Environmental Impact Statement for LLNL. This creates a significant burden on community groups and agencies with limited staff resources, and raises additional issues requiring analysis concerning the appropriate relationship between these two environmental reviews.

We believe that public comment is vital to the NEPA process, and helps produce NEPA documents that are more informative and useful to the public and to decision makers. Please inform us of your decision regarding this matter as soon as possible.

Sincerely,

Andrew M. Lichterman

Western States Legal Foundation Comments on the Environmental Assessment for the Biosafety Level 3 Laboratory at Lawrence Livermore National Laboratory.

Submitted by Andrew Lichterman, Program Director

Summary

Western States Legal Foundation (WSLF) is a nonprofit organization that provides information, analysis, and legal support for peace and environmental activists. WSLF has monitored the activities of the Lawrence Livermore National Laboratory (LLNL) for twenty years, and has worked on broader Department of Energy weapons complex issues for approximately fifteen years.

WSLF believes that the construction of a Biosafety Level 3 (BSL- 3) laboratory at LLNL requires an Environmental Impact Statement. The proposed action, which will include research using significant quantities of dangerous organisms and the aerosolization of pathogens and biotoxins for various purposes including animal exposure tests, has significant foreseeable environmental impacts. The potential health risks, although perhaps difficult to quantify, are substantial. Because of the particular nature of biological warfare research, a known or suspected release may have disproportionately large direct economic and social impacts. The Environmental Assessment here provides only boilerplate assertions that the risks are negligible, and relies on adherence to procedures, some of which DOE laboratories have not followed in the past and others of which are not yet in place, for risk reduction. Because of the significance of the potential impacts, WSLF believes that an Environmental Impact Statement (EIS) is required here.

Because of the intrinsic risks of placing a laboratory that will handle dangerous biological materials in a densely populated urban area, a careful analysis of alternatives is both essential and required. The Environmental Assessment addresses in detail only various ways to construct a BSL- 3 facility at the Livermore Laboratory, without comparing in detail any of the other possibilities for accomplishing the same mission, ranging from using other existing government or contract facilities, using government facilities slated to be constructed in the near future, or constructing a new BSL 3 facility at another Department of Energy (DOE) site. These issues would be addressed in detail the more extensive analysis required in an EIS.

Adequate environmental review for this action, furthermore, would best be assured by preparing a Programmatic Environmental Impact Statement (PEIS) for the DOE Chemical and Biological National Security Program (CBNP) prior to site-specific environmental review. This would best allow comparison of both alternative means for fulfilling the purposes of the action, i.e. conducting various kinds of non-medical biological warfare defense research, (including, for example, use of contract laboratories), and alternative sites for a new BSL- 3 laboratory if it is determined that one is needed. In addition, this would allow more systematic consideration of reasonable alternatives not under the direct jurisdiction of the agency, such as conducting research requiring BSL- 3 facilities at Department of Defense or other government facilities doing similar work. A PEIS also would help to inform a broader assessment and discussion of responses to the risk of biological attack, including whether resources are best used on

biowarfare defense technologies as opposed to such other responses as improvements in overstretched emergency medical resources and existing public health systems for reporting, tracking, and responding to disease outbreaks.

Finally, the Programmatic NEPA review of DOE's biological warfare defense research should be accompanied by a Nonproliferation Impact Review. The potential for the development of offensive technologies intrinsic to "defensive" biowarfare research raises dangers of diffusion of technology, disruption of global nonproliferation efforts due to perceptions of a potential offensive threat from growing U.S. technical capabilities, and theft or diversion of dangerous materials.

The Environmental Assessment does not provide an alternatives analysis sufficient to allow meaningful comparison of the proposed action with other reasonable alternatives.

The discussion of alternatives here is deficient even for an Environmental Assessment. DOE has dismissed alternatives other than "No Action" and construction of a BSL- 3 laboratory at LLNL from the outset by defining the "purpose and need" for the action as "the purpose and need for NNSA to conduct future BSL-3 level work at LLNL in support of its assigned national NNSA security –and science mission responsibilities." EA at 26.

The EA claims that a BSL-3 facility must be built at LLNL. According to the EA, DOE is constructing another BSL- 3 laboratory at the Los Alamos National Laboratory. It also appears that DOE is constructing a facility that could be used for BSL- 3 work at the Oak Ridge National Laboratory, although the EA fails to mention it.[1] These would seem to provide alternative sites for the BSL-3 activities contemplated for LLNL.. DOE acknowledges that "it is possible to construct such a facility at any of the national security laboratories at approximately the same cost and schedule,"(EA at 26) but rules out any other options because they fail to meet DOE's self-fulfilling requirement of "need for NNSA to conduct future BSL-3 Level work at LLNL." The primary rationale for limiting alternatives to LLNL on-site construction of the BSL-3 laboratory appears to be that LLNL has supporting infrastructure, past program experience, and expertise that make it an appropriate site for the required work. EA at pp. 4-7. It is worthy of note in this connection that when conducting its NEPA analysis for the National Ignition Facility, an advanced laser facility, DOE considered a wide variety of sites, despite the fact that LLNL arguably has a far greater claim to the unique character of its laser programs and supporting infrastructure than can be made here for its biological research programs.[2]

[1] According to a February 2001 DOE Inspector General Report, DOE constructed a laboratory at Oak Ridge National Laboratory intended for BSL-3 work, but failed to do an environmental assessment. According to the Inspector General report, "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." "Investigation of Department of Energy Activities Involving Biological Select Agents," DOE/IG-0492, February 2001, p.23

[2] The National Ignition Facility environmental review considered sites at three DOE laboratories, and the Nevada Test Site. See U.S. Department of Energy, Final Programmatic

Further, DOE's work in this area is by no means unique. The General Accounting Office in 2000 found a lack of coordination and potential duplication of effort in federal non-medical chemical and biological research, including DOE's Chemical and Biological Nonproliferation Program (apparently the forerunner of the current Chemical and Biological National Security Program). GAO

> found many similarities among these programs in terms of the research and development activities they engage in, the threats they intend to address, the types of capabilities they seek to develop, the technologies they pursue in developing those capabilities, and the organizations they use to conduct the work. "Chemical and Biological Defense, Observations on Nonmedical Chemical and Biological R&D Programs," Statement of Kwai-Cheung Chan, Director, Special Studies and Evaluations, National Security and International Affairs Division, U.S. General Accounting Office, Before the Subcommittee on National Security, Veterans' Affairs, and International Relations, Committee on Government Reform, House of Representatives, March 22, 2000, GAO/NSIAD-00-130, p.2. (Hereafter GAO 2000)

This also would suggest that there are reasonable alternatives to conducting CBNP program research requiring a BSL-III at DOE facilities, and at LLNL in particular. Given the risks of conducting the types of research characteristic of a BSL-3 facility, and particularly such activities as the aerosolization of pathogens and biotoxins, possibly in forms that could be used as biological weapons, an alternatives analysis must be conducted that is sufficiently broad to inform choices on whether a new BSL-3 facility is needed at all, and if so whether a particular location is most appropriate.

DOE should prepare a Programmatic EIS for its Chemical and Biological National Security Program and for similar and related work performed at its facilities.

As the above GAO report makes clear, the work performed by the DOE CBNP program is closely related to that being done by several other agencies, particularly within the Department of Defense (DoD). That report also noted that funding for chemical and biological warfare defense research is increasing rapidly, and that there is a danger that resources will be wasted due to inadequate coordination of programs proceeding simultaneously in different agencies.[3]

Environmental Impact Statement for Stockpile Stewardship and Management, 1996, V.III, pp. I-S2-IS3.

[3] Although the four programs we examined currently use both formal and informal mechanisms for coordination, we found several problems that may hamper their coordination efforts. First, we found that participation in current coordination mechanisms, whether formal or informal, is inconsistent. Second, program officials cited a lack of comprehensive information on which chemical and biological threats to the civilian population are the most important and on what capabilities for addressing threats are most needed. More detailed information could help guide and coordinate R&D. Third, several programs do not formally incorporate existing information on chemical and biological threats or needed capabilities in deciding which R&D projects to

This was before September 11, and budgets for research of this kind continue to increase rapidly. A useful alternatives analysis for the type of work proposed in the action reviewed here– 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'" (EA at 7)-- could best be performed as part of a Programmatic Environmental Impact Statement. (PEIS). A PEIS would allow comparison of both alternative means for fulfilling the purposes of the action, i.e. conducting various kinds of non-medical biological warfare defense research, (including, for example, use of contract laboratories), and alternative sites for a new BSL- 3 laboratory if it is determined that one is needed. In addition, this would allow more systematic consideration of reasonable alternatives not under the direct jurisdiction of the agency, such as conducting research requiring BSL-3 facilities at Department of Defense or other government facilities doing similar work. In this regard, it is noteworthy that the Department of the Army is preparing a PEIS for the Department of Defense Chemical and Biological Research Program.[4]

A PEIS also would help to inform a broader assessment and discussion of responses to the risk of biological attack, including whether resources are best used on biowarfare defense technologies as opposed to such other responses as improvements in overstretched emergency medical resources and existing public health systems for reporting, tracking, and responding to disease outbreaks. The current martial atmosphere, with its emphasis on military and technological solutions, may prevent adequate attention to other approaches that may actually be more effective in protecting the public, and is likely to strengthen tendencies to provide funding with little question to military and other weapons research laboratories for research that may be less useful.[5]

In addition, the DOE Inspector General has identified a variety of operational issues that are common to DOE facilities doing biological warfare defense work, and that are likely to pose greater hazards if the volume of work increases and if more dangerous agents are used:

> 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

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fund. Because of these problems, these programs may not be developing the most important capabilities or addressing the highest priority threats. GAO 2000, p.9

[4] See Department of Defense, Department of the Army, Notice of Intent, Preparation of a Programmatic Environmental Impact Statement (PEIS) on the Chemical and Biological Defense Program, Federal Register: June 4, 2001, (Volume 66, Number 107) pp. 29935-29936

[5] On this point, see generally Victor W. Sidel, M.D.; Robert M. Gould, M.D.; Hillel W. Cohen, Dr.Ph., "Bioterrorism Preparedness: Cooptation of Public Health?" *Medicine and Global Survival,* v.7 no.2, February 2002, pp.82-89. (Herafter Sidel 2002) As Sidel and his co-authors note, "In a world of finite resources, it is impossible to adequately prepare for all "what-if" catastrophic scenarios. What is needed is a thorough, objective, and scientific analysis of probabilities and alternatives that would guide the setting of priorities for programs to defend populations at risk."

> exposure to biological select agents and select agent materials maintained by the Department. "Investigation of Department of Energy Activities Involving Biological Select Agents," DOE/IG-0492, February 2001, p.2

The Inspector General recommended that DOE

> 1. Identify the types and locations of activities being conducted by the Department involving biological select agents and select agent materials.
>
> 2. Initiate actions 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 United States Army, supplementing CDC [Centers for Disease Control and Prevention] 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 agents and select agent materials 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 CDC guidelines." "Investigation of Department of Energy Activities Involving Biological Select Agents," DOE/IG-0492, February 2001, p.25

These issues are particularly noteworthy given the types of activities proposed in this EA, and for the DOE Chemical and Biological National Security Program in general. As the Inspector General report noted, "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." at 4. The list in the environmental assessment of organisms to be used is very open ended, with the EA stating that organisms could include "other bacterial or viral infectious organisms not specifically or currently regulated by CDC or other Federal agencies such as those shown in the tables at the end of Appendix A," (EA at Appendix A, p.22)-- a list including hundreds of organisms. The EA also notes that "[i]t is possible that the facility would receive genetically altered microorganisms."Appendix A, p.17.

Both the operational and management issues and the increase in lethality of the agents being studied are issues that apply across DOE's Chemical and Biological National Security Program. The use of genetically modified organisms poses particular problems that are not specific to any one facility. The problems identified by the Inspector General may be exacerbated by the management changes that may come with the establishment of a Department of Homeland Security, which may change lines of authority yet again in institutions where unclear responsibility and lax oversight has been a chronic problem. The DOE CBNP is clearly a "program" responsible for a discrete set of interconnected activities with similar environmental risks and impacts at a number of different locations, and common operational and management

issues. For all of these reasons, DOE should prepare a PEIS for this program. Scoping for this PEIS could examine what other DOE biological research activities (e.g. similar or related "work for others" programs) should be included.

DOE should conduct a Nonproliferation Impact Review for its Chemical and Biological National Security Program

The Programmatic NEPA review of DOE's biological warfare defense research should be accompanied by a Nonproliferation Impact Review. Such a review is not unprecedented, having been conducted in the past by DOE for the National Ignition Facility to assess the effects of a new advanced nuclear weapons research facility on the nuclear nonproliferation regime. The potential for the development of offensive technologies intrinsic to "defensive" biowarfare research raises dangers of diffusion of technology, disruption of global nonproliferation efforts due to perceptions of a potential offensive threat from growing U.S. technical capabilities, and theft or diversion of dangerous materials. The risk that techniques or agents will be developed that have offensive applications is significant where "defensive" research weaponizes organisms or biological toxins to test defensive technologies to develop medical responses such as vaccines.

The Nonproliferation Impact Review should be similar in form to a NEPA proceeding, with an opportunity for the public to participate in scoping, and a draft circulated for public comment. If biowarfare defense research must be conducted, keeping secrecy to a minimum is critical to reduce both perceptions and the real possibility that "defensive" programs will be used to develop technologies with offensive capabilities. A review of this kind would allow the civilian medical, scientific, public health, and arms control communities, as well as the general public, to make suggestions for how such research could be conducted in the most open possible manner and how unnecessarily dangerous or provocative activities could be avoided.

DEFICIENCIES IN THE IMPACTS ANALYSIS IN THE ENVIRONMENTAL ASSESSMENT

In general, the EA assumes that a significant release of pathogens or biological toxins from the proposed facility is an event too unlikely to require detailed analysis. The EA presumes that a the most hazardous conceivable release would require a structural breach in the facility, and even then that the potential hazard is insignificant. The pathway of worker exposure, and of subsequent transmission to other LLNL workers or to people off-site, also is dismissed as insignificant. These conclusions are based, however, on a number of assumptions that are questionable. In particular, we believe that the risks of worker exposure are understated, as are risks of subsequent transmission of illness to other workers or people off-site.

The CEQ NEPA regulations list elements to be taken into account in determining whether an environmental impact is "significant" for the purposes of determining whether an EIS should be prepared. Factors of particular relevance here include:

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

> The degree to which the effects on the quality of the human environment are likely to be highly controversial.
>
> The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.... 40 C.F.R. § 1508.27

Here, the nature of the proposed action is inextricably related to "public health and safety." The EA states that the proposed facility may handle a wide range of dangerous organisms and biotoxins, including genetically engineered organisms. Some of these materials will be aerosolized in the course of doing the research. The research is on defense against biological weapons, so it appears possible that some of these materials will be in weaponized form. The EA states that work at the facility will include aerosolization of materials for animal inhalation tests, which means that the material will be reduced to small, easily respirable particles in quantities sufficient to cause disease in the test animals. This work is inherently dangerous, and unless done with a high level of physical and procedural safeguards appears likely to pose a high level of hazard to both workers and the public.

Both the likelihood of exposure of workers or the public are " highly uncertain"and "involve unique or unknown risks." The uncertainty comes form the difficulty of assessing the risk that facility workers, other LLNL personnel, or people off-site will be harmed as a consequence of a release or a worker exposure. The EA's conclusions that this risk is insignificant are based on a number of questionable assumptions about the reliability of both physical and procedural safeguards, the specifics of which we will return to below. The "unique or unknown risks" element results from the purposes of the proposed facility and the work that may be performed there. Biological warfare agents are seldom encountered by the general public, or by emergency personnel and regional medical workers who would have to respond if there were a substantial disease outbreak as a result of the proposed activities. Since they in most cases have not been tested on human subjects, the consequences of exposure of a human population may be only theoretically grounded, and not proven. Genetically modified organisms pose a particular problem in this regard. It is worth noting here that an EIS also would provide an opportunity for more extensive participation in the impact analysis by state and local agencies concerned with emergency services and medical response, which both will improve the quality of the analysis and help to provide responders with an understanding of the risks posed by the proposed activities.

The effects on human health and the environment of the kinds of research here are without doubt controversial. There is extensive debate over the degree of risk presented by research of this kind, and particularly by research in which genetically modified organisms are used and may be accidentally released.

Finally, a particular characteristic of biological warfare research that the EA fails to address is the peculiarly terrifying nature of biological warfare agents themselves. If there were a release or exposure at such a facility, it might be difficult for some time to determine the nature or extent of the hazard. As was demonstrated by the anthrax attacks of Fall 2001, even the possibility of small quantities of dangerous organisms can close down entire facilities, or change

the way that a region– or even an entire country– functions, despite the fact that only a relatively small number of people actually become ill or die.

Particular deficiencies in the Impact Analysis

The analysis of the risk that workers may be exposed to dangerous organisms or toxins, and of the possibility that this may lead to transmission of disease to other workers or off-site, rests on a number of assumptions. These include:

--Procedures for handling of biohazard materials will be consistently followed.

Much of the analysis is devoted to listing the procedures that will be followed by laboratory personnel to assure that materials are properly tracked, handled, and disposed of. The EA also relies heavily on the 1989 Final Programmatic Environmental Impact Statement for its Biological Defense Research Program. There is no explanation for why we should believe that the safety culture at the Army laboratories is the same as that at the Department of Energy, whose past record of adherence to health and safety procedures has not been good. Again, as the DOE Inspector General noted in regard to the type of activity at issue here,

> 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. "Investigation of Department of Energy Activities Involving Biological Select Agents," DOE/IG-0492, February 2001, p.2

--Physical safeguards, and particularly HEPA filter systems, will function well.

The Department of Energy has a long history of difficulty with HEPA filters at its facilities. Two recent reports by the Defense Nuclear Facilities Safety Board document DOE nuclear weapons complex-wide problems with confinement ventilation systems, and particularly with HEPA filters. These problems are not limited to existing or older facilities, since they concern a wide range of issues including problems with safety analyses, filter design, behavior of filter and ventilation systems under fire and other accident conditions, and filter production quality control. See Defense Nuclear Facilities Safety Board Technical Report, "HEPA Filters Used in the Department of Energy's Hazardous Facilities," DNFSB Tech-23, May 1999, and Defense Nuclear Facilities Safety Board Technical Report, "Improving Operation and Performance of Confinement Ventilation Systems at Hazardous Facilities of the Department of Energy," DNFSB/Tech-26, February 2000.

These reports addressed DOE nuclear facilities; the EA, however, fails to address why, given the systemic nature of the problems, things would be any better at a BSL-3 facility.

-- Even if workers are exposed, they are unlikely to become ill because they will be immunized, and even if they get sick, the risk of a widespread outbreak is small because of the nature of the organisms and toxins handled at a BSL-3 facility:

> "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." EA at 48.
>
> "The worker(s) would have the appropriate prophylaxis available or immunization prior to working in the laboratory and would not become symptomatic." EA at 51
>
> "Last, but not least, Risk Group 3 agents (those handled in BSL-3 laboratories) are associated with serious or lethal human diseases for which preventative or therapeutic intervention may be available (high individual risk but low community risk). EA at 51.

These assumptions are problematic. The first assumes that there would be "prophylaxis or immunization available" for all pathogens handled. This seems questionable in a laboratory that may handle an open-ended array of biological warfare agents, particularly for example that "immunizations" will be available for genetically altered agents. It also implies that all workers would be immunized. This seemed dubious enough to the DOE Inspector General to recommend that the DOE 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. "Investigation of Department of Energy Activities Involving Biological Select Agents," DOE/IG-0492, February 2001, p. 25.

The latter assumption, that "preventative or therapeutic intervention may be available," also seems weak for a biowarfare defense lab that may employ genetically altered organisms. There also is an implication that this will be sufficient to contain an outbreak at 'acceptable' levels, whatever that may be.

These assumptions, drawn from a long list of assumptions cited as support for the "conservatism" of the EA's limit case accident analysis, are important because they are key underpinnings of the EA's broader assumption that workers will not get sick in the ordinary scheme of things, and if they do it they are unlikely to infect many others on or off-site. Here too the EA relies heavily on the 1989 Army PEIS (see generally EA Appendix B). Again, it is worth noting the relevance of DOE's past difficulties with health and safety regulation compliance (not addressed in the EA). And worker exposures do happen:

> [A] researcher at the US Army Medical Research Institute of Infectious Diseases (USAMRID) developed a case of glanders, a disease considered to have biowarfare

> potential. The researcher spent considerable time in his community before the diagnosis was made. Sidel 2002, citing Srinivasan A, Kraus CN, DeShazer D, et al., "Glanders in a military research microbiologist, " N Engl J Med 2001;345:256-8.

Another unanswered question relevant to DOE's reliance on past data from military labs is the relative risk of different types of research activities. Aerosolization studies that may include biowarfare agents would seem to be a fairly high-risk activity, and there is no indication of what proportion of the labs whose experience provided the data for the studies relied on by the EA did work posing similar or greater hazards.

The EA does note that "[o]nly by prior approval of the LLNL Institutional Biosafety Committee (IBC), and after a risk analysis is conducted, would any infectious agent be considered for use in the proposed laboratories." Appendix A p.22. But this promise of a future procedure, with no guarantee of public participation, is no substitute for adequate environmental review before the facility is built.

There are other flaws in the EA's analysis both of a bounding accident and of possible worker exposures from far smaller mishaps in routine operations. Both the bounding accident discussion and Appendix B, which addresses the issue of worker exposure during operations, appear to assume that agents only could be aerosolized at the proposed facility by accident– a centrifuge accident in the case of the accident analysis, and various other laboratory errors or incidental releases in the Appendix (see Appendix B-4). One of the activities proposed for the facility, however, is aerosolization of agents, including aerosolization for animal experiments.

> "The proposed facility would have the unique capability within DOE/NNSA to perform aerosol studies to include challenges of rodents using infectious agents or biologically derived toxins (biotoxins)." EA at ii.

It would seem possible that this process would produce more efficiently aerosolized particles, possibly even in larger quantities, that the scenarios posited by the EA. The possibilities of other accidents– earthquakes, facility fires, etc.-- seems more likely during the routine, intended process of aerosolizing agents than the unlikely string of events the EA claims as the bounding accident. In addition, the possibility of failure of filter systems, both within the facility and leading outside, during aerosolization of agents is not addressed. This failure could be partial or complete, and could, depending on circumstances, go unnoticed at the time. Filters that are not functioning properly on a routine basis, and possible consequences, also are not addressed. These possibilities would seem to pose a risk of worker exposure, particularly given if DOE's past systemic problems with HEPA filters have not been fully remedied, and also of further disease spread, and should be analyzed.

Other questions and areas where past practices suggest caution

–Disposal of liquid waste.

The EA states that "Soluble or liquid waste materials generated from laboratory operations can be disposed in the laboratory sinks after first being treated with disinfectants."

p.23 It is unclear from the EA whether this waste will be discharged directly to the sanitary sewer or first to retention tanks. The EA states at page 34 that these wastes will first go to retention tanks, but at p.45 it states in connection with hazardous wastes that "There would be no retention tanks or need for waste accumulation areas since no hazardous waste would be produced (hazardous chemicals would be used up in process or leave the building as a stabilizing product for microorganisms and biological material)." Presumably this applies only to hazardous wastes, and there will be retention tanks for other liquid waste.

Discharge of improperly characterized retention tanks to the sewer system has been a problem in the past at LLNL with hazardous and radioactive wastes. This too is an area that requires further analysis, since a discharge of toxins or pathogens to the sewer system is a possibility. Sewage sludge should be analyzed as a possible transmission route for organisms discharged to the sewer.

-----Original Message-----
From: Joan M. MacIntyre [mailto:jmmmmac@pacbell.net]
Sent: Friday, September 06, 2002 3:07 PM
To: rich.mortensen@oak.doe.gov
Subject: Re: BSL-3 facility at LLNL

September 6, 2002

Dear Mr. Mortensen:

**Here are my concerns about the Environmental Assessment (DOE/EA-1442) for
the construction and operation of a Biosafety Level 3 (BSL-3) facility at the Department of Energy's (DOE) Lawrence Livermore National Laboratory
(LLNL).**

Constructing and operating a BSL-3 facility represents a new direction and program for DOE and LLNL; one that could have serious health and environmental consequences. Therefore, this proposal to create a BSL-3 facility at LLNL merits both a programmatic and project specific EIS.

**The Livermore Lab has a history of leaks, spills, fires, explosions and accidents. In recent years, these have included, but are not limited to, a chlorine gas leak that forced an evacuation, a filter shredding accident that contaminated workers with curium, numerous inadvertent releases to the
sanitary sewer and an explosion that sent one employee to the hospital. Radioactive and toxic contaminants have found their way from DOE operations
at LLNL into the air, groundwater and soil on-site and off-site, and have jeopardized the health of workers and surrounding communities.
And you propose working with bio-toxins and biological agents including anthrax, bubonic plague, botulism, small pox and even genetically modified lethal bio-warfare agents.**

Experimenting with these kinds of agents and claiming that all the work is defensive and none of it offensive will be a hard sell internationally as well as nationally.

Please rethink this idea.

Sincerely

Joan and Stuart MacIntyre

478 Jean St.

Oakland CA 94610 510 451 2712

Joan MacIntyre
Oakland CA

NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

8/20/02 — CALLED DR. MCKINZIE TO ACKNOWLEDGE RECEIPT OF FAX.

August 19, 2002

Mr. Richard Mortensen
DOE NEPA Document Manager
U.S. Department of Energy
Livermore Site Office
M/S L-293, P.O. Box 808
Livermore, CA 94551-0808
Fax: (925) 423-5650

8/21/02 - CALLED DR. MCKINZIE AND INFORMED HIM OF THE 15 DAY EXTENSION TO 9/7/02.

Dear Mr. Mortensen,

On behalf of the Natural Resources Defense Council (NRDC), we request that the comment period for the draft environmental assessment for a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory (LLNL) be extended an additional 30 days.

Given the many technical issues raised in the draft environmental assessment, the existing 30-day comment period set to expire on August 23, 2002 is an insufficient length of time to provide stakeholders with the opportunity to evaluate the proposed action and formulate comments.

Sincerely,

Matthew G. McKinzie, Ph.D.
Staff Scientist, Nuclear Program

Geoffrey H. Fettus
Staff Attorney, Nuclear Program

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nuclear watch new mexico

August 19, 2002

Mr. Richard Mortensen
DOE NEPA Document Manager
U.S. Department of Energy
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Mail Stop L-293
PO Box 808
Livermore, CA 94551-0808
rich.mortensen@oak.doe.gov

Via email

Dear Mr. Mortensen,

I am writing to you to ask that you extend the comment period for the "Draft Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California, DOE/EA-1442." As your are aware, the comment period for this Environmental Assessment (EA) is slated to end August 23, 2002. Being mindful of the intent of the National Environmental Policy Act (NEPA) and the Council on Environmental Quality (CEQ) regulations, as well as DOE's own implementing regulations, it would be in the best interest of the Agency and the public to provide the greatest possible opportunity for discourse on the proposed facility. The NEPA process is designed to provide Agencies a path for sound policy and planning decisions. It has been my experience that public input through this process has greatly aided Agencies to make wise decisions.

Though I recognize that DOE is not obligated by law to provide an extended comment period on the Draft EA, the significance of the proposed action and the great potential for public concern as a result of the unprecedented nature of the action make this a reasonable request. Furthermore, DOE did extend the comment period on the Draft EA for the proposed BSL-3 at Los Alamos National Laboratory when they realized that more time was required to discuss the proposed action. An extension of the comment period by 10-15 days could be considered reasonable.

I appreciate your consideration of this matter.

Sincerely,

Colin King
Research Director

September 7, 2002

To: Rich Mortenson
USDOE Livermore Site Office L-293
P.O. Box 808
Livermore, CA 94551

As a resident of the San Francisco Bay Area for the past 16 years, I have many concerns involving the Department of Energy's proposition regarding the building of a Biosafety Level 3 Facility at Lawrence Livermore Laboratory.

As a student at the University of California at Davis, I am pursuing a Bachelors of Science in Genetics. I am supportive of the research of the extremely harmful pathogens and agents that are classified as BSL-3. I believe that we need to understand them and develop ways to combat them should an outbreak ever occur. I also believe that development of the HANAA and the APDS at LLNL are phenomenal steps in the fight against terrorism. My concern with the pending BSL-3 facility is not the facility itself, but the location and potential use of it.

To start with, I would like to address the issue of a laboratory of this magnitude at a facility known for the manufacture of nuclear weapons. While I understand that DOE and LLNL are trying to expand their biology program to ensure national security, I do not believe building the BSL-3 at LLNL is the answer. LLNL was built in 1952 to help with the country's nuclear weapon's research, and today 50 years later, the main focus of the lab is still nuclear weaponry. As the mission of LLNL states: "Our primary mission is to ensure that the nation's nuclear weapons remain safe, secure, and reliable and to prevent the spread and use of nuclear weapons worldwide."

Since the mission of LLNL is still primarily nuclear weaponry, it makes me wonder about the intent of the biological research program. There is a fine line between defensive research and offensive research, and there is no guarantee that the BSL-3 facility at LLNL will not be used in the future for the manufacture of biological weaponry. Technically speaking under the guise of "national security" that the BSL-3 is being built on, down the road, the manufacturing of biological weaponry could also be considered national security.

With this in mind, my next concern is the threat of a terrorist attack on LLNL. With the building of the BSL-3 at the nuclear weapons facility, it does not send the message to other countries that the BSL-3 is being used purely for research purposes. LLNL is a concern as a target as it is, but adding another threat to other countries could put it over the top.

In addition to a terrorist attack, the threat of a terrorist break-in looms overhead. With so many deadly pathogens in one location, it is the prime target for a terrorist to break in and steal some to release into our country. With the past security concerns surrounding LLNL, this is not something that should be overlooked. A recent POGO (Project On Government Oversight) report found that during mock terrorist attacks at DOE facilities, the "terrorist" penetrated security and gained access to sensitive nuclear material over 50% of the time. This statistic is appallingly large, especially regarding nuclear material. I do not believe that the DOE's security problems will magically disappear when the BSL-3 facility is built at LLNL. If anything, I fear they may become worse. With the recent anthrax scare following the September 11 attacks and the concern

that the anthrax was obtained from one of our nation's own labs, this is a valid concern. Being responsible for releasing deadly pathogens into the country is not something that LLNL needs to have on their shoulders.

I am also concerned with the mode of transportation for the pathogens mentioned in the Environmental Assessment. On page 20 of the EA, it is stated the "Biological materials or infectious agents could only be shipped to LLNL by commercial package delivery services, the U.S. Postal Service (USPS), other authorized entity, or delivered to the receiving area from an origination point within LLNL by a designated LLNL employee acting as a courier". Three paragraphs down, the EA continues and says "Biological shipments to and from LLNL could initially be as much as ten time the current levels (4 in and 2 out per month now) of shipments to existing LLNL biological research laboratories." With this statistic there will be about 40 shipments in and 20 out each month, which is about 2 general shipments a day. My concern is regarding the safety of the shipments, especially traveling through USPS. I understand that the pathogens will be in safe containers, but the security of USPS itself is in question. The possibility of a shipment of pathogens being intercepted en route is something that has not been adequately analyzed in the EA. Especially with the increase in shipments, this is a danger that must be considered.

I would also like to address the issue of earthquakes and a BSL facility. The possibility of an earthquake was briefly mentioned, but not in adequate detail. On page 47 it is stated, "An earthquake, explosion, or similar event that would result in a breech or rupture of the facility's walls would be bounded by the hypothetical centrifuge-accident analysis of a *Coxiella burnetti* release from the proposed BSL-3 facility structure described later in this section. The probability of catastrophic events (due to earthquake) is already very low. The low probability of an earthquake capable of rupturing the facility containment, coupled with an additionally low probability of such an even occurring during a daytime activity where microorganism containment would be vulnerable, also make it an unlikely event."

This statement provides no significant data regarding how the conclusion was drawn about the probability of an earthquake. If in fact this statement is true, more data needs to be provided regarding the finding of this conclusion. Also, there is no significant data providing information as to why the hypothetical centrifuge accident analysis is comparable to an earthquake. What if an earthquake occurs while a lab technician is doing an injection and sticks himself? What if a lab technician is carrying a tray of petri dishes with bacterial cultures when the earthquake happens and the petri dishes get dropped on the floor, causing the bacteria to spread? These types of scenarios have not been adequately addressed for me to feel confident about the safety of the community.

A final concern I have is the need for two BSL-3 facilities at the DOE sites. In the Executive Summary on page ii, it states "DOE does not currently have under its administrative control any microbiological laboratory facility beyond Biosafety Level (BSL)-2." While this statement is currently true, I know that an Environment Assessment had been issued for the building of a BSL-3 facility at Los Alamos National Laboratory (LANL) on October 30, 2001 and that a Finding of No Significant Impact was Issued on February 26, 2002. Knowing all of this, I assume that plans are underway for the BSL-3 at LANL, which would render the statement in the Executive Summary

false in a matter of time. With this in mind, I wonder why it is necessary for the DOE to have two BSL-3 facilities under its jurisdiction, when the research could be done at one location, minimizing the potential risk.

Since DOE is currently looking to have two BSL-3 facilities at two of their nuclear weapons facilities, built within a short time frame, I would like to request a Programmatic Environmental Impact Statement (EIS). LLNL and LANL are introducing new programs that will be very intertwined with each other--these are not unrelated projects, and a full assessment of this new operation is needed.

In addition to the Programmatic EIS, I believe a project specific EIS also needs to be issued for LLNL. The draft EA that was issued does not adequately consider the impact on the environment, including providing significant data, relative accident scenarios, and a response to safety threats.

Signed:

Whitney Tiedemann
4057 Terra Alta Dr.
San Ramon, CA 94583
wetiedemann@ucdavis.edu

-----Original Message-----
From: Robin Wood [mailto:robinwood@attbi.com]
Sent: Saturday, August 10, 2002 2:48 PM
To: Rich Mortensen
Subject: biosafety

Dear Mr. Mortensen,
I live one block from the lab. I want to know what plans the lab has in case there is an accident with the biosafety level 3 facility. How would neighbors such as myself be notified of a problem? How would we know how to protect ourselves?

Thanks in advance for your response,

Robin Wood