U.S. Department of Energy
Revised Finding of No Significant Impact
for the Biosafety Level 3 Facility
at Lawrence Livermore National Laboratory

AGENCY: U.S. Department of Energy

ACTION: Finding of No Significant Impact

SUMMARY: An Environmental Assessment (EA) and a Finding of No Significant Impact for a proposed BSL-3 facility was issued in December 2002 (BSL-3 EA, DOE/EA-1442), and construction of the facility began. On September 16, 2003, Tri-Valley CARES filed a lawsuit in the federal district court in San Francisco challenging the adequacy of the EA for the proposed BSL-3 facility. On September 10, 2004, the district court found the EA to be adequate. On November 8, 2004, Tri-Valley CARES filed a notice of appeal with the Ninth Circuit Court of Appeals. On October 16, 2006, the appellate court issued a memorandum opinion (D.C No CV-03-03926-SBA). In light of the Ninth Circuit's recent ruling in an unrelated case, the court remanded the matter for DOE to consider whether the threat of potential terrorist activity necessitates the preparation of an environmental impact statement.

The U.S. Department of Energy (DOE) has prepared a Revised Environmental Assessment (EA), DOE/EA-1442R, to assess the potential environmental impacts associated with the construction and operation of the proposed Biosafety Level 3 Facility (BSL-3) at the Lawrence Livermore National Laboratory (LLNL) in Livermore, California, including those impacts potentially associated with terrorist activities.

DOE became involved in bioscience work in support of its biology and biotechnology research programs, work for other agencies, and work in support of the Chemical and Biological National Security Program (CBNP). The National Nuclear Security Administration's CBNP mission was 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." Since this EA was originally published, many of DOE's missions relating to biological security have been transferred to the Department of Homeland Security (DHS) by the Homeland Security Act of 2002. The Act authorizes DHS to access the capabilities of DOE's laboratories and other sites to further DHS mission objectives. As a result, DOE and Lawrence Livermore National Laboratory continue to support this mission by performing work for the DHS on a "work for others" basis.

In order to meet these 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 mission, therefore, also requires the capability to handle operations

involving rodent challenges of bioagents (and possibly biotoxins) and the ability to produce small amounts of biological material (enzymes, DNA, ribonucleic acid [RNA], etc.) using infectious agents and potentially, genetically modified agents under conditions that would require management of a facility at the BSL-3 level.

An on-site BSL-3 facility would provide safe and secure handling and storage of infectious microorganisms at a time when these issues are imperative to national security research. 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.

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. The operational design life of the proposed facility would be at least 30 years.

No significant environmental impacts are expected as a result of the proposed action. Site preparation and construction impacts associated with the proposed action have already occurred.. The potential environmental consequences from routine operation would be minor and would not differ greatly between the Proposed Action and alternatives. By adopting the guidelines established mutually by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) as standards, the potential human health effects of operating the proposed BSL-3 laboratory would be very low, as have been those demonstrated for operating similar existing CDC-registered laboratories that are required to implement the same guidelines. Relevant human health information indicates that laboratory-acquired or laboratory-associated infections should be considered abnormal events due to their infrequency of occurrence. No cases of illness would be expected to result from implementing the Proposed Action.

All room air used within the facility would be doubly HEPA-filtered before release. Such air emissions from the facility would not result in any significant human health or environmental impact. There would be no radionuclides and no chemicals present in the facility other than routine industrial cleaners and process chemicals. As a result, no significant quantities of such materials that could adversely impact human health or the environment would be susceptible to release in the event of an accident. Liquid biological-material wastes to be released from the proposed facility to the sanitary sewer would not be hazardous and would not require any upgrade to the sewer system or the Livermore Water Reclamation Plant (LWRP). Such liquid wastes would be first autoclaved or chemically disinfected before release to the sanitary sewer system. Construction activities would not occur at a depth at which finding of cultural or paleontological resources would be anticipated. Furthermore, no significant cumulative impacts or environmental justice issues are expected.

On September 16, 2003, suit was filed in federal district court challenging the adequacy of the prior version of this EA. The district court ruled that the EA was adequate and plaintiffs appealed to the Ninth Circuit. In October 2006, the appellate court issued its decision. It concluded that while NNSA did take a hard look at identified environmental concerns and that its decision was fully informed and well-considered, the NNSA had not considered whether the threat of potential terrorist activity necessitated the preparation of an environmental impact statement. The Court therefore remanded the matter to NNSA.

In accordance with the Ninth Circuit's remand, NNSA has reviewed the threat to the facility from terrorists and the potential environmental effects that might derive from various terrorist acts against the facility. This review finds that, because of the extensive layered security programs at the LLNL, no environmental impacts are expected as a result of potential terrorist activities directed against this facility.
Based on the analysis in the EA and considering public comment, DOE/NNSA has determined that the proposed action does not constitute a major federal action significantly affecting the quality of the human environment within the meaning of the *National Environmental Policy Act of 1969*, 42 U.S.C. 4321 et seq. Therefore, preparation of an Environmental Impact Statement is not required and DOE/NNSA is issuing this notice of Finding of No Significant Impact (FONSI).

PROPOSED ACTION: DOE proposes to construct and operate a new facility, the Biosafety Level 3 (BSL-3) Facility, at LLNL. The proposed facility would be approximately 1,500-ft^2 located near the center of the LLNL Livermore site.

The proposed facility would consist of a one-story permanent prefabricated BSL-3 laboratory facility assembled on-site, which would have three individual BSL-3 laboratory rooms (one of which would be capable of holding 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. The proposed action would include minor modifications to existing parking areas and site landscaping.

The Proposed Action and its alternatives differ mainly in how the facility would be constructed. The BSL-3 facility would be designed and operated in accordance with guidance for BSL-3 laboratories established by the CDC and the 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 a capability to perform small-volume aerosol challenges of rodents, using infectious agents or biologically derived toxins (biotoxins). Sample shipments would be received only in compliance with all established Department of Transportation (DOT) and CDC 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.

ALTERNATIVES: Three alternatives to the Proposed Action were considered and discussed in the EA.

- The No-Action Alternative
- Construct and Operate an On-Site-Constructed BSL-3 Facility
- Remodel/Upgrade a Single-Room Laboratory in Building 365 to BSL-3

Three other alternatives were considered in the EA, but were eliminated from detailed analysis for a number of reasons.

- Construction and Operation of the Proposed BSL-3 Facility at Another Main Site LLNL Location
- Construction and Operation of the Proposed BSL-3 Facility at Site 300
- Construction and Operation of the BSL-3 Facility at Another National Security Laboratory

No-Action Alternative. Under the No Action Alternative, NNSA would not construct or operate a BSL-3 facility at LLNL. In this event, NNSA would continue to have its BSL-3-level needs met by exporting work and staff to 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 DOE's purpose and need.

Construct and Operate an On-site-Constructed BSL-3 Facility. This alternative would meet NNSA's purpose and need for action. This alternative does not differ significantly from the Proposed Action in terms of operation and decontamination and decommissioning, with one exception. The longer time it would take to construct the facility under this alternative would increase the duration of noise, traffic, and disruption of workers in adjacent buildings. This longer period also means it would be months longer before the facility would be operational.

Remodel/Upgrade a Single-Room Laboratory in Building 365 to BSL-3. Under the Remodel/Upgrade Alternative, NNSA would create a single-room BSL-3 laboratory from an existing BSL-2 laboratory at LLNL. This would require substantial building modification and probable disruption of other ongoing work in the current facility. This alternative would have the lowest waste generation during construction and operation since it would be only a single laboratory while the other two options consist of a facility of three laboratories each. This alternative would meet NNSA's purpose and need for action, but, being only a single BSL-3 laboratory, it would be self-limiting to the amount of research that could be conducted.

ENVIRONMENTAL CONSEQUENCES: The construction and operation of the proposed facility would not pose any significant impacts, either directly or cumulatively when considered in the context of other planned actions, on human health or the environment.

Less than one-quarter acre of previously disturbed land would be used for site preparation, utility installation, and other construction activities. Except for the

temporary disturbance of up to a few feet in depth on parts of the land during site preparation and construction, the effect upon geology, soils, or seismicity would be negligible. Soil erosion-prevention measures (application of the Storm Water Pollution Prevention Plan for mainsite LLNL activities) would be in place during construction. The disturbed construction areas not covered by the building footprint or by parking areas would be reseeded and landscaped to control and minimize erosion from stormwater runoff. No threatened or endangered species habitat are located at or adjacent to the proposed BSL-3 laboratory facility. Due to the previously disturbed nature of the area and the shallow nature of any proposed excavation, there are not expected to be any impacts to potential cultural or paleontological resources. However, if any items of cultural or paleontological significance are uncovered, work would halt until the LLNL archaeologist can assess the find.

Human Health.
Human health effects during construction of the proposed BSL-3 laboratory would be very minor and localized, affecting only workers or officially-sponsored visitors. The proposed action is expected to have no substantial effect on the health of any non-LLNL construction workers. There would be no public human health effects during construction.

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. 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. Experience with biological research laboratories at LLNL spans a period of many years. LLNL has operated BSL-1- and BSL-2-equivalent laboratories for at least the last 20 years without any infections associated with their operation. Also, there were no unintentional releases to the environment or to the public associated with the LLNL biological research laboratories. 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 a significant impact from normal operations to the workers or the public. 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 infectious agents that would be best characterized as minor. Also, a substantial release of infectious microorganisms from the confinement of the facility (specifically at greater than infectious dose quantities) would be unlikely to occur under those operating parameters. The maximum potential impact per liter of air at 125 ft (38 m) from the building exhaust that could derive from the bounding accident that might occur from handling infectious material is projected to be less than one one-hundredth of the dose that would be infectious to an individual 50% of the time (HID_{50}). The nearest site boundary to the general public would actually be approximately one-half mile away,

further reducing the potential for even a tiny fraction of one individual HID_{50} reaching the site boundary. There would be no discernible public human health effect from BSL-3 laboratory operations at the proposed facility.

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:

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. Operations as described minimize opportunities for direct transmission. This potential is further reduced through the intervention of effective vaccines or therapeutic measures.

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 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 sterilization by autoclave or chemically. The guidelines (established by the CDC and NIH) to be followed within the proposed BSL-3 facility would minimize this potential for a worker to unknowingly transport infectious microbes from the facility.

Airborne Transmission. Air leaving the BSL-3 laboratories during operating conditions would be doubly HEPA-filtered prior to emission through stacks on the building roof. HEPA filters at the LLNL BSL-3 facility (including those in the biosafety cabinets [BSC]) 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). The number of viable vegetative microorganisms after HEPA filtration would be near zero. Also, regardless of the presence or failure of HEPA filters, many environmental factors (including ultraviolet light, dehydration, high temperatures, freezing temperatures, and the presence of free oxygen) present would effectively and naturally kill airborne microbes in their vegetative state.

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.

Rodent Handling Operations. The proposed facility would use a state-of-the-art ventilated caging system designed for easy cleaning, with high rates of exchange air, and 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. An inadvertent needlestick (autoinjection) or rodent bites and scratches can be

averted by adhering to standard operating procedures (SOPs) and safety procedures using safety equipment that virtually eliminate these occurrences. 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 being handled. Human pathogens for which there is no immunization or prophylaxis would not be handled in the proposed BSL-3 laboratory, in accordance with the CDC/NIH guidelines.

Rodent Challenge Studies. Aerosol studies using rodents such as mice and rats to be planned for the proposed activity would only be done inside a biosafety cabinet (BSC) that meets all currently applicable CDC/NIH requirements for the materials involved. The small aerosol-challenge device (collision nebulizer) would have its reservoir filled while in the BSC. The rodent challenged with the aerosol would be placed into a clean cage. The nebulizer would be cleaned and chemically disinfected while still in the BSC. Compressed air 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 also would be put into an autoclave to insure sterilization.

Biotoxin Research. The proposed facility would have appropriate procedures in place prior to operation of the facility. The probability of being exposed to a biotoxin would be extremely low when appropriate safeguards and other safety procedures are followed. The nearest member of the public would be about one-half mile away and would have a very low likelihood of being exposed to even a small dose of biotoxins. Adverse health effects to uninvolved workers in adjacent buildings or visitors would be extremely unlikely to develop from this activity. Any adverse effect to the environment from the accidental release of non-indigenous organisms would be extremely unlikely as well.

Transportation. The addition of milliliter-quantity samples being shipped to and from the BSL-3 facility through the U.S. Postal Service or by commercial or private courier would not be expected to change the overall 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.

Chemicals/Materials Use.
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 would be brought in only when required for room fumigation. The chemicals used and stored would be tracked using ChemTrack (LLNL's computerized chemical inventory system) and would be handled in accordance with LLNL directives and guidelines for environment, safety, and health.

Noise.
Members of the public would not be exposed during construction to noise levels exceeding City of Livermore 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), predicated on the distance of the proposed facility being about one-half mile to the nearest residence.

Air Quality.
The proposed action would not lead to an adverse impact on air quality. Dust suppression measures would be implemented during site preparation and construction, as necessary, to minimize any temporary increase in particulate emissions. Since very few pieces of heavy equipment generating combustive-engine exhausts would be used, and for limited time, their potential effect on ambient air quality would be temporary and localized. 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 of air contaminants due to BSL-3 laboratory operation.

Waste.
The incremental increase in waste materials produced during site preparation and construction (construction debris and excess uncontaminated soil from excavation activities) would be minimal with respect to the waste production of the entire LLNL facility. The incremental sanitary sewer waste production associated with the operation of the proposed facility would be minimal when compared to the total waste volumes generated by the entire LLNL facility and negligible with respect to the City of Livermore's sewer system discharge. Although no discharge limits currently exist for infectious materials which are commonly discharged by BSL-3-level healthcare and veterinary facilities and laboratories or homes, liquid waste as generated from the proposed BSL-3 laboratory operations would be discharged first to a retention tank system (for containment, characterization, and further disinfection as needed) prior to discharge to the sanitary sewer system. Minimal amounts of hazardous waste (less than 2 gallons per year) would be generated by the facility. Most hazardous chemicals would be used up in process or leave the building as a stabilizing product for microorganisms and biological material.

Other impacts.
The proposed action would include very minimum hiring and, therefore, would not result in an increase in demand for local housing, when considered cumulatively with other DOE actions that could increase employment. In addition, the increase in employees would not contribute to any additional traffic congestion at the LLNL site or in the local

area. No adverse impact is expected to any minority or low-income populations and, therefore, no environmental justice issues are associated with this project.

Terrorism
NNSA has reviewed the threat to the facility from terrorists and the potential environmental effects that might derive from various terrorist acts against the facility. Three terrorist acts were considered: 1) a terrorist attack resulting in facility damage; 2) a theft of pathogenic agent by a terrorist from outside of LLNL; 3) a theft of pathogenic agent by an insider. This review finds that:

1. a successful terrorist attack involving facility damage and loss of containment is not expected to occur due to the extensive layered security programs at the LLNL; in any event, the environmental consequences would be bounded by the effects that would occur during catastrophic events or operational accidents;
2. because pathogenic agents are available in nature and other, less secure locations, operation of the LLNL BSL-3 facility would not make pathogenic agents more readily available to an outside terrorist, or increase the likelihood of an attack by an outside terrorist; and
3. the theft of pathogenic materials by an insider from any bio research facility could have very serious consequences; this scenario is not expected to occur at LLNL due to human reliability programs, security procedures, and management controls at the BSL-3 facility.

NNSA believes that the probability of a successful terrorist attack on the BSL-3 facility is so uncertain that the possibility of such an event cannot be accurately quantified. The systems and technologies developed in the proposed facility would likely reduce the probability and consequence of a bio-terrorist act against the public in general.

PUBLIC COMMENTS ON THE REVISED EA: The EA was circulated for review and comment to the State of California and other interested stakeholders for a 30-day comment period that ended on June 11, 2007. Appendix C of the EA contains the DOE/NNSA responses to specific comments received during that public comment period.

DETERMINATION: Based on the analysis in the EA, and after consideration of all comments received, DOE/NNSA has determined that the proposed action does not constitute a major federal action significantly affecting the quality of the human environment within the meaning of the *National Environmental Policy Act of 1969*, 42 U.S.C. 4321 et seq. Therefore, preparation of an Environmental Impact Statement is not required and DOE/NNSA is issuing this notice of Finding of No Significant Impact (FONSI).

PUBLIC AVAILABILITY: Copies of this EA (DOE/EA-1442R) and FONSI are available from:

Samuel Brinker
Document Manager
Livermore Site Office
U.S. Department of Energy
P.O. Box 808, L-293
Livermore, CA 94550
Phone: (925) 422-0710

For further information regarding the NEPA process, contact:

Karin King
NEPA Compliance Officer
Livermore Site Office
U.S. Department of Energy
P.O. Box 808, L-293
Livermore, CA 94550
Phone: (925) 422-0756

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Camille Yuan-Soo Hoo, Manager
Livermore Site Office