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Final Environmental Assessment

Biomedical Research at Existing Biosafety Level 3 Laboratories with Registered Select Agent Programs

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1.0 PURPOSE AND NEED

1.1 Introduction

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. § 4321 et seq.) requires Federal agency officials to consider the environmental consequences of their proposed actions before decisions are made to proceed. The United States (U.S.) Department of Energy (DOE) adheres to Council on Environmental Quality (CEQ) regulations (40 Code of Federal Regulations [CFR] Parts 1500-1508) and DOE's own NEPA implementing regulations (10 CFR Part 1021) in pursuit of NEPA compliance. This Environmental Assessment (EA) has been prepared to assess the environmental consequences resulting from DOE's proposed action to access and use existing, operating biosafety level 3 (BSL-3) facilities with select agent registration to conduct biomedical research. The purpose of this EA is to provide Federal decision-makers with sufficient information and analysis to determine whether to prepare an Environmental Impact Statement (EIS) for the proposed action or issue a Finding of No Significant Impact. This EA discusses the need for the proposed action, alternatives to the proposed action, and the potential environmental impacts of both the proposed action and the alternative.

1.2 Background

DOE's Pacific Northwest National Laboratory (PNNL) provides critical biological research capabilities to the Department of Homeland Security (DHS) in support of its mission in the areas of bioforensics and biothreat characterization, detection, and assessment, and to other Federal agencies' research missions related to bio-agent counter-terrorism technologies and improved prevention and treatment of emerging natural diseases. PNNL technologies and capabilities in the biological sciences include biological threat signature science, pathogen characterization, medical countermeasures development, early diagnostics, biodetection, and bioforensics for improved health and biosecurity.

Biomedical research in support of Federal agencies' research missions is typically conducted in laboratories with biosafety containment levels specified by the Department of Health and Human Services' (HHS's) Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) manual *Biosafety in Microbial and Biomedical Laboratories* (BMBL) (CDC and NIH 2009). Biosafety containment levels are ranked from one to four and are selected based on the agents or organisms used in the research. The primary risk criteria used to define the four ascending levels of containment are infectivity of the organisms, severity of disease, transmissibility, and the nature of the work being conducted. Each level builds on the containment and protection of the previous level, adding constraints and barriers. The recommendations in the BMBL are not requirements, however, the BMBL recommendations are considered best practices in biomedical research, and they are typically followed in biosafety laboratories. Brief summary descriptions of the recommendations for each biosafety level are presented in Table 1-1.

BSL-3 laboratory facilities that follow the BMBL recommendations are specifically designed for work with bio-agents 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). The purpose of BSL-3 containment is to reduce or eliminate exposure of laboratory workers, other facility personnel, and the outside environment to potentially hazardous agents (CDC and NIH 2009). Examples of common BSL-3 facilities include hospital surgical suites, clinical, diagnostic, and teaching laboratories associated with medical or veterinary schools, and research and development laboratories.

The CDC and the Animal and Plant Health Inspection Service (APHIS) are the governmental agencies responsible for the management of the Federal Select Agent Program (FSAP), which was established to satisfy requirements of the USA PATRIOT Act of 2001 (Public Law 107-56) and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). Under this program, the CDC and APHIS regulate the possession, use, and transfer of biological agents or toxins (i.e., select agents and toxins) that have the potential to be used for bioterrorism and that could pose a severe threat to public, plant or animal health and safety. Unless exempted, individuals or entities operating BSL-3 or BSL-4 laboratories must register with the CDC if they possess, use, or transfer select agents or toxins that are harmful to human health. Entities or individuals operating BSL-3 laboratories that possess, use, or transfer select agents or toxins that are harmful to plant or animal health must register with APHIS under the U.S. Department of Agriculture (USDA). If an entity has agents harmful to both human and animal health, it must submit its registration information to either the CDC or APHIS, but is not required to submit the application to both. In 2010, almost 1,500 BSL-3 laboratories with select agent programs, registered with the CDC and APHIS, were operating in the United States (Kaiser 2011). The process for individuals and entities registering with APHIS is essentially the same as the process for registering with the CDC. The CDC and APHIS select agent registration process includes consideration of BMBL recommendations through their Inspection Checklist for BSL-3 Laboratories (FSAP 2014a). The current list of the CDC and APHIS select agents and toxins is available on the FSAP website (FSAP 2016).

Table 1-1. Summary of Recommendations for Laboratory Biosafety Levels 1–4

	BSL-1	BSL-2	BSL-3	BSL-4
Agents	Not known to consistently cause disease	Agents associated with disease	Serious or lethal disease, vaccines and/or treatments available	Serious or lethal disease for which there are no vaccines or treatments
Practices	Standard microbial	BSL1-practice plus: Limited access Sharps precautions	BSL-2 practice plus: Controlled access Decon of all waste Decon of lab clothing before laundering	BSL-3 practice plus: Clothing change before entering Shower on exit All material decontaminated on exit from facility
Primary barriers and equipment	PPE[(a)] as needed	BSC[(b)] or other containment used for aerosols PPE: lab coats, gloves, face and eye protection	BSC or other containment used for all open manipulations of agents PPE: protective lab clothing, gloves, face, eye, and respiratory protection	All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full body, air supplied, positive-pressure suits
Facilities	Lab bench and sink	BSL-1 plus: Autoclave available	BSL-2 plus: Physical separation from access corridors Self-closing, double-door access Exhausted air not recirculated Negative air flow Entry through anteroom	BSL-3 plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decontamination systems

(a) Personal protective equipment
(b) Biosafety cabinet

DOE does not currently operate any microbiological laboratory facilities at PNNL above biosafety level 2 (BSL-2). Current research in PNNL's BSL-2 laboratory space relies on the use of surrogate organisms, which are organisms with similar characteristics to those requiring BSL-3 containment but without the same health risks. However, research using surrogates does not always directly translate

to research using the fully virulent organisms that require BSL-3 containment and select agent controls. Consequently, PNNL collaborates with others to culture, manipulate, and inactivate samples in a BSL-3 environment. The inactivated samples, which are not infectious and do not require BSL-3 containment, are then shipped to PNNL to complete the requisite research in PNNL's BSL-1/BSL-2 laboratory space. This process leads to decreased efficiency and a potentially reduced level of scientific quality for several reasons. First, cross-contamination and degradation in samples may occur during handling and transportation. Second, the intricate nature of the experiments and research protocols and limited cognizance of the collaborators of the full research context have resulted in scientific quality and repeatability challenges, lost time due to repeated work, and an inability to capture details that may be pertinent to the sensitive aspects of the research. For these reasons, some research requires all phases to be performed by PNNL-affiliated staff[1] in BSL-3 space with select agent registration.

1.3 Purpose and Need for Agency Action

In support of sponsors' missions, PNNL's biological research program requires the study and use of live organisms and select agents, some of which require BSL-3 containment. PNNL-affiliated research staff need access to one or more currently operating BSL-3 facilities with select agent registration because PNNL currently lacks any qualified BSL-3 select agent facilities. The proposed action is needed to provide options for trained PNNL-affiliated research staff to conduct biological research activities in existing laboratories operating with BSL-3 containment conforming to the recommendations in the BMBL and having the CDC and/or APHIS select agent registration as appropriate for the pathogens used.

[1] *PNNL-affiliated staff* include all PNNL staff, subcontractors, and/or collaborators that are working directly or indirectly on a PNNL project, under PNNL requirements for BSL-3 work.

2.0 DESCRIPTION OF PROPOSED ACTION AND ALTERNATIVES

2.1 Proposed Action to Access and Use Existing Operational Offsite BSL-3 Facilities

The proposed action is for PNNL-affiliated staff to access and use existing BSL-3 facilities with the CDC and/or APHIS select agent registration to conduct biomedical research. The facilities considered for the proposed biomedical research would already possess all other necessary operating licenses and/or other authorizations necessary to perform similar work. Given the diversity of research needs, as well as facility capabilities and availability, use of multiple currently unidentified BSL-3 facilities with select agent registration is proposed. The proposed action does not include any research using live animals.

The description of the proposed action in this EA presents DOE's assumptions for the configurations of BSL-3 facilities accessed and PNNL's planned usage. Facilities ultimately selected for access and use are expected to be similar to the described configurations and usage. Therefore, DOE expects that the impacts from access and use of any actual facilities chosen would be within the bounds of the environmental impacts identified and analyzed in this EA. Prior to accessing any facility, the facility's configuration, containment, and procedures would be reviewed by DOE and compared to the facility parameters assumed in this EA.

2.1.1 Description of Typical BSL-3 Facilities

All facilities to be accessed and used by PNNL-affiliated staff would follow the BMBL recommendations, as appropriate, based on the pathogens being used. The CDC and APHIS select agent registration process includes consideration of BMBL recommendations through their *Inspection Checklist for BSL-3 Laboratories* (FSAP 2014a). During the inspection, the CDC or APHIS reviews how the BMBL is being applied to facility and laboratory activities using a graded approach. Registration provides assurance that a facility has adopted the BMBL recommendations applicable to operations conducted at that facility.

Primary and secondary containment recommendations for BSL-1, BSL-2 and BSL-3 laboratories are described in detail in the BMBL, which is incorporated by reference (CDC and NIH 2009). According to the CDC, safety equipment and personal protective equipment (PPE) in BSL-3 laboratories form the primary barriers to exposure (CDC and NIH 2009). Safety equipment includes biosafety cabinets (BSCs), enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The BSC is the principal device used to provide containment of infectious droplets or aerosols generated by many microbiological procedures. Three types of BSCs (Class I, II, and III) used in microbiological laboratories are described and illustrated in the BMBL, Appendix A. Open-fronted Class I and Class II BSCs are primary barriers that offer significant levels of protection to laboratory personnel and to the environment when used with good microbiological techniques. Class II BSCs also provide protection from external contamination of the materials (e.g., cell cultures and microbiological stocks) being manipulated inside the cabinet. Gas-tight Class III BSCs provide the highest attainable level of protection to personnel and the environment.

Figure 2-1. NUAIRE Class II, Type A2 Biosafety Cabinet[2]

Safety equipment may also include PPE such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, and safety glasses or goggles. PPE is often used in combination with BSCs and other devices that contain the agents or materials being handled. In some situations in which it is impractical to work in BSCs, PPE may form the primary barrier between personnel and the infectious materials. Examples include agent production activities, and activities relating to maintenance, service, or support of the laboratory facility.

Facility design and construction provide secondary barriers to exposure, contribute to the laboratory workers' protection, provide a barrier to protect workers outside the laboratory, and protect persons or animals in the surrounding community from infectious agents that may be accidentally released from the laboratory. At BSL-3 facilities, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the public, and the environment from exposure to potentially infectious aerosols than at BSL-1 or BSL-2 levels. Secondary barriers for BSL-3 space include controlled access to the laboratory and ventilation requirements that minimize the release of infectious aerosols from the laboratory. Controlled access measures typically include locked access doors and storage freezers. Ventilation requirements typically include double HEPA filtration systems on exit stacks from the building.

The BMBL provides recommendations for typical BSL-3 practices and laboratory configurations (CDC and NIH 2009). The recommendations listed in the BMBL include the following guidelines:

1. *Laboratory doors must be self-closing and have locks in accordance with the institutional policies. The laboratory must be separated from areas that are open to unrestricted traffic*

[2] The use of a trade name does not constitute an endorsement. This is only shown to be representative of the type of equipment that would be used.

flow within the building. Laboratory access is restricted. Access to the laboratory is through two self-closing doors. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.

2. *Laboratories must have a sink for hand washing. The sink must be hands-free or automatically operated. It should be located near the exit door. If the laboratory is segregated into different laboratories, a sink must also be available for hand washing in each zone. Additional sinks may be required as determined by the risk assessment.*
3. *The laboratory must be designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted. Seams, floors, walls, and ceiling surfaces should be sealed. Spaces around doors and ventilation openings should be capable of being sealed to facilitate space decontamination.*
    a. *Floors must be slip resistant, impervious to liquids, and resistant to chemicals. Consideration should be given to the installation of seamless, sealed, resilient or poured floors, with integral cove bases.*
    b. *Walls should be constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated.*
    c. *Ceilings should be constructed, sealed, and finished in the same general manner as walls.*

    Decontamination of the entire laboratory should be considered when there has been gross contamination of the space, a significant change in laboratory usage, a major renovation, or a maintenance shutdown. Selection of the appropriate materials and methods used to decontaminate the laboratory must be based on the risk assessment.
4. *Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment must be accessible for cleaning.*
    a. *Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.*
    b. *Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectants.*
5. *All windows in the laboratory must be sealed.*
6. *BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.*
7. *Vacuum lines must be protected with HEPA filters, or their equivalents. Filters must be replaced as needed. Liquid disinfectant traps may be required.*
8. *An eyewash station must be readily available in the laboratory.*
9. *A ducted air ventilation system is required. This system must provide sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas. The laboratory shall be designed such that under failure conditions the airflow will not be reversed.*
    a. *Laboratory personnel must be able to verify directional airflow. A visual monitoring device, which confirms directional airflow, must be provided at the laboratory entry. Audible alarms should be considered to notify personnel of air flow disruption.*
    b. *The laboratory exhaust air must not recirculate to any other area of the building.*

c. *The laboratory building exhaust air should be dispersed away from occupied areas and from building air intake locations or the exhaust air must be HEPA filtered.*

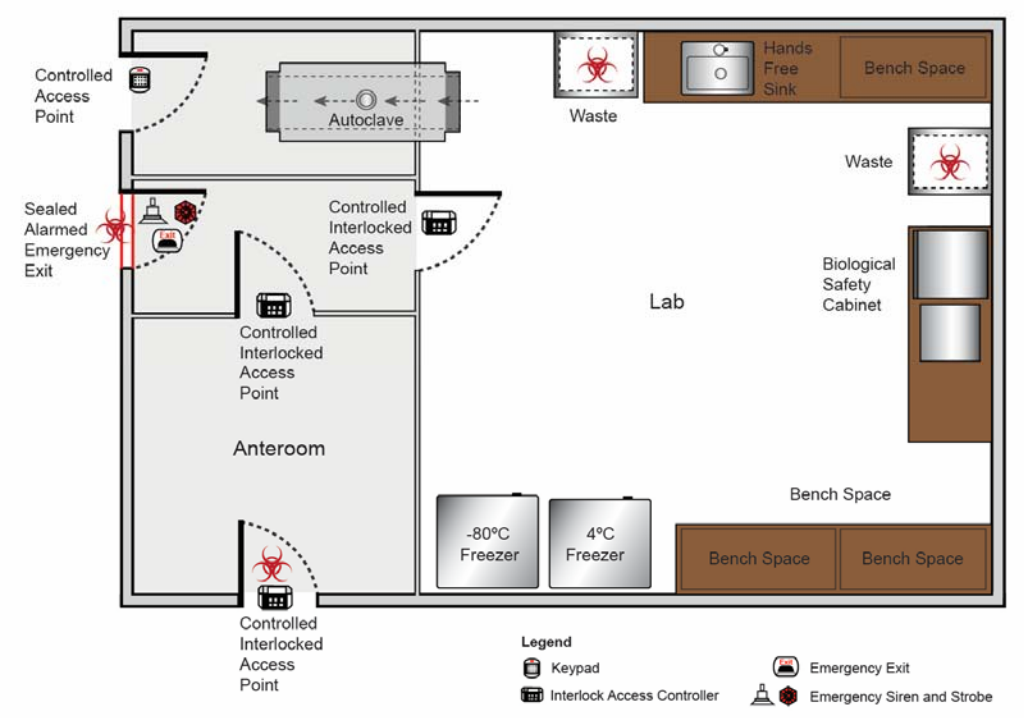
HEPA filter housings should have gas-tight isolation dampers, decontamination ports, and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing should allow for leak testing of each filter and assembly. The filters and the housing should be certified at least annually.

10. *HEPA filtered exhaust air from a Class II BSC can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified. BSCs should be certified at least annually to assure correct performance. Class III BSCs must be directly (hard) connected up through the second exhaust HEPA filter of the cabinet. Supply air must be provided in such a manner that prevents positive pressurization of the cabinet.*
11. *A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, or other validated decontamination method).*
12. *Equipment that may produce infectious aerosols must be contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters should be tested and/or replaced at least annually.*
13. *Facility design consideration should be given to means of decontaminating large pieces of equipment before removal from the laboratory.*
14. *Enhanced environmental and personal protection may be required by the agent summary statement, risk assessment, or applicable local, state, or Federal regulations. These laboratory enhancements may include, for example, one or more of the following: an anteroom for clean storage of equipment and supplies with dress-in, shower-out capabilities; gas-tight dampers to facilitate laboratory isolation; final HEPA filtration of the laboratory exhaust air; laboratory effluent decontamination; and advanced access control devices, such as biometrics.*
15. *The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually.*

(CDC and NIH 2009: pp. 42–45).

A typical BSL-3 laboratory is shown in Figure 2-2. An anteroom is located at the entrance to the laboratory to provide space for personnel to don personal protective gowns, respirators, and other PPE. Research activities in the laboratory are typically conducted in a BSC. Air pressure differentials in the building create airflows from the anteroom into the laboratory, then into the BSCs. Locked freezers are used to store organisms when not in use. A pass-through autoclave is typically used to decontaminate all lab materials and equipment exiting the facility as waste. An autoclave is a pressure chamber used to carry out high temperature sterilization. Waste containers are marked as appropriate for the level of stored waste. Air exhaust from BSCs, autoclaves, and from room spaces passes through double HEPA filtration banks prior to release from the facility stack. Liquid wastes from sinks or floor drains are typically collected in carboys or facility collection tanks for treatment.

Figure 2-2. Typical BSL-3 Laboratory



2.1.2 Select Agent Registration

PNNL biomedical research in any given BSL-3 facility could include several select agents, including but not limited to *Bacillus anthracis*, *Yersinia pestis*, *Clostridium botulinum*, *Coccidioides immitis*, *Brucella* spp., *Francisella tularensis*, *and Rickettsia* spp. Research under the proposed action would only be conducted in BSL-3 facilities with an active select agent program registered with the CDC and/or APHIS, as appropriate for the pathogens being used. Facilities are registered with a unique registration number obtained from the CDC according to regulations at 42 CFR Part 73, or from APHIS according to regulations at 7 CFR Part 331 and 9 CFR Part 121, after providing sufficient information that the facility meets biosafety level requirements for working with the particular biological agent. The CDC (42 CFR Part 73) and APHIS (7 CFR Part 331 and 9 CFR Part 121) FSAPs for handling of select agents contain several components and provisions, which include the following:

1. registration of the entity or individual;
2. filing of approved transfer forms;
3. verification using audits, quality control, and accountability mechanisms;
4. agent disposal requirements; and
5. research and clinical exemptions.

The CDC and APHIS regulations are similar, with the primary difference being the list of select agents pathogens (e.g., the CDC regulates human health pathogens and APHIS regulates animal and plant pathogens). To assure that entities are complying with the requirements of the select agent regulations, the CDC or APHIS inspects entities using standardized checklists to certify that laboratories have the appropriate measures in place to deter the unauthorized access, theft, loss, or release of select agents (CDC 2015) as part of their registration process. For BSL-3 laboratories using select agents, the checklist includes the recommendations in the BMBL for BSL-3 level

containment. Entities applying for select agent registration are required to provide explanations for any variance from BMBL recommendations. Through this checklist process, recommendations for BSL-3 containment levels are incorporated into the CDC and APHIS select agent registration process.

The CDC and APHIS regulations require select agent facilities to develop and implement a security plan establishing policies and procedures to maintain the security of areas containing select agents and toxins based on a site-specific risk assessment. The key minimum security requirements are lockable refrigerators and freezers to store select agents, and controlling access to areas where select agents and toxins are stored or used from the public areas of the building. In addition to physical security measures described above, and as specified in 42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121, persons possessing, using, or transferring select agents and toxins would first:

- successfully pass the Department of Justice Security Risk Assessment;
- be authorized by the HHS Secretary or APHIS administrator; and
- be registered with the CDC and/or APHIS.

The CDC and APHIS also require personnel having access to specific select agents and toxins to enroll in and be approved by the facility Human Suitability Program. Under this program, the host facility would be responsible for training and monitoring PNNL-affiliated staff whose work requires unescorted access to select agents and toxins. Personnel are screened for physical, mental, and personality disorders potentially affecting their judgment and reliability and any other condition or circumstances that may be a security concern. In addition, personnel with access to select agents must be approved by the host facility's Responsible Official (RO) as having received the appropriate education, training, and experience for access to select agents regulated by the CDC under 42 CFR Part 73 and by APHIS under 7 CFR Part 331 and 9 CFR Part 121. (The RO is the person charged with assuring compliance with the applicable regulations.) Access to select agents in the proposed BSL-3 laboratories would be limited to a very small number (generally less than 10) of qualified PNNL-affiliated staff that are part of the host facility's Human Suitability Program and that are listed on the host facility's CDC and/or APHIS select agent registration.

The CDC and APHIS regulations require extensive documentation of activities involving select agents. Only the PNNL-affiliated staff on the host facility's CDC and/or APHIS registration would be allowed to handle the agents. All access to select agent handling areas would be recorded. Records would be kept every time an individual enters or leaves an area with select agent samples, regardless of how briefly or how often they do so. Freezers would have logs to record access, transfer, and use of the stored select agents. To satisfy the requirements of 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121, the host facility's RO would assure that detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins access and operations are maintained.

2.1.3 Typical Research Activities

All planned research activities in existing, operating BSL-3 facilities would be in conformance with guidance and requirements established by the respective facility Institutional Biosafety Committee (IBC) and by the CDC (CDC and NIH 2009), DOE, and PNNL. IBCs provide local review and oversight of nearly all forms of research utilizing biological agents, other biological materials, and toxins. Any research conducted by PNNL affliated staff would be subject to review by both PNNL's IBC and the host facility's IBC before proceeding.

In addition to approval by the host facility and PNNL IBCs, all PNNL BSL-3 work in the proposed facility would be approved and authorized by DOE and PNNL before such work could be undertaken. At a minimum, the PNNL review and approval process would include an internal review of the facility prior to startup to confirm that the building systems and procedures for safe operation are implemented, and that the health and safety of workers, public, and the environment is protected. These reviews and continued management oversight assure that operation of the BSL-3 facilities would also be in compliance with a variety of state and Federal regulations, including those promulgated by the USDA (7 CFR Part 330, 9 CFR Part 92), U.S. Department of Commerce (15 CFR Part 730), OSHA (29 CFR Part 1910), U.S. Postal Service (USPS) (39 CFR Part 111), U.S. Department of Transportation (49 CFR Part 171-178), and the HHS (42 CFR Part 73).

2.1.3.1 Sample Arrival at a BSL-3 Facility for PNNL Processing

Sample shipments would only be received at a BSL-3 facility operating within the parameters specified in all established guidelines and requirements. The PNNL Principal Investigator conducting research and receiving shipments would be registered with the CDC and/or APHIS as appropriate for the pathogens being used, and hold the correct permitting for shipping and receipt of select agents (e.g., an Animal and Plant Health Inspection Service 16-6A permit for organisms such as *Bacillus anthracis*). Biological materials or infectious agents could only be shipped to the facility by commercial package delivery services. Generally, shipment sample sizes would be small; a typical sample would consist of about one 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.

All incoming packages containing infectious agents (regardless of origination point) would be packaged in Department of Transportation (DOT)–approved packages (49 CFR Part 172). These packages would be about 15 to 20 cm in height and about 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 Part 71), the Public Health Service, and DOT regulations. Additionally, the USDA regulates the importation and interstate shipment of animal or plant pathogens (7 CFR Part 330 and 9 CFR Part 92). Other non-governmental organizations that provide requirements/guidance for transportation of infectious agents include the *Dangerous Goods Regulations*, the *Infectious Substances Shipping Guidelines* of the International Air Transport Association (IATA 2006), and the *Guidelines for Safe Transport of Infectious Substances and Diagnostic Specimens* of the World Health Organization (WHO 1997).

External packaging material from packages received at the facility would be inspected, removed, autoclaved, and disposed of according to the facility's solid waste handling procedures. The biological material samples and their packaging would be left intact and in accordance with the established chain-of-custody record for the facility. The packages would be placed in safe and secure condition within the BSL-3 laboratory where workers would process them. The samples would be stored in the BSL-3 laboratory within a locked freezer or refrigerator, according to the sample's preservation requirements. All preparations and manipulations of cultures or samples would occur within a fully operating BSC. Shipment of samples from the BSL-3 facility to other researchers or the CDC would adhere to the same guidelines and requirements that apply to incoming samples received at the facility.

2.1.3.2 General Procedures

The following general safety provisions and procedures would be in place as determined appropriate and necessary by both the PNNL and facility IBCs:

- Typical PPE would include eye protection, nitrile surgical 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 would be worn as an additional safety measure for some tasks.
- Materials used in the BSL-3 facility would be disposable (subsequent to inspection and autoclaving) according to the facility's solid waste handling procedures, except for some reusable laboratory apparatus needed for minor amounts of sterile work.
- No open flames would be allowed within the BSCs.
- Work in the laboratories would be scheduled and planned to avoid conflicts within the laboratory areas.
- 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 immunocompetence, and would have medical treatment readily available to them in the event of an accidental exposure.
- PNNL would not use or store radiological material in the BSL-3 facility.

Quantities of each cultured microorganism would be limited by experiment-specific procedures under the facility IBC approval. Less than 1 liter of cultured microorganisms in their stationary growth phase (maximum cell density of about 10^8 cells per milliliter) 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-milliliter 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.

2.2 No Action Alternative

The No Action Alternative provides a description of the environmental impacts that would likely occur if the proposed action were not implemented. This alternative is used for comparison with the potential environmental effects of the proposed action. Under the No Action Alternative, PNNL affilitated staff would not access and use existing operating BSL-3 facilities with select agent registration for biomedical research. In this event, PNNL would continue to be limited to the use of surrogates in BSL-1/BSL-2 space at PNNL, or continue to rely on others to culture, manipulate, and inactivate samples in a BSL-3 environment, with inactivated samples being shipped to PNNL to complete the requisite research.

PNNL's biological research program requires efficient sample processing, handling of a variety of organisms concurrently, and assurance of sample security and integrity by PNNL-affiliated staff. The No Action Alternative would not meet the identified purpose and need.

2.3 Alternatives Considered but Eliminated from Further Analysis

2.3.1 Construction and Operation of a New Stand-Alone BSL-3 Facility at the PNNL Richland Campus

A new laboratory facility could be constructed and operated at the PNNL Site with BSL-3 containment that conforms to BMBL recommendations and would meet the requirements for the CDC and/or APHIS select agent registration. Should a facility be constructed, it would include all of the appropriate security features necessary for BSL-3 research and work with select agents as specified in 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121. PNNL would develop and implement the necessary procedures for laboratory operations following the BMBL as implemented through PNNL's Integrated Management System. There is adequate space, utility access, site infrastructure and security at the PNNL Site for safe and secure operations.

A new BSL-3 facility at the PNNL Site would require a significant capital investment in planning, construction, startup, and operations. Currently anticipated research activities, including anticipated growth in work for DHS and other Federal agency sponsors, are not of sufficient scope or volume to justify the required capital investment. New construction was therefore deemed unreasonable. Anticipated research needs and existing capabilities to develop strategic long-term capital investment plans are continually evaluated. If a need is identified for BSL-3 space that would justify an investment in a new laboratory at the PNNL Site, a NEPA review for that proposed action would be required.

2.3.2 Retrofitting Existing PNNL Laboratory Space

Existing PNNL laboratory space could be modified and upgraded to implement the BMBL recommendations for BSL-3 containment. If facility modifications were to occur, PNNL would also develop procedures and other institutional requirements necessary for safe BSL-3 operations. Facility modifications would include security features necessary for a select agent program, such as door and freezer locks. In addition, PNNL would institute a Human Suitability Program and other security measures to meet the security requirements for select agent work as specified in 42 CFR Part 73, 7 CFR Part 331, and /or 9 CFR Part 121. Retrofitting an existing facility for the conduct of research requiring BSL-3 containment and to meet the CDC or APHIS security requirements of a select agent program would meet the identified purpose and need.

It is expected that the cost of upgrading an existing facility, such as laboratory space in PNNL Building 331, would approach or exceed the cost of constructing a new facility with the same single-laboratory capabilities. In addition to modifying space to meet BSL-3 containment, laboratory space would need to be physically isolated to meet the requirements for select agent work. Facilities not originally constructed for these purposes do not lend themselves 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.

As with the alternative of constructing a new BSL-3 facility, retrofitting an existing facility at the PNNL Site would require significant capital investment in planning, construction, startup, and operations. Similarly, currently anticipated research activities, including anticipated growth in work for DHS and other Federal agency sponsors, is not of sufficient scope or volume to justify the required capital investment in retrofitting existing space. Retrofitting an existing facility was therefore deemed unreasonable. If a need is identified for creating BSL-3 space in an existing building at the PNNL Site in the future, a NEPA review for that proposed action would be conducted.

3.0 AFFECTED ENVIRONMENT

3.1 General Assumptions for Environmental Setting

In 2010, there were almost 1,500 operating facilities in the United States with BSL-3 laboratories and Select Agent Programs registered with the CDC (Kaiser 2011). These facilities are located in a variety of environmental settings, including urban, suburban, industrial, and rural locations. The following assumptions regarding the facilities to be accessed and used under the proposed action are made:

- Accessed facilities and any associated infrastructure are fully constructed and require no additional construction or upgrades to allow the proposed PNNL access and use. Minor modifications, such as the addition of a power outlet, could be required.
- Accessed facilities and associated infrastructure are fully compliant with any applicable Federal, state, and local laws, regulations, permits and licenses required for operation. Minor changes could be required, for instance to add PNNL-affiliated staff to an existing Select Agent Program registration.
- At a minimum, containment measures, equipment, and procedures implementing the CDC's guidelines for operating a BSL-3 facility are in place at accessed facilities. Physical security measures and other programs and procedures required for a Select Agent Program are in place. PNNL-affiliated staff accessing and using these facilities would receive orientation and training in procedures and equipment use specific to any facilities accessed.

3.2 Environmental Resources Considered but Not Evaluated in Detail

The following resource areas were considered and determined to have no reasonable foreseeable nexus to the proposed action. Therefore, these resources are not considered in further detail in this EA.

3.2.1 Land Use

It is assumed any facility accessed for PNNL research activities has been constructed, is operational, and is fully compliant with local land use restrictions and zoning ordinances. Typical facilities to be accessed are already operational and are fully integrated into local land use practices.

3.2.2 Surface and Groundwater Hydrology

Currently operating facilities are assumed to be compliant with any local laws and regulations that limit releases from the facilities to surface waters and groundwater. None of the facilities accessed would have any direct release of waste streams to either surface or ground water.

3.2.3 Cultural and Historic Resources

Important cultural and historic resources can be directly impacted if they are disturbed or damaged during construction activities. Since any accessed facilities would have been fully constructed prior to PNNL access and use, any impacts to these resources would have already occurred. The continuing operation and presence of a facility may also present a visual feature that changes an important aspect of a cultural or historic resource.

3.2.4 Aquatic and Terrestrial Ecology

It can be assumed that any facility accessed by PNNL would already be operational, and therefore the impacts associated with construction would have already occurred. Operational facilities can cause ongoing ecological impacts, e.g., large structures can present obstacles for birds and can result in collisions and mortality.

3.2.5 Noise and Visual Resources

Operational facilities to be accessed by PNNL are assumed to be contributing to the ambient noise levels and visual character of the facility's location. It is assumed that these contributions are minimal, generally consistent with the character of the community, and compliant with state and local laws and regulations.

3.2.6 Socioeconomics and Environmental Justice

Facilities to be accessed by PNNL typically impact local communities through increased use of public infrastructure, utilities and services, through increased demand for housing and local business services, and through changes in tax revenues to local districts.

Environmental justice refers to a Federal policy under which each Federal agency identifies and addresses any disproportionately high and adverse human health or environmental effects of its programs, policies, or activities on minority or low-income populations (59 FR 7629). It is not known whether facilities to be accessed by PNNL under the proposed action would be located near any minority or low-income populations.

3.3 Environmental Resources Potentially Affected

3.3.1 Meteorology and Air Quality

BSL-3 facilities accessed under the proposed action could be located in multiple states in a variety of settings, including urban, suburban, industrial, and rural environments. Each setting would have unique meterological conditions and associated typical air quality. Emissions during normal operations from BSL-3 facilities are not subject to the National Ambient Air Quality Standards (40 CFR Part 50). Energy consumption by BSL-3 facilities is typical of small hospitals and other medical facilities.

3.3.2 Public Infrastructure for Waste Management

Ongoing operations in existing BSL-3 facilities to be accessed produce both solid and liquid municipal waste streams. Solid wastes result from packaging, used equipment, lab supplies, and biological materials. All solid wastes pass through an autoclave prior to exiting the facility, in order to deactivate any contamination. The resulting deactivated waste is managed in accordance with the facility's approved waste disposal procedures which typically involves disposal at municipal landfills or via municipal sewer systems.

3.3.3 Human Health

The type and rate of injuries and illnesses at a BSL-3 laboratory is presumably the same as those demonstrated for select agent–registered laboratories at hospitals and universities and other research laboratories such as U.S. Army Biological Defense Research Program (BDRP) laboratories. For the

purposes of discussing potential impacts to human health, the following categories of potentially impacted staff and public members are defined:

- **Involved worker**. The involved worker is a staff member working in the proposed facility, either directly in the biosafety laboratory space or in building areas near the laboratory space. These staff members would be aware of the potential hazards associated with biomedical research, and would have chosen to accept any risks associated with the conduct of their job.
- **Uninvolved worker**. The uninvolved worker is a staff member at the facility where the work would take place, but on a day-to-day basis has no direct involvement with research activities. They would be aware that biomedical research is conducted in the facility in which they work, but their jobs would not typically involve any potential exposure to biomedical research hazards.
- **Member of the Public**. Members of the public are any others that could be in proximity to the facility and potential release of infectious agents.

There has been an extremely low incidence of laboratory-acquired infections associated with operations in select agent–registered laboratories since the implementation of the CDC-developed biosafety containment guidelines issued in 1974. The CDC/APHIS Form 3, *Report of Theft, Loss, or Release of Select Agents and Toxins* (FSAP 2014b) is the mechanism by which the theft, loss, or release of a select agent is reported to the CDC and APHIS. The types of events that are recorded include small spills in biosafety cabinets, inventory discrepencies, and autoclave malfunctions. Henkel et al. (2012) found that a total of 727 Theft, Loss, or Release Incident Reports were received between 2004 and 2010. Based on information contained in these reports, there were 11 total laboratory-acquired infections associated with select agent releases reported between 2004 and 2010, in an average annual population of approximately 10,000 individuals with approved access to select agents. No fatalities resulted from these infections, and there were no reported cases of secondary transmission to other humans. These results show that the FSAP has been successful in implementing a monitoring program and increasing compliance of registered and exempt laboratories to determine that biosafety and security in U.S. labs is being sustained.

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, resulting in the *Final Programmatic Environmental Impact Statement [PEIS]: Biological Defense Research Program* (USAMRDC 1989). As discussed in the PEIS, "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 (USAMRDC 1989)." Since then there was one incident in 2000 (CDC 2000) where a worker was exposed to *Burkholderia mallei*, the causative agent of human glanders. The individual was hospitalized and shortly recovered. The BDRP PEIS (USAMRDC 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 (USAMRDC 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 (USAMRDC 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 five orders of magnitude higher (USAMRDC 1989).

4.0 ENVIRONMENTAL CONSEQUENCES

4.1 Environmental Consequences of the Proposed Action

This section evaluates the environmental consequences of the Proposed Action and the No Action Alternative. This evaluation addresses potential impacts resulting from routine access and use of existing BSL-3 facilities with registered Select Agent Programs by PNNL-affiliated staff and potential abnormal events (accidents or malicious acts). Environmental impacts result when there is a direct or indirect connection or "nexus" between an action and the environment, and as a result, some identifiable change in an environmental resource occurs. Impacts associated with Land Use, Surface and Groundwater Hydrology, Cultural and Historic Resources, Aquatic and Terrestrial Ecology, Noise and Visual Resources, and Socioeconomic and Environmental Justice would have been primarily associated with the construction of the existing facilities and any related infrastructure, and would have already occurred prior to the proposed action. There would not be any discernable impact to or from these resource areas as a result of the proposed action, and they are not discussed in detail in this section. The potential impacts discussed in this section are those in which PNNL research activities could potentially contribute in some way to ongoing impacts of facility operations.

4.1.1 Air Quality

There may be both direct and indirect air quality effects during the operation of the facilities' access by PNNL-affliated staff. Direct effects include the periodic use of disinfecting gases that could be part of the routine ongoing operation of the facility. Release of gases or vapors, such as formaldehyde (from paraformaldehyde) would be extremely small. Effects of these gases, if any, would be temporary and localized and would dissipate very quickly. HEPA filtration of all laboratory exhausts in BSL-3 laboratories removes virtually all biological particles and therefore there would be an extremely low probability of releases of biological agents due to PNNL's access and use.

There would be indirect effects related to the generation of gas-combustion engine emissions from private motor vehicles during workers' commutes to and from work. The addition of PNNL workers would produce a very small increase in these ongoing contributions to local air emissions. No new emergency generators, boilers, or other fuel-burning equipment would need to be added as a consequence of PNNL's access and use. The proposed operation would require very limited energy usage and therefore very low emission of greenhouse gases.

4.1.2 Waste Management

The proposed action would be expected to result in very limited changes in BSL-3 facility waste streams compared to current operations. There would be no need for additional waste accumulation areas since minimal quantities of hazardous waste would be generated. Hazardous chemicals would typically be used up in process. Waste storage, treatment, discharge and disposal would be the responsibility of BSL-3 facility staff and would be in accordance with approved waste management procedures in place for operations at laboratories accessed under the proposed action.

During operation of the BSL-3 laboratories, waste products would be generated by the disinfection of the interior working surfaces of the BSCs after each use. Other generated wastes would include sample packaging materials, culture materials, petri dishes, PPE, and associated process wastes. All wastes generated in the laboratories of the facility would leave the laboratories only after being autoclaved or chemically decontaminated. Chemical decontamination involves the use of bleach or other chemical disinfectants. Solid waste landfills may accept autoclaved or chemically decontaminated wastes for disposal depending on their individual waste acceptance criteria and

operating permit requirements. Alternatively, the BSL-3 facility could contract to send wastes to a licensed commercial incinerator located offsite for waste disposal.

Chemical disinfectants would be used to decontaminate 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 decontaminated 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 which would also specify the frequency of treatment. 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 Part 300) and the Emergency Planning and Community Right-to-Know Act (EPCRA) (40 CFR Part 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 year individually.

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 an absence of storage space in BSL-3 laboratories. These small quantities of chemicals would be used up during the research activities. Therefore, the proposed action would require very limited waste management at the existing facilities.

4.1.3 Human Health

According to the BMBL (CDC and NIH 2009), the primary hazards to personnel working with biological agents in a BSL-3 facility result from accidental injections, ingestion, and exposure through the airborne pathway. As discussed in Section 3.3, there has been an extremely low incidence of laboratory-acquired infections associated with operations in the CDC- and APHIS-registered laboratories since the implementation of the CDC-developed guidelines first issued in 1974 (CDC and NIH 2009). The type and rate of injuries and illnesses expected during PNNL's access and use of existing BSL-3 laboratories would be the same as those expected under current operations at these facilities or as demonstrated for other select agent–registered laboratories. 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 Bureau of Labor Statistics) do occur, they should be considered abnormal events due to their infrequency of occurrence. Abnormal events are discussed in Section 4.1.4.

The potential risk of illness to site workers, visitors or the public from operations involving select agents is minor because any BSL-3 facility accessed under the proposed action would have implemented safety equipment and facility safety barriers following the guidelines, standards, practices, and procedures established by the CDC, NIH, and HHS. These would include secondary barriers such as controlled access and building HEPA filtration as described in the BMBL and summarized in Section 2 above. Based on an assumed effort of 6000 in-laboratory staff hours per year, and statistics compiled by the U.S. Army presented in Chapter 3, the probability of a laboratory-acquired infection would be extremely low.

PNNL-affiliated staff accessing an existing BSL-3 facility could also be involved in traffic accidents. In the United States in 2013, there were 1.1 fatalities per 100 million vehicle-miles traveled (DOT 2014). Under the proposed action, a small number of PNNL-affiliated staff would travel periodically

to the accessed facilities to conduct research. To estimate the potential for traffic fatalities by PNNL-affiliated staff, the following assumptions are made:

- PNNL-affiliated staff could travel once a week from Richland, Washington approximately 300 miles to the BSL-3 laboratory.
- During the week, PNNL-affiliated staff could commute 20 miles per day round trip to the laboratory from local lodgings.
- Typical research activities could involve no more than three staff members. Each could drive separately.
- Work could be conducted 48 weeks a year, allowing for holidays.

Under these assumptions, PNNL-affiliated staff could travel approximately 100,000 vehicle-miles each year. When compared with U.S. statistics from 2013 (DOT 2014), the probability of a fatality involving PNNL-affiliated staff working at an existing BSL-3 facility would be extremely small.

4.1.4 Abnormal Events

NEPA EAs typically consider potential impacts associated with abnormal events at a proposed facility or during a proposed action, such as extreme weather events, operational accidents, transportation accidents and intentional destructive acts. However, instead of presenting a unique new facility or action, the proposed action consists of PNNL-affiliated staff accessing and using existing operating facilities. Research conducted by PNNL-affiliated staff would be largely the same as other research currently being conducted in these facilities. PNNL-affiliated staff would work with biological organisms and select agents that are specified in the facility's select agent registration. The facilities accessed and used would also have attributes of most microbiological laboratories in that they would have physical, electrical, and chemical hazards. Laboratory operations by PNNL-affiliated staff would be conducted according to plans and procedures already approved and followed at any accessed facility. PNNL-affiliated staff would be trained biological professionals that would be fully proficient in BMBL BSL-3 procedures required to prevent contamination or release of biological agents in the laboratory. PNNL-affiliated staff would also receive additional training to become familiar with the equipment, plans, and procedures in place at any accessed facility. The proposed action would not likely increase any current and ongoing risk that an abnormal event could occur in an accessed facility, nor change the severity of the consequences should an abnormal event occur. However, because abnormal events could occur during PNNL access and use, the following discussion of possible abnormal events in BSL-3 facilities is provided to disclose the potential impacts under conservative assumptions.

4.1.4.1 Accidental Release Due to a Catastrophic Event

The possibility of an accidental release of a biological agent to the environment from existing, operating BSL-3 facilities due to a catastrophic event, such as a fire, earthquake, or tornado is extremely remote. 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 Medical Research and Development Command (USAMRDC 1989), the likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable.

4.1.4.2 Releases Due to Laboratory Accidents

Although the potential for catastrophic accidents is very low, historical information suggests that other types of accidents involving infectious material are reasonably foreseeable. The potential effects that accidental aerosol releases of harmful biological agents could have on the health of members of the public and noninvolved workers have been evaluated in previous NEPA reviews for other BSL-3 facilities (e.g., USAMRDC 1989; DOE 2008). In each, a maximum credible event (MCE) scenario was used as the quantitative risk assessment method for analyzing a hypothetical biological release to the atmosphere. An MCE analysis is a realistic conservative analysis that applies credible information about the effectiveness of existing safeguards, such as engineering controls, design features, and adherence to standard operating procedures by workers (U.S. Army Medical Research and Materiel Command [USAMRMC] 2004). The following brief descriptions of the accident scenarios assessed in these other NEPA reviews and the resulting impacts to human health are presented as being representative of potential accidents that could occur at BSL-3 facilities being accessed and used under the proposed action.

The accident analysis prepared by the DA for its BDRP Programmatic EIS (USAMRDC 1989) covering multiple facilities across the United States is considered relevant to the proposed action. The DA serves as the executive agent of the Chemical and Biological Defense Program (CBDP), a research, development, testing, and evaluation program being conducted by the U.S. Department of Defense. Much of the information utilized in this PEIS hazard analysis was obtained by the U.S. Army during its long-standing leading role in the U.S. biological defense program. The DA PEIS addresses the entire BDRP, including multiple facilities and levels of research operations far greater than DOE proposes at existing, operating BSL-3 facilities. The accident scenario evaluated in the DA PEIS analyzed BSL-3 facilities with engineering and operating characteristics typical of BSL-3 facilities to be accessed and used under the proposed action, such as HVAC system designs for negative pressure and air turnover and HEPA filtration (USAMRDC 1989). The facilities would also operate under the same procedures established by the CDC (CDC and NIH 2009) and the facilities would be designed to handle the same types of microorganisms and select agents.

Coxiella burnetii (a National Institute of Allergy and Infectious Diseases Category B agent, the CDC select agent, and Q fever causative agent) was chosen as the microorganism to represent all types of BSL-1, BSL-2, and BSL-3 laboratory microorganisms. It was considered an appropriate (i.e., conservative) choice for modeling in this release assessment for several reasons. The probability of infection is high, it is very persistent in the environment, and resistant to environmental conditions. It also presents a potential human health hazard because it can survive being aerosolized and has a high survival rate in the environment. The study of many viruses also requires the use of BSL-3 laboratories; however, most viruses cannot survive long in the environment without a human or animal host. Bacteria can represent a high risk to human health, and the study of many bacteria requires the use of BSL-3 or BSL-4 laboratories. The infective dose for *C. burnetii* ranges from only ten organisms to possibly as few as one (USAMRMC 2004). Planned research by PNNL-affiliated staff under the proposed action could involve the study of *C. burnetii*.

4.1.4.3 Initial Conditions and Accident Scenario Assumptions

The following assumptions about the initial conditions and accident scenario for an MCE analysis were developed for the postulated accidental release of a biological aerosol from a BSL-3 laboratory (USAMRMC 2004).

- A single worker prepares 990 mL of slurry containing a total of 9.9×10^{12} (9.9 trillion) human infective doses (HID_{50}) of *C. burnetii*. Note: One HID_{50} is the dose that infects 50% of exposed humans.
- The worker places 165 mL of the slurry into each of six 250-mL polypropylene centrifuge tubes. The worker fails to insert O-rings or tighten the screw-on centrifuge caps, which are designed to prevent leakage into the centrifuge compartment that houses the rotor.
- All six tubes spill slurry into the rotor cups, and some of this slurry leaks into the rotor compartment, which is not sealed against the release of organisms in a small-particle aerosol.
- Ten percent of the slurry spills. One percent of this spill leaks into the rotor compartment, where 0.1% of the leakage is aerosolized. Ninety percent of the aerosol settles as liquid droplets inside the chamber.
- Thus, 10% (spilled from tubes) × 1% (leaked from rotor cups) × 0.1% (aerosolized) × 10% (did not settle out) = 0.00001% of the original slurry placed in the centrifuge tubes for processing is released into the room.
- The most serious consequence of this laboratory accident would be the release of enough concentrated aerosol to pass through the air filter system, with the subsequent release of infectious doses into the surrounding community.
- On the basis of the above assumptions, 9.9×10^5 (990,000) HID_{50} (0.00001% × 9.9×10^{12} HID_{50}) would reach the filter.
- When it is further assumed that the air filter system is 95% efficient, approximately 5×10^4 (50,000) HID_{50} (5% not removed × 9.9×10^{12} HID_{50}) would be released to the atmosphere from the exhaust vent.

4.1.4.4 Impacts to the Involved Laboratory Worker

In this accident scenario, the centrifuge operator is at the greatest risk of becoming ill. It is estimated that 1.3×10^3 airborne infectious doses per liter of air would be present immediately above and around the centrifuge compartment after the accident. Individuals that receive the greatest exposure would be treated with doxycycline or other appropriate antibiotics and monitored. Other laboratory workers that came to assist in response to the accident would receive similar treatment. However, it is not certain the operator would become sick. Typical BSL-3 operating procedures include requirements for immunization for the organisms in use, when appropriate. Benenson (1959) reported that previously vaccinated men, when exposed to defined aerosols of 150 to 150,000 infectious doses of virulent *C. burnetii*, AD strain, did not consistently become ill. Thus, the expected impact of the postulated accident to the involved worker would be bounded by a temporary, non-life threatening and treatable illness. Prior to beginning work with any organism, PNNL would work with the host facility to develop appropriate vaccination policies and procedures for PNNL-affliated staff.

4.1.4.5 Impacts to the Uninvolved Worker and General Public

Building filtration systems typically release building air through an exhaust stack to the atmosphere. An uninvolved worker or a member of the public could be present near or downwind from the building stack release point. A simple Gaussian puff model was used to quantify risk for uninvolved workers and members of the public in the MCE scenario (USAMRMC 2004). Accounting for the air handling unit's capacity and the building volume, the release would only last for several minutes. On the basis of the conservative assumption of an instantaneous release occurring, the quantity of human

infectious doses is expected to be dissipated to less than 1 HID_{50} per liter of air in less than two meters from the stack, less than 0.1 HID_{50} per liter at 16 meters from the stack, and less than 0.01 HID_{50} per liter at 38 meters from the stack. These concentrations are calculated using conservative meteorological conditions that would limit dispersion. There are no CDC, NIH or other standards or guidelines for a minimum infective dose. However, because the total exposure of a person breathing ground-level air would be less than 1 HID_{50} per liter of air of *C. burnetii* at all downwind distances under conservative meteorological conditions, it is expected that this concentration of organisms would not pose a risk to human health (USAMRMC 2004).

Treatment would be provided to individuals developing acute Q fever following exposure to *C. burnetii*. Doxycycline is usually prescribed for acute Q fever and has the highest therapeutic efficacy against *C. burnetii* (NASPHV 2013). When treated, the fatality rate for Q fever is negligible (Maurin and Raoult 1999).

Similar accident scenarios were assessed in the EAs for the BSL-3 Facility at the Lawrence Livermore National Laboratory (LLNL) (DOE 2008) and the Howard T. Ricketts Laboratory at the Argonne National Laboratory (HHS and DOE 2006), and in the *Final Environmental Impact Statement for the Construction and Operation of New U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) Facilities and Decommissioning and Demolition and/or Re-use of Existing USAMRIID Facilities at Fort Detrick, Maryland* (USAMRMC and USAG 2006). In each case, the accident scenario initially developed by the DA was assumed for the initial event in the laboratory and through the building filtration system. Conservative site-specific meteorological parameters and conditions were assumed for atmospheric dispersion following releases from the building stacks. Modeled releases of *C. burnetii* from the LLNL BSL-3 facility were predicted to be less than 1 HID_{50} per liter of air at a distance of 2 meters from the stack, less than 0.1 HID_{50} per liter of air at 16 meters from the stack, and less than 0.01 HID_{50} per liter of air at a distance of 38 meters from the stack. At the Howard T. Ricketts facility, a maximum 10-minute concentration of *C. burnetii* was estimated at 1.3×10^{-2} organisms per cubic meter at the stack. Assuming a typical breathing rate of 20 cubic meters per day, the maximum inhalation dose over the 10-minute exposure duration is then estimated at 1.8×10^{-3} organisms. At the proposed new USAMRIID facilities, the EIS assumed that the release of organisms overwhelmed the HEPA system, making it inoperable. The total exposure of a receptor at the center of the plume from the rooftop stack in this scenario would fall below 1 HID_{50} of *C. burnetii* at a distance less than 38 meters (at an elevation of 20.1 meters above ground level). Ground-level concentrations would be effectively zero.

These hypothetical accidents can be used as a bounding accident analysis for a typical BSL-3 facility that would be accessed and used by DOE under the proposed action. However, they are exceedingly conservative. The U.S. Army notes that possibility of an accident of this degree, which is based on the sequential or simultaneous failure of multiple operational and procedural controls, is remote (USAMRMC and USAG 2006). Realistically, actual conditions during routine use would significantly lessen the possible outcome to the point that it would not produce even one HID_{50} at the end of the exhaust stack. Some of these are as follows:

- The hypothetical accident results of even these extremely small effects rely on 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, and the worker opens the lid not realizing the tubes have leaked).
- Cultures in a centrifuge in their stationary phase (with 10^8 cells per milliliter) 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).

- 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 normal high rate of air-changes for laboratories accessed and used under the proposed action would not generate a single "concentrated slug" of aerosolized material to exit the building as proposed in the model.
- 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 dioctyl phthalate (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.
- 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. Any possible resuspension of settled particulates would be at much lower concentrations than the initial release.

The conclusion is that members of the public near any BSL-3 facility accessed and used by PNNL-affiliated staff under the proposed action would have a very low likelihood of being exposed to even a small fraction of one HID_{50} as a result of the postulated accident. Treatment of any exposed individuals that developed symptoms of Q fever following an accidental release would further reduce the risk of any long-term adverse health impacts.

4.1.4.6 Transportation Accidents

Infectious substances (etiologic agents) in transit on the nation's highways, railways, and airports are regulated by DOT regulations (49 CFR Parts 171, 172, 173, and 178). Of the 800,000 hazardous materials shipments per day in the United States, at least 10,000 involve hazardous materials identified generally as medical wastes; 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.

Samples to be shipped under the proposed action could consist of milliliter quantities of cells in media contained within DOT-certified packages. There have been no recorded cases of illness attributable to the release of infectious material during transport, although incidents of damage to the outer packaging of properly packaged materials have been reported (WHO 1997). Consequences of such an accident if one did occur would be anticipated to be minor, based on the historical data.

4.1.4.7 Intentional Destructive Acts

The attacks on September 11, 2001 made it clear that the United States is vulnerable to significant acts of terrorism. At BSL-3 facilities accessed under the proposed action, deliberate facility damage with the intention of releasing small tube-stored samples or working cultures of pathogenic agents would be possible if an individual were able to gain direct access to the facility or cause a catastrophic breach of all containment systems. For example, a suicidal airplane crash could breach the facility's containment. Similarly, an explosive device delivered by a vehicle or an individual on foot could breach facility containment. Depending on the time of day and the type of research underway, a loss of containment could result in a release of pathogenic materials. However, the consequences of a malicious act designed to breach containment are bounded by the accident evaluated in this EA because they would result in a similar release of biological agents and loss of containment. As with releases following catastrophic events, heat, fire, sunlight, and wind effects following an intentional destructive act would usually result in exposed microorganisms being killed. A terrorist act, such as an airplane crash, would not be expected to result in a release of greater magnitude than releases from other laboratory accidents already considered in this document.

The requirements for possession, use, and transfer of select agents and toxins in the United States are established in 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121. Section 73.11 of 42 CFR Part 73 requires facilities subject to the regulations to develop and implement a security plan establishing policies and procedures to maintain the security of areas containing select agents and toxins based on a risk assessment. Similar requirements for plant and animal select agents and toxins are found in 7 CFR Part 331 and 9 CFR Part 121. At any BSL-3 facility with select agent registration accessed under the proposed action, security plans, policies and procedures would be in place to comply with the requirements of these regulations. These security procedures would also reflect the update to the BMBL (CDC and NIH 2009), which now includes guidance on security and emergency response procedures for laboratories working with agents (Richmond and Nesby-O'Dell 2002). The CDC and NIH recommendations address physical security concerns as well as more recent information regarding personnel, risk assessments, and inventory controls. Appendix F of the updated BMBL (Richmond and Nesby-O'Dell 2002) addresses the following biosecurity policies and procedures:

- Risk and threat assessment;
- Facility security plans;
- Physical security;
- Data and electronic technology systems;
- Security policies for personnel;
- Policies regarding access to laboratory and animal areas;
- Specimen accountability;
- Receipt of agents into the laboratory;
- Transfer or shipping of agents from the laboratory;
- Emergency response plans; and
- Reporting of incidents, unintentional injuries, and security breaches.

Based on adherence with biosecurity policies and procedures and historical data, the probability of a successful terrorist act at an operating BSL-3 facility is very low. Existing, operational BSL-3 facilities accessed and used under the proposed action would have security plans, policies, and

procedures for the security of areas containing select agents and toxins that would conform with 42 CFR Part 73, 7 CFR Part 331, and/or 9 CFR Part 121 as appropriate for the pathogens being used. PNNL's proposed access and use of these facilities would be of a similar nature as other ongoing operations and would involve similar microorganisms. As with potential accidents, the proposed action would not result in any change in the probability of an intentional destructive act occurring, nor the environmental consequences of such an act if it did occur. While the theft of pathogenic materials by an insider from any biological research facility could have very serious consequences, this scenario is not expected to occur due to the facility's human suitability programs, security procedures, and management controls at the facilities accessed and used under the proposed action.

4.2 Environmental Consequences of the No Action Alternative

Under the No Action Alternative, PNNL would continue collaborating with other BSL-3 laboratories for research. The No Action Alternative would represent no change in the level of research operations or impacts at PNNL. 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. All potential environmental impacts at the existing operating facilities that would have been accessed under the proposed action would still occur, except that PNNL-affiliated staff would not be directly involved.

5.0 CUMULATIVE EFFECTS

The National Environmental Policy Act of 1969, as amended (42 U.S.C. § 4321 et seq.), requires Federal agencies to consider the cumulative impacts of proposed actions under their review. CEQ regulations define cumulative impacts as the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time (40 CFR 1508.7).

In 2010, there were almost 1,500 operating facilities in the United States with BSL-3 containment and select agent programs registered with the CDC (Kaiser 2011). DOE's proposed action is the access and use of one or more of these existing, operating BSL-3 facilities with the CDC or APHIS select agent registration. The proposed action would not result in any identifiable incremental change in national, regional, or local BSL-3 facility capacity or biomedical research programs. Laboratory space accessed by PNNL-affiliated staff would presumably be utilized by other researchers.

Facilities to be accessed under the proposed action are typically located in developed areas where other activities may be occurring or planned, e.g., other research facilities, housing, shopping, manufacturing, roads, schools, etc. Since this EA does not identify specific facilities for BSL-3 research, identification of specific geographically related impacts would be speculative. Since research activities to be conducted in these facilities by PNNL-affiliated staff would be largely of the same type and of a similar scale as current activities, with no identifiable difference in staffing levels or waste streams, the proposed action would not result in a scenario where it, when added to these other existing or proposed activities, would be directly responsible for a large impact in any resource area.

6.0 AGENCIES AND PERSONS CONSULTED

6.1 Public Comment Period and Comments Received

The Draft Environmental Assessment "Biomedical Research at Existing Biosafety Level 3 Laboratories with Registered Select Agent Programs" was transmitted for a 30-day public comment on March 1, 2016. The comment period closed on March 31, 2016. The following comment emails were received from stakeholders.

Organization	Commenter	Comments Received	Comment No.	Page No.
Ohio Environmental Protection Agency	Bonnie Buthker	March 2, 2016	A-1	1
Battelle Biomedical Research Center	Gregory W. Bowen	March 4, 2016	B-1	1
			B-2	1
			B-3	2

6.2 Comment Summaries and Responses

6.2.1 Comments from Bonnie Buthker, Ohio Environmental Protection Agency

Comment (A-1): It is my understanding from your previous correspondence that DOE is evaluating doing this research at existing facilities in Ohio. Would you please confirm? Also, Is there any way I can get additional information regarding where these facilities are located? It is difficult to comment on potential environmental impacts when you don't know where something is located, especially when we have different sensitive environments in different parts of the state. For example, we have a buried valley aquifer in SW Ohio that is a critical resource water for several cities, but we don't have this same resource in the northern part of the state. I don't need exact location (and I realize that may be sensitive info), just a general area should work.

> ***Response:*** *The proposed action is for PNNL-affiliated staff to access and use existing BSL-3 facilities with CDC and/or APHIS select agent registration to conduct biomedical research. One or more of these facilities could be in Ohio. For instance, the proposed action could include accessing the Battelle Biomedical Research Center, which is located in West Jefferson. Accessing other BSL-3 facilities in Ohio is also possible. However, the proposed action would result in only low or extremely low potential impacts over current operations in the areas of air quality, waste management, and human health. It is likely that the impacts from the proposed action would be indistinguishable from impacts that are currently occurring and that would continue to occur regardless of whether the proposed action is implemented. For other resources areas such as impacts to groundwater or sensitive environments, the proposed action would not result in any identifiable change in any ongoing impacts to these resources, regardless of the location.*
>
> *No changes were made in the text in reponse to this comment.*

6.2.2 Comments from Gregory W. Bowen, Battelle Biomedical Research Center

Comment (B-1): Section 2.1.2, line 198 and beyond, page 2–6 states: "The CDC and APHIS regulations require extensive documentation of activities involving select agents. Only personnel on the host facility's CDC and/or APHIS registration would be allowed to handle the agents. All access to select agent handling areas would be recorded."

Comment: Based on the technical discussions that I had with the research staff at PNNL, and the types of studies and work that are envisioned to be conducted in the BSL-3 facility, it is likely that the PNNL staff will also need to have direct access to agents and be included on the host facilities Select Agent registration as well as the host facilities Suitability Program. Any movement, manipulation, processing, or working with Select Agents is considered access.

> Per the CDC regulations (42 CFR 73.10 (b)):
> Access: An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin (e.g., There are no security barriers between the individual and the select agent or toxin preventing that individual from gaining access to the agent or toxin).

Recommendation: recommend PNNL staff be included on the host labs CDC Select Agent Registration and their Suitability Program.

> ***Response:*** *PNNL staff would be included on the host labs CDC Select Agent Registration and their Suitability Program. In section 2.1.2, line 198–199, it is noted that "Access to select agents in the proposed BSL-3 laboratories would be limited to a very small number (generally less than 10) of qualified PNNL-affiliated staff."*
>
> *Text was added in Section 2.1.2 to further clarify the requirement for inclusion of PNNL-affiliated staff in the host facility's Select Agent Registration and their Suitability Program*

Comment (B-2): Section 4.1.4.3, Line 192 and beyond, page 4–5 states: "When it is further assumed that the air filter system is 95% efficient, approximately 5 x I04 (50,000) HJD50 (5% not removed x 9.9 x 1012 HIDSO) would be released to the atmosphere from the exhaust vent."

Comment: Most BSL-3 facilities exhaust all lab air and exhaust air through HEPA filters. By definition, HEPA filters have a higher removal efficiency than in the assumed scenario above. The following is referenced in the BMBL, Appendix A, Section II -The High Efficiency Particulate Air (HEPA) Filter and the Development of Biological Containment Devices HEPA filters remove the most penetrating particle size (MPPS) of 0.3 µm with an efficiency of at least 99.97%. Particles both larger and smaller than the MPPS are removed with greater efficiency. Bacteria, spores and viruses are removed from the air by these filters. HEP A filter efficiency and the mechanics of particle collection by these filters have been studied and well documented. If a lower (i.e. 95% efficiency) filter is being used, then they are not using HEPA filters as they should with a BSL-3 containment laboratory.

Recommendation: Recommend recalculating using a 99.7% removal efficiency for the HEPA filters.

> ***Response:*** *A 95% HEPA filter efficiency was assumed in the bounding accident analysis for a typical BSL-3 facility that would be accessed and used by DOE under the proposed action. As noted in the Section 4.1.4.5, this is one of several exceedingly conservative assumptions. The purpose of the MCE analysis is to demonstrate that even with these conservative assumptions, an accident would not pose an undue health risk. The analysis is not meant to indicate that sub-standard HEPA filtration would be used. Facilities accessed under the proposed action would utilize HEPA filtration as recommended by the BMBL, with ratings of at least 99.97 percent efficiency at the most penetrating design point of 0.3 microns.*
>
> *No changes were made in the text in reponse to this comment.*

Comment (B-3): Section 4.1.4.4, line 201 and beyond, page 4–5, states: "Typical BSL-3 operating procedures include requirements for immunization for the organisms in use. Benenson (1959) reported that previously vaccinated men, when exposed to defined aerosols of 150 to 150,000 infectious doses of virulent C. burnetii, AD strain, did not consistently become ill."

Comment: The assumption that BSL-3 labs typically require immunizations for organisms in use is not universally true. There are no FDA approved vaccinations for some of the Select Agents. Also for some Select Agents there may be vaccines that have limited availability or effectiveness. Also a BSL-3 facility may make a decision to not use or limit use of a vaccine to special cases due to limited effectiveness or potentially severe side effects of the vaccine. For the Q Fever Vaccine (Coxiella burnetii) the BMBL, Section VIII-D: Rickettsial Agents, Coxiella burnetii states:

> Vaccines: An investigational Phase I, Q fever vaccine (IND) is available on a limited basis from the Special Immunizations Program (301-619-4653) of the USAMRIID, Fort Detrick, Maryland, for at-risk personnel under a cooperative agreement with the individual 's requesting institution. The use of this vaccine should be restricted to those who are at high risk of exposure and who have no demonstrated sensitivity to Q fever antigen. The vaccine can be reactogenic in those with prior immunity, thus requires skin testing before administration. The vaccine is only administered at USAMRIID and requires enrollment in their Q fever IND Immunization Program. For at-risk laboratory workers to participate in this program, fees are applicable.

The USAMRIID Occupational Health Manual (2011) states that for working with C. burnetii they recommend vaccination but it is only available at USAMRIID. It is not currently licensed in the US. It is only licensed in Australia. The same section of the USAMRIID Occupational Health Manual states that after using the vaccine in the 60's, only one confirmed case of Q Fever occurred at RIID and it was due to agent present in a workers hair infecting the workers wife at home because this person did not wash their hair after showering out of the lab.

An additional reference that should be reviewed and followed is the "Occupational Health Program Guidance Document for Working with Tier 1 Select Agents and Toxins," 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73; 05 July 2013; Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins Animal and Plant Health Inspection Service (APHIS) Agriculture Select Agent Program.

The following text is copied directly from the above referenced document:

> Commercial vaccines should be made available to workers to provide protection against infectious agents to which they may be occupationally exposed. Current, applicable vaccine information statements must be provided whenever a vaccine is administered. Each worker's immunization history should be evaluated for completeness and currency at the time of employment and re-evaluated when the individual is assigned job responsibilities with a new biohazard. At present time, the following vaccines are available for Tier 1 BSAT:
>
> - Francisella tularensis
> - Vario/a major virus
> - Vario/a minor virus, and
> - Bacillus anthracis.
>
> The vaccines for smallpox (vaccinia vaccine) and anthrax are FDA licensed. The vaccines for tularemia are available through US. Food and Drug Administration (FDA) investigational new drug (IND) protocols. Immunization with IND vaccines should be optional. If indicated

by risk assessment, the IND vaccines may be made available on a voluntary basis under FDA research protocols with informed consent.

The Anthrax vaccine is recommended by the U S. Department of Health and Human Services' (HHS) Advisory Committee for Immunization Practices (ACIP)for groups at risk for repeated exposures to B. anthracis spores. 5 Groups at risk for repeated exposure include:

- laboratory personnel handling environmental specimens (especially powders) and performing confirmatory testing for B. anthracis in the US. Laboratory Response Network (LRN),
- workers who will be making repeated entries into known B. anthracis-spore-contaminated areas, and
- workers in other settings in which repeated exposure to aerosolized B. anthracis spores might occur.

Recommendation: PNNL management, and the host BSL-3 facility management, will need to define their vaccination policies and requirements before any work begins. It should also be noted that for some BSL-3 Select Agent vaccines, several months and numerous vaccinations are required to achieve the desired effectiveness and protections. It has been Battelle's practice in our BSL-3 facility to always reduce the risks of exposure rather than perform high exposure risk procedures and rely on vaccines for protection. We do however require vaccinations for work with some agents and some high risk procedures.

Response: The comment and recommendation are noted. In Section 4.1.4.4, it is stated that "Prior to beginning work with any organism, PNNL would work with the host facility to develop appropriate vaccination policies and procedures." Among other considerations, the development of these policies and procedures would consider "Occupational Health Program Guidance Document for Working with Tier 1 Select Agents and Toxins," 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73; 05 July 2013; Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins Animal and Plant Health Inspection Service (APHIS) Agriculture Select Agent Program, as noted by the commenter.

Section 4.1.4.4 was updated to clarify that vaccines would only be required when appropriate.

7.0 REFERENCES

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7 CFR Part 331. *Code of Federal Regulations*, Title 7, *Agriculture*, Part 331, "Possession, Use, and Transfer of Select Agents and Toxins." Washington, D.C.

9 CFR Part 92. *Code of Federal Regulations*, Title 9, *Animals and Animal Products*, Part 92, "Procedures for Requesting Recognition of Regions." Washington, D.C.

9 CFR Part 121. *Code of Federal Regulations*, Title 9, *Animals and Animal Products*, Part 121, "Possession, Use, and Transfer of Select Agents and Toxins." Washington, D.C.

10 CFR Part 1021. *Code of Federal Regulations*, Title 10, *Energy*, Part 1021, "National Environmental Policy Act Implementing Procedures." Washington, D.C.

15 CFR Part 730. *Code of Federal Regulations*, Title 15, *Commerce and Foreign Trade*, Part 730, "Export Administration General Information." Washington, D.C.

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U.S. Department of Energy
Finding of No Significant Impact

Biomedical Research at Existing Biosafety Level 3 Laboratories with Registered Select Agent Programs

(DOE/EA-2026)

AGENCY: U.S. Department of Energy

ACTION: Finding of No Significant Impact

DESCRIPTION OF THE PROPOSED ACTION

Proposed Action: The proposed action is for Pacific Northwest National Laboratory (PNNL) affiliated staff to access and use existing Biosafety Level 3 (BSL-3) facilities, with the Centers for Disease Control (CDC) and/or Animal and Plant Health Inspection Service (APHIS) select agent registration, to conduct biomedical research. The facilities considered for the proposed biomedical research would already possess all other necessary operating licenses and/or other authorizations necessary to perform similar work. Given the diversity of research needs, as well as facility capabilities and availability, use of multiple currently unidentified BSL-3 facilities with select agent registration is proposed. The proposed action does not include any research using live animals.

Purpose and Need: PNNL provides critical biological research capabilities to the Department of Homeland Security in support of its mission in the areas of bioforensics and biothreat characterization, detection, and assessment, and to other Federal agencies' research missions related to bio-agent counter-terrorism technologies and improved prevention and treatment of emerging natural diseases. In support of sponsors' missions, PNNL's biological research program requires the study and use of live organisms and select agents, some of which require BSL-3 containment. PNNL-affiliated research staff need access to one or more currently operating BSL-3 facilities with select agent registration because PNNL currently lacks any qualified BSL-3 select agent facilities. The proposed action is needed to provide options for trained PNNL-affiliated research staff to conduct biological research activities.

Alternatives: In addition to the No-Action Alternative, two alternatives were considered but eliminated from further analysis:

1) Construction and operation of a new BSL-3 facility at the PNNL
2) Redeployment and associated retrofitting to BSL-3 standards of existing PNNL laboratory space

Either alternative would require significant investment in planning, construction/retrofitting, startup, and operations. Similarly, currently anticipated research activities, including anticipated growth in work for other Federal agency sponsors, are not of sufficient scope or volume to justify the required investment. Both were therefore deemed unreasonable and not fully analyzed.

ENVIRONMENTAL IMPACTS

The following resource areas were considered and determined to have no reasonably foreseeable nexus to the proposed action: **Land Use, Surface and Groundwater Hydrology, Cultural and Historic Resources, Aquatic and Terrestrial Ecology, Noise and Visual Resources, and Socioeconomics and Environmental Justice**. The proposed action would not result in any identifiable change in any ongoing impacts to these resources.

Other resource areas would have low or extremely low potential impacts.

Meteorology and Air Quality: Periodic use of disinfecting gases would be part of the routine ongoing operation of the facility. Release of associated gases or vapors, such as formaldehyde (from paraformaldehyde) would be extremely small. Effects of these gases, if any, would be temporary and localized and would dissipate very quickly. HEPA filtration of all laboratory exhausts in BSL-3 laboratories removes virtually all biological particles.

Waste Management: The proposed action would be expected to result in very limited changes in BSL-3 facility waste streams compared to current operations. Solid waste would be autoclaved or chemically decontaminated prior to disposal. There would be no need for additional hazardous waste accumulation areas since minimal quantities of waste would be generated. Hazardous chemicals would typically be used up in process. Waste management would be in accordance with approved procedures in place for operations at laboratories accessed under the proposed action.

Human Health: Research conducted by PNNL-affiliated staff would be largely the same as other research currently being conducted in these facilities. The potential risk of illness to site workers, visitors or the public from operations involving select agents is minor, because any BSL-3 facility accessed under the proposed action would have implemented safety equipment and facility safety barriers following the guidelines, standards, practices, and procedures established by the CDC, NIH, and HHS. These would include secondary barriers such as controlled access and building HEPA filtration as described in the manual *Biosafety in Microbial and Biomedical Laboratories*, which was incorporated by reference into the EA. Based on statistics compiled by the U.S. Army, the probability of a laboratory-acquired infection would be extremely low. The proposed action would not likely increase any current and ongoing risk that an abnormal event could occur in an accessed facility, nor change the severity of the consequences should an abnormal event occur.

Cumulative Impacts: The proposed action would not result in any identifiable incremental change in national, regional, or local BSL-3 facility capacity or biomedical research programs. Laboratory space accessed by PNNL-affiliated staff would presumably be utilized by other researchers. Specific facilities to be accessed under the proposed action are typically located in developed areas where other activities may be occurring or planned, e.g., other research facilities, housing, shopping, manufacturing, roads, schools, etc. Since this EA does not identify specific facilities for BSL-3 research, identification of specific geographically related impacts would be speculative.

PUBLIC COMMENT ON THE DRAFT EA

On March 1, 2016, DOE announced via letters to various state and Federal government officials and other stakeholders the availability of the EA for a 30-day review period. Section 6.2 was added to the EA to document the comments and respond to them.

DETERMINATION

The environmental assessment for *Biomedical Research at Existing Biosafety Level 3 Laboratories with Registered Select Agent Programs* is hereby approved. Based on the analysis contained therein and consideration of public comments received on the draft, DOE has determined that the Proposed Action does not constitute a major Federal action that would individually or cumulatively have a significant effect on 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. With this determination, DOE may proceed with the BSL-3 Proposed Action.

Prior to accessing any facility, the facility's configuration, containment, and procedures would be reviewed by DOE and compared to the facility parameters assumed in the EA. If the facilities chosen differ substantially from the assumptions presented, DOE would determine whether any additional NEPA review would be required, including whether to modify the EA to reflect actual configuration and use. If DOE determines that a subsequent EA is required, DOE will recirculate the EA for comment prior to any decision to access and use the proposed facilities.

PUBLIC AVAILABILITY

The EA may be viewed on-line at http://science.energy.gov/pnso/nepa-documents/pnso-ea-eis/

Copies of the EA are available by contacting:

Public Affairs/BSL-3 EA
U.S. Department of Energy
Pacific Northwest Site Office
Richland, WA 99352
Telephone: 509-372-4005 (or x4365)
E-Mail: pnsomanager@science.doe.gov

For further information regarding the BSL-3 NEPA process or the DOE NEPA process in general, contact:

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Issued in Richland, Washington, this 4th day of April 2016.

for RES

Roger E. Snyder
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