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

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