GENERIC CATEGORICAL EXCLUSION FOR MICROBIOLOGICAL AND BIOMEDICAL RESEARCH, PACIFIC NORTHWEST NATIONAL LABORATORY, RICHLAND, WASHINGTON

Proposed Action:

The U.S. Department of Energy (DOE) Pacific Northwest Site Office (PNSO) proposes to conduct microbiological, biomedical, and diagnostic research projects.

Location of Action:

The proposed activities would occur on the Pacific Northwest National Laboratory (PNNL) campuses in Richland and Sequim, Washington, and elsewhere within the United States.

Description of the Proposed Action:

DOE proposes to conduct microbiological and biomedical projects to support research in areas including, but not limited to:

- molecular-level understanding of the physical, chemical, and biological processes that underlie environmental remediation, biomolecular systems, waste processing and storage, and human health effects
- experimental and modeling studies of chemical phenomena and mechanisms on mineral and microbe surfaces and on complex heterogeneous environmental materials from soils, sediments, and groundwater zones
- nuclear magnetic resonance, electron paramagnetic resonance, and similar instrumentation for determining molecular structures that impact environmental remediation and biological health effects
- spectrometric capabilities that focus on microbiology, global proteomics research and visualization, and analyses of cell contents, such as proteins
- technology and systems management focusing on efforts such as improving health care delivery processes and systems through re-engineering and other processes
- microbiological and biomedical diagnostic products and instruments focusing on efforts such as providing early detection of disorders or measurement of exposures with sensitive, generally non-invasive devices and systems
- scientific advancements and breakthroughs in selected domain sciences through computational modeling and simulation on next-generation, extreme-scale computers, including an interdisciplinary approach that brings together high-performance computer science, applied mathematics, and computational domain science to develop the next-generation, extreme-scale bio-modeling and simulation applications
- therapeutic products focusing on efforts such as providing targeted delivery of medical therapeutics with minimal adverse effects
- beneficial use of microbiological and biomedical ultrasonics, bioelectromagnetics, molecular toxicology, radiopharmaceuticals, and medical isotopes

- experiments in biotoxicology
- development of real-time ultrasonic visualization of blood flow, automated lung ventilation diagnosis, ultrasonic measurement of bone density, dissolvable vascular connectors, *in vivo* and *In vitro* effects of magnetic fields, biological intake and exhalation rate of volatile organic compounds, analysis of nuclear magnetic resonance spectroscopy, medical 3D imaging, optical *in vivo* blood characterization, portable ultrasensitive biological sensors, and radium-223 immunoconjugates for cancer therapy.

Microbiological and biomedical research would include those activities that are conducted under Biosafety Levels 1 and 2,[1] as identified in "Biosafety in Microbiological and Biomedical Laboratories", 6th Edition, June 2020, U.S. Department of Health and Human Services. Biosafety Level 2 work would be performed according to the requirements of this document. Actions that involve Biosafety Levels 3 or 4 (using viable inhalable or aerosol agents that may cause serious or potentially life-threatening disease) would not be conducted under this categorical exclusion (CX).

Ongoing activities also include collaboration with other laboratories, universities, research hospitals, and agencies. PNNL staff occasionally offer microbiological and biomedical technical assistance to offsite groups and organizations and participate in offsite research and clinical trials. These types of activities would be addressed by this CX.

Minor modification of facilities used for microbiological and biomedical projects would also be included under this CX. This would include areas such as laboratories and offices that are within or contiguous to previously disturbed or developed area where active utilities and currently used roads are readily accessible.

The proposed action includes the purchase, installation, use, and eventual removal of research equipment and instruments such as laminar flow hoods, biological safety cabinets, gloveboxes, lasers, mass spectrometers, ultrasonic instrumentation, centrifuges, etc. This CX would also include those actions foreseeably necessary for research project implementation, such as associated transportation activities, waste disposal activities, remodeling of individual rooms and laboratories, and award of grants and contracts. These activities would be managed in accordance to, and in compliance with, DOE orders, as well as federal and state regulations and guidelines.

Each proposed activity must meet the CX eligibility criteria (10 Code of Federal Regulations [CFR) 1021.410) and all of the following criteria:

1. Activities would be conducted with appropriate safety systems, exhaust ventilation, air filtration, and additional confinement or controls appropriate to the nature of the materials and equipment used in the project.

[1] Level l activities involve well characterized agents not known to cause disease in healthy adult humans and pose minimal potential hazard to laboratory personnel and the environment. Level 2 activities involve agents of moderate potential hazard to personnel and the environment. It differs from Level 1 activities in that: 1) laboratory personnel have specific training in handling pathogenic agents, 2) access to the laboratory is limited when work is being conducted, 3) extreme precautions are taken with contaminated sharp items, and 4) certain procedures in which infectious aerosols or splashes may be created arc conducted in biological safety cabinets or other physical-containment equipment.

2. Activities would comply with applicable administrative controls and requirements identified in the Facility Use Agreement or equivalent procedure established for the facility in which the work would be conducted. Facility Use Agreements outline specific requirements for elements such as safety systems, operating parameters, training requirements, radiological controls, and entry requirements.

3. Activities could use hazardous and/or radioactive materials should the use be necessary to the research project inventories would be maintained at the lowest practicable levels while remaining consistent with applicable safety or hazards analyses, continuing operations, and research goals.

4. All releases of liquid and/or airborne substances (i.e. chemicals, radionuclides) to the environment would be compliant with applicable permits, local, state, and federal regulations, DOE Orders and PNNL guidelines, as applicable.

5. The types of waste generated by each activity would be limited to those with an available treatment, storage, or disposal pathway. Volumes of waste generated by each activity would be reduced as much as possible by pollution-prevention measures and waste-minimization practices. Wastes would be handled, packaged, transported, stored, and/or disposed of in accordance with applicable local, state, and federal regulations, DOE Orders, and PNNL guidelines.

6. If human subjects, human DNA, RNA, or blood are involved in any aspect of biomedical research, protocols developed by the PNNL Institutional Review Board for Human Subject Research would be rigorously followed in accordance with 10 CFR 745.

7. If animal subjects are involved, protocols from the "Guide for the Care and Use of Laboratory Animals", 8th Edition, 2011, National Research Council, as well as regulations from the U.S. Department of Agriculture and Public Health Service would be followed.

8. If plant or animal pathogens, select agents, dual-use agents, biological toxins, Biosafety Level 2 materials, or recombinant DNA are involved in any aspect of biological research, the PNNL Institutional Biological Safety Committee would be required to review projects that use the agents to develop compliant experimental conditions for safe conduct of the biological work.

Biological and Cultural Resources:

Biological and cultural resources reviews will be conducted prior to such activities to assure that impacts to sensitive resources are avoided or minimized.

The biological resources review will identify the occurrence of federally and state-protected species and habitats in the project area such as avian species protected under the Migratory Bird Treaty Act (MBTA); species protected by the Marine Mammal Protection Act (MMPA); essential fish habitat as defined by the Magnuson-Stevens Fisheries Conservation and Management Act (MSA); plant and animal species and critical habitat protected under the Endangered Species Act (ESA), including candidates for such protection; and state species listed as threatened or endangered. Resource review recommendations will be followed during microbiological and

biomedical research activities to assure there are no adverse impacts to sensitive species and resources.

DOE will conduct a cultural resources review as part of the Section 106 process of the National Historic Preservation Act (NHPA). The Section 106 process assesses undertakings to determine if the undertaking will have an adverse effect/impact to historic properties.

If the biological and/or the cultural resources review determines that resources may be adversely affected/impacted, the use of this CX would be reevaluated. Potential options could be, but are not limited to, changing the proposed activity location, the development of mitigation measures to render the impacts not significant, or the performance of additional National Environmental Policy Act (NEPA) analysis and review.

Categorical Exclusion to Be Applied:

As the proposed action is to perform microbiological and biomedical research, the following CX, as listed in the DOE NEPA implementing procedures, 10 CFR 1021, would apply:

B3.12 Siting, construction, modification, operation, and decommissioning of microbiological and biomedical diagnostic, treatment and research facilities (excluding Biosafety Level-3 and Biosafety Level-4), in accordance with applicable requirements and best practices (such as Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, Dec. 2009, U.S. Department of Health and Human Services) including, but not limited to, laboratories, treatment areas, offices, and storage areas within or contiguous to a previously disturbed or developed area (where active utilities and currently used roads are readily accessible). Operation may include the purchase, installation, and operation of biomedical equipment (such as commercially available cyclotrons that are used to generate radioisotopes and radiopharmaceuticals, and commercially available biomedical imaging and spectroscopy instrumentation).

Generic CXs are authorized by 10 CFR 1021.410(f) for recurring activities to be undertaken during a specified period of time, after considering potential aggregated impacts.

Eligibility Criteria:

The proposed activity meets the eligibility criteria of 10 CFR 1021.410(b) because the proposed action does not have any extraordinary circumstances that might affect the significance of the environmental effects, is not connected to other actions with potentially significant impacts [40 CFR 1508.25(a)(l)], is not related to other actions with individually insignificant but cumulatively significant impacts [40 CFR 1508.27(b)(7)], and is not precluded by 40 CFR 1506.1 or 10 CFR 1021.211 concerning limitations on actions during environmental impact statement preparation.

The "Integral Elements" of 10 CFR 1021 are satisfied as discussed below:

INTEGRAL ELEMENTS, 10 CFR 1021, SUBPART D, Appendix B (1)-(5)	
Would the Proposed Action:	**EVALUATION**:

Threaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health?	The proposed action would not threaten a violation of regulations or DOE or Executive Orders.
Require siting and construction or major expansion of waste storage, disposal, recovery, or treatment facilities?	No waste management facilities would be constructed under this CX. Any generated waste would be managed in accordance with applicable regulations in existing facilities. Waste disposal pathways would be identified prior to generating waste and waste generation would be minimized.
Disturb hazardous substances, pollutants, or contaminants that preexist in the environment such that there would be uncontrolled or unpermitted releases?	No preexisting hazardous substances, pollutants, or contaminants would be disturbed in a manner that or results in uncontrolled or unpermitted releases.
Involve genetically engineered organisms, synthetic biology, governmentally designated noxious weeds, or invasive species?	The proposed action would not involve the use of genetically engineered organisms, synthetic biology, governmentally designated noxious weeds, or invasive species (unless the proposed activity would be contained or confined in a manner designed and operated to prevent unauthorized release into the environment and conducted in accordance with applicable requirements).
Have the potential to cause significant impacts on environmentally sensitive resources, including, but not limited, to: • protected historic/archaeological resources • protected biological resources and habitat • jurisdictional wetlands, 100-year floodplains • Federal- or state-designated parks and wildlife refuges, wilderness areas, wild and scenic rivers, national monuments, marine sanctuaries, national natural landmarks, and scenic areas.	No environmentally sensitive resources would be adversely affected by the proposed research-related actions. The proposed action would not adversely affect floodplains, wetlands regulated under the Clean Water Act, national monuments, or other specially designated areas, prime agricultural lands, or special sources of water. Potential impacts to Biological or Cultural resources would be addressed as described above.

Summary of Environmental Impacts:

The following table summarizes environmental impacts considered when preparing this CX determination.

Environmental Impacts Considered when Preparing this CX Determination	
Would the Proposed Action:	Evaluation
Result in more than minimal air impacts?	During research operations and minor facility modifications there might be temporary and localized air emissions as well as dust and fumes from construction equipment. Any air emissions generated during facility modification are not expected to be substantial; they would be minimized as necessary by using water applications or other emission controls. Air emissions during research operations would be compliant with applicable permits, local, state, and federal regulations, DOE orders, and PNNL guidelines.

Increase offsite radiation dose measurably?	Research involving microbiological or biomedical use of radioactive tracer isotopes might result in radioactive air emissions. In accordance with the National Emission Standards for Hazardous Air Pollutants (40 CFR 61), continuous air sampling is in place for those facilities whose cumulative emissions are likely to result in an annual dose to the public that is greater than 0.1 mrem. In addition, high-efficiency particulate air filters are in place to control emissions. After controls, abated emissions from research operations would not be expected to result in measurable offsite radiological dose.
Require a radiological work permit?	Although not expected, research operations and minor laboratory modification activities might require a radiological work permit. Activities would be performed in compliance with as low as reasonably achievable (ALARA) principles, applicable state and federal regulations, DOE Orders, and PNNL guidelines. The radiation received by workers during the performance of activities would be administratively controlled below DOE limits as defined in 10 CFR 835.202(a). Under normal circumstances, those limits control individual radiation exposure to below an annual effective dose equivalent of 5 rem.
Discharge any liquids to the environment?	Liquid wastes would be generated during biological research activities and possibly during facility modification activities. Liquid wastes generated by research operations would be discharged into existing treatment systems and/or in accordance with applicable regulations and best management practices. All liquid biological wastes would be autoclaved or chemically disinfected prior to discharge. During construction or modification activities, there might be minor quantities of liquid effluents, for example, fire or safety system- proofing wastewater, hydrotest water, and cleanup rinse water. Effluents would be managed in accordance with applicable regulations and best management practices.
Require a Spill Prevention, Control, and Countermeasures plan?	Microbiological and biomedical research activities are not likely to require a Spill Prevention, Control, and Countermeasures plan. Laboratory operations will be conducted in accordance with PNNL safety procedures.
Use carcinogens, hazardous, or toxic chemicals/materials?	Proposed research and minor modification activities would be expected to use small quantities of carcinogens, hazardous and/or toxic chemicals and materials. Project inventories would be maintained at the lowest practicable levels, and chemical wastes would be recycled, neutralized, or regenerated if possible. Product substitution (use of less toxic chemicals in place of more toxic chemicals) would be considered where reasonable. In addition, modifications of existing laboratory rooms could generate minor amounts of debris and excess equipment. These materials would be recycled, re-used, or excessed for other uses to the extent practical.
Involve hazardous, radioactive, polychlorinated biphenyl, or asbestos waste?	Proposed research and minor modification activities would be expected to result in small quantities of hazardous, radioactive, polychlorinated biphenyl, and/or asbestos wastes. If unrecyclable, such wastes would either be returned to the client or characterized, handled, packaged, transported, treated, stored, and/or disposed of in existing treatment, storage, and disposal facilities in accordance with applicable regulations.

Cause more than a minor or temporary increase in noise level?	Microbiological and biomedical research would not create significant noise impacts. Facility modifications may result in increases in noise level, but these increases are expected to be minor and temporary in nature.
Create light / glare, or other aesthetic impacts?	Microbiological and biomedical research would not create light, glare, or other aesthetic impacts.
Require an excavation permit (e.g., for test pits, wells, utility installation)?	Though expected to be a rare occurrence, it is possible that modifications to laboratories might result in exterior changes that require an excavation permit, such as a PNNL or Hanford Site excavation permit. Stipulations in the excavation permit to minimize potential impacts to safety and the environment would be followed.
Disturb an undeveloped area?	Microbiological and biomedical research would not disturb undeveloped areas, any new structures or building modifications to support the research would be within previously disturbed or developed areas with existing access to roads and utilities.
Result in more than minimal impacts on transportation or public services?	Microbiological and biomedical research would not result in more than minimal impacts to transportation or public services.
Disproportionately impact low-income or minority populations?	Microbiological and biomedical research would not disproportionately impact low-income or minority populations.
Require environmental or other permits from federal, state, or local agencies?	Although not expected, modification activities might require submittal of a notice of construction to the relevant Department of Health, for example, when modifications result in changes to an existing radiological control system. Notifications and approvals might be required from air regulatory agencies to use temporary and portable air pollution sources, such as engines or generators, or modify or maintain permanent facilities and equipment subject to emission standards. Activities will abide by all applicable permit requirements.

Compliance Action:

I have determined that the proposed action satisfies the DOE NEPA eligibility criteria and integral elements, does not pose extraordinary circumstances, and meets the requirements for the CX referenced above. Therefore, using the authority delegated to me, I have determined that the proposed action may be categorically excluded from further NEPA review and documentation. This determination must be reviewed at least once every 5 years.

Signature: Digitally signed by THOMAS MCDERMOTT Date: 2023.03.31 10:42:48 -07'00'

Tom McDermott
PNSO NEPA Compliance Officer

cc: ES Norris, PNNL