CATEGORICAL EXCLUSION DETERMINATION FOR MICROBIOLOGICAL AND BIOMEDICAL RESEARCH PROJECTS, AND DIAGNOSTIC AND TREATMENT ACTIVITIES, HANFORD SITE RICHLAND, WASHINGTON

PROPOSED ACTION: The U.S. Department of Energy (DOE), Richland Operations Office (RL) proposes to conduct microbiological and biomedical research projects through the Pacific Northwest National Laboratory (PNNL) and biomedical diagnostic and treatment activities through the Hanford Environmental Health Foundation (HEHF).

LOCATION OF ACTION: Buildings and structures that are owned and leased by both DOE and Battelle on the Hanford site, as well as other offsite buildings and structures that are used to conduct work for RL, PNNL, or HEHF.

DESCRIPTION OF THE PROPOSED ACTION: The proposed action would be to conduct microbiological and biomedical projects to support the following general research areas:

- diagnostic products, which would provide early detection of disorders or measurement of exposures with sensitive, generally non-invasive devices and systems;
- therapeutic products, which would provide targeted delivery of medical therapeutics with minimal adverse effects;
- technology and systems management products, which would improve health care delivery processes and systems through re-engineering and policy reform;
- developing a molecular-level understanding of the physical, chemical, and biological processes that underlie environmental remediation, waste processing and storage, and human health effects; and
- the beneficial use of biomedical ultrasonics, bioelectromagnetics, molecular toxicology, and medical isotopes.

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." Actions that involve Biosafety Levels 3 or 4 (or those using inhalable or aerosol agents that may cause serious or potentially life-threatening disease) would not be conducted under this CX.

HEHF supports two missions for DOE that would be addressed by this CX: (1) provide occupational health risk management and (2) provide occupational health services to personnel at Hanford. The health risk management program helps to identify and analyze the hazards that Hanford personnel face in the work environment. The occupational health services provide elements such as occupational medicine and nursing, medical surveillance, ergonomics

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[1] Level 1 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 are conducted in biological safety cabinets or other physical containment equipment.

assessment, exercise physiology, psychology and counseling, fitness for duty evaluations, immediate health care, health education, industrial hygiene, and health, safety, and risk assessments.

DOE funds a variety of activities at PNNL that are currently covered under the bench-scale CX, but which are better addressed by this microbiological and biomedical research CX. These research activities include efforts such as the development of real-time ultrasonic visualization of bloodflow, 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 (using rodents), 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. PNNL expects growth in the microbiological and biomedical fields over the next several years.

The majority of the PNNL microbiological and biomedical research activities occur in facilities such as 2400 Stevens, 326, 331, Sigma V, PSL, Math, RTL, LSL II, and the Environmental Molecular Sciences Laboratory. Ongoing activities also include collaboration with other laboratories, research hospitals, and other federal 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 determination. The majority of HEHF activities occur in the Hanford Square Buildings and individual health care centers.

The proposed action includes the operation and minor modification (if necessary) of facilities used for microbiological and biomedical projects and the purchase, installation, and eventual removal of research equipment such as laminar flow hoods, biological safety cabinets, gloveboxes, lasers, ultrasonic instrumentation, centrifuges, etc. These research projects would include those actions foreseeably necessary for implementation, such as associated transportation activities, waste disposal activities, small-scale decommissioning of individual rooms and laboratories, and award of grants and contracts. Each proposed activity must meet the CX eligibility criteria (10 Code of Federal Regulations [CFR] 1021.410) and all of the following criteria:

1. Each activity would be conducted within existing or newly modified structures that provide 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.

2. Each activity 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 class systems, operating parameters, radiological controls, and entry requirements.

3. Each activity 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 existing 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 existing permits, local, state, and federal regulations, DOE Orders, and PNNL or HEHF guidelines, as applicable.

5. 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.

6. Wastes generated by each activity would be handled, packaged, transported, stored, and/or disposed of in accordance with applicable local, state, and federal regulations, DOE Orders, and PNNL or HEHF guidelines.

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

Funding for the proposed activities would be obtained on a project-specific basis from DOE Program Secretarial Offices or other sources.

CX TO BE APPLIED: The following CX is listed in the DOE NEPA Implementing Procedures, 10 CFR 1021, Appendix B to Subpart D, published in the Tuesday, July 9, 1996, Federal Register (61 FR 36221):

B3.12 "Siting, construction (or modification), operation, and decommissioning of microbiological and biomedical diagnostic, treatment and research facilities (excluding Biosafety Level 3 and Biosafety Level 4; reference: Biosafety in Microbiological and Biomedical Laboratories, 3rd Edition, May 1993, U.S. Department of Health and Human Services Public Health Service, Centers for Disease Control and Prevention, and the National Institutes of Health (HHS Publication No. (CDC) 93-8395)) including, but not limited to, laboratories, treatment areas, offices, and storage areas, within or contiguous to an already 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."

ELIGIBILITY CRITERIA: The proposed activity meets the eligibility criteria of 10 CFR 1021.410(b), since there are no extraordinary circumstances that might affect the significance of the environmental effects of the proposal. The proposed activity is not connected to other actions with potentially significant impacts (40 CFR 1508.25[a][1]), or with cumulatively significant impacts (40 CFR 1508.25[a][2]), and is not precluded by 10 CFR 1021.211.

The "Integral Elements" of 10 CFR 1021 are satisfied as discussed in the following table:

INTEGRAL ELEMENTS, 10 CFR 1021, APPENDIX B, SUBPART D	
WOULD THE PROPOSED ACTION:	COMMENT OR EXPLANATION:
Threaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, or health (ES&H), including requirements of DOE and/or Executive Orders?	The proposed action would not threaten a violation of ES&H regulations or Executive or DOE Orders.
Require siting and construction or major expansion of waste storage, disposal, recovery, or treatment facilities (including incinerators), but the proposal may include categorically excluded waste storage, disposal, recovery, or treatment actions?	Wastes created by the proposed action would be treated, stored, or disposed of in existing waste facilities.
Disturb hazardous substances, pollutants, contaminants, or CERCLA-excluded petroleum and natural gas products that pre-exist in the environment such that there would be uncontrolled or unpermitted releases?	No pre-existing hazardous substances pollutants, contaminants, or CERCLA-excluded petroleum and natural gas products would be disturbed in a manner that would result in uncontrolled releases.
Adversely affect environmentally sensitive resources including but not limited to: (I) Property (e.g., sites, buildings, structures, objects) of historic, archeological, or architectural significance designated by federal, state, or local governments or property eligible for listing on the National Register of Historic Places (ii) Federally-listed threatened or endangered species or their habitat (including critical habitat), Federally-proposed or candidate species or their habitat or state-listed endangered or threatened species or their habitat (iii) Wetlands regulated under the Clean Water Act (33 U.S.C. 1344) and floodplains (iv) Federally- and state-designated wilderness areas, national parks, national natural landmarks, wild and scenic rivers, state and federal wildlife refuges, and marine sanctuaries (v) Prime agricultural lands (vi) Special sources of water (such as sole-source aquifers, wellhead protection areas, and other water sources that are vital in a region) (vii) Tundra, coral reefs, or rainforests?	No environmentally sensitive resources would be adversely affected. When appropriate, cultural and/or biological resources reviews would be performed to ensure that sensitive resources are not adversely affected by the proposed action. The proposed action would not adversely affect floodplains or wetlands regulated under the Clean Water Act; wilderness areas or other specially designated areas; prime agricultural lands; special sources of water; or tundra, coral reefs, or rainforests.

COMPLIANCE ACTION: I have reviewed the documentation and have determined that the proposed action may be categorically excluded from further NEPA review and documentation.

Signature: Paul F.X. Dunigan Jr. Date: 3/12/97
Paul F. X. Dunigan, Jr.
RL NEPA Compliance Officer

Attachment:
Checklist Summarizing Environmental Impacts

Distribution w/attach:
S. M. McInturff, HEHF
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K. A. Piper, HEHF
R. S. Weeks, PNNL

Attachment 1

The following checklist summarizes environmental impacts that were considered. Answers to relevant questions are explained in detail in the text following the checklist.

IMPACT TO AIR

	Would the proposed action:	YES	NO
1	Result in more than minor and temporary gaseous discharges to the environment?		X
2	Release other than nominal and temporary particulates or drops to the atmosphere?		X
3	Result in more than minor thermal discharges?		X
4	Increase offsite radiation dose to >0.1 mrem (40 CFR 61 Subpart H)?	X	

IMPACT TO WATER

	Would the proposed action:	YES	NO
5	Discharge any liquids to the environment?	X	
6	Discharge heat to surface or subsurface water?		X
7	Release soluble solids to natural waters?		X
8	Provide interconnection between aquifers?		X
9	Require installation of wells?		X
10	Require a Spill Control and Prevention and Countermeasures Plan? (40 CFR 112 and 761)		X
11	Violate water quality standards (WAC 173-200, Table 1)?		X

IMPACT TO LAND

	Would the proposed action:	YES	NO
12	Conflict with existing zoning or land use?		X
13	Involve hazardous, radioactive, PCB, or asbestos waste?	X	
14	Cause erosion?		X
15	Occur on the Arid Lands Ecology Reserve or Wahluke Slope?		X
16	Require an excavation permit?	X	
17	Disturb an undeveloped area?		X

GENERAL

	Would the proposed action:	YES	NO
18	Cause other than a minor or temporary increase in noise level?		X
19	Make a long-term commitment of large quantities of nonrenewable resources?		X
20	Require new utilities or modifications to utilities?	X	
21	Use pesticides, carcinogens, or toxic chemicals?	X	
22	Require a radiation work permit?	X	

4. Research involving biomedical use of radioactive isotopes might result in instances where unabated offsite radiological doses are greater than 0.1 mrem for the maximally exposed offsite individual. 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 be above 0.1 mrem. In addition, high-efficiency particulate air filters are in place to control emissions. Unabated radiological emissions would not be released from microbiological or biomedical research activities.

5. Liquid wastes generated by proposed activities would be discharged into existing treatment systems or in accordance with applicable regulations. For activities conducted at the Hanford Site, liquid wastes would be processed through systems such as the City of Richland publicly-owned treatment works, process sewer, retention process sewer, septic systems, or radioactive liquid waste sewer, whichever is appropriate. Liquid waste treatment and disposal would be compliant with applicable local, state, and federal regulations and permit requirements, DOE Orders, and PNNL or HEHF guidelines.

13. Proposed activities might result in small quantities of hazardous, radioactive, PCB, and/or asbestos wastes. If unrecyclable, such wastes would be characterized, handled, packaged, transported, stored, and/or disposed of in existing Hanford Site or offsite treatment, storage, and disposal facilities in accordance with applicable local, state, and federal regulations, DOE Orders, and PNNL or HEHF guidelines.

16. Facility modification to support microbiological or biomedical research might require an excavation permit if earth-disturbing activity is involved.

20. Proposed activities might require minor modifications to utilities that serve existing facilities.

21. Proposed activities might use small quantities of pesticides, carcinogens, and/or toxic chemicals. Project inventories would be maintained at the lowest practicable levels, and chemicals would be recycled or regenerated if possible.

22. Proposed activities would be performed in compliance with as low as reasonably achievable 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 five rem.

CULTURAL RESOURCES REVIEW: Minor facility modifications foreseeably necessary to perform microbiological and biomedical research would be conducted under this CX. If the facility is listed in Appendix C, Table 1 of the "Programmatic Agreement for the Maintenance, Deactivation, Alteration, and Demolition of the Built Environment on the Hanford Site," the Hanford Cultural Resources Laboratory would

review the proposed modification activity prior to commencement. This review would evaluate potential impacts to culturally sensitive resources, including consideration of the historical significance of the facilities. In accordance with the PA Section (V) (C), the Project will assess the contents of each affected facility to locate and identify artifacts or museum property prior to activities associated with this CX.

BIOLOGICAL RESOURCES REVIEW: A biological resources review would be completed for facility modification activities with the potential to adversely affect sensitive plant and animal species. This review would not generally be required for those activities that are internal to a building or facility.