Sitewide Categorical Exclusion for Siting, Construction, Operation and Decommissioning of Microbiological and Biomedical Facilities

Introduction

As defined in the U.S. Department of Energy's (DOE) Richland Operations Office Integrated Management System Procedure, *NEPA Analysis at Hanford*, a sitewide categorical exclusion is:

An application of DOE categorical exclusions described in 10 CFR 1021, Appendices A and B, which may apply to Hanford Site proposed actions (activities) that are "sitewide" in nature and extent, which the cognizant DOE Hanford NCO has determined fit within the scope (i.e., same nature and intent, and of the same or lesser scope) of DOE categorical exclusions described in 10 CFR 1021 Appendices A and B. The cognizant DOE Hanford NCO may issue specific sitewide categorical exclusions for use on proposed actions in which separate DOE approval to proceed is not required.

The nature of the proposed action subject of this sitewide categorical exclusion, as well as guidance to implement this exclusion as described herein, may be revised to reflect contemporary experience from the application of this exclusion; changes to, or development of, relevant policy and guidance; and changes to DOE's categorical exclusions resulting from future rulemakings.

Proposed Action

The DOE's Richland Operations Office and Office of River Protection propose to conduct microbiological and biomedical research projects.

Location of Action

On and near the Hanford Site, Richland, Washington.

Description of Proposed Action

DOE's proposed action is to conduct microbiological and biomedical research projects to support development of:

- 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

- Molecular-level understanding of the physical, chemical, and biological processes that underlie environmental remediation, waste processing and storage, and human health effects, and
- Beneficial use of biomedical ultrasonics, bioelectromagnetics, molecular toxicology, and medical isotopes.

Research activities also would include efforts to support:

- 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, for example)
- Medical three-dimensional imaging
- Optical in-vivo blood characterization
- Portable ultrasensitive biological sensors, and
- Radium immunoconjugates for cancer therapy.

Research activities would be undertaken at DOE and contractor owned and leased facilities on and near the Hanford Site. Research activities also would be undertaken in collaboration with other laboratories, research hospitals, and other federal agencies.

In addition, DOE would provide occupational health risk management and occupational health services to Hanford Site personnel. The health risk management program would help identify and analyze the hazards that personnel face in the work environment. Occupational health services would provide, for example, occupational medicine and nursing, medical surveillance, ergonomics assessment, exercise physiology, psychology and counseling, fitness for duty evaluations, immediate health care, health education, industrial hygiene, and health, safety and risk assessments.

Implementing the proposed action would require siting (if needed), constructing (or modifying), operating and decommissioning facilities dedicated to microbiological and biomedical projects. Such facilities would include, but are 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). Implementing the proposed action also would require, for example, the purchase, installation, use, and eventual removal of equipment such as laminar flow hoods, biological safety cabinets, gloveboxes, lasers, ultrasonic instrumentation, and centrifuges.

Implementing these proposed activities also would require hazardous and/or radioactive materials for research purposes, and the activities would generate small (incidental) quantities of

hazardous and/or radioactive wastes. Consistent with DOE's procedures that implement NEPA (10 CFR 1021), DOE would undertake actions foreseeably necessary to implement this proposed action, and therefore would manage these materials and wastes in compliance with DOE orders, and Federal, and state regulations and guidelines. Wastes would be packaged, staged for transport, transported, and disposed of at onsite or offsite facilities.

In addition, DOE would move equipment and materials necessary to construct (or modify), operate and decommission facilities. Use of the equipment and associated vehicles would generate air pollutants from combustion and possibly limited ground-disturbance, local noise levels would increase, and nonrenewable resources such as petroleum products would be consumed. In all instances, the demand for resources and environmental impacts resulting from implementation of these proposed activities would be small and temporary in nature.

Applicable Categorical Exclusion

DOE's Categorical Exclusion 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 of 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.

Implementing Guidance

This sitewide categorical exclusion may be applied to activities under the proposed actions that would require construction of small facilities, or the modification, operation and decommissioning of existing facilities that are "sitewide" in nature and extent. For example, this exclusion may be implemented as a one-time yearly application in instances where the proposed action would involve the same type of modifications to existing, dedicated microbiological and biomedical facilities located across (or near) the Hanford Site.

As a general matter, this sitewide categorical exclusion may only be applied to proposed microbiological and biomedical research activities that would be conducted under Biosafety Levels 1 and 2; actions that would 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 subject of this exclusion. In addition, this exclusion may only be applied to facilities having (or proposed to have) appropriate safety systems, exhaust ventilation, air filtration, and any other confinement or controls appropriate to the nature of the materials and equipment to be used in the proposed research activities.

Application of this sitewide categorical exclusion requires compliance with the Richland Integrated Management System Procedure, *NEPA Analysis at Hanford*. Sitewide categorical exclusions are determined solely by the cognizant DOE Hanford NCO and are applied through a screening process which documents that the proposed action:

1. Fits within the scope of actions identified in a DOE Hanford NCO-approved sitewide categorical exclusion
2. Meets the eligibility requirements for Appendix B categorical exclusion ("integral elements") of 10 CFR 1021, Subpart D, Appendix B, B(1) through B(4)
3. Is not connected to other actions with potentially significant impacts (see 40 CFR 1508.25(a)(1)) or with cumulatively significant impacts (see 40 CFR 1508.25(a)(2))
4. Is absent extraordinary circumstances that may affect the significance of the environmental effects of the proposed action
5. Is not located on nor directly impacts the Hanford Reach National Monument, Rattlesnake Mountain, Gable Mountain, Gable Butte, within ¼ mile of the Columbia River, other known Traditional Cultural Properties, or properties of historic, archaeological or architectural significance designated by Federal, state or local governments or properties eligible for listing on the National Register of Historic Places, and
6. Is not located on nor cause direct impacts to sensitive species or their habitats, such as old-growth sagebrush.

This sitewide categorical exclusion may not be applied to actions that would require rebuilding or modifying substantial portions of buildings and structures, or that would result in a significant change in the expected useful life, design capacity, or function of the facility. It also may not be applied to actions involving facilities in which widespread and persistent contamination would need to be removed to enable facility modification to proceed (i.e., more than incidental contamination). It also may not be applied at locations in which previously undisturbed land would be occupied by vehicles, equipment or temporary structures, or would require extensive excavation (i.e., beyond that necessary to implement the proposed action).

Compliance Action

I have determined that the proposed action meets the requirements for Categorical Exclusion B3.12 and that there are no extraordinary circumstance related to this action that may affect the significance of the environmental effects of the action; this action is not "connected" to other actions with potentially significant impacts, is not related to other proposed actions with cumulatively significant impacts, and is not precluded by 40 CFR 1506.1 or 10 CFR 1021.211.

All activities to be conducted under this Sitewide Categorical Exclusion Determination must be documented with the NEPA Review Screening Form (see Hanford Site Form RL-721) pursuant to *NEPA Analysis at Hanford* and demonstrably meet the criteria described in 1 through 6 above. Accordingly, I have determined that the proposed action may be categorically excluded from further NEPA review and documentation. This exclusion is being implemented as a one-time yearly application for the proposed action described herein.

Ralph W. Russell, DOE NEPA Compliance Officer

June 21, 2011
Date