



U.S. Department of Energy Categorical Exclusion Determination Form

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Proposed Action Title: Biosafety Level-2 (BSL-2) Laboratory in Building 3-216

Program or Field Office: Los Alamos Site Office (DOE/NNSA)

Location(s) (City/County/State): Los Alamos, NM

Proposed Action Description:

This cooperative research and development agreement project would develop a biological detection system to identify and quantify microorganisms for an organization leading in supply of detection technologies to the United States and international pharmaceutical firms. This proposal would assist pharmaceutical companies looking for a real-time detection method to reduce time delays and improve product quality control.

LANL would set up a Biosafety Level (BSL) 2 laboratory in an unused optical laboratory in Technical Area 3, Building 216 to develop and test the efficacy of a molecular probe for bacteria and fungi and determine if the microorganism is alive or dead. Building 3-216 is in a Q-cleared facility with proximity to investigator/collaborators. Further work would include development of a prototype instrument/system for determining system capabilities that could lead to the manufacture of a commercial detection system for use by pharmaceutical companies to test "in vivo" drugs, and production line contamination including surfaces, air, and water. The proposed work requires operation as a BSL-2 laboratory because validation testing would require a set of microorganisms used for standard quality control tests by pharmaceutical companies to include vegetative cells, bacterial spores, yeasts and molds.

Categorical Exclusion(s) Applied:

B3.12 - Microbiological and biomedical facilities

For the complete DOE National Environmental Policy Act regulations regarding categorical exclusions, including the full text of each categorical exclusion, see Subpart D of [10 CFR Part 1021](#).

Regulatory Requirements in 10 CFR 1021.410(b): (See full text in regulation)

The proposal fits within a class of actions that is listed in Appendix A or B to 10 CFR Part 1021, Subpart D.

To fit within the classes of actions listed in 10 CFR Part 1021, Subpart D, Appendix B, a proposal must be one that would not: (1) threaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health, or similar requirements of DOE or Executive Orders; (2) 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 or facilities; (3) disturb hazardous substances, pollutants, contaminants, or CERCLA-excluded petroleum and natural gas products that preexist in the environment such that there would be uncontrolled or unpermitted releases; (4) have the potential to cause significant impacts on environmentally sensitive resources, including, but not limited to, those listed in paragraph B(4) of 10 CFR Part 1021, Subpart D, Appendix B; (5) involve 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, such as those listed in paragraph B(5) of 10 CFR Part 1021, Subpart D, Appendix B.

There are no extraordinary circumstances related to the proposal that may affect the significance of the environmental effects of the proposal.

The proposal has not been segmented to meet the definition of a categorical exclusion. This proposal is not connected to other actions with potentially significant impacts (40 CFR 1508.25(a)(1)), 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 preparation of an environmental impact statement.

Based on my review of the proposed action, as NEPA Compliance Officer (as authorized under DOE Order 451.1B), I have determined that the proposed action fits within the specified class(es) of action, the other regulatory requirements set forth above are met, and the proposed action is hereby categorically excluded from further NEPA review.

NEPA Compliance Officer:

Date Determined: Dec 16, 2013