



National Nuclear Security Administration Categorical Exclusion Determination Form



NEPA ID#: NA-19-0009

Proposed Action Title: Niowave's Domestic Production of Molybdenum-99 and other Fission Fragments from LEU without a Nuclear Reactor

Program or Field Office: NNSA/Office of Material Management and Minimization, NA-23

Location(s) (City/County/State): Lansing, MI

Proposed Action Description:

The U.S. Department of Energy (DOE) National Nuclear Security Administration (NNSA) Office of Material Management and Minimization proposes to provide financial assistance to Niowave, Inc. to develop domestic production of Molybdenum-99 (Mo-99) and other fission fragments from low enriched uranium (LEU) without a nuclear reactor. Niowave's Mo-99 program would produce radioisotopes using an accelerator-driven subcritical uranium target assembly.

Mo-99 is a critical radioisotope whose decay byproduct technetium-99m (Tc-99m), is used in approximately 40,000 nuclear medicine diagnostic procedures performed daily in the United States. However, due to its short half-life it must be produced continuously to meet the medical community's requirements. The United States does not currently have a domestic production capability for Mo-99 sufficient to meet the needs of the U.S. healthcare community. The United States is at the nexus of two related priorities: the need to ensure a reliable, robust Mo-99 supply for U.S. patient care and discouraging the use of proliferation-sensitive HEU in civilian applications. The purpose of providing federal funding is to accelerate commercial Mo-99 projects' time to market so that industry and government can fulfill these two critical priorities and decrease the U.S. medical community's reliance on foreign supplies of Mo-99.

Eventually, Niowave plans to produce 20 kCi/week (3,100 6-day Ci/week of Mo-99); more than half the nation's weekly demand. Niowave would approach full-scale production in four phases completing in 2027. DOE/NNSA funding would be used only for Phase 2. During Phases 1 and 2, Niowave would process only source material, i.e. natural uranium, to harvest radioisotopes and operate at a pilot scale. Niowave would process special nuclear material in Phase 3 which would require an environmental impact statement issued by the Nuclear Regulatory Commission (NRC) according to 10 CFR 51.20(b)(7).

Categorical Exclusion(s) Applied:

B 3.6 Small-Scale Research and Development, Laboratory Operations, and Pilot Projects
B3.10 Particle Accelerators

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 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 of the Department of Agriculture, the Environmental Protection Agency, and the National Institutes of Health.

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 information conveyed to me and in my possession concerning the proposed action, as NEPA Compliance Officer (as authorized under NNSA NAP 451.1 and DOE P 451.1), I have determined that the proposed action fits within the specified class(es) of action and that other-regulatory requirements set forth above are met. Therefore, the application of a categorical exclusion is appropriate.

NEPA Compliance Officer: Amy Miller

Date Determined: 4/29/2019