National Nuclear Security Administration
Categorical Exclusion Determination Form

NEPA ID#: NA-19-0010

Proposed Action Title: SHINE Mo-99 Commercial Production Project

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

Location(s) (City/County/State): Janesville, WI and Monona, WI

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 SHINE Medical Technologies, Inc. to assist in the establishment of the capability to produce at least 3,000 6-day curies of Molybdenum-99 (Mo-99) per week, steady state, without the use of HEU in the United States as soon as possible. SHINE's production facility would use low-energy, accelerator-based neutron sources and low-enriched uranium (LEU) to produce Mo-99.

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.

DOE/NNSA funding would be used for only four purposes within the entire scope of work for the project: (1) demonstration of SHINE's First Production Unit (FPU) with tritium at full yield, (2) completion and submittal of the operating license application to the Nuclear Regulatory Commission (NRC), (3) completion of detailed design through procurement specifications on major plant systems, and (4) project management support and oversight for the entire project. The demonstration of SHINE's FPU with tritium at full yield would occur at SHINE Building One. SHINE Building One is an 11,250 square foot leased facility next to the location of the planned medical isotope production facility. Its primary purpose is testing and development, with a secondary purpose of training. No commercial production is expected to occur at SHINE Building One, nor would DOE funding be used for commercial production.

The Nuclear Regulatory Commission (NRC) has issued a Final Environmental Impact Statement (EIS) for the construction permit for the medical isotope production facility (NUREG-2183). SHINE would need to be issued an operating license from the NRC before it would be able to operate the new facility. The

NRC would also issue a supplement to the EIS in support of the Operating License issuance according to 10 CFR 51.95(b).

Categorical Exclusion(s) Applied:
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.

AMY MILLER Digitally signed by AMY MILLER
Date: 2019.04.29 17:42:58
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NEPA Compliance Officer: Amy Miller Date Determined: 4/29/2019