

July 14, 2017

Gregory Piefer, Ph.D.
Chief Executive Officer
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101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. – U.S. NUCLEAR REGULATORY
COMMISSION STAFF RESPONSE TO REQUEST REGARDING THE
APPLICABILITY OF THE DEFINITION OF UTILIZATION FACILITY TO THE
SHINE DEMONSTRATION UNIT

Dear Dr. Piefer:

On February 29, 2016, the U.S. Nuclear Regulatory Commission (NRC or Commission) authorized the construction of the SHINE Medical Isotope Production Facility, consisting of eight utilization facilities (irradiation units) and one production facility, under Construction Permit No. CPMIF-001 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML16041A471) for the production of medical radioisotopes.

By letters dated March 17, 2017, and June 22, 2017 (ADAMS Accession Nos. ML17079A476 and ML17173A013, respectively), SHINE Medical Technologies, Inc. (SHINE) submitted to the NRC information on its plans to conduct a series of short-duration tests within an accelerator-driven subcritical operating assembly (demonstration unit) using a less than critical mass of low enriched uranium (LEU). SHINE would operate this demonstration unit to show certain operating characteristics of the proposed irradiation units described in the preliminary safety analysis report (PSAR) (ADAMS Accession No. ML15258A431) included in its construction permit application and assigned Docket No. 50-608. SHINE's March 17, 2017, letter requests that the NRC staff confirm that the planned demonstration unit would not meet the definition of "utilization facility" in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.2, "Definitions."

Previously, the NRC staff had determined in SECY-14-0061, "Direct Final Rule: Adding SHINE Medical Technologies, Inc.'s Accelerator-Driven Subcritical Operating Assembly to the Definition of Utilization Facility," that the safety considerations associated with SHINE's proposed irradiation units closely resembled those of former and currently operating non-power reactors (ADAMS Accession No. ML14052A123). The NRC staff thus proposed, and the Commission approved, a direct final rule that modified the definition of "utilization facility" in 10 CFR 50.2 to include SHINE's proposed irradiation units. The direct final rule was published in the *Federal Register* on October 17, 2014 (79 FR 62329).

As described in the March 17, 2017, letter, the demonstration unit would primarily consist of a deuterium-tritium accelerator, full-scale multiplier, and solution vessel. The demonstration unit would be contained within a concrete, light water-filled pit of dimensions similar to the irradiation unit cells of SHINE's proposed irradiation facility described in the construction permit application assigned Docket No. 50-608.

However, unlike the proposed irradiation units, SHINE does not expect that the demonstration unit would need to include a primary or other active cooling system; reactivity protection system; engineered safety features to meet 10 CFR Part 20, "Standards for Protection Against Radiation," dose limits; or safety systems for the control of fission gases, the radiolytic decomposition of water and associated oxygen and hydrogen gas generation, or fission product inventory.

In response to SHINE's request, the NRC staff considered the definitions of "utilization facility" in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and the Atomic Energy Act of 1954, as amended (AEA); the safety and security characteristics of the demonstration unit and associated special nuclear material (SNM); and the relationship between SHINE's proposed irradiation units and the demonstration unit. In particular, the NRC staff considered the thermal power level, effective multiplication factor, potential accident scenarios, quantities of SNM, intended use, and location associated with the proposed operation of the demonstration unit to support its conclusions.

As described in the enclosure to this letter, the NRC staff has concluded that the demonstration unit would not meet the definitions of "utilization facility" in either 10 CFR 50.2 or the AEA. In particular, the demonstration unit, as described, is not a nuclear reactor. It is also not an accelerator-driven subcritical operating assembly used for the irradiation of materials containing SNM and described in the application assigned Docket No. 50-608. Further, it appears that the demonstration unit, if designed to operate as described, would not require engineered safety features or other safety systems to mitigate radiological releases to meet 10 CFR Part 20 dose limits and would not require a physical protection system. Therefore, the demonstration unit would not be capable of making use of SNM or atomic energy "in such quantity as to be of significance to the common defense and security" or "in such manner as to affect the health and safety of the public" and would not be considered an important component part especially designed for a utilization facility.

Since the information provided in SHINE's March 17, 2017, and June 22, 2017, letters is preliminary and does not constitute a license application, this NRC staff response does not constitute either a review or approval of the design of the demonstration unit or a verification that the planned demonstration unit would perform as described. In addition, if the actual demonstration unit differs from the descriptions and information in SHINE's March 17, 2017, and June 22, 2017, letters, the NRC staff could reach different conclusions.

If you have any questions, please contact Steven Lynch at 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Sincerely,

/RA/

Louise Lund, Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Enclosure:
Response on Applicability of Definition of Utilization Facility

cc: See next page

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ADAMS Accession Nos.: Package: ML17142A431; Letter: ML17142A432;
Enclosure: ML17142A433; *concurring via email NRR-088

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