OFFICE OF NUCLEAR REACTOR REGULATION RESPONSE TO REQUEST

REGARDING THE APPLICABILITY OF THE DEFINITION OF UTILIZATION FACILITY TO THE

DEMONSTRATION UNIT

SHINE MEDICAL TECHNOLOGIES, INC.

INTRODUCTION:

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 the 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."

SHINE states in its March 17, 2017, letter, that it intends to build and operate the demonstration unit on or directly to the south of the SHINE Medical Isotope Production Facility site. SHINE's Medical Isotope Production Facility will be located on previously undeveloped agricultural property in Rock County, Wisconsin, within the southern corporate boundaries of the City of Janesville as is described in the SHINE PSAR. However, SHINE acknowledges that the exact location of its demonstration unit could change.

As described, the demonstration unit would primarily consist of a deuterium-tritium accelerator, full-scale neutron 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 its review of 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 (k_{eff}), potential accident scenarios, quantities of SNM, intended use, and location associated with the proposed operation of the demonstration unit to support its conclusions.

BACKGROUND:

Previously, the NRC staff had determined that the safety considerations associated with SHINE's proposed accelerator-driven subcritical operating assemblies (or irradiation units) closely resembled those of former and currently operating non-power reactors. As described in SECY-14-0061, "Direct Final Rule: Adding SHINE Medical Technologies, Inc.'s Accelerator-Driven Subcritical Operating Assembly to the Definition of Utilization Facility" (ADAMS Accession No. ML14052A123), the NRC staff evaluated the safety considerations associated with the fission rate and thermal power level of SHINE's proposed irradiation units, including:

- Provisions for removal of fission heat during operation;
- Consideration of decay heat generation after shutdown;
- Reactivity feedback mechanisms;
- Control of fission gas release during operation and subsequent gas management engineering safety features;
- Control of radiolytic decomposition of water and generated oxygen and hydrogen gases;
- Control of fission product inventory buildup; and
- Accident scenarios, such as coolant loss, reactivity additions, and fission product release.

Although the NRC staff determined that these safety considerations closely resembled those of non-power reactors, since SHINE's proposed irradiation units did not meet the definition of "nuclear reactor" in 10 CFR 50.2, they could not be licensed as utilization facilities under 10 CFR Part 50, as of the writing of the SECY paper. However, based on the considerations above, the NRC staff determined that SHINE's proposed irradiation units could meet the AEA's definition of "utilization facility" at Section 11cc. because they would be capable of making use of SNM "in such quantity as to be of significance to the common defense and security," and in "such a manner as to affect the health and safety of the public."

The NRC staff also considered whether SHINE's proposed irradiation units could be licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." While the requirements of 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," could have been applied to the proposed irradiation units, the NRC staff determined that the operating characteristics of the irradiation units did not resemble those of the facilities typically licensed under 10 CFR Part 70. Specifically, facilities typically licensed under 10 CFR Part 70, generally referred to as fuel cycle facilities, have a common objective of maintaining a significant margin of subcriticality under normal operating and accident conditions. In contrast, SHINE's proposed irradiation units would

have a routine operating margin of subcriticality of less than what had previously been approved for 10 CFR Part 70 licensees. Additionally, distinct from fuel cycle facilities, SHINE's proposed irradiation units were designed to operate with a k_{eff} and inherent negative reactivity feedback mechanisms similar to those found in nuclear reactors. As such, the NRC staff determined that it would be more appropriate to license SHINE's proposed irradiation units under the regulations in 10 CFR Part 50 than under the regulations in 10 CFR Part 70.

Due to the similarities between SHINE's proposed irradiation units and non-power reactors and the dissimilarities between SHINE's proposed irradiation units and fuel cycle facilities, the NRC staff proposed, and the Commission approved, a direct final rule that would modify 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* (FR) on October 17, 2014 (79 FR 62329). It modified the 10 CFR 50.2 definition of "utilization facility" to include "an accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608."

In order to preclude unintended consequences on the regulation of other applicants or licensees, the NRC purposefully limited the scope of the direct final rule to include only the proposed irradiation units described in the application assigned Docket No. 50-608 at the time of the direct final rule's publication (79 FR 62333). This rule does not apply to similar technologies proposed by other applicants, since each application would be assigned a distinct docket number. Also, the rule would not apply to SHINE if it were to propose a technology other than the proposed irradiation units described in its application assigned Docket No. 50-608.

DISCUSSION:

SHINE's Demonstration Unit Would Not Meet the 10 CFR 50.2 Definition of Utilization Facility

The NRC staff considered whether the demonstration unit would meet the 10 CFR Part 50 definition of "utilization facility." In order to license SHINE's demonstration unit as a utilization facility under 10 CFR Part 50, it would need to meet one of the two definitions of "utilization facility" in 10 CFR 50.2, which states:

> *Utilization facility* means:
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> (1) Any nuclear reactor other than one designed or used primarily for the formation of plutonium or U–233; or
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> (2) An accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50–608.

In the first definition, a utilization facility is described as a type of nuclear reactor. The regulations in 10 CFR 50.2 further define a "nuclear reactor" as "an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission in a self-supporting chain reaction." Because the demonstration unit would be operated using a less than critical mass of SNM (i.e., $\leq$ 350 grams (g) uranium-235 (U-235)), it would be unable to sustain nuclear fission in a self-supporting chain reaction and, therefore, would not meet the definition of a nuclear reactor in 10 CFR 50.2. SHINE estimates that under optimum geometric and reflective conditions, the demonstration unit would remain below a k_{eff} of 0.80. Therefore, the demonstration unit would not meet the first definition of "utilization facility" in 10 CFR 50.2.

In the second definition, the scope of what is considered to be a utilization facility is specifically limited to include only the eight proposed irradiation units described in SHINE's application assigned Docket No. 50-608. To date, SHINE's March 17, 2017, and June 22, 2017, letters provide the only written correspondence describing the demonstration unit to the NRC. In these letters, SHINE acknowledges that the demonstration unit could be built on the SHINE Medical Isotope Production Facility site in Rock County, Wisconsin. However, there are significant differences between the demonstration unit and the proposed irradiation units described in the application assigned Docket No. 50-608 that would preclude the demonstration unit from being considered one of SHINE's previously described irradiation units. For example, SHINE does not expect the demonstration unit to include several key structures, systems, and components of the proposed irradiation units, including: 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. So, while SHINE's demonstration unit, as described, may be an accelerator-driven subcritical operating assembly used for the irradiation of materials containing SNM, these differences would make the demonstration unit different than the accelerator-driven subcritical operating assemblies described in the application assigned Docket No. 50-608. Therefore, regardless of physical location, the demonstration unit is not one of the eight proposed irradiation units described in SHINE's application assigned Docket No. 50-608, and would not meet the second definition of "utilization facility" in 10 CFR 50.2.

SHINE's Demonstration Unit Would Not Meet the AEA Definition of Utilization Facility

The NRC staff also considered whether SHINE's demonstration unit would meet the AEA's definition of "utilization facility." Specifically, Section 11cc. of the AEA provides that "utilization facility" means:

> (1) any equipment or device, except an atomic weapon, determined by rule of the Commission to be capable of making use of special nuclear material 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, or peculiarly adapted for making use of 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; or
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> (2) any important component part especially designed for such equipment or device as determined by the Commission.

To determine whether the demonstration unit would be capable of making use of SNM or peculiarly adapted for making use of atomic energy in such quantity as to affect the health and safety of the public, the NRC staff considered routine and accident operating conditions of the demonstration unit. SHINE's March 17, 2017, letter states that the demonstration unit would be used to irradiate a less than critical mass of SNM (i.e., $\leq$ 350 g U-235) during short-duration tests (e.g., irradiations lasting several minutes at a time). In between tests, the demonstration unit would be shut down for an extended period of time (e.g., 24 hours). According to SHINE, the thermal and decay power of the demonstration unit would be sufficiently low as to not require provisions for the removal of fission heat during operation or decay heat following shutdown. With respect to reactivity feedback mechanisms, SHINE estimates that under optimum reflective and geometric conditions, the subcritical mass of SNM would remain below a k_{eff} of 0.80. As such, it would not be necessary to consider reactivity feedback mechanisms for

criticality control. Small amounts of fission gases, along with oxygen and hydrogen generated from the radiolytic decomposition of water, would be stored in the head space of the solution vessel during operation. In the event of a release of fission gas from the demonstration cell, SHINE does not anticipate the need for mitigation systems or other engineered safety features to meet 10 CFR Part 20 occupational and public dose limits. Hydrogen gas concentrations are also expected to be sufficiently low that no active blowers or other safety systems would be needed to maintain hydrogen concentration levels below the lower flammability limit. In between runs of the demonstration unit, gases stored in the solution vessel would be purged and transferred to storage tanks for decay, preventing long-term accumulation. SHINE also expects that, due to the short run times of the demonstration unit and minimal inventory of fissionable material, it would not be necessary to control the buildup of fission products.

SHINE also evaluated potential accident scenarios associated with the demonstration unit based on its previous irradiation unit analysis, including a release of fission products (maximum hypothetical accident); insertion of excess reactivity and inadvertent criticality; and loss of cooling. Similar to its proposed irradiation units, SHINE expects that the most significant accident sequence involving the demonstration unit would include a release of irradiated solution following the rupture of the solution vessel. However, due to the limited quantities of SNM in solution and "assuming conservative choices for airborne release fraction, respirable fraction, and leak path factor," SHINE does not anticipate that its demonstration unit would require a confinement or other safety systems. SHINE estimates that the dose consequences resulting from a release of its solution would remain below 10 CFR Part 20 dose limits without mitigation. SHINE also determined that initiating events related to reactivity insertions, inadvertent criticalities, or reductions in cooling did not require evaluation due to the demonstration unit's anticipated operation using a subcritical mass of SNM and low thermal power level.

To determine whether the demonstration unit would be capable of making use of SNM or peculiarly adapted for making use of atomic energy in such quantity as to be of significance to the common defense and security, the NRC staff considered the potential physical protection requirements. The regulations in 10 CFR Part 73, "Physical Protection of Plants and Materials," prescribe the requirements for the physical protection of SNM at fixed sites and in transit. Based on the limited quantities of SNM projected to be used at the demonstration unit site (i.e., $\leq$ 350 g U-235 contained in uranium enriched to less than 20 percent in U-235), SHINE would possess less than a quantity of SNM of low strategic significance, as defined in 10 CFR 73.2, "Definitions." Thus, if the material is licensed by the NRC, SHINE would not be required to establish and maintain a physical protection system in accordance with 10 CFR Part 73. However, SHINE would still be responsible for the security of stored material and the control of material not in storage as required by 10 CFR Part 20, Subpart I, "Storage and Control of Licensed Material."

Based on the description of the demonstration unit and associated SNM in the March 17, 2017, and June 22, 2017, letters, the NRC staff has determined that the demonstration unit 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. Based on these considerations, the NRC staff finds that the demonstration unit, if designed to operate as described, would not be capable of making use of SNM or peculiarly adapted for making use of 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."

With respect to the second definition of “utilization facility” in Section 11cc. of the AEA, the demonstration unit would be physically and operationally distinct and independent from utilization facilities, including SHINE’s proposed irradiation units. For that reason, the NRC would not consider the SHINE demonstration unit to be an important component part especially designed for a utilization facility.

Therefore, the NRC staff concludes that the demonstration unit proposed by SHINE in its March 17, 2017, and June 22, 2017, letters would not satisfy the definitions of “utilization facility” in Section 11cc. of the AEA.

CONCLUSION:

Based on the information provided in SHINE’s March 17, 2017, and June 22, 2017, letters, the NRC staff concludes 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 peculiarly adapted for making use of 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 will 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.