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U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, Inc. - Issuance of Construction Permit for Medical Isotope Facility," dated February 26, 2016 (ML16041A473)

Request for Confirmation of the 10 CFR Part 140 Financial
Protection Requirements for the SHINE Facility

In accordance with Section 170 of the Atomic Energy Act of 1954 as amended (the Act), and the condition described in Section 4(d) of the SHINE Medical Technologies, Inc. (SHINE) Construction Permit (Reference 1), SHINE is required to submit proof of financial protection and execute an indemnity agreement with the NRC prior to issuance of a license authorizing operation of the SHINE facility. The NRC regulations implementing Section 170 of the Act are set forth in 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements." The regulations of 10 CFR Part 140 do not prescribe financial protection requirements that can be applied directly to the SHINE facility.

Enclosure 1 provides SHINE's analysis of the requirements of Section 170 of the Act and 10 CFR Part 140 as they relate to the amount of financial protection required for the SHINE facility. SHINE plans to obtain and maintain financial protection in the amount of \$1.5 million and to execute and maintain an indemnification agreement with the NRC. In an effort to reduce regulatory uncertainty, SHINE is requesting confirmation by NRC staff that the proposed financial protection amount is an acceptable method of compliance with the financial protection requirements of Section 170 of the Act and Reference (1). SHINE requests confirmation from the NRC within three months of the date of this letter.

If you have any questions, please contact me at 608/210-1735.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Jeffrey M. Bartelme', written over a horizontal line.

Jeffrey Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

REQUEST FOR CONFIRMATION OF THE 10 CFR PART 140 FINANCIAL PROTECTION REQUIREMENTS FOR THE SHINE FACILITY

1. Introduction

This analysis assesses the financial protection requirements applicable to SHINE Medical Technologies, Inc. (SHINE). SHINE's facility, approved for construction as described in Reference (1), encompasses the systems, structures, and components required for the irradiation and processing of special nuclear material to produce medical radioisotopes, primarily molybdenum-99. The SHINE facility will consist of eight utilization facilities and a production facility as defined in 10 CFR 50.2, licensed under Section 103 of the Atomic Energy Act of 1954 as amended (the Act), and in accordance with 10 CFR 50.22.

2. Statutory Requirements for Financial Protection

The financial protection requirements for NRC licensees are specified in the Price Anderson Act, which is set forth in Section 170 of the Act and was enacted into law on September 2, 1957. The Price Anderson Act, as amended, addresses the risk of liability for a nuclear incident. The Price Anderson Act establishes a comprehensive statutory scheme that is designed to: (a) protect the public against losses from personal injury or property damage arising out of nuclear incidents involving the design, construction, operation, or maintenance of nuclear facilities or the possession, handling, or use of nuclear materials; and (b) encourage the development of the nuclear industry by imposing a statutory limitation on the total liability arising out of any nuclear incident and indemnifying any person or entity who might otherwise be liable in connection with such an incident up to the statutory limitation on liability.

The NRC enters into Price Anderson Act indemnity agreements with licensees, as required or authorized by Section 170 of the Act. The indemnity provides an aggregate amount of coverage for liability claims not to exceed \$500 million, and this amount is "reduced by the amount that the financial protection required" exceeds \$60 million. The indemnity agreements provide financial protection to each licensee and every other person indemnified (i.e., any other person or entity who might be liable) against public liability for any nuclear incident occurring at the licensee's facility, or in the course of transportation of nuclear materials to or from the facility.

The limit of liability under the Price Anderson Act is based upon the amount of financial protection and applicable indemnity to be provided. Special provisions apply to Department of Energy (DOE) contractors or large commercial facilities designed for the production of electricity, but for all other licensees, the statutory limit of liability will be between \$500 million and \$560 million. If the financial protection required for the licensee is greater than \$60 million, then \$560 million becomes the limit of liability. If the financial protection required is less than \$60 million, the statutory limit of liability is equal to the amount of financial protection plus \$500 million. For example, if the financial protection requirement is \$1.5 million, the limit of liability would be \$501.5 million.

Subsection 170.a of the Act requires that any license issued under Section 103 or 104 of the Act shall have a license condition mandating that the licensee maintain financial protection “to cover public liability claims” in the amount established by the NRC. Subsection 170.b of the Act describes acceptable types of financial protection required for licensees, and includes considerations for determining the amount of financial protection required for licensees. Subsection 170.c of the Act directs that the NRC shall issue an indemnity agreement to any licensee that is required to maintain financial protection of less than \$560 million. Consistent with Section 170 of the Act, and Section 4(d) of the SHINE Construction Permit (Reference 1), the NRC must impose a financial protection requirement on SHINE, and the NRC must execute an indemnity agreement with SHINE. However, these requirements do not directly specify the amount of financial protection applicable to the SHINE facility.

3. Correlation of Regulatory Requirements to SHINE’s Utilization Facilities

The NRC regulations implementing Section 170 of the Act are set forth in 10 CFR Part 140. Subpart B of 10 CFR Part 140 provides regulations concerning the amount of financial assurance applicable to nuclear reactor facilities delineated by reactor power level, as well as other facilities. The financial protection amounts specified in 10 CFR Part 140 for other facilities are clearly not applicable to SHINE (e.g., plutonium processing facilities and fuel fabrication plants licensed under 10 CFR Part 70, or uranium enrichment facilities licensed under 10 CFR Part 40 or 10 CFR Part 70). While SHINE does not meet the definition of “nuclear reactor” specified in 10 CFR 140.3, the regulations of 10 CFR 140.11 which specify financial protection amounts delineated by reactor power level are the most relevant for the SHINE facility. The relevant financial assurance amount is specified within 10 CFR 140.11(a), which states, in part:

“(a) Each licensee is required to have and maintain financial protection:

...

(2) In the amount of \$1,500,000 for each nuclear reactor he is authorized to operate at a thermal power level in excess of ten kilowatts but not in excess of one megawatt; ...”

SHINE’s eight utilization facilities each include an irradiation unit (IU). The thermal power level for the SHINE IUs, as described in Section 4a2.1 of Reference (2), are within the power level range of 10 CFR 140.11(a)(2). As such, SHINE believes that the appropriate amount of financial protection should be \$1.5 million for the proposed utilization facilities.

This conclusion is consistent with the NRC staff’s review of the SHINE facility. Throughout their review, the NRC staff has acknowledged the similarity of the SHINE facility and reactor sites for regulatory basis determinations. Section 1.5 of Reference (3) discusses regulatory safety considerations for the SHINE facility, similar to non-power reactors with comparable thermal power levels, as follows:

“While the NRC staff concludes that the IUs represent new technology, the accelerator and neutron multiplier add sufficient external neutrons to the TSV to achieve a fission rate with a thermal power level comparable to non-power reactors typically licensed under 10 CFR Part 50 as utilization facilities.¹ Given this fission power, the IUs also have many safety considerations similar to those of non-power reactors, including the following:

- Provisions for removal of fission heat during operation.*
- Consideration of decay heat generation after shutdown.*

- *Reactivity feedback mechanisms similar to non-power reactors.*
- *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.*
- *Accident scenarios similar to non-power reactors, such as loss of coolant, reactivity additions, and release of fission products.*

As such, given that SHINE's proposed IUs closely resemble non-power reactors, which are licensed as utilization facilities under 10 CFR Part 50, the NRC staff determined that it would be most appropriate to license SHINE's IUs as utilization facilities under 10 CFR Part 50.

...

¹ *Non-power reactors currently licensed to operate by the NRC range in thermal power from 5 watts to 20 megawatts. In the past, the NRC has licensed 12 aqueous homogeneous reactors (AHRs) with thermal power levels ranging from 5 watts to 50 kilowatts. An AHR is similar to the SHINE target solution vessel in that both contain fissile material in an aqueous solution; the difference is that the target solution vessel has insufficient fissile material for a sustained chain reaction."*

Additionally, several sections of Reference (3) (e.g., see Sections 2.3.2, 3.3.2, 4a.3.2, 5a.3.2, 6a.3.2, 6b.3.2, and others) acknowledge the relevance of regulatory guidance developed for reactor facilities as comparable to the SHINE facility. The staff noted the similarities in SHINE's proposed facility and reactor facilities to use established reactor facility guidance documents to determine the acceptance criteria for demonstrating SHINE's compliance with 10 CFR regulatory requirements.

While the NRC staff noted the similarity of the SHINE facility and nuclear reactor facilities of comparable power levels in order to establish the regulatory basis for the SHINE facility, the NRC staff also recognized SHINE's reduced accident potential. Section 13a.4.1 of Reference (3) acknowledges SHINE's limited accident potential as compared to reactor technologies as follows:

"The [SHINE] facility power and power density are sufficiently low such that insufficient energy is available to drive a large energetic release of radioactive material, as could occur in a nuclear power reactor."

As noted above, Reference (3) acknowledges the relevance of nuclear reactor regulatory bases to SHINE's regulatory basis in considering emergency planning, accident assessments, radiological, and safety issues. By applying an increasing financial protection amount based on increasing reactor power level, the 10 CFR 140.11 requirements for financial protection are predicated on the same considerations (e.g., emergency planning, accident assessments, radiological, and safety). The same considerations for which the NRC staff has already applied regulatory requirements to the SHINE facility based on nuclear reactors of comparable power levels, are applicable to the financial protection requirements of 10 CFR 140.11. Therefore, SHINE considers the financial protection amount as described within 10 CFR 140.11(a)(2) based on SHINE's IU power level applicable to the SHINE facility.

4. Correlation of SHINE's Utilization Facilities and Production Facility

The regulatory requirements of 10 CFR 140.11, delineating financial protection amounts based on reactor power levels, can be correlated to SHINE's IUs (and thereby correlated to SHINE's utilization facilities) as discussed above. The same correlation can be applied to the production facility. SHINE's utilization facilities and production facility, located in SHINE's production building as described in Reference (2), include the irradiation facility (IF) and radioisotope production facility (RPF) respectively. These are not independent facilities. The IF and RPF are integrally connected to support SHINE's medical isotope production processes. The IF includes the IUs and supporting systems, while the RPF includes irradiated material processing equipment and supporting systems. The radiological scenarios associated with the IF and RPF are consequentially equivalent in the context of financial protection requirements of 10 CFR 140.11.

The NRC staff has applied accident consequence parameters to the SHINE facility (i.e., the IF and RPF combined) based on nuclear reactors of comparable power levels to the SHINE IUs, without applying additional requirements to address RPF-specific activities. Section 12.4.7 of Reference (3) discusses emergency planning guidance for the SHINE facility based on the SHINE IU power level, as follows:

"The potential radiological hazards to the public associated with the operation of research and test reactors and fuel facilities licensed under 10 CFR Part 50 involve considerations different than those associated with nuclear power reactors. As endorsed by Regulatory Guide 2.6, ANSI/ANS-15.16 describes an acceptable approach for emergency planning commensurate with the potential risk involved for facilities of various authorized power level.

*...
The staff understands the applicant's position that there may not be a radiological emergency resulting in an off-site plume that would exceed the criteria established for establishing an EPZ beyond the operational site boundary. However, consistent with the guidance in ANSI/ANS-15.16, for a facility with the anticipated authorized power level of the SHINE facility, an acceptable EPZ size would be the operational boundary."*

The NRC staff correlated the potential accident consequences of the SHINE facility (i.e., the IF and RPF combined) with reactor facilities of comparable power levels to the SHINE IUs, in order to apply emergency planning regulatory guidance. The NRC staff's application of emergency planning guidance is directly analogous to SHINE's proposal to apply 10 CFR Part 140 requirements for the entire SHINE facility based on IU power level. This is appropriate because the accident scenarios associated with the IF and RPF are consequentially equivalent for the purpose of applying the financial protection requirements described in 10 CFR 140.11 (i.e., accident consequences for the IF and RPF are bounded by the same accident dose criterion). The SHINE facility produces medical isotopes from irradiation of low-enriched uranium (LEU). In the IF, the LEU target solution is irradiated in a subcritical assembly in batch processes. The irradiated target solution is then batch processed in the RPF to extract and purify medical isotopes. The primary material at risk associated with these batch processes within the IF and RPF are the same (i.e., the LEU, and fission product inventory which is proportional to the IU power level). Therefore, applying the financial protection requirements of 10 CFR 140.11 to both the IF and RPF based on IU power level is justified.

The equivalence of the radiological consequences of IF and RPF accident scenarios is further highlighted in the engineered safety features discussion of Reference (3). Tables 6a2.2-11-1

and 6b.2-6-1 of Reference (3) provide projected radiological dose consequences of accidents for the IF and RPF respectively. These tables indicate that the radiological consequences identified for the IF and RPF accident scenarios are similar. While the dose projections provided in these tables are based on SHINE's preliminary safety analysis report and may change, SHINE's analysis methodology remains unchanged. Potential accident scenarios at the SHINE facility are identified by the application of hazard analysis methodologies to inform the facility design. These methodologies, assessing potential hazards and consequences and applying mitigation with additional process design requirements, result in accident consequences at the SHINE facility that are bounded by the same accident dose criterion for both the IF and RPF.

The radiological scenarios associated with the IF and RPF are consequentially equivalent in the context of financial protection requirements described in 10 CFR 140.11. The NRC staff has applied accident consequence parameters to the SHINE facility (i.e., the IF and RPF combined) based on nuclear reactors of comparable power levels to the SHINE IUs, without applying additional requirements to address RPF-specific activities. The radiological consequences from accidents at the SHINE facility, whether from IF or RPF scenarios, remain bounded by the same accident dose criterion. For these reasons, the SHINE IU power level should be used to identify the applicable financial protection amount as described within 10 CFR 140.11, for the entire SHINE facility.

5. Correlation of 10 CFR 140.11(b) to the SHINE Facility

The provisions of 10 CFR 140.11(b) should be applied to the SHINE facility encompassing the eight planned utilization facilities and the production facility. 10 CFR 140.11(b) states:

"In any case where a person is authorized under parts 50, 52, or 54 of this chapter to operate two or more nuclear reactors at the same location, the total primary financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such primary financial protection covers all reactors at the location."

As discussed above, SHINE's IUs (i.e., utilization facilities) can be correlated to the 10 CFR 140.11 requirements for nuclear reactors of similar power levels to the SHINE IUs. Therefore, the provisions of 140.11(b) for reactors can be applied to SHINE's eight utilization facilities.

Also as discussed above, the financial protection requirements of SHINE's production facility can be correlated to the financial protection requirements of SHINE's utilization facilities based on IU power level. Accident scenario consequences at the SHINE facility, from both the IF and RPF are bounded by the same accident dose criterion. The primary material at risk (i.e., the LEU, and fission product inventory which is proportional to the IU power level) is similar within SHINE's IF and RPF. As such, the provisions of 10 CFR 140.11(b) should be applied to SHINE's production facility as well as the utilization facilities.

For these reasons, the appropriate amount of financial protection should be \$1.5 million for the proposed SHINE facility, provided that the financial protection covers each of the planned eight utilization facilities and the production facility.

6. Conclusion

The financial assurance requirements of 10 CFR 140.11(a)(2) should be applied to the SHINE facility, encompassing the eight planned utilization facilities and the production facility, based on the comparable power level of SHINE's IUs. Applying 10 CFR 140.11(a)(2) and 10 CFR 140.11(b), the appropriate amount of financial protection for the SHINE facility is \$1.5 million, provided that the financial protection covers each of SHINE's eight utilization facilities and the production facility.

7. References

- (1) NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, Inc. - Issuance of Construction Permit for Medical Isotope Facility," dated February 26, 2016 (ML16041A473)
- (2) SHINE Medical Technologies, Inc., "Preliminary Safety Analysis Report," dated August 27, 2015 (ML15258A431)
- (3) U.S. Nuclear Regulatory Commission, NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility Docket Number 50-608," dated August 2016