



March 28, 2018

2018-SMT-0017

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

References: (1) U.S. Nuclear Regulatory Commission, "Pre-Application Meeting on Topics Associated with SHINE Medical Technologies Operating License Application and Facility Construction," Meeting Notice, March 20, 2018 (ML18079A150)

Meeting Slides for the April 3, 2018 Public Meeting between SHINE Medical Technologies, Inc. and the NRC

A meeting is scheduled between SHINE Medical Technologies, Inc. (SHINE) and the NRC staff to discuss topics related to financial protection, preparation of an environmental report supplement, and construction inspection associated with the SHINE Medical Technologies medical isotope production project.

Enclosure 1 provides the SHINE meeting slides.

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

Very truly yours,

A handwritten signature in black ink that reads 'Jeff M. Bartelme'. The signature is fluid and cursive, with the first name 'Jeff' being the most prominent.

Jeff 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.

**MEETING SLIDES FOR THE APRIL 3, 2018 PUBLIC MEETING
BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC**



**Required Financial Protection and the SHINE
Supplement to the Environmental Report**
April 3, 2018

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Agenda

- I. Financial Protection and Execution of a Price-Anderson Indemnification Agreement**
- II. Supplement to Applicant's Environmental Report – Operating License Stage**
- III. Construction Inspector Introduction and Inspection Expectations**

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Financial Protection and Execution of a Price-Anderson Indemnification Agreement

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Regulatory Requirement to Execute Agreement

- Section 170 of the Atomic Energy Act of 1954, as amended (the Act), “Indemnification and Limitation of Liability”
 - Subsection 170.a requires, for each license issued under Section 103 or 104, that the licensee have and maintain financial protection of such type and in such amounts as the NRC requires in accordance with Subsection 170.b
 - Subsection 170.b requires the amount of primary financial protection be the amount of liability insurance available from private sources, except that the Commission may establish a lesser amount on the basis of criteria set forth in writing, which it may revise from time to time, taking into consideration such factors as the following:
 - The cost and terms of private insurance;
 - The type, size, and location of the licensed activity and other factors pertaining to the hazard; and
 - The nature and purpose of the licensed activity
- The SHINE Construction Permit (CPMIF-001) is conditioned to require that SHINE submit proof of financial protection and execute an indemnity agreement as required by Section 170 of the Act prior to the issuance of a license authorizing operation of the facility



Codified Financial Protection Requirements

- 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements,” specifies the amount of financial protection required of various licensees:
 - Nuclear reactors, based on maximum thermal power level (§§ 140.11 and 140.12)
 - Certain holders of construction permits and combined licenses under 10 CFR Part 52 (§ 140.13)
 - Plutonium processing and fuel fabrication plants (§ 140.13a)
 - Uranium enrichment facilities (§ 140.13b)
- 10 CFR Part 140 does not prescribe financial protection requirements which can be applied directly to the SHINE facility (i.e., requirements applicable to a non-power production or utilization facility or a medical isotope production facility)



Financial Protection Amount Relevant to SHINE

- 10 CFR § 140.11(a)(2) requires each licensee to have and maintain financial protection in the amount of \$1.5M for each nuclear reactor authorized to operate at a thermal power level in excess of ten kilowatts but not in excess of one megawatt
- 10 CFR § 140.11(b) states that, 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
- Based on the above financial protection requirements applicable to non-power reactors of comparable thermal power level, SHINE believes \$1.5M to be an appropriate level of financial protection for the SHINE facility



Basis for the Proposed Amount of Financial Protection

- SHINE will be challenged in obtaining private liability insurance, as American Nuclear Insurers (ANI) has declined to quote nuclear liability insurance for the SHINE project, stating the SHINE facility does not meet the definition of “nuclear facility”
- While SHINE’s irradiation units (IUs) do not meet the definition of “nuclear reactor” in 10 CFR § 140.3, the NRC has previously acknowledged the similarities in safety considerations between the SHINE IUs and non-power reactors in establishing the appropriate regulatory framework
 - Direct Final Rule – Definition of a Utilization Facility, dated October 17, 2014 (79 FR 62329)
 - NUREG-2189, “Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility,” dated October 2015



Conclusions/Next Steps for SHINE

- Taking into consideration the factors described in Section 170.b of the Act, the similarities in safety considerations between the SHINE IUs and non-power reactors, and the financial protection requirements for non-power reactors of comparable thermal power level, SHINE believes that \$1.5M provides an appropriate level of financial protection for the SHINE facility
- SHINE will formally submit a letter to the NRC, requesting the NRC confirm the amount of financial protection (i.e., \$1.5M) SHINE is required to have and maintain
- Upon confirmation of the amount of financial protection required for the SHINE facility, SHINE will work to execute an indemnity agreement in accordance with Section 170.c of the Act.



Supplement to Applicant's Environmental Report— Operating License Stage

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Format of the Supplement to the Environmental Report

- As discussed in a letter from the NRC to SHINE, dated December 2, 2014, SHINE will generally follow the same guidance on form and content that it used to prepare the initial environmental report (ER) submitted as part of the construction permit application.
 - SHINE will develop the Supplement to the ER using the numbering format used in the original ER, with the exception that numbering associated with “Chapter 19” will be removed (e.g., Section 19.2.1 in the ER will be 2.1 in the Supplement to the ER).
- In accordance with 10 CFR § 51.53(b), SHINE will not provide new or different information related to the “Alternatives Technologies”, “Alternative Sites” or “Purpose and Need for the Proposed Action” sections of the ER.
 - SHINE will include the headings for those sections, with explanation that they are not required, to preserve consistency of numbering between the ER and the Supplement to the ER.



Supplement to the ER Content – Level of Detail

- In order to meet the requirements of 10 CFR § 51.53(b), to discuss matters that differ from those discussed or reflect new information in addition to that discussed in the final environmental impact statement (EIS), the Supplement to the ER will include a level of detail comparable to the information that was included in the Final EIS.
- To minimize duplication of information provided to the NRC, to the extent practical, information that is found in the final safety analysis report (FSAR) will not be repeated in the Supplement to the ER. Instead, the Supplement to the ER will reference the section of the FSAR where the relevant information may be found.



Supplement to the ER Content – Field Activities

- SHINE will not conduct new site geotechnical investigations, groundwater level monitoring, archaeological surveys, or reconnaissance surveys to characterize the types of flora and fauna that use the site. This type of information, included in the ER, is not anticipated to have changed since the issuance of the Final EIS.
- SHINE has conducted a traffic analysis, including recent traffic counts near the site, and will include this new information in the Supplement to the ER.
- SHINE will provide new and different information related to the existing and affected environment in the Supplement to the ER, as appropriate, in cases where the new information is self-revealing (e.g., new construction near the site), or is readily available and retrievable (e.g., more recently published data).



Supplement to the ER Content – Static Information

- SHINE will not re-perform research or investigations related to information that is considered “static” (e.g., historic site usage, geologic environment, seismic setting, climate, and meteorological environment). This type of information, included in the ER, is not anticipated to have changed since the issuance of the Final EIS.
- SHINE will provide new and different information related to the facility and the existing and affected environment in the Supplement to the ER, as appropriate, where changes are known or expected to have occurred since the issuance of the Final EIS (e.g., information affected by facility design, population, or transportation changes).



Supplement to the ER Content – Impact of Construction

- SHINE will provide new and different information in connection with the impacts of proposed operations and decommissioning in Section 4.0 of the Supplement to the ER.
- SHINE will not include information related to the construction of the facility, as this activity was addressed in the original ER, and is not pertinent to the “Supplement to the Applicant’s Environmental Report – Operating License Stage”.



Construction Inspector Introduction and Inspection Expectations

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