

June 18, 2018

LICENSEE: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF APRIL 3, 2018, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC. (EPID NO. L-2017-PMP-0014)

On April 3, 2018, a Category 1 public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) staff and representatives of SHINE Medical Technologies, Inc. (SHINE) at NRC Headquarters, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland. The purpose of this meeting was to discuss topics related to financial protection, preparation of an environmental report supplement, and construction inspection associated with the SHINE medical isotope production project. The meeting notice and agenda, dated March 29, 2018, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML18088A398. A list of meeting attendees is provided as an enclosure.

NRC staff opened the meeting at 9:30 a.m. with a summary of the status of its interactions with SHINE. SHINE has proposed to construct a medical isotope facility in Janesville, Wisconsin for the production of molybdenum-99. A construction permit was issued to SHINE on February 29, 2016, authorizing SHINE to construct eight accelerator-driven subcritical operating assemblies and one production facility for the irradiation and processing of special nuclear material. As of this public meeting, the NRC expects SHINE to begin construction of its facility and submit an operating license application in the fall of 2018.

Following the NRC's opening remarks, SHINE presented on topics related to financial protection and the execution of an indemnification agreement. To begin its presentation, SHINE noted that its construction permit is conditioned to require that SHINE submit proof of financial protection and execute an indemnity agreement prior to the issuance of an operating license for its facility. However, the regulations in Title 10 of the *Code of Federal Regulations* Part 140, "Financial Protection Requirements and Indemnity Agreements," only specify amounts of financial protection required for certain licensees, including nuclear reactors, plutonium processing and fuel fabrication plants, and uranium enrichment facilities. As such, the regulations do not prescribe financial protection requirements that can be directly applied to the SHINE facility. SHINE is proposing to maintain financial protection in the amount of \$1.5 million consistent with the financial protection requirements for non-power reactors operating at a comparable thermal power level to SHINE's proposed subcritical operating assemblies. SHINE intends to submit a letter to the NRC staff requesting confirmation of the amount of financial protection needed for its facility.

The next portion of the public meeting covered information related to the preparation of a supplement to SHINE's environmental report, initially submitted with its construction permit application, to support the issuance of an operating license. The NRC staff introduced the topic with a presentation that covered the regulatory background for an applicant's preparation of an environmental report supplement and the NRC staff's preparation of a supplemental

environmental impact statement (EIS). As part of its presentation, the NRC staff covered the consideration of new or different information in an environmental report supplement, best practices, and formatting. SHINE responded to the NRC staff's presentation with a discussion on its plans to prepare its environmental report supplement, including formatting, level of detail to be included in the report, field activities, static information, and the impact of construction. SHINE stated that it intends to develop its environmental report supplement generally following the formatting used in the original environmental report. While SHINE is only required to provide information that is new and different from that contained in the final EIS, SHINE indicated that it would also provide a basis for not including information that has not changed since publication of the final EIS.

In the final portion of the meeting, the NRC staff from Region II that would be responsible for inspecting SHINE's facility during construction provided an overview of its expectations for engagement in preparation for construction oversight. In particular, NRC staff emphasized the need to conduct scoping meetings with SHINE in advance of the beginning of construction to inform the development of facility-specific inspection plans. Such scoping meetings would cover information related to accident sequences; types, number, and location of safety-related structures, systems, and components; and application of codes and standards, including anticipated deviations, to construction of the facility. The NRC staff also requested that SHINE consider creating an electronic document portal to more efficiently share information necessary to support construction inspection.

Further details on the discussions had during this meeting are included in the presentation slides (ADAMS Accession Nos. ML18087A389 and ML18096A455).

Please direct any inquiries to me at 301-415-1524 or Steven.Lynch@nrc.gov.

Sincerely,

/RA/

Steven Lynch, Project Manager
Research and Test Reactors Licensing Branch
Division of Licensing Projects
Office of Nuclear Reactor Regulation

Docket No. 50-608

Enclosure:
As stated

cc w/enclosure:

Mr. Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

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DATE	06/13/2018	6/13/18	6/15/18	6/18/18

OFFICIAL RECORD COPY

LIST OF ATTENDEES

APRIL 3, 2018 MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

9:30 A.M. - 12:00 P.M.

<u>Name</u>	<u>Organization</u>
Jeff Bartelme	SHINE Medical Technologies, Inc.
Catherine Kolb	SHINE Medical Technologies, Inc.
Christina Barrett	SHINE Medical Technologies, Inc.
Ron Sacco	SHINE Medical Technologies, Inc.
Joe LaPrad	SHINE Medical Technologies, Inc.
Phil Ray	SHINE Medical Technologies, Inc.
Steve Miltenberger	SHINE Medical Technologies, Inc.
Abbey Donahue	SHINE Medical Technologies, Inc.
Jim Costedio	SHINE Medical Technologies, Inc.
Eric Van Abel	SHINE Medical Technologies, Inc.
Steven Lynch	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
David Drucker	U.S. Nuclear Regulatory Commission
Kevin Folk	U.S. Nuclear Regulatory Commission
Mable Henderson	U.S. Nuclear Regulatory Commission
MaryJane Ross-Lee	U.S. Nuclear Regulatory Commission
Anthony Bowers	U.S. Nuclear Regulatory Commission
Richard Jervey	U.S. Nuclear Regulatory Commission
Alexander Sapountzis	U.S. Nuclear Regulatory Commission
Edward Helvenston	U.S. Nuclear Regulatory Commission
Nancy Martinez	U.S. Nuclear Regulatory Commission
William Rautzen	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Michelle Moser	U.S. Nuclear Regulatory Commission
Carl Weber	U.S. Nuclear Regulatory Commission
Donna-Beth Howe	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Michele Kaplan	U.S. Nuclear Regulatory Commission
Phil O'Bryan	U.S. Nuclear Regulatory Commission
Charity Pantalo	U.S. Nuclear Regulatory Commission
Darren Piccirillo	U.S. Nuclear Regulatory Commission
Jason Eargle	U.S. Nuclear Regulatory Commission
Michael Ernestes	U.S. Nuclear Regulatory Commission
Paul Carman	U.S. Nuclear Regulatory Commission
Cassandra Frazier	U.S. Nuclear Regulatory Commission
Geoffrey Wertz	U.S. Nuclear Regulatory Commission
Tilda Liu	U.S. Nuclear Regulatory Commission

Enclosure