UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 17, 2018

LICENSEE: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF JUNE 28, 2018, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC. (EPID NO. L-2017-PMP-0014)

On June 28, 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, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The purpose of this meeting was to discuss topics related to the development of SHINE's operating license application for a medical radioisotope facility, including instrumentation and control (I&C), material control and accounting (MC&A) of special nuclear material (SNM), and design changes. This meeting served to inform NRC staff of the development status of key design and programmatic elements of SHINE's proposed medical radioisotope production project. Portions of this meeting were closed to public participation to discuss proprietary information related to SHINE's process vessel vent system and safety-related I&C design updates. The meeting notice and agenda, dated June 27, 2018, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML18178A651. A list of meeting attendees is provided as an enclosure to this summary.

NRC staff opened the meeting at 8:30 a.m. with a summary of the status of its interactions with SHINE. SHINE has proposed to construct a medical radioisotope 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 SNM. 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 and requested NRC staff feedback on its approach to the development of an MC&A plan for its proposed facility. As part of its presentation, SHINE described the preliminary stages of the development of an MC&A plan that meets the requirements of Subpart D of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 74, "Material Control and Accounting of Special Nuclear Material." SHINE indicated that it is basing its MC&A plan on the draft guidance contained in NUREG-2159, "Acceptable Standard Format and Content for the Material Control and Accounting Plan Required for Special Nuclear Material of Moderate Strategic Significance," issued in September 2013. SHINE intends to submit its MC&A plan as part of its operating license application.

In response to SHINE's MC&A presentation, NRC staff confirmed that meeting the requirements of Subpart D of 10 CFR Part 74 and following the draft guidance in NUREG-2159 are an acceptable approach to developing an MC&A plan for SHINE's proposed facility. However, the staff acknowledged that the current 10 CFR Part 74 requirements and draft guidance in

NUREG-2159 are likely to change with the expected publication of a final rule revising and consolidating the requirements for MC&A of SNM in 10 CFR Part 74 in 2019. Draft versions of documents the final rule package, including specific rule language and guidance revisions, will be made publicly available in the coming months following internal NRC concurrence.

During the portions of the meeting that was closed to the public, SHINE went into proprietary-level detail related to design updates and improvements to its process vessel vent system as well as safety-related I&C system. SHINE has selected Rock Creek Innovations (RCI) to design and build its I&C systems. RCI has designed the Highly Integrated Protection System (HIPS) platform, which has previously been selected by NuScale for its I&C systems. The HIPS platform is logic-based and does not use software or microprocessors for operation. The HIPS platform is implemented using discrete components and field programmable gate array technology to implement complex digital circuits that do not incorporate software for their operation. The HIPS platform incorporates several design principles for safety; including independence; redundancy; diversity and defense-in-depth; and predictability and repeatability.

Further details on the discussions had during this meeting are included in the presentation slides (ADAMS Accession No. ML18187A216).

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

/RA/

Steven T. 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.
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Janesville, WI 53545

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DATE	08/09/2018	08/14/2018	08/17/2018	08/17/2018

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LIST OF ATTENDEES

June 28, 2018 MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

8:30 A.M. - 4:30 P.M.

Name	Organization
Jeff Bartelme	SHINE Medical Technologies, Inc.
Jim Costedio	SHINE Medical Technologies, Inc.
Eric Van Abel	SHINE Medical Technologies, Inc.
Matt Coe	SHINE Medical Technologies, Inc.
Adam Gonnering	SHINE Medical Technologies, Inc.
Gregg Clarkson	Rock Creek Innovations, LLC
Jason Pottorf	Rock Creek Innovations, LLC
Martha Williams	Talisman International
Steven Lynch	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
Glenn Tuttle	U.S. Nuclear Regulatory Commission
David Ditto	U.S. Nuclear Regulatory Commission
Tom Pham	U.S. Nuclear Regulatory Commission
Duane Hardesty	U.S. Nuclear Regulatory Commission
Carl Weber	U.S. Nuclear Regulatory Commission
James Rubenstone	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Edward Helvenston	U.S. Nuclear Regulatory Commission
Jeremy Wachutka	U.S. Nuclear Regulatory Commission
Norbert Carte	U.S. Nuclear Regulatory Commission
Rossnyev Alvarado	U.S. Nuclear Regulatory Commission
Luis Betancourt	U.S. Nuclear Regulatory Commission
Rick Jervey	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Ismael Garcia	U.S. Nuclear Regulatory Commission
Charity Pantalo	U.S. Nuclear Regulatory Commission
Lynnea Wilkins	U.S. Nuclear Regulatory Commission
Paul Carman	U.S. Nuclear Regulatory Commission
Darren Piccirillo	U.S. Nuclear Regulatory Commission

Enclosure