



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

March 22, 2019

LICENSEE: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF JANUARY 31, 2019, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC. (EPID NO. L-2017-PMP-0014)

On January 31, 2019, 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 SHINE Medical Isotope Production Facility technology and design, as well as to discuss the organization and content of the SHINE operating license application. 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 to prepare the NRC staff for the review of an operating license application. Portions of this meeting were closed to public participation to discuss proprietary and security-related information related to SHINE's technology and structural analysis. The meeting notice and agenda, dated January 29, 2019, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML19029B344. A list of meeting attendees is provided as an enclosure to this summary.

The NRC staff opened the meeting at 9:00 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 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 2019.

Following the NRC's opening remarks, SHINE provided the NRC staff with an overview of its proposed medical radioisotope production technology. In the portion of this presentation that was open to the public, SHINE described, in part, its company mission; the location of its proposed Medical Isotope Production Facility in Janesville, Wisconsin; its medical radioisotope production process; and technological approach. SHINE also provided details on its safety philosophy, which includes a focus on a low decay heat, low pressure, and low temperature system; limited common cause failures, and ability to respond safely to accidents without required operator actions. Additionally, SHINE discussed the completion of construction of Building One, which will be used to demonstrate technology, including accelerator demonstrations, mockups, and prototypes. Building One will also be used for future employee training and technology development. During the portion of the technology overview presentation that was closed to the public, SHINE provided additional information on its facility layout, systems, and processes.

Following the technology overview presentation, SHINE presented on the structural design of its facility in a closed meeting session. During this session, SHINE provided an update on the building design and construction method; the safety-related building envelope; the seismic analysis methodology; the aircraft impact analysis methodology; and an overview of other structural loads. In an update to a May 2018 public meeting presentation on a pre-cast building design, SHINE announced that it had returned to its plans for using cast-in-place construction.

In the final public meeting session of the day, SHINE discussed the scope of its proposed operating license application, including a description of the general information to be submitted with the application, the final safety analysis report, and other programs and plans to be submitted with the application. In addition to the submission of an operating license application, SHINE also anticipates submitting a materials license application for use of material onsite prior to facility operation. The operating license application will describe all eight proposed irradiation units and one production facility. After a period of time following the initial submission of the operating license application, SHINE anticipates submitting a supplement requesting staggered licensing approach.

Further details on the information discussed during this meeting are included in the public presentation slides (ADAMS Accession No. ML19024A352).

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.
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

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ML1907A180, Withholding Ltr.; ML19024A352, Slides *concurred via email NRC-001

OFFICE	NRR/DLP/PRLB/PM	NRR/DLP/PRLB/LA	NRR/DLP/PRLB/ABC	NRR/DLP/PRLB/PM
NAME	SLynch	NParker	WKennedy	SLynch
DATE	03/11/2019	03/13/2019	03/21/2019	03/22/2019

OFFICIAL RECORD COPY

LIST OF ATTENDEES

JANUARY 31, 2019, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

9:00 A.M. - 4:00 P.M.

<u>Name</u>	<u>Organization</u>
Jim Costedio	SHINE Medical Technologies, Inc.
Jeff Bartelme	SHINE Medical Technologies, Inc.
Eric Van Abel	SHINE Medical Technologies, Inc.
Abbey Donahue	SHINE Medical Technologies, Inc.
Christopher Hewitt	Simpson, Gumpertz, & Heger
Diane Mlynarczyk	Information Systems Laboratories, Inc.
Dan Prelewicz	Information Systems Laboratories, Inc.
Terry Gitnick	Information Systems Laboratories, Inc.
Brian Grimes	NUMARK Associates
Abe Weitzburg	Information Systems Laboratories, Inc.
Jason Williams	Information Systems Laboratories, Inc.
John Atchison	Information Systems Laboratories, Inc.
Steven Lynch	U.S. Nuclear Regulatory Commission
Charles Teal	U.S. Nuclear Regulatory Commission
Phil Natividad	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Tom Pham	U.S. Nuclear Regulatory Commission
Anita Gray	U.S. Nuclear Regulatory Commission
Rebecca Susko	U.S. Nuclear Regulatory Commission
Richard Jervey	U.S. Nuclear Regulatory Commission
David Hanks	U.S. Nuclear Regulatory Commission
Jeremy Wachutka	U.S. Nuclear Regulatory Commission
James Hammelman	U.S. Nuclear Regulatory Commission
Glenn Tuttle	U.S. Nuclear Regulatory Commission
Suzanne Ani	U.S. Nuclear Regulatory Commission
Mirabelle Shoemaker	U.S. Nuclear Regulatory Commission
Michael Salay	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
David Ditto	U.S. Nuclear Regulatory Commission
Donna-Beth Howe	U.S. Nuclear Regulatory Commission
William Kennedy	U.S. Nuclear Regulatory Commission
Yawar Faraz	U.S. Nuclear Regulatory Commission
James Rubenstone	U.S. Nuclear Regulatory Commission
Michelle Moser	U.S. Nuclear Regulatory Commission
Joseph Staudenmeier	U.S. Nuclear Regulatory Commission
Benjamin Beasley	U.S. Nuclear Regulatory Commission
Dan Barss	U.S. Nuclear Regulatory Commission
Paul Carman	U.S. Nuclear Regulatory Commission
Patricia Pelke	U.S. Nuclear Regulatory Commission
Carl Weber	U.S. Nuclear Regulatory Commission

Enclosure

LIST OF ATTENDEES (Continued)

JANUARY 31, 2019, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

9:00 A.M. - 4:00 P.M.

<u>Name</u>	<u>Organization</u>
Charity Pantalo	U.S. Nuclear Regulatory Commission
Cassandra Frazier	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
Lisa Dimmick	U.S. Nuclear Regulatory Commission
Alex Sapountzis	U.S. Nuclear Regulatory Commission