

June 18, 2018

LICENSEE: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF MAY 23 - 24, 2018, MEETING WITH SHINE
MEDICAL TECHNOLOGIES, INC. (EPID NO. L-2017-PMP-0014)

On May 23 - 24, 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 construction planning, licensing strategy, and the results of preliminary hazards analysis associated with the SHINE medical isotope production project. This meeting served to inform NRC staff of SHINE's significant facility design changes and schedules for beginning construction and submitting an operating license application. Portions of this meeting were closed to public participation to discuss proprietary information related to SHINE's construction planning, preliminary hazards and operability study results, and elements of the structural facility design. The meeting notice and agenda, dated May 11, 2018, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML18131A371. A list of meeting attendees for each day is provided as an enclosure to this summary.

NRC staff opened the May 23, 2018, meeting at 9:00 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 construction planning. As part of its presentation, SHINE covered topics related to the initial scope of construction and shared systems; configuration management; modifications to its operating units; provisions for constructing during operations; design packages; and construction schedule. Significant discussions during this presentation related to SHINE's proposed phased approach to operations, including how SHINE would track progress of construction during operation and efficiently share information with the NRC to inform construction and operation oversight activities. With respect to its construction schedule, SHINE indicated that it anticipates beginning concrete work in October 2018 with process system installation starting nine months later.

SHINE's next presentation addressed its licensing strategy for its medical isotope production facility. SHINE indicated that it intends to request the issuance of a single operating license for its eight proposed utilization facilities and one production facility. As part of its operating license application, SHINE will also include an addendum to its final safety analysis report describing a phased approach to full operation of its facility. For each phase of operation, SHINE will

describe and analyze structures, systems, and components (SSCs) to be installed or impacted and will address necessary administrative controls to be in place. To support this phased approach to licensing, SHINE also recommended that the NRC condition its operating license to require NRC approval before SHINE may begin operation of additional utilization facilities or expand processing capacity of its production facility. At this time, SHINE intends to submit its operating license application in October 2018.

During the portion of the May 23, 2018, meeting that was closed to the public, SHINE went into proprietary-level detail related to the scope of construction; design changes; and its hazard evaluation. Discussions during this portion of the meeting focused on the evolution of SHINE's facility design since the issuance of its construction permit, including details on its design and safety philosophies; identification of safety-related SSCs; and hazard analysis methodology. The May 24, 2018, meeting on the structural design of SHINE's proposed facility was closed in its entirety to the public due to the proprietary nature of certain design changes and SHINE's approach to construction.

Further details on the discussions had during this meeting are included in the presentation slides (ADAMS Accession No. ML18138A291).

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

Sincerely,

/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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OFFICE	NRR/DLP/PRLB/PM	NRR/DLP/PRLB/LA	NRR/DLP/PRLB/BC	NRR/DLP/PRLB/PM
NAME	SLynch	NParker	AAdams	SLynch
DATE	06/14/18	06/14/18	06/15/18	06/18/18

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LIST OF ATTENDEES

May 23, 2018 MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

9:00 A.M. - 4:30 P.M.

<u>Name</u>	<u>Organization</u>
Jeff Bartelme	SHINE Medical Technologies, Inc.
Steve Miltenberger	SHINE Medical Technologies, Inc.
Jim Costedio	SHINE Medical Technologies, Inc.
Eric Van Abel	SHINE Medical Technologies, Inc.
Joe Christensen	SHINE Medical Technologies, Inc.
John Olvera	SHINE Medical Technologies, Inc.
Steve Hunt	SHINE Medical Technologies, Inc.
Steven Lynch	U.S. Nuclear Regulatory Commission
Alexander Adams, Jr.	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
MaryJane Ross-Lee	U.S. Nuclear Regulatory Commission
Richard Jervey	U.S. Nuclear Regulatory Commission
Charles Teal	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
Jason Eargle	U.S. Nuclear Regulatory Commission
Cassandra Frazier	U.S. Nuclear Regulatory Commission
Geoffrey Wertz	U.S. Nuclear Regulatory Commission
Yawar Faraz	U.S. Nuclear Regulatory Commission
Victor Hall	U.S. Nuclear Regulatory Commission
Annie Ramirez	U.S. Nuclear Regulatory Commission
Mollie Semmes	U.S. Nuclear Regulatory Commission
Jonathan Marcano	U.S. Nuclear Regulatory Commission
David Tiktinsky	U.S. Nuclear Regulatory Commission
James Hammelman	U.S. Nuclear Regulatory Commission
Jeremy Wachutka	U.S. Nuclear Regulatory Commission
Tom Pham	U.S. Nuclear Regulatory Commission
Kentaro Ozaki (foreign assignee)	U.S. Nuclear Regulatory Commission
Joseph Staudenmeier	U.S. Nuclear Regulatory Commission
Pete Karcz	National Nuclear Security Administration

Enclosure

LIST OF ATTENDEES

May 24, 2018 MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

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

<u>Name</u>	<u>Organization</u>
Jeff Bartelme	SHINE Medical Technologies, Inc.
Jim Costedio	SHINE Medical Technologies, Inc.
Eric Van Abel	SHINE Medical Technologies, Inc.
Steven Hunt	SHINE Medical Technologies, Inc.
Christopher Hewitt	Sargent & Lundy
Sungjin Bae	Sargent & Lundy
Ronald Hamburger	Simpson Gumpertz & Heger Inc.
Steve Lynch	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
Alexander Adams, Jr.	U.S. Nuclear Regulatory Commission
MaryJane Ross-Lee	U.S. Nuclear Regulatory Commission
Richard Jervey	U.S. Nuclear Regulatory Commission
Mitzi Young	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
Phil O'Bryan	U.S. Nuclear Regulatory Commission
Charity Pantalo	U.S. Nuclear Regulatory Commission
Jason Eargle	U.S. Nuclear Regulatory Commission
James Hammelman	U.S. Nuclear Regulatory Commission
Jonathan Marcano	U.S. Nuclear Regulatory Commission
Patrick Koch	U.S. Nuclear Regulatory Commission
David Tiktinsky	U.S. Nuclear Regulatory Commission
Jeremy Wachutka	U.S. Nuclear Regulatory Commission
Jacob Zimmerman	U.S. Nuclear Regulatory Commission