

August 4, 2016

APPLICANT: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF MAY 26, 2016, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

On May 26, 2016, 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 inform SHINE of its addition to the U.S. Eligible Facilities List and discuss topics related to construction inspection. The meeting notice and agenda dated May 12, 2016, are available in the Agencywide Documents Access and Management System (ADAMS), Accession No. ML16133A094. A list of meeting attendees is provided as an enclosure.

The NRC staff opened the meeting at 1:00 p.m. with a presentation on the implementation of International Atomic Energy Agency (IAEA) safeguards within the United States (U.S.), with a focus on the implications of SHINE's inclusion on the U.S. Eligible Facilities List. Topics during the presentation included a history of international safeguards and an overview of the U.S. international safeguards agreements. NRC staff explained that the IAEA has the right, not an obligation, to apply safeguards measures in the U.S. The IAEA selects facilities to apply safeguards measures from a list of facilities provided by the U.S. This list is updated annually and contains approximately 300 facilities, including both Department of Energy locations and NRC licensees. Facilities remain on the list until they are decommissioned. If a facility is selected by the IAEA, the NRC will notify the licensee of its selection and assist in the completion of the IAEA Design Information Questionnaire. The IAEA will then perform a Design Information Verification and may conduct inspections of the facility. Other topics covered during this presentation included the four U.S. facilities currently selected by the IAEA, examples of IAEA safeguards technologies, reporting requirements, complementary facility access, and regulatory requirements. Further details on this discussion are included in the presentation slides (ADAMS Accession No. ML16215A409).

The next portion of the meeting covered topics related to implementation of the NRC's construction inspection program at the SHINE facility. NRC staff began this discussion by providing an overview of the construction inspection program, including discussions on Inspection Manual Chapter 2550, as well as the inspection procedures related to structures, systems, and components; quality assurance; and operational readiness. NRC staff then covered insights related to construction oversight and inspections. This portion of the presentation emphasized the importance of establishing and maintaining communication between the licensee and the NRC during construction inspection. Key aspects of effective communication include up-to-date information on construction status and schedule; the NRC inspection schedule; status of key licensing actions; and meetings. Electronic reading rooms are also effective ways of sharing certain licensing and inspection documents.

The NRC staff also shared its observations that SHINE should perform its own inspections prior to NRC inspections, develop a robust corrective action program, and demonstrate the importance of safety culture.

The next topic of discussion covered by the NRC staff related to lessons learned from the construction of new reactors and fuel cycle facilities. The topics covered during this portion of the presentation included design control, corrective action programs, commitments in licensing documents, managing a change control process, and quality assurance. The NRC staff concluded its presentation by providing an overview of the NRC enforcement program to be applied during construction of the SHINE facility. The NRC staff discussed the enforcement process, traditional enforcement, notices of violation, escalated enforcement, enforcement panels, and pre-decisional enforcement conferences. Further details on this discussion are included in the presentation slides (ADAMS Accession No. ML16215A410).

The final portion of the meeting included a presentation from SHINE that covered an overview of its facility design, update on project schedule, design change control process, and comments on the NRC's construction inspection program. During the presentation, SHINE shared that it has begun detailed design of its facility. Site preparations will likely begin in early 2017, followed by submission of an operating license application in mid-2017. SHINE currently expects to begin operation of its facility in late 2019. Further details on this discussion are included in the presentation slides (ADAMS Accession No. ML16139A593).

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

/RA/

Steve Lynch, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-608

Enclosure:
As stated

cc: Mr. Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

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ADAMS Accession Nos. Pkg: ML16215A398; Notice: ML16133A094; Summary: ML16215A408
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OFFICE	DPR/PRLB/PM	DPR/PRLB/LA*	DPR/PRLB/BC	DPR/PRLB/PM
NAME	SLynch	NParker	AAdams (LTran for)	SLynch
DATE	8/4/16	8/4/16	8/4/16	8/4/16

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LIST OF ATTENDEES

MAY 26, 2016, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

1:00 P.M – 5:00 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.
Bill Hennessy	SHINE Medical Technologies, Inc.
Catherine Kolb	SHINE Medical Technologies, Inc.
George Hansrote	SHINE Medical Technologies, Inc.
Steve Lynch	U.S. Nuclear Regulatory Commission
Charles Teal	U.S. Nuclear Regulatory Commission
Ossy Font	U.S. Nuclear Regulatory Commission
Michael Balazik	U.S. Nuclear Regulatory Commission
Patrick Isaac	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Phil O'Bryan	U.S. Nuclear Regulatory Commission
Al Adams	U.S. Nuclear Regulatory Commission
David Tiktinsky	U.S. Nuclear Regulatory Commission
William Gloersen	U.S. Nuclear Regulatory Commission
Carl Weber	U.S. Nuclear Regulatory Commission
Hilary Lane	U.S. Nuclear Regulatory Commission
David H. Hanks	U.S. Nuclear Regulatory Commission
Pete Habighorst	U.S. Nuclear Regulatory Commission
Yawar Faraz	U.S. Nuclear Regulatory Commission
Thomas Marenchin	U.S. Nuclear Regulatory Commission
Robert K. Johnson	U.S. Nuclear Regulatory Commission
Bill Jones	U.S. Nuclear Regulatory Commission
Deborah Seymour	U.S. Nuclear Regulatory Commission
Chris Regan	U.S. Nuclear Regulatory Commission
Jenny Weil	U.S. Nuclear Regulatory Commission
Joe Staudenmeier	U.S. Nuclear Regulatory Commission
Andrea Keim	U.S. Nuclear Regulatory Commission
Tom Boyle	U.S. Nuclear Regulatory Commission
Sandy Frazier	U.S. Nuclear Regulatory Commission
Alex Sapountzis	U.S. Nuclear Regulatory Commission
Mike Rodriguez	U.S. Nuclear Regulatory Commission
Bill Schuster	U.S. Nuclear Regulatory Commission
Arlon Costa	U.S. Nuclear Regulatory Commission
Cathy Kanatas	U.S. Nuclear Regulatory Commission

Enclosure