

January 27, 2017

APPLICANT: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF DECEMBER 1, 2016, MEETING WITH SHINE  
MEDICAL TECHNOLOGIES, INC.

On December 1, 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 discuss SHINE's operating license structure and design changes. The meeting notice and agenda, dated December 1, 2016, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML16320A607. A list of meeting attendees is provided as an enclosure.

The 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 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 operating assemblies and one production facility for the irradiation and processing of special nuclear material (SNM). As of this public meeting, the NRC expects SHINE to begin construction of its facility and submit an operating license application in the summer of 2017.

Following the NRC's opening remarks, SHINE presented an evaluation of potential operating license structures. SHINE considered whether it should apply for (1) a single facility operating license for eight utilization facilities and one production facility or (2) individual operating licenses for each of its the eight utilization facilities and one production facility. Based on its analysis, SHINE determined that a single license authorizing the operation of eight utilization facilities and one production facility would be its preferred licensing approach. Benefits of a single facility operating license include administrative efficiencies, standardization across utilization facilities, consistency with the structure of SHINE's construction permit, and common technical specifications (TSs) across all eight utilization facilities. SHINE identified perceived administrative burdens and delays as detractors from applying for and maintaining multiple operating licenses. In response to SHINE's presentation, NRC staff identified technical and licensing topics associated with SHINE's proposed license approach for further consideration. At future meetings, the NRC staff asked that SHINE consider presenting on configuration control, component obsolescence, structure of safety analysis report, and potential for staggered operating periods (e.g., permanent shutdown of one of the utilization facilities prior to the termination of the license).

The next portion of the meeting addressed SHINE's anticipated facility design changes since the issuance of the construction permit. To introduce SHINE's design changes, it first provided an overview of its facility, including discussions on the types of isotopes to be produced at the facility, site location, facility layout, process overview, and accident analysis summary. SHINE identified one design change of the process technology. As a result of increased waste disposal

certainty and reduced product purity concerns, SHINE is working to remove the uranium extraction (UREX) process from its facility design. SHINE believes that replacing the UREX process with another chemical separation process will improve facility safety. Such improvements to safety would include the elimination of potential accident sequences, simplified design, reduced processing involving SNM, elimination of red oil potential, and reduction in working dose. Other design changes included the consideration of exhaust filter train location, relocation of noble gas handling equipment, updated heat exchanger sizing, and re-arrangement of tank vaults to minimize rebar detail work.

The final portion of SHINE's presentation covered an overview of its design control and change processes, which are part of the SHINE configuration management program. SHINE has established processes for requesting, screening, evaluating, and approving (or rejecting) design changes. These processes ensure that potential deviations from the approved design are appropriately reviewed and approved. The change control process also ensure that design requirements, physical configuration, and facility documentation remain consistent.

To close out the meeting, the NRC staff and SHINE identified technical and licensing topics for discussion at future pre-application meetings supporting SHINE's operating license application. These topics included the applicability of regulations to SHINE's operating license application, operator licensing, criticality control, verification of criticality safety codes, and TSs.

Further details on this discussion are included in the presentation slides ADAMS Accession No. ML16327A183.

Please direct any inquiries to Steven Lynch at 301-415-1524 or [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov).

Sincerely,

/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: List of Attendees

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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TECHNOLOGIES, INC. DATED January 27, 2017

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NAME	SLynch	NParker	AAdams	SLynch
DATE	1/26/17	1/26/17	1/26/17	1/27/17

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## LIST OF ATTENDEES

DECEMBER 1, 2016 MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

8:30 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.
Stephen Burdick	Morgan Lewis
Steve Lynch	U.S. Nuclear Regulatory Commission
Charles Teal	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
Yawar Faraz	U.S. Nuclear Regulatory Commission
Joseph Staudenmeier	U.S. Nuclear Regulatory Commission
Jim Hammelman	U.S. Nuclear Regulatory Commission
William Gott	U.S. Nuclear Regulatory Commission
John Tomon	U.S. Nuclear Regulatory Commission
Rebecca Tadesse	U.S. Nuclear Regulatory Commission
Jeffrey Rikhoff	U.S. Nuclear Regulatory Commission
Kara McCullough	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Mirela Gavrilas	U.S. Nuclear Regulatory Commission
Jim Lynch	U.S. Nuclear Regulatory Commission

Enclosure