

July 13, 2012

POTENTIAL APPLICANT: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF JUNE 21, 2012 MEETING HELD WITH SHINE MEDICAL TECHNOLOGIES, INC. ON TOPICS RELATED TO THE SUBMISSION OF AN ENVIRONMENTAL REPORT (TAC NO. ME1401)

On June 21, 2012, 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. SHINE requested this meeting to discuss topics related to the preparation of the environmental report associated with its proposed application for a medical isotope production facility. A list of attendees is provided as Enclosure 1. A meeting agenda was included with the meeting notice dated June 8, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12158A596). An updated agenda has been included as Enclosure 2.

SHINE informed NRC staff that it will not have a complete listing of all credible design basis accidents when it submits its preliminary safety analysis report (PSAR). Instead it will provide a bounding accident analysis; however, SHINE indicated that this proposed analysis will be re-examined during the preparation of the final safety analysis report (FSAR) to ensure that all design basis accidents have been analyzed. NRC staff informed SHINE that Interim Staff Guidance (ISG) augmenting NUREG-1537, Parts 1 and 2, anticipates all possible credible accidents and not all of these may apply to each individual technology. NRC staff further emphasized that while a bounding analysis is acceptable, it is expected that SHINE shall verify that its analysis is truly bounding as it continues to develop its application. Additionally, NRC staff reminded SHINE to consider chemical hazards and consequences in its accident analysis. SHINE indicated that it would evaluate all accidents associated with both production and processing of molybdenum-99.

SHINE informed NRC staff that, they intend to submit its environmental report with only 9 months of water quality data as opposed to the required 12 months of data. The remaining three months of data will be provided as a supplement after it is collected. Prior to submitting the supplemental data, SHINE will provide three months worth of historical aquifer data on water quality covering the months for which SHINE's water quality data is pending. NRC staff responded saying that SHINE's application will be evaluated upon submittal for completeness. At that time, it will be determined if enough information has been provided to docket the application.

SHINE shared with NRC staff that it believes that the requirements in the ISG relating to alternate site evaluations is excessive and not meaningful and will therefore not be submitting all of the information related to alternate sites as recommended by the ISG. NRC staff informed SHINE that the ISG is provided as guidance and adherence to the ISG is not a requirement. NRC staff will conduct a review of the environmental report and construction permit application as long as sufficient data, as required by regulation, is provided.

The next topic of discussion related to a tentative NRC staff visit to SHINE's proposed site in Janesville, Wisconsin in August 2012. SHINE informed NRC staff that the current version of its environmental report will be available for review during the visit as well as all other relevant documents and calculations. SHINE will also have technical experts available to answer background questions. NRC staff informed SHINE that it will confirm the August visit soon and reminded SHINE that it cannot consult during the visit. The visit will be used as an opportunity for questions and answers to allow the NRC to better plan and allocate its resources for the review. The visit may also be used as an opportunity for the NRC to have a public meeting in the city of Janesville.

Finally, SHINE informed the NRC that it will be submitting a letter requesting a regulatory interpretation of Title 10 of the *Code of Federal Regulations* Section 2.101(a)(5).

Two members of the public were in attendance via telephone. During the time allotted for public questions and comments, one individual expressed concern over the threat SHINE's facility posed to the ground water quality in Janesville. This same individual also expressed interest in participating in a public meeting held in Janesville.

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

/RA/

Linh N. Tran, Senior Project Manager  
Research and Test Reactor Licensing Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

Project No. PROJ0792

Enclosures:

1. List of Attendees
2. Revised Agenda

cc w/encl: See next page

cc w/encls:

Dr. Gregory Piefer, PhD  
CEO-SHINE Medical Technologies, Inc.  
2555 Industrial Drive  
Monona, WI 53713

Mr. James Freels  
Licensing Project Manager  
SHINE Medical Technologies, Inc.  
2555 Industrial Drive  
Monona, WI 53713

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**ADAMS Accession Nos.**    **PKG: ML121870713**; Meeting Notice: ML12158A596; Meeting Summary: ML121870716

OFFICE	DPR/PRLB/PM	DPR/PRLB/PM	DPR/PRLB/LA	DPR/PRLB/BC	DPR/PRLB/PM
NAME	SLynch	LTran	GLappert	JQuichocho	LTran
DATE	07/06/12	07/06/12	7/11/2012	7/12/2012	7/13/2012

OFFICIAL RECORD COPY

LIST OF ATTENDEES

JUNE 21, 2012, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC. REGARDING

TOPICS RELATED TO THE SUBMISSION OF AN ENVIRONMENTAL REPORT

<u>NAME</u>	<u>ORGANIZATION</u>
Vann Bynum	SHINE Medical Technologies, Inc.
Dick Jason	SHINE Medical Technologies, Inc.
Brenda Furlow	SHINE Medical Technologies, Inc.
Jim Freels	SHINE Medical Technologies, Inc.
Bill McCoy	Public Participant
Al Hulick	Public Participant
Steve Lynch	U.S. Nuclear Regulatory Commission
Jessie Quichocho	U.S. Nuclear Regulatory Commission
Bill Rautzen	U.S. Nuclear Regulatory Commission
Michelle Moser	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Jim Lynch	U.S. Nuclear Regulatory Commission
Adam Gendelman	U.S. Nuclear Regulatory Commission
Yosef Lindell	U.S. Nuclear Regulatory Commission
Alexander Adams	U.S. Nuclear Regulatory Commission
Jill Shepherd	U.S. Nuclear Regulatory Commission
Patricia Pelke	U.S. Nuclear Regulatory Commission
Raymond Skarda	U.S. Nuclear Regulatory Commission

AGENDA (REVISED)

FORTHCOMING MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

Meeting on Thursday, June 21, 2012

3:00 p.m. - 5:00 p.m.

<u>Time</u>	<u>Topic</u>	<u>Lead</u>
3:00 p.m. - 3:05 p.m.	Opening Remarks	NRC
3:05 p.m. - 3:30 p.m.	Postulated Accident Considerations	SHINE
3:30 p.m. - 3:50 p.m.	Ground Water Data	SHINE
3:50 p.m. - 4:10 p.m.	Alternate Site Data	SHINE
4:10 p.m. - 4:30 p.m.	Site Visit and Draft Environmental Report	SHINE
4:30 p.m. - 4:45 p.m.	Environmental Report Submittal Requirements	SHINE
4:45 p.m. - 4:55 p.m.	Public Questions and Comments	NRC
4:55 p.m. - 5:00 p.m.	Closing Remarks and Adjourn	NRC