

September 6, 2012

POTENTIAL APPLICANT: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF AUGUST 7, 2012, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC. TO DISCUSS PROCESS CHEMISTRY ASSOCIATED WITH MEDICAL RADIOISOTOPE PRODUCTION (TAC NO. ME1401)

On August 7, 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 the process chemistry associated with its proposed application for a medical isotope production facility. A portion of this meeting was closed to the public to discuss proprietary information. A list of attendees is provided as an enclosure.

NRC staff opened the meeting with a discussion of pre-application meeting expectations. Staff agreed with SHINE that the best path forward for an effective application review is to hold pre-application or "working" meetings. At these meetings, it is important to have all the participants engaged. NRC staff will use these meetings as an opportunity to ask questions about proposed application submissions to allow better planning and allocation of resources to ensure a thorough and efficient application review. These meetings are also an opportunity for potential applicants to provide updates on their latest design plans and overall application status. While the NRC staff hopes that this exchange will invite a mutually beneficial dialogue between NRC staff and potential applicants, these meetings are not intended to be a forum for NRC staff to provide a design review nor to make regulatory decisions.

In the coming months, NRC staff continues to expect that SHINE will continue to request open and closed pre-application meetings, as appropriate; provide regular updates on the status of the SHINE project; and provide timely document submittals.

NRC staff provided SHINE with a labor-hour and cost estimate for the review of a single medical isotope production facility application. NRC staff expects the review of such an application to require 15,000 - 20,000 labor-hours and cost an additional \$3,000,000 in contracted work.

SHINE's presentation on the cleanup of uranyl sulfate solutions, presented by George Vandegrift, covered four methods of extracting uranyl sulfate from the rest of the irradiated solution. Of the four methods presented, SHINE intends to convert the uranyl-sulfate solution to a nitrate solution and apply the UREX solvent extraction process as the surest means of solution cleanup. Further details on this discussion are included in the presentation slides (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12249A302).

NRC staff asked SHINE if the chemical properties of the fuel were expected to change during the cleanup process. SHINE responded stating that the chemical properties of the reconstituted fuel after cleanup are expected to be identical to the fresh fuel. NRC staff also asked SHINE

SHINE Medical Technologies, Inc.

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how often the cleanup of the uranyl sulfate solution would occur. SHINE anticipates cleaning the fuel solution once a month.

During the portion of the meeting closed to the public to discuss proprietary information, SHINE presented material on the modified Cintichem process for producing molybdenum-99 utilizing low-enriched uranium. A redacted version of the slides used in this presentation is available in ADAMS, Accession No. ML12208A028.

There were no members of the public in attendance at this meeting.

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

**/RA/**

Alexander Adams, Senior Project Manager  
Research and Test Reactor Licensing Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

Project No. PROJ0792

Enclosure: List of Attendees

cc w/encl.: See next page

cc w/encl.:

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: ML12249A318, Notice: ML12208A001, MTGSummary: ML12236A237, Slides: ML12249A302  
NRC-001**

OFFICE	DPR/PRLB/PM	DPR/PRLB/PM	DPR/PRLB/LA	DPR/PRLB/BC	DPR/PRLB/PM
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DATE	08/21/12	9/6/2012	9/6/2012	9/6/2012	9/6/2012

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## LIST OF ATTENDEES

### AUGUST 7, 2012, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC. REGARDING PROCESS CHEMISTRY ASSOCIATED WITH MEDICAL RADIOISOTOPE PRODUCTION

<u>NAME</u>	<u>ORGANIZATION</u>
Vann Bynum	SHINE Medical Technologies, Inc.
Jim Freels	SHINE Medical Technologies, Inc.
Jeff Driscoll	SHINE Medical Technologies, Inc.
George Vandegriff	Argonne National Laboratory
Peter Tkac	Argonne National Laboratory
John Matthews	Morgan, Lewis & Bockius
Steve Lynch	U.S. Nuclear Regulatory Commission
Michelle Moser	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Alexander Adams	U.S. Nuclear Regulatory Commission
Mary Adams	U.S. Nuclear Regulatory Commission
Kimberly Gambone	U.S. Nuclear Regulatory Commission
John Adams	U.S. Nuclear Regulatory Commission
Alex Sapountzis	U.S. Nuclear Regulatory Commission
Maria Guardiola	U.S. Nuclear Regulatory Commission
Greg Chapman	U.S. Nuclear Regulatory Commission
Matthew Panicker	U.S. Nuclear Regulatory Commission
Lisa London	U.S. Nuclear Regulatory Commission
Mary Muessle	U.S. Nuclear Regulatory Commission
Marcus Voth	U.S. Nuclear Regulatory Commission
Cassandra Frasier	U.S. Nuclear Regulatory Commission
Maitri Banerjee	U.S. Nuclear Regulatory Commission

Enclosure