May 2, 2014

APPLICANT: SHINE Medical Technologies, Inc.

SUBJECT: SUMMARY OF MARCH 19 AND 20, 2014, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

On March 19 and 20, 2014, a series of Category 1 public meetings were 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 these meetings was to discuss the licensing and technical aspects associated with the SHINE's construction permit application. Portions of these meetings were closed to the public to discuss proprietary information related to the specifics of design and operation of SHINE's proposed medical radioisotope production facility. A list of attendees at each meeting is provided as Enclosure 1.

The NRC staff opened the meeting beginning at 9:00 a.m. on March 19, 2014, by emphasizing the importance of communication between SHINE and the NRC. SHINE responded, remarking that it had a positive experience working with the NRC and appreciated the NRC's time and feedback. SHINE then transitioned into a presentation on its proposed facility design changes and the impact these changes would have on its preliminary safety analysis report (PSAR). SHINE proposed nine changes in order to enhance safety, optimize resources, improve constructability, and facilitate efficient operations and maintenance. SHINE's design changes proposed to eliminate a crane in the supercell area, reduce the height of the radioisotope production facility, reduce the thickness of the of the radioisotope production facility's roof, relocate the noble gas storage, eliminate a crane in the radioisotope production facility tank farm area, optimize equipment layout in the irradiation facility, resize the irradiation facility crane, relocate bulk chemical storage, and relocate normal switchgear. Further details on this discussion are included in the presentation slides (ADAMS Accession No. ML14070A236).

During the portion of the meeting closed to the public, SHINE went into proprietary-level detail related to the specific design and layout of its proposed design changes. A meeting dedicated to the discussion of security-related information was also held the afternoon of March 19, 2014. Due to the sensitive nature of material covered in this meeting, it was entirely closed to the public. Discussions during this meeting focused on the development of a safeguards information program and design considerations that could impact the development of SHINE's physical security plan.

On March 20, 2014, two meetings were held to cover discussion topics related to SHINE's irradiation facility and radioisotope production facility, respectively. No formal presentations were made at these meetings; however, the list of discussion topics covered during these meetings has been provided as Enclosure 2. These meetings allowed SHINE to provide additional information on aspects of its application that NRC staff felt required additional clarification. NRC staff used the information provided in these meetings to better inform and develop their formal requests for additional information.

A portion of each of the meetings held on March 20, 2014, were closed to the public to discuss proprietary details of those discussion topics that could not be completely addressed in the open portion of the meeting.

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

/RA/

Steven T. Lynch, Project Manager
Research and Test Reactor Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-608

Enclosure 1: List of Attendees
Enclosure 2: Discussion Topics

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

A portion of each of the meetings held on March 20, 2014, were closed to the public to discuss proprietary details of those discussion topics that could not be completely addressed in the open portion of the meeting.

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

/RA/

Steven T. Lynch, Project Manager
Research and Test Reactor Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-608

Enclosure 1: List of Attendees
Enclosure 2: Discussion Topics

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

DISTRIBUTION:

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ADAMS Accession Nos.: Pkg: ML14120A482; Notice: ML14063A588; Summary: ML14120A473 **NRC-001**

OFFICE	DPR/PRLB/PM	DPR/PRLB/LA	DPR/PRLB/BC	DPR/PRLB/PM
NAME	SLynch	PBlechman	AAdams	SLynch
DATE	05/01/2014	05/01/2014	05/01/2014	05/02/2014

OFFICIAL RECORD COPY

LIST OF ATTENDEES

MARCH 19, 2014, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

9:00 A.M – 12:00 P.M.

Name	Organization
Vann Bynum	SHINE Medical Technologies, Inc.
Jim Costedio	SHINE Medical Technologies, Inc.
Eric Van Abel	SHINE Medical Technologies, Inc.
Bill Hennessy	SHINE Medical Technologies, Inc.
Katrina Pitas	SHINE Medical Technologies, Inc.
Devon Engleman	SHINE Medical Technologies, Inc.
Steve Lynch	U.S. Nuclear Regulatory Commission
Lawrence Kokajko	U.S. Nuclear Regulatory Commission
Mirela Gavrilas	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
Maria Guardiola	U.S. Nuclear Regulatory Commission
Cassandra Frasier	U.S. Nuclear Regulatory Commission
Robert Hoffman	U.S. Nuclear Regulatory Commission
Joan Olmstead	U.S. Nuclear Regulatory Commission
Michelle Moser	U.S. Nuclear Regulatory Commission
Larry Harris	U.S. Nuclear Regulatory Commission
Maitri Banerjee	U.S. Nuclear Regulatory Commission
Tarek Zaki	U.S. Nuclear Regulatory Commission
Thomas Boyle	U.S. Nuclear Regulatory Commission
Victoria Huckabay	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Donna-Beth Howe	U.S. Nuclear Regulatory Commission
Joseph Staudenmeier	U.S. Nuclear Regulatory Commission
Matthew Panicker	U.S. Nuclear Regulatory Commission
J. Stewart Bland	Chesapeake Nuclear
Thomas Essig	Chesapeake Nuclear
Terry Gitnick	Information Systems Labs Inc.
Diane Mlynarczyk	Information Systems Labs Inc.
Abe Weitzberg	Information Systems Labs Inc.
Greg Hofer	Information Systems Labs Inc.
Dan Cronin	University of Florida

LIST OF ATTENDEES

MARCH 20, 2014, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

9:00 A.M – 12:00 P.M.

Name	Organization
Richard Vann Bynum	SHINE Medical Technologies, Inc.
Jim Costedio	SHINE Medical Technologies, Inc.
Eric Van Abel	SHINE Medical Technologies, Inc.
Bill Hennessy	SHINE Medical Technologies, Inc.
Katrina Pitas	SHINE Medical Technologies, Inc.
Devon Engleman	SHINE Medical Technologies, Inc.
Steve Lynch	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
Maria Guardiola	U.S. Nuclear Regulatory Commission
Greg Chapman	U.S. Nuclear Regulatory Commission
Patrick Isaac	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Christopher Tripp	U.S. Nuclear Regulatory Commission
Soly Soto	U.S. Nuclear Regulatory Commission
Donna-Beth Howe	U.S. Nuclear Regulatory Commission
Jason Lising	U.S. Nuclear Regulatory Commission
Larry Harris	U.S. Nuclear Regulatory Commission
Robert Hoffman	U.S. Nuclear Regulatory Commission
Kevin Morrissey	U.S. Nuclear Regulatory Commission
Patricia Silva	U.S. Nuclear Regulatory Commission
Jeremy Munson	U.S. Nuclear Regulatory Commission
Matthew Panicker	U.S. Nuclear Regulatory Commission
Thomas Essig	Chesapeake Nuclear
Greg Hofer	Information Systems Labs Inc.
Terry Gitnick	Information Systems Labs Inc.
Ray Vollert	Information Systems Labs Inc.
Stephen Marschke	Information Systems Labs Inc.
John Atchison	Information Systems Labs Inc.
William Newmyer	Nuclear Associates

LIST OF ATTENDEES

MARCH 20, 2014, MEETING WITH SHINE MEDICAL TECHNOLOGIES, INC.

1:00 P.M – 4:00 P.M.

Name	Organization
Vann Bynum	SHINE Medical Technologies, Inc.
Jim Costedio	SHINE Medical Technologies, Inc.
Eric Van Abel	SHINE Medical Technologies, Inc.
Bill Hennessy	SHINE Medical Technologies, Inc.
Katrina Pitas	SHINE Medical Technologies, Inc.
Devon Engleman	SHINE Medical Technologies, Inc.
Steve Lynch	U.S. Nuclear Regulatory Commission
Linh Tran	U.S. Nuclear Regulatory Commission
Alexander Adams	U.S. Nuclear Regulatory Commission
Patrick Isaac	U.S. Nuclear Regulatory Commission
Ray Skarda	U.S. Nuclear Regulatory Commission
Mark Blumberg	U.S. Nuclear Regulatory Commission
Joseph Staudenmeier	U.S. Nuclear Regulatory Commission
Mitzi Young	U.S. Nuclear Regulatory Commission
Thomas Boyle	U.S. Nuclear Regulatory Commission
Jason Lising	U.S. Nuclear Regulatory Commission
Robert Hoffman	U.S. Nuclear Regulatory Commission
Mirela Gavrilas	U.S. Nuclear Regulatory Commission
Donna-Beth Howe	U.S. Nuclear Regulatory Commission
Tarek Zaki	U.S. Nuclear Regulatory Commission
Thomas Essig	Chesapeake Nuclear
Stephen Alexander	Information Systems Labs Inc.
Terry Gitnick	Information Systems Labs Inc.
John Atchison	Information Systems Labs Inc.
Greg Hofer	Information Systems Labs Inc.
William Newmyer	Nuclear Associates

Discussion Topics for SHINE Meeting
Thursday, March 20, 2014

Radioisotope Production Facility

- Identification of each potential accident sequence, including the consequence; likelihood of occurrence; and mitigation or prevention of each potential accident sequence.
- Aspects of the quality assurance and procurement programs and measures assuring long term reliability and availability of engineered controls
- Identification and justification of subcritical margin used for nuclear criticality safety evaluations, accident analyses, and development of safety controls
- Commitment to nuclear criticality safety (NCS) safety limits and NCS operating limits
- Applicability of heterogeneous effects
- Configuration management program, including details on the configuration control process and procedures; and assurance that changes to NCS basis are incorporated into safety-basis documentation.
- Potential for planned exceptions to the double contingency principle
- Controlled parameters (e.g., moderator, concentration, mass, density, enrichment, reflection, interaction, volume, etc.)
- Accident sequences resulting in high or intermediate consequences
- Quality assurance measures applied to design, procurement, construction, operation, maintenance, inspection, testing, and modification of items relied on for safety
- Identification and reliability of passive and active engineered items relied on for safety
- Adequate segregation and isolation between chemicals stored onsite, including the identification of incompatible chemicals and their storage and use locations

Discussion Topics for SHINE Meeting
Thursday, March 20, 2014

Irradiation Facility

- The extent and effect of potential nonuniformities of power, void, temperature, or chemical species within the target solution vessel (TSV) that may limit operating conditions
- Pressure excursions within the TSV
- The uncertainty in the radiolysis rate and the impact this uncertainty may have on sizing of systems in the irradiation units
- Reactivity insertions by the cooling system
- Validation of radiolytic gas formation calculations
- Uncertainty associated with estimated k_{eff} values in the irradiation units
- Types of chemicals and radioactive or contaminated materials contained within fire areas
- Facility design modifications based on as low as reasonably achievable (ALARA) considerations