



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 15, 2021

LICENSEE: SHINE Medical Technologies, LLC

SUBJECT: SUMMARY OF SEPTEMBER 27, 2021, MEETING WITH SHINE MEDICAL
TECHNOLOGIES, LLC (EPID NO. L-2019-NEW-0004)

On September 27, 2021, an Observation public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) staff and representatives of SHINE Medical Technologies, LLC (SHINE). The purpose of this meeting was to improve the NRC staff's understanding of the engineered safety features and auxiliary systems associated with the SHINE operating license application. Portions of this meeting were closed to public participation to discuss proprietary information. The meeting notice and agenda, dated September 17, 2021, are available in the Agencywide Documents Access and Management System at Accession No. ML21260A252. A list of meeting attendees is provided as Enclosure 1 to this summary.

During the public meeting, SHINE staff answered questions from NRC staff relating to the engineered safety features and auxiliary systems associated with the SHINE operating license application. The questions discussed during the meeting are provided as Enclosure 2 to this summary.

Please direct any inquiries to me at 301-415-2856, or at Michael.Balazik@nrc.gov.

A handwritten signature in blue ink, appearing to read "Michael Balazik", is positioned above the typed name.

Signed by Balazik, Michael
on 11/15/21

Michael Balazik, Project Manager
Non-Power Production and Utilization Facility
Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Docket No. 50-608

Enclosures:
As stated

cc w/enclosures: See next page

Shine Medical Technologies, LLC

Docket No. 50-608

cc:

Jeff Bartelme
Licensing Manager
SHINE Technologies, LLC
3400 Innovation Court
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548

Gregory Piefer, Ph.D.
Chief Executive Officer
SHINE Technologies, LLC
3400 Innovation Court
Janesville, WI 53546

Nathan Schleifer
General Counsel
SHINE Technologies, LLC
3400 Innovation Court
Janesville, WI 53546

Christopher Landers
Director, Office of Conversion
National Nuclear Security Administration,
NA 23
U.S. Department of Energy
1000 Independence Ave SW
Washington, DC 20585

Mark Paulson, Supervisor
Radiation Protection Section
Wisconsin Department of Health Services
P.O. Box 2659
Madison, WI 53701-2659

Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
Dept of Materials Science
and Engineering
University of Maryland
4418 Stadium Drive
College Park, MD 20742-2115

Mark Freitag
City Manager
P.O. Box 5005
Janesville, WI 53547-5005

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

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DATED: NOVEMBER 15, 2021

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MBalazik, NRR

NParker, NRR

JBorromeo, NRR

MKGavello, NRR

**ADAMS Accession Nos.: ML21260A252 Public Meeting Notice;
ML21313A428 Public Meeting Summary
NRC-001**

| OFFICE | NRR/DANU/UNPL/PM | NRR/DANU/UNPL/LA | NRR/DANU/UNPL/BC | NRR/DANU/UNPL/PM |
|--------|------------------|------------------|------------------|------------------|
| NAME | MBalazik | NParker | JBorromeo | MBalazik |
| DATE | 11/09 /2021 | 11/10/2021 | 11/12/2021 | 11/15 /2021 |

OFFICIAL RECORD COPY

LIST OF ATTENDEES

SEPTEMBER 27, 2021, MEETING WITH SHINE MEDICAL TECHNOLOGIES, LLC

12:00 P.M. - 1:00 P.M.

| <u>Name</u> | <u>Organization</u> |
|-----------------------|---|
| Michael Balazik | U.S. Nuclear Regulatory Commission |
| Molly-Kate Gavello | U.S. Nuclear Regulatory Commission |
| Steven Lynch | U.S. Nuclear Regulatory Commission |
| Nageswara Karipineni | U.S. Nuclear Regulatory Commission |
| Jim Costedio | SHINE Medical Technologies, LLC |
| Jeffrey Bartelme | SHINE Medical Technologies, LLC |
| Joseph LaPrad | SHINE Medical Technologies, LLC |
| Alisa McClelland | SHINE Medical Technologies, LLC |
| Dennis LeBlanc | SHINE Medical Technologies, LLC |
| Nick Kaiser | SHINE Medical Technologies, LLC |
| Ian Soderling | SHINE Medical Technologies, LLC |
| Anthony Palumbo | SHINE Medical Technologies, LLC |
| Tracy Radel | SHINE Medical Technologies, LLC |
| Vicken Khatchadourian | Engineering Planning and Management, Inc. |
| Thomas Eiden | Atomic Alchemy, Inc. |
| Michael Grochowski | Atomic Alchemy, Inc. |
| John Witkowski | United Pharmacy Partners, Inc. |
| Michelle Thomson | United Pharmacy Partners, Inc. |
| James Bowen | Pacific Northwest National Laboratory |

DISCUSSION QUESTIONS

Question 1

SHINE final safety analysis report (FSAR), Section 6a.2.2.1.1, "Primary Confinement Boundary" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21095A214), states, in part, the following in the second paragraph of page 6a2.2-2:

The [primary closed loop cooling system (PCLS)] expansion tank has a connection to radiological ventilation zone 1 exhaust subsystem (RVZ1e) which provides a vent path for radiolysis gases produced in the PCLS and light water pool, to avoid buildup of hydrogen gas. The PCLS expansion tank is located in the [irradiation unit (IU)] cell but draws air from the [target solution vessel off-gas system (TOGS)] cell atmosphere. A small line connecting the IU cell and TOGS cell atmosphere creates a flow path from the IU cell, into the TOGS cell, and out through the PCLS expansion tank to RVZ1e. This flow path normally maintains the cells at a slightly negative pressure.

Could SHINE clarify the location of the flow path connecting IU cell and TOGS cell shown in the flow diagrams?

Question 2

SHINE FSAR, Section 5a2.6, "Facility Demineralized Water System" (ADAMS Accession No. ML21095A222), states, in part, that "[t]he [facility demineralized water system (FDWS)] provides a water supply to the radiological ventilation zone 2 (RVZ2) system and the facility ventilation zone 4 (FVZ4) system for humidity control."

Could SHINE confirm this statement and explain how FDWS provides humidity control? The NRC staff did not identify a direct connection between the FDWS and any RVZ2 and FVZ4 equipment (e.g. cooling coils).

Question 3

SHINE FSAR, Section 5a.2.2.7, "Hydrogen Limits" (ADAMS Accession No. ML21095A222), states, in part:

Radiolysis of the primary cooling water and the light water pool results in the generation of hydrogen and oxygen gases. These gases must be vented to prevent the buildup of hydrogen. The RVZ1e draws air from the primary confinement and through the PCLS expansion tank headspace to dilute hydrogen within the primary confinement and expansion tank while the PCLS system is required to be in operation.

RVZ1e provides a nominal flowrate of approximately 1 standard cubic feet per minute (scfm) (28 standard liter per minute [slpm]) to the expansion tank headspace while the PCLS system is required to be in operation. The relatively low nominal flow rate maintains hydrogen concentrations within the primary containment and expansion tank below 1 percent by volume while minimizing release of Az-41 to the facility stack.

SHINE FSAR, Section 9a2.1.1.3, "System Operation" (ADAMS Accession No. ML21095A225), states, in part:

The IU cell exhaust flow path of RVZ1e provides ventilation of the IU cell and TOGS cell via the PCLS expansion tank headspace. This path is equipped with radiation monitoring instrumentation and redundant isolation valves. Between the RVZ1e IU cell radiation instrumentation and RVZ1e IU cell isolation valves is an isolation lag tank. If the RVZ1e IU cell radiation measurements exceed 60 times normal background radiation, the [target solution vessel (TSV)] reactivity protection system (TRPS) initiates an IU Cell Safety Actuation, which closes the RVZ1e IU cell isolation valves. The isolation lag tank provides an exhaust gas delay time greater than the closing time of the valves.

- 1) Given that the confinement boundary is designed to minimize leakage, how is it assured that 1 scfm leakage would occur? The NRC staff recognizes that the leakage is a small quantity, but since it is relied upon to keep hydrogen concentrations below 1 percent by volume, this information needs to be verified.
- 2) Could SHINE provide a discussion on the expected operation and function of the PCLS expansion tank and isolation lag tank?

General Questions and Comments

- Could SHINE clarify if the bubble tight dampers are all safety related?
- Flow diagrams in the FSAR do not appear to show any damper operators. How are the dampers operated?
- Do the flow diagrams for ventilation and water in the FSAR show all manual dampers and valves in the systems?
- The facility chilled water system and facility heating water system are described in Chapter 9 of the FSAR, but no flow diagrams were included. Could SHINE clarify the reasoning for not including such flow diagrams?
- Figure 9a2.1-6 shows Recirculation Units RVZ2R3, RVZ2R4, and RVZ2R5. It is not clear if the function of the units is recirculation only, with no cooling or heating capabilities, or if the units require water, chilled water, and heating water systems for operation. Could SHINE clarify how the recirculation units operate?
- Could SHINE elaborate on the considerations associated deuterium source gas as described in its response to request for additional information 9-1, item e. (ADAMS Accession No. ML21095A229)? Specifically, can SHINE take the NRC staff through Figures 5a2.2-1, 6a2.2-1 and 9a2.1-3 and explain how the deuterium gas enters the RVZ1e exhaust line?