



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

December 2, 2022

Dr. Gregory Piefer, Chief Executive Officer  
SHINE Medical Technologies, LLC  
101 East Milwaukee Street, Suite 600  
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – SUMMARY OF REGULATORY  
AUDIT OF FIRE PROTECTION PROGRAM DESCRIBED IN OPERATING  
LICENSE APPLICATION (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

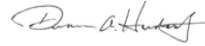
By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ML19337A275), March 27, 2020 (ML20105A295), August 28, 2020 (ML20255A027), November 13, 2020 (ML20325A026), December 10, 2020 (ML20357A084), and December 15, 2020 (ML21011A264), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities."

To enhance its review of fire protection topics described in SHINE's operating license application, the NRC staff conducted a virtual regulatory audit on April 8, 2021, consistent with NRC Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-111, "Regulatory Audits," dated October 31, 2019 (ML19226A274). The NRC staff performed its audit in accordance with an electronic mail to SHINE on June 29, 2020 (ML20202A607) and the regulatory audit plan provided to SHINE by letter dated April 8, 2021 (ML21096A248). A summary of the regulatory audit is enclosed.

The audit report does not make any licensing conclusions or findings, but it is part of the administrative record of the NRC staff's review of the operating license application and may provide information supporting the NRC staff's safety evaluation.

If you have any questions, please contact me at (301) 415-2856, or by electronic mail at [Michael.Balazik@nrc.gov](mailto:Michael.Balazik@nrc.gov).

Sincerely,



Hardesty, Duane signing on behalf  
of Balazik, Michael  
on 12/02/22

Michael F. 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  
Construction Permit No. CPMIF-001

Enclosure:  
Regulatory Audit Summary  
cc: See next page

SHINE Medical Technologies, LLC

Docket No. 50-608

cc:

Jeff Bartelme  
Licensing Manager  
SHINE Medical Technologies, LLC  
101 East Milwaukee Street, Suite 600  
Janesville, WI 53545

Nathan Schleifer  
General Counsel  
SHINE Medical Technologies, LLC  
101 East Milwaukee Street, Suite 600  
Janesville, WI 53545

Christopher Landers  
Director, Office of Conversion  
National Nuclear Security Administration,  
NA 23  
U.S. Department of Energy  
1000 Independence Avenue, 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

Alfred Lembrich  
541 Miller Avenue  
Janesville, WI 53548

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC - SUMMARY OF REGULATORY  
AUDIT OF FIRE PROTECTION PROGRAM DESCRIBED IN OPERATING  
LICENSE APPLICATION (EPID NO. L-2019-NEW-0004)  
DATED: DECEMBER 2, 2022

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**ADAMS Accession No.: ML22322A223**

**NRR-106**

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| <b>NAME</b>   | MBalazik    | JRobinson    | (HCruz for)<br>JBorromeo | (DHardesty for)<br>MBalazik |
| <b>DATE</b>   | 11/18/2022  | 12/1/2022    | 12/2/2022                | 12/2/2022                   |

**OFFICIAL RECORD COPY**

**OFFICE OF NUCLEAR REACTOR REGULATION**  
**REGULATORY AUDIT SUMMARY**  
**REGARDING FIRE PROTECTION PROGRAM DESCRIBED IN**  
**OPERATING LICENSE APPLICATION**  
**CONSTRUCTION PERMIT NO. CPMIF-001**  
**SHINE MEDICAL TECHNOLOGIES, LLC**  
**SHINE MEDICAL ISOTOPE PRODUCTION FACILITY**  
**DOCKET NO. 50-608**

## **1.0 BACKGROUND**

The U.S. Nuclear Regulatory Commission (NRC) staff is continuing its review of the SHINE Medical Technologies, LLC (SHINE) operating license application, submitted July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ML19337A275), March 27, 2020 (ML20105A295), August 28, 2020 (ML20255A027), November 13, 2020 (ML20325A026), December 10, 2020 ( ML20357A084), and December 15, 2020 (ML21011A264). This regulatory audit is intended to assist the NRC staff in its review of fire protection topics described in the SHINE final safety analysis report (FSAR), submitted as part of SHINE's operating license application.

The NRC staff performed its audit in accordance with an electronic mail to SHINE on June 29, 2020 (ML20202A607) and the regulatory audit plan provided to the SHINE by letter dated April 8, 2021 (ML21096A248). The purpose of this regulatory was to review additional information necessary in determining that a reasonable assurance of adequate protection of public health and safety exist, that applicable regulatory requirements are met, and to identify information that requires docketing to support a regulatory finding regarding fire protection.

The audit entrance meeting was held on April 8, 2021, via teleconference and video conference. The audit included the NRC staff's review of docketed and non-docketed information via the SHINE electronic reading room and teleconferences with SHINE.

## **2.0 REGULATORY BASIS AND GUIDANCE DOCUMENTS**

This audit supported the NRC staff's review of the SHINE's fire protection topics in accordance with the applicable regulatory requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) and applicable guidance, as well as the guidance contained in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ML042430055), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ML042430048).

The NRC staff is also using the “Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ML12156A069), and “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ML12156A075). As applicable, additional guidance cited in SHINE’s FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE operating license application.

### **3.0 AUDIT LOCATION AND DATES**

The audit was conducted via teleconference and video conference.

Dates: April 8, 2021

Location: SHINE electronic reading room

### **4.0 NRC AUDIT TEAM MEMBERS**

- Steven Lynch, Senior Project Manager
- Jay Robinson, Senior Fire Protection Engineer
- Charles Moulton, Fire Protection Engineer
- Naeem Iqbal, Fire Protection Engineer

### **5.0 APPLICANT PARTICIPANTS**

- Jeff Bartelme, SHINE Medical Technologies, LLC et al.

### **6.0 DESCRIPTION OF AUDIT ACTIVITIES AND SUMMARY OF OBSERVATIONS**

The following information, as listed in the audit plan dated April 8, 2021, was reviewed, and discussed with the SHINE:

- SHINE updated fire protection program.
- SHINE updated fire hazard analysis.
- SHINE safe shutdown analysis.
- SHINE radiological fire hazard analysis.
- SHINE regulatory commitment listed in Appendix A of NUREG-2189, “Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility.”
- SHINE fire protection facility design control process, design change control process, and the fire protection design criteria.

## **7.0 EXIT BRIEFING**

The NRC staff conducted an audit exit meeting via a teleconference and video conference on April 8, 2021. The NRC staff summarized its observations and described information needs that would likely be issued in a request for additional information as a result of the audit.

## **8.0 OPEN ITEMS AND PROPOSED CLOSURE PATHS**

Not applicable.

## **9.0 DEVIATIONS FROM THE AUDIT PLAN**

Not applicable.