



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

April 21, 2021

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 AUDIT RELATED  
TO THE PHYSICAL SECURITY PLAN (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 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Accession No. ML20357A084), and December 15, 2020 (ADAMS Accession No. 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."

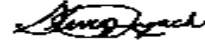
To enhance the review of SHINE's physical security plan associated with its operating license application the NRC staff conducted a regulatory audit from August 31, 2020, to September 3, 2020. A summary of the regulatory audit is enclosed.

G. Piefer

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If SHINE has any questions please contact me at 301-415-1524, or by electronic mail at [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov).

Sincerely,



Signed by Lynch, Steven  
on 04/20/21

Steven T. Lynch, Senior 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:  
As stated

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 AUDIT RELATED  
TO THE PHYSICAL SECURITY PLAN (EPID NO. L-2019-NEW-0004)  
DATED: APRIL 21, 2021

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**ADAMS Accession No.: ML21089A228****NRR-106**

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**OFFICIAL RECORD COPY**

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

Location: SHINE Medical Technologies, LLC, Janesville, Wisconsin

Dates: August 31, 2020 – September 3, 2020

Audit Team Members: Steven Lynch (Senior Project Manager)  
Elizabeth Reed (Security Specialist, Research and Test Reactors)  
Tim Harris (Senior Program Manager, Materials Security)  
Charles Teal (Program Manager, Materials Security)

Licensee Representatives: Jeff Bartelme, Director of Licensing  
Jim Costedio, Vice President of Regulatory Affairs and Quality  
Catherine Kolb, Operations Manager  
Bill Hennessy, Contractor  
Roger Thomas, Electrical Engineer  
Marty Price, Electrical Engineer

1.0 BACKGROUND

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Accession No. ML20357A084), and December 15, 2020 (ADAMS Accession No. ML21011A264), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical

Enclosure

Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." This regulatory audit was intended to assist the NRC staff in its review of the physical security plan (PSP) described in the SHINE final safety analysis report (FSAR), submitted as part of SHINE's operating license application.

This audit supported the NRC staff's review of the licensee's PSP using the applicable 10 CFR requirements, 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 (ADAMS Accession No. 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 (ADAMS Accession No. 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 (ADAMS Accession No. 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 (ADAMS Accession No. 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.

The NRC staff also conducted this regulatory audit in response to direction provided in the Commission's Staff Requirements Memorandum (SRM)-18-0063<sup>1</sup>, "Response to (SRM)-COMSECY-17-0008 on Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99," dated September 26, 2019.

The audit was conducted in accordance with the audit plan and associated topics (ADAMS Accession No. ML20240A253).

## 2.0 AUDIT ACTIVITIES AND OBSERVATIONS

### *Entrance Briefing*

The NRC staff discussed the goals and objectives of the audit at the entrance briefing, which focused on gaining a better understanding of the proposed SHINE PSP. In addition, it was discussed that the regulatory audit may identify additional information that would be required to be docketed to support the basis of the licensing decision and allow the NRC staff to more efficiently gain insights on the operating license application. Further, the NRC staff indicated

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<sup>1</sup> SRM-18-0063 and associated documents, including SECY-18-0063, "Response to (SRM)-COMSECY-17-0008 on Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99," dated June 4, 2018; SRM-COMSECY-17-0008, "Staff Requirements-COMSECY-17-0008-Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99," dated August 1, 2017; and COMSECY-17-0008, "Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99," dated February 22, 2017, are withheld from public disclosure to protect security-related information.

that the information gained from the audit review would assist the NRC staff to better focus any requests for additional information (RAIs) needed to support the review.

#### *Site Tour*

The licensee provided the NRC staff with a comprehensive site tour. The NRC staff observed the areas for the use and storage of special nuclear material and radioactive material.

#### *Review of Audit Information*

The topics and questions that were discussed during the regulatory audit were primarily based on the non-public regulatory audit topics provided to SHINE on August 13, 2020.

The following information, as listed in the audit plan dated August 28, 2020, was reviewed and discussed with the licensee:

- Discussion on SHINE compliance with 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.”

The licensee indicated that it would provide information demonstrating compliance with the reference regulation in a supplement to its PSP.

- Discussion on SHINE compliance with 10 CFR Part 73, “Physical Protection of Plants and Materials.”

The licensee indicated that it would provide information demonstrating compliance with the reference regulation in a supplement to its PSP.

- SHINE draft PSP, technical specification requirements, and supporting reference documentation related to the SHINE PSP.

NRC staff reviewed the documents listed above as applicable to the PSP. The licensee indicated that it would provide updated information reflecting agreements made onsite in a supplement to its PSP.

#### *Exit Briefing*

On September 3, 2020, the audit team held an exit briefing with the licensee. No issues or concerns were identified by the licensee during the on-site audit exit briefing. The NRC staff indicated the on-site audit was concluded but the audit would continue until the NRC staff determined that it had sufficient information to complete its review of the PSP.

### 3.0 RESULTS OF REGULATORY AUDIT

The NRC audit team discussed the need for RAIs to capture the information on the docket consistent with the applicable regulatory requirements in 10 CFR Parts 37, 50, and 73.

The NRC staff discussed the need to obtain the information in the following areas in support of its review of the PSP in a RAI to be issued following the regulatory audit:

- A request to update the PSP to include more details on detection, assessment, and response procedures;
- A request to clarify which site-specific supplemental security measures will be incorporated into the SHINE operating license; and
- A request to update the PSP to include more details on the access authorization program.