SHINE® Medical Technologies

THIS LETTER CONTAINS PROPRIETARY AND EXPORT CONTROLLED INFORMATION IN ACCORDANCE WITH 10 CFR 2.390

March 27, 2020

2020-SMT-0025
10 CFR 50.30

99902034

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) SHINE Medical Technologies, LLC letter to the NRC, SHINE Medical Technologies, LLC Application for an Operating License, dated July 17, 2019
(2) SHINE Medical Technologies, LLC letter to the NRC, SHINE Medical Technologies, LLC Operating License Application Supplement No. 1, dated November 14, 2019

SHINE Medical Technologies, LLC Operating License Application Supplement No. 2

Pursuant to 10 CFR Part 50.30, SHINE Medical Technologies, LLC (SHINE) submitted an application for an operating license for a medical isotope production facility to be located in Janesville, WI via Reference 1. SHINE submitted a supplement to the application via Reference 2. SHINE has determined that an additional supplement to the application is necessary to address facility design changes and to provide administrative revisions.

This application supplement contains information which SHINE requests to be withheld from public disclosure, including proprietary information in accordance with 10 CFR 2.390(a)(4), export controlled information (ECI) in accordance with 10 CFR 2.390(a)(3), and security-related information (SRI) in accordance 10 CFR 2.390(d). SRI was identified utilizing the guidance contained in Regulatory Issue Summary (RIS) 2005-31, Revision 1. The revised application documents are provided via optical storage media (OSM).

Enclosure 1 provides a non-public version of the SHINE Final Safety Analysis Report (FSAR) Change Summary, including a markup of affected FSAR pages. Enclosure 1 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390.

Enclosure 2 provides a public version of the SHINE FSAR Change Summary.

Enclosure 3 provides a non-public revision to the SHINE FSAR, incorporating the changes described in Enclosure 1. Enclosure 3 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. SHINE requests that the NRC withhold Enclosure 3 from public disclosure under 10 CFR 2.390.

Enclosure 4 provides a public revision to the SHINE FSAR.

Enclosures 1 and 3 contain security-related information.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 1, 3, and 5, this letter is uncontrolled.

A053

101 E. Milwaukee Street, Suite 600 | Janesville, WI 53545 | P (608) 210-1060 | F (608) 210-2504 | www.shinemed.com

YGD1
NRR

Enclosure 5 provides a non-public revision to the SHINE Technical Specifications. Revision 2 of the SHINE Technical Specifications incorporates conforming changes associated with the FSAR changes described in Enclosure 1, as well as administrative updates. Enclosure 6 contains proprietary information, a subset of which has been determined to be ECI. SHINE requests that the NRC withhold Enclosure 6 from public disclosure under 10 CFR 2.390.

Enclosure 6 provides a public revision to the SHINE Technical Specifications.

Enclosure 7 provides a revision to the SHINE Quality Assurance Program Description (QAPD). Revision 15 of the SHINE QAPD incorporates organizational changes as well as administrative updates.

Enclosure 8 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosures 1, 3, and 5, pursuant to 10 CFR 2.390. SHINE requests that the NRC withhold Enclosures 1, 3, and 5 from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1, 3, and 5, this letter is uncontrolled.

The SHINE FSAR is provided in its entirety in Enclosures 3 (Non-Public) and 4 (Public); however, not every FSAR chapter has been revised. Revision bars within Enclosures 3 and 4 indicate the changes incorporated into the FSAR via this supplement. The following table identifies which FSAR chapter files, submitted within the enclosed OSM, have been modified from the files previously submitted in Reference 2.

Enclosure	Title	Modified
3	FSAR Chapter 01 - The Facility	Yes
3	FSAR Chapter 02 - Site Characteristics	No
3	FSAR Chapter 03 - Design of Structures, Systems, and Components	Yes
3	FSAR Chapter 04 - Irradiation Unit and Radioisotope Production Facility Description	Yes
3	FSAR Chapter 05 - Cooling Systems	Yes
3	FSAR Chapter 06 - Engineered Safety Features	Yes
3	FSAR Chapter 07 - Instrumentation and Control Systems	Yes
3	FSAR Chapter 09 - Auxiliary Systems	Yes
3	FSAR Chapter 11 - Radiation Protection Program and Waste Management	Yes
3	FSAR Chapter 13 - Accident Analysis	Yes
3	FSAR Chapter 15 - Financial Qualifications	No
4	FSAR Chapter 01 - The Facility	Yes
4	FSAR Chapter 02 - Site Characteristics	No
4	FSAR Chapter 03 - Design of Structures, Systems, and Components	Yes
4	FSAR Chapter 04 - Irradiation Unit and Radioisotope Production Facility Description	Yes
4	FSAR Chapter 05 - Cooling Systems	Yes
4	FSAR Chapter 06 - Engineered Safety Features	Yes
4	FSAR Chapter 07 - Instrumentation and Control Systems	Yes
4	FSAR Chapter 08 - Electrical Power Systems	Yes
4	FSAR Chapter 09 - Auxiliary Systems	Yes

Enclosure	Title	Modified
4	FSAR Chapter 10 - Experimental Facilities	No
4	FSAR Chapter 11 - Radiation Protection Program and Waste Management	Yes
4	FSAR Chapter 12 - Conduct of Operations	Yes
4	FSAR Chapter 13 - Accident Analysis	Yes
4	FSAR Chapter 14 - Technical Specifications	No
4	FSAR Chapter 15 - Financial Qualifications	No
4	FSAR Chapter 16 - Other License Considerations	No
4	FSAR Chapter 17 - Decommissioning and Possession-Only License Amendments	No
4	FSAR Chapter 18 - Highly Enriched to Low Enriched Uranium Conversion	No

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on March 27, 2020.

Very truly yours,

FOR

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, LLC
Docket No. 50-608

Enclosures

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosures 1, 3, and 5)

ENCLOSURE 8

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION SUPPLEMENT NO. 2

AFFIDAVIT OF JAMES COSTEDIO

2 pages follow

SHINE®
Medical Technologies

AFFIDAVIT OF JAMES COSTEDIO

STATE OF WISCONSIN)
) ss.
COUNTY OF ROCK)

I, James Costedio, Vice President of Regulatory Affairs and Quality of SHINE Medical Technologies, LLC (SHINE), do hereby affirm and state:

1. I am authorized to execute this affidavit on behalf of SHINE. I am authorized to review information submitted to or discussed with the Nuclear Regulatory Commission (NRC) and apply for the withholding of information from public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial and financial information submitted in the operating license application by letter 2020-SMT-0025 with enclosures. SHINE requests that the confidential information contained in Enclosures 1, 3, and 5 be withheld from public disclosure in their entirety.

2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.

3. Pursuant to the provisions of paragraph (a)(4) of 10 CFR 2.390, the following is furnished for consideration by the NRC in determining whether the information sought to be withheld from public disclosure should be withheld.

   a. The information sought to be withheld from public disclosure contained in Enclosures 1, 3, and 5 of 2020-SMT-0025 is owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.

   b. The information sought to be protected in Enclosures 1, 3, and 5 is not available to the public to the best of my knowledge and belief.

c. The information contained in Enclosures 1, 3, and 5 is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, commercial financial information, commercial information, or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know," and subject to maintaining confidentiality.

d. The proprietary information sought to be withheld from public disclosure in Enclosures 1, 3, and 5 includes, but is not limited to: structural configuration, primary and supporting systems of the medical isotope production facility, process and system locations, and process details. This would include information regarding the types, quantities, and locations of materials stored on site as would be referenced in facility configuration drawings. Public disclosure of the information in Enclosures 1, 3, and 5 would create substantial harm to SHINE because it would reveal trade secrets owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality.

e. Public disclosure of the information in Enclosures 1, 3, and 5 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes, and current position. Its use by a competitor could substantially improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.

f. The information contained in Enclosures 1, 3, and 5 of 2020-SMT-0025 is transmitted to the NRC in confidence and under the provisions of 10 CFR 2.390; it is to be received in confidence by the NRC. The information is properly marked.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on March 27, 2020.

FOR

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, LLC