



50-608

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

March 23, 2021

2021-SMT-0032
10 CFR 50.30

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 (ML19211C143)
 - (2) NRC letter to SHINE Medical Technologies, LLC, "Issuance of Request for Additional Information Related to the SHINE Medical Technologies, LLC Operating License Application (EPID No. L-2019-NEW-0004)," dated January 27, 2021
 - (3) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Operating License Application Supplement No. 5 and Response to Request for Additional Information," dated December 10, 2020
 - (4) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Operating License Application Supplement No. 6 and Response to Request for Additional Information," dated December 15, 2020
 - (5) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Operating License Application Response to Request for Additional Information," dated January 29, 2021
 - (6) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Operating License Application Revision 1 of SHINE Response to Request for Additional Information 2.4-1," dated March 16, 2021
 - (7) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Operating License Application Response to Request for Additional Information and Supplement No. 3," dated August 28, 2020

SHINE Medical Technologies, LLC Operating License Application
Response to Request for Additional Information and Supplement No. 7

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. Via Reference 2, the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE operating license application. SHINE has determined that a supplement to the operating license application is necessary to address facility design changes and to provide administrative revisions.

YGD1
NRR

Enclosures 1, 3, 5, and 9 contain ~~security-related information.~~
~~Withhold from public disclosure under 10 CFR 2.390.~~
Upon removal of Enclosures 1, 3, 5, 7, and 9, this letter is uncontrolled.

This submittal 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 with 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 the non-public version of the SHINE response to the NRC staff's request for additional information. 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 response to the NRC staff's request for additional information.

Enclosure 3 provides a non-public version of the SHINE Final Safety Analysis Report (FSAR) Change Summary, including a markup of affected FSAR pages. 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 version of the SHINE FSAR Change Summary.

Enclosure 5 provides a non-public revision to the SHINE FSAR. In addition to incorporating the changes described in Enclosures 1 and 3, this revision incorporates the changes described in References 3, 4, 5, and 6. Enclosure 5 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. SHINE requests that the NRC withhold Enclosure 5 from public disclosure under 10 CFR 2.390.

Enclosure 6 provides a public revision to the SHINE FSAR.

Enclosure 7 provides a non-public revision to the SHINE Technical Specifications. In addition to incorporating the changes described in Enclosure 1, this revision incorporates the changes described in References 3, 4, and 5. Enclosure 7 contains proprietary information, a subset of which has been determined to be ECI. SHINE requests that the NRC withhold Enclosure 7 from public disclosure under 10 CFR 2.390.

Enclosure 8 provides a public revision to the SHINE Technical Specifications.

Enclosure 9 provides a non-public revision to the SHINE Emergency Plan. Enclosure 9 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. SHINE requests that the NRC withhold Enclosure 9 from public disclosure under 10 CFR 2.390.

Enclosure 10 provides a public revision to the SHINE Emergency Plan.

Enclosure 11 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosures 1, 3, 5, 7, and 9, pursuant to 10 CFR 2.390. SHINE requests that the NRC withhold Enclosures 1, 3, 5, 7, and 9 from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1, 3, 5, 7, and 9, this letter is uncontrolled.

The SHINE FSAR is provided in its entirety in Enclosures 5 (Non-Public) and 6 (Public); however, not every FSAR chapter has been revised. Revision bars within Enclosures 5 and 6 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 7.


Enclosure	Title	Modified
5	FSAR Chapter 01 - The Facility	Yes
5	FSAR Chapter 02 - Site Characteristics	Yes
5	FSAR Chapter 03 - Design of Structures, Systems, and Components	Yes
5	FSAR Chapter 04 - Irradiation Unit and Radioisotope Production Facility Description	Yes
5	FSAR Chapter 05 - Cooling Systems	Yes
5	FSAR Chapter 06 - Engineered Safety Features	Yes
5	FSAR Chapter 07 - Instrumentation and Control Systems	Yes
5	FSAR Chapter 09 - Auxillary Systems	Yes
5	FSAR Chapter 11 - Radiation Protection Program and Waste Management	Yes
5	FSAR Chapter 13 - Accident Analysis	Yes
5	FSAR Chapter 15 - Financial Qualifications	Yes
6	FSAR Chapter 01 - The Facility	Yes
6	FSAR Chapter 02 - Site Characteristics	Yes
6	FSAR Chapter 03 - Design of Structures, Systems, and Components	Yes
6	FSAR Chapter 04 - Irradiation Unit and Radioisotope Production Facility Description	Yes
6	FSAR Chapter 05 - Cooling Systems	Yes
6	FSAR Chapter 06 - Engineered Safety Features	Yes
6	FSAR Chapter 07 - Instrumentation and Control Systems	Yes
6	FSAR Chapter 08 - Electrical Power Systems	Yes
6	FSAR Chapter 09 - Auxillary Systems	Yes
6	FSAR Chapter 10 - Experimental Facilities	No
6	FSAR Chapter 11 - Radiation Protection Program and Waste Management	Yes
6	FSAR Chapter 12 - Conduct of Operations	Yes
6	FSAR Chapter 13 - Accident Analysis	Yes
6	FSAR Chapter 14 - Technical Specifications	No
6	FSAR Chapter 15 - Financial Qualifications	Yes
6	FSAR Chapter 16 - Other License Considerations	No
6	FSAR Chapter 17 - Decommissioning and Possession-Only License Amendments	No
6	FSAR Chapter 18 - Highly Enriched to Low Enriched Uranium Conversion	No

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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 23, 2021.

Very truly yours,

DocuSigned by:

F52DB90989224FF

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, 5, 7, and 9)

ENCLOSURE 11

SHINE MEDICAL TECHNOLOGIES, LLC

**SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION AND SUPPLEMENT NO. 7**

AFFIDAVIT OF JAMES COSTEDIO



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 supplement by letter 2021-SMT-0032 with enclosures. SHINE requests that the confidential information contained in Enclosures 1, 3, 5, 7, and 9 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, 5, 7, and 9 of 2021-SMT-0032 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, 5, 7, and 9 is not available to the public to the best of my knowledge and belief.

- c. The information contained in Enclosures 1, 3, 5, 7, and 9 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, 5, 7, and 9 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, 5, 7, and 9 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, 5, 7, and 9 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, 5, 7, and 9 of 2021-SMT-0032 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 23, 2021.

DocuSigned by:
Jim Costedio
F82DB96906224FF.

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