



50-608

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

July 17, 2019

2019-SMT-0054
10 CFR 50.30
10 CFR 50.33
10 CFR 50.37

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

- References:
- (1) NRC letter to SHINE Medical Technologies, Inc., SHINE Medical Technologies, Inc. - Issuance of Construction Permit for Medical Isotope Facility, dated February 26, 2016 (ML16041A473)
 - (2) SHINE Medical Technologies, LLC letter to the NRC, SHINE Medical Technologies, LLC Submittal of the SHINE Physical Security Plan, dated July 17, 2019

SHINE Medical Technologies, LLC Application for an Operating License

Pursuant to 10 CFR Part 50.30, SHINE Medical Technologies, LLC (SHINE) hereby submits an application for an operating license for a medical isotope production facility to be located in Janesville, WI. The U.S. Nuclear Regulatory Commission (NRC) issued Construction Permit No. CPMIF-001 for the SHINE medical isotope production facility in February 2016 (Reference 1).

This application 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. This application is provided via optical storage media (OSM).

Enclosure 1 provides a non-public version of the SHINE General and Financial Information required to support submittal of an application for an operating license. Enclosure 1 contains proprietary information. 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 General and Financial Information.

Enclosure 3 provides a non-public version of the SHINE Final Safety Analysis Report (FSAR), provided in accordance with 10 CFR 50.34(b). 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.

<p>Enclosures 3, 5, 8, and 9 contain security-related information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1, 3, 5, 6, 8, and 9, this letter is uncontrolled.</p>
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Enclosure 4 provides a public version of the SHINE FSAR.

Enclosure 5 provides a non-public version of the SHINE Integrated Safety Analysis (ISA) Summary, provided in accordance with 10 CFR 70.65(b). 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, in its entirety, from public disclosure under 10 CFR 2.390.

Enclosure 6 provides a non-public version of the SHINE Technical Specifications, provided in accordance with 10 CFR 50.36(a)(1). 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 7 provides a public version of the SHINE Technical Specifications.

Enclosure 8 provides a non-public version of the SHINE Material Control and Accounting (MC&A) Plan, provided in accordance with 10 CFR 74.41. Enclosure 8 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. SHINE requests that the NRC withhold the Enclosure 8, in its entirety, from public disclosure under 10 CFR 2.390.

Enclosure 9 provides a non-public version of the SHINE Emergency Plan, provided in accordance with 10 CFR 50.34(b)(6)(v) and 10 CFR 50, Appendix E. 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 version of the SHINE Emergency Plan.

Enclosure 11 provides the SHINE Supplement to the Environmental Report – Operating License Stage, provided in accordance with 10 CFR 51.53(b). The supplement is provided in lieu of providing an update to Chapter 19 of the SHINE Preliminary Safety Analysis Report.

Enclosure 12 provides the SHINE Licensed Operator Continuing Training Program, provided in accordance with 10 CFR 50.34(b)(8).

Enclosure 13 provides the SHINE Licensed Operator Initial Training Program. While not explicitly required by regulation to support an application for an operating license, SHINE is providing the Licensed Operator Initial Training Program as supplemental information to support the NRC Staff's review of the SHINE operator training and requalification plan.

Enclosure 14 provides the SHINE Quality Assurance Program Description (QAPD), provided in accordance with 10 CFR 50.34(b)(6)(ii).

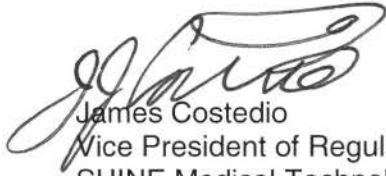
Enclosure 15 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosures 1, 3, 5, 6, 8, and 9, pursuant to 10 CFR 2.390. SHINE requests that the NRC withhold Enclosures 1, 3, 5, 6, 8, and 9 from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1, 3, 5, 6, 8, and 9, this letter is uncontrolled.

SHINE is also submitting the Physical Security Plan under separate cover (Reference 2) in accordance with 10 CFR 73.67(c)(1). The Physical Security Plan, designated as safeguards information (SGI), is submitted under separate cover in accordance with SHINE's NRC-approved SGI protection program.

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 July 17, 2019.

Very truly yours,

A handwritten signature in black ink, appearing to read 'James Costedio', is written over the printed name.

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

Enclosures

cc: Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosures 1, 3, 5, 6, 8, and 9)

ENCLOSURE 15

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE

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 by letter 2019-SMT-0054 with enclosures. SHINE requests that the confidential information contained in Enclosures 1, 3, 5, 6, 8, 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, 6, 8, and 9 of 2019-SMT-0054 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, 6, 8, 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, 6, 8, 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, 6, 8, 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, 6, 8, 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, 6, 8, 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, 6, 8, and 9 of 2019-SMT-0054 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 July 17, 2019.



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