



50-608

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

July 30, 2020

2020-SMT-0062  
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 May 26, 2020 (ML20148M278)
  - (3) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Operating License Application Response to Request for Additional Information," dated June 17, 2020

**SHINE Medical Technologies, LLC Application for an Operating License**  
**SHINE Response to Request for Additional Information 4a-4**

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, Wisconsin 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 responded to a portion of the NRC staff's requests via Reference 3.

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) and export controlled information (ECI) in accordance with 10 CFR 2.390(a)(3).

Enclosure 1 provides the non-public version of the SHINE response to Request for Additional Information (RAI) 4a-4. Enclosure 1 contains proprietary information, a subset of which has been determined to be ECI. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390.

Enclosure 2 provides the public version of the SHINE response to RAI 4a-4.

YGBI  
NRR

Enclosure 1 contains proprietary and export controlled information.  
Withhold from public disclosure under 10 CFR 2.390.  
Upon removal of Enclosure 1 this letter is uncontrolled.

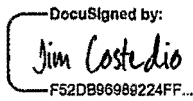
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Enclosure 3 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosure 1, pursuant to 10 CFR 2.390. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390.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

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 30, 2020.

Very truly yours,

DocuSigned by:  
  
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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 Enclosure 1)

**ENCLOSURE 3**

**SHINE MEDICAL TECHNOLOGIES, LLC**

**SHINE MEDICAL TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE  
SHINE RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 4A-4**

**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 response to request for additional information by letter 2020-SMT-0062 with enclosures. SHINE requests that the confidential information contained in Enclosure 1 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 Enclosure 1 of 2020-SMT-0062 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 Enclosure 1 is not available to the public to the best of my knowledge and belief.

- c. The information contained in Enclosure 1 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 Enclosure 1 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 Enclosure 1 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 Enclosure 1 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 Enclosure 1 of 2020-SMT-0062 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 30, 2020.

DocuSigned by:

*Jim Costedio*

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