



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

August 31, 2021

2021-SMT-0095
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, "SHINE Medical Technologies, LLC – Request for Additional Information Related to Accident Analysis, Criticality Safety, and Electrical Power Systems (EPID No. L-2019-NEW-0004)," dated June 2, 2021 (ML21145A060)
 - (3) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License Response to Request for Additional Information," dated July 2, 2021

SHINE Medical Technologies, LLC Application for an Operating License
Response to Request for Additional Information

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 (Reference 1). The NRC staff determined that additional information was required to enable the staff's continued review of the SHINE operating license application (Reference 2). SHINE responded to a portion of the NRC staff's request 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), 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.

Enclosure 1 provides the non-public version of the remaining SHINE responses 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 the public version of the remaining SHINE responses to the NRC staff's request for additional information.

Enclosure 1 contains security-related 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 August 31, 2021.

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)