



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

September 29, 2021

2021-SMT-0125
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 Instrumentation and Control Systems (EPID No. L-2019-NEW-0004)," dated July 1, 2021 (ML21172A195)
 - (3) SHINE Medical Technologies, LLC letter to the NRC, "Application for an Operating License Response to Request for Additional Information," dated August 27, 2021 (ML21239A049)

SHINE Medical Technologies, LLC Application for an Operating License
Supplement No. 8 and 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, 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 SHINE Final Safety Analysis Report (FSAR) Change Summary, identifying changes to the SHINE FSAR not related to the SHINE responses to the NRC staff's request for additional information.

Enclosure 2 provides the non-public version of the remaining SHINE responses to the NRC staff's Reference 2 request for additional information. Enclosure 2 contains proprietary information, a subset of which has been determined to be ECI. SHINE requests that the NRC withhold Enclosure 2 from public disclosure under 10 CFR 2.390.

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Page 2


Enclosure 3 provides the public version of the remaining SHINE responses to the NRC staff's request for additional information.

Enclosure 4 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosure 2, pursuant to 10 CFR 2.390. SHINE requests that the NRC withhold Enclosure 2 from public disclosure under 10 CFR 2.390. Upon removal of Enclosure 2, 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 September 29, 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 2)