



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

July 2, 2021

2021-SMT-0070  
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)

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).

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 the NRC staff's request for additional information. 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 the NRC staff's request for additional information.

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.

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Enclosure 1 provides the SHINE Response to Reference 2 requests for additional information (RAIs), with the exception of RAI CE-1, RAI CE-2, RAI CE-3, RAI CE-4, RAI CE-5, RAI 13-14, RAI 13-15, RAI 13-16, RAI 13-19, RAI 13-20, RAI 13-22, and RAI 13-23. The SHINE Response to these remaining RAIs will be provided by August 31, 2021.

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 2, 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)