



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

September 28, 2021

2021-SMT-0123
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 October 16, 2020
 - (3) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Operating License Application Supplement No. 6 and Response to Request for Additional Information," dated December 15, 2020 (ML21011A264)

SHINE Medical Technologies, LLC Application for an Operating License
Revision 1 of SHINE Response to Request for Additional Information 3.4-12

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 the SHINE operating license application (Reference 2). SHINE provided the response to the NRC staff's request for additional information (RAI) via Reference (3). SHINE has determined that the SHINE Response to RAI 3.4-12, provided via Reference (3), required revision to correct an administrative error.

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 Revision 1 of the SHINE Response to RAI 3.4-12. Revision 1 supersedes the previously provided SHINE Response to RAI 3.4-12, provided via Reference (3), in its entirety. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390.

Enclosure 2 provides the public version of Revision 1 of the SHINE Response to RAI 3.4-12.

Document Control Desk

Page 2

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 September 28, 2021.

Very truly yours,

DocuSigned by:

F52DB96989224FF...

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

Enclosure

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosure 1)