

THIS LETTER CONTAINS SECURITY RELATED INFORMATION **IN ACCORDANCE WITH 10 CFR 2.390**

January 29, 2021 2021-SMT-0008 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) 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 November 10, 2020
 - (4) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Operating License Application Supplement No. 5 and Response to Request for Additional Information," dated December 10, 2020
 - (5) 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

SHINE Medical Technologies, LLC Operating License Application 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 via Reference 1. Via References 2 and 3, 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 References 4 and 5.

This submittal contains security-related information which SHINE requests to be withheld from public disclosure in accordance 10 CFR 2.390(d). Security-related information was identified utilizing the guidance contained in Regulatory Issue Summary (RIS) 2005-31, Revision 1.

Enclosure 1 provides the remaining SHINE responses to the NRC staff's Reference 2 request for additional information.

> Enclosure 2 contains security-related information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosure 2, this letter is uncontrolled.

Document Control Desk Page 2

Enclosure 2 provides a non-public version of the remaining SHINE responses to the NRC staff's Reference 3 request for additional information. Enclosure 2 contains security-related information. SHINE requests that the NRC withhold Enclosure 2 from public disclosure under 10 CFR 2.390.

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

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 January 29, 2021.

Very truly yours,



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