



July 06, 2022

2022-SMT-0076
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 Cyber Security (EPID No. L-2019-NEW-0004)," dated August 13, 2021 (ML21210A438)
 - (3) SHINE Technologies, LLC letter to the NRC, "SHINE Technologies, LLC Application for an Operating License Response to Request for Additional Information," dated November 11, 2021 (ML21315A003)

SHINE Technologies, LLC Application for an Operating License
Revision 1 of the Response to Requests for Additional Information Related to Cyber Security

Pursuant to 10 CFR Part 50.30, SHINE 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 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 the NRC staff's request for additional information (RAI) via Reference 3.

SHINE has determined that the SHINE Responses to RAI CS-1 and RAI CS-2, provided via Reference 3, require revision.

This submittal contains security-related information which SHINE requests to be withheld from public disclosure in accordance with 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 Revision 1 of the SHINE Responses to RAI CS-1 and RAI CS-2. Revision 1 of these responses supersede the previously provided SHINE Responses to RAI CS-1 and RAI CS-2. Enclosure 1 contains security-related information. SHINE requests the NRC withhold Enclosure 1 from public disclosure, in its entirety, under 10 CFR 2.390.

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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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 06, 2022.

Very truly yours,

DocuSigned by:

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James Costedio
Vice President of Regulatory Affairs and Quality
SHINE 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)