



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

September 28, 2022

2022-SMT-0101
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) SHINE Technologies, LLC letter to the NRC, "SHINE Technologies, LLC Application for an Operating License Supplement No. 15, Submittal of the Phased Startup Operations Application Supplement," dated January 27, 2022 (ML22027A353)
 - (3) NRC letter to SHINE Technologies, LLC, "SHINE Medical Technologies, LLC Regulatory Audit Related to Phased Startup Operations Application Supplement, Session 1 (EPID No. L-2022-NEW-0004)," dated August 24, 2022 (ML22061A212)
 - (4) NRC letter to SHINE Technologies, LLC, "SHINE Medical Technologies, LLC Regulatory Audit Related to Phased Startup Operations Application Supplement, Session 2 (EPID No. L-2022-NEW-0004)," dated May 23, 2022 (ML22094A114)

SHINE Technologies, LLC Application for an Operating License Supplement No. 31
Revision to the Phased Startup Operations Application Supplement

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, Wisconsin via Reference 1. On January 27, 2022, SHINE submitted Supplement No. 15 to the application for an operating license describing the SHINE approach to initial facility startup and operations (Reference 2). SHINE has determined that revision is required to the Phased Startup Application Supplement to address gaps identified during regulatory audit interactions with the NRC Staff (References 3 and 4).

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), export controlled information (ECI) in accordance with 10 CFR 2.390(a)(3), and security-related information (SRI) in accordance with 10 CFR 2.390(d). SRI was identified utilizing the guidance contained in Regulatory Issue Summary (RIS) 2005-31, Revision 1.

Enclosure 1 provides the SHINE Phased Startup Operations Application Supplement Change Summary, including a mark-up of affected Phased Startup Operations Application Supplement pages not previously submitted.

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

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Enclosure 2 provides a non-public version of the SHINE Phased Startup Operations Application Supplement. Enclosure 2 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. SHINE requests that the NRC withhold Enclosure 2 from public disclosure under 10 CFR 2.390.

Enclosure 3 provides a public version of the SHINE Phased Startup Operations Application Supplement.

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 28, 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

Enclosures

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