



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

January 27, 2022

2022-SMT-0019
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 Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Overview of Phased Approach to Initial Facility Operations," dated February 26, 2021 (ML21057A340)
 - (3) SHINE Technologies, LLC letter to the NRC, "SHINE Technologies, LLC Operation License Application Supplement No. 12 Submittal of a Revision to the SHINE Supplement to the Environmental Report," dated November 16, 2021 (ML21320A066)
 - (4) SHINE Technologies, LLC letter to the NRC, "SHINE Technologies, LLC Application for an Operating License Supplement No. 14," dated January 26, 2022

SHINE Technologies, LLC Application for an Operating License Supplement No. 15
Submittal of 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. To meet the national need for molybdenum-99 production as soon as possible, while ensuring all requirements to protect public health and safety are met, and to provide flexibility for challenges that may arise during the procurement, installation, and testing of process equipment for the SHINE facility, SHINE has identified the need to pursue a phased approach to initial facility startup and operations. An overview of the SHINE phased approach to initial facility startup and operations was provided via Reference 2.

SHINE has prepared a supplement to the SHINE Final Safety Analysis Report (FSAR) describing the impacts of phased startup operations. The phased startup operations application supplement describes new or different information from the full facility system descriptions and analyses provided in the FSAR resulting from the SHINE phased approach to initial facility startup and operations.

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 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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Enclosure 1 provides the non-public version of the SHINE Phased Startup Operations Application Supplement. Enclosure 1 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. 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 Phased Startup Operations Application Supplement.

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.

SHINE also reviewed the program/plan documents which make up the SHINE operation license application under review by the NRC Staff for impacts from phased startup operations. SHINE determined that the Supplement to the Environmental Report and the Technical Specifications required revision to support phased startup operations, while the Material Control and Accounting Plan, Emergency Plan, Licensed Operator Initial and Continued Training Programs, Quality Assurance Program Description, and Physical Security Plan were not affected by phased startup operations. Those programs/plans not affected will be implemented as described in the program/plan documents currently under review by the NRC Staff. A revision to the SHINE Supplement to the Environmental Report, incorporating phased startup operations considerations, was submitted via Reference 3. A revision to the SHINE Technical Specifications, incorporating phased startup operations considerations, was submitted via Reference 4.

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 27, 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)