



September 19, 2022

2022-SMT-0100
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 electronic mail to SHINE Technologies, LLC, "SHINE Medical Technologies, LLC – Request for Confirmatory Information Related to Phased Startup Operations (EPID No. L-2019-NEW-0004)," dated September 19, 2022

SHINE Technologies, LLC Application for an Operating License
Response to Request for Confirmatory Information

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 (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). The NRC staff determined that confirmatory information was required to enable the staff's continued review of the SHINE operating license application (Reference 3).

Enclosure 1 provides the SHINE responses to the NRC staff's request for confirmatory 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 September 19, 2022.

Very truly yours,

DocuSigned by:

F52DB96989224FF...

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

ENCLOSURE 1

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE RESPONSE TO REQUEST FOR CONFIRMATORY INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff determined that confirmatory information was required (Reference 1) to enable the continued review of the SHINE Technologies, LLC (SHINE) operating license application (Reference 2) and subsequent Supplement No. 15 to the application for an operating license describing the SHINE approach to initial facility startup and operations (Reference 3). The following information is provided by SHINE in response to the NRC staff's request.

RCI 9-1

By letter dated, May 23, 2022 (ML22094A114), the NRC staff issued audit questions to SHINE related to phased startup and operations approach. The NRC staff was seeking to better understand SHINE's approach to safe load handling of heavy loads during phased startup operations. During a review of information made available during the audit, SHINE provided information in response to the NRC staff audit questions 8.a and 8.b.

Confirm that SHINE will implement the guidance in NUREG-0612, "Control of Heavy Loads at Nuclear Power Plants," and safety features defined in FSAR Section 9b.7.2 "Material Handling System," prior to lifting any heavy loads in the IF or RPF after the start of Phase 1 operations through the end of Phase 4 operations.

SHINE Response

SHINE confirms that prior to lifting any heavy loads in the irradiation facility (IF) or radioisotope production facility (RPF) after the start of Phase 1 operations through the end of Phase 4 operations, the guidance in NUREG-0612, "Control of Heavy Loads at Nuclear Power Plants" (Reference 4) and safety features defined in Subsection 9b.7.2 of the FSAR will be implemented.

RCI HFE-1

By letter dated, August 23, 2022 (ML22061A212), the NRC staff issued audit questions to SHINE related to phased startup and operations approach. During an audit discussion on August 25, 2022, SHINE indicated that crane operators will consist of either operations or maintenance personnel and, furthermore, that their training and qualification process will include coverage of both the specific administrative controls and procedures that are associated with crane-related lifting and rigging operations.

Confirm the accuracy of this information regarding the training of crane operators.

SHINE Response

SHINE confirms the information regarding the personnel, qualifications, and training of crane operators is accurate.

References

1. NRC electronic mail to SHINE Technologies, LLC, "SHINE Medical Technologies, LLC – Request for Confirmatory Information Related to Phased Startup Operations (EPID No. L-2019-NEW-0004)," dated September 19, 2022
2. SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)
3. 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)
4. U.S. Nuclear Regulatory Commission, "Control of Heavy Loads at Nuclear Power Plants," NUREG-0612, July 1980