December 22, 2022

2022-SMT-0127
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 electronic mail to SHINE Technologies, LLC, "SHINE Technologies, LLC – Request for Confirmatory Information Related to Final Safety Analysis Report and Technical Specifications Updates (EPID No. L-2019-NEW-0004)," dated December 22, 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). The NRC staff determined that confirmatory information was required to enable the staff's continued review of the SHINE operating license application (Reference 2).

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 December 22, 2022.

Very truly yours,

DocuSigned by:
Jim Costedio
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). The NRC staff requested SHINE confirm the below updates will be made in the next final safety analysis report (FSAR) update and revision of the Technical Specifications. The following information is provided by SHINE in response to the NRC staff's request.

RCI 6b.3-28

Criticality Validation Report FSAR Update

Addition to FSAR Section 6b.3.1.5, "Computational System Validation"

NCS program documentation, evaluations, and calculations are maintained in accordance with the SHINE records management system. Equipment characteristics relied on to maintain NCS limits are identified as NCS controls and are maintained by the SHINE configuration management system.

All non-administrative changes (e.g., factors or methods that would adversely affect the minimum margin of subcriticality or the basis of the minimum margin of subcriticality) to the validation report, as described in FSAR Section 6b.3.1.5, "Computational System Validation," are evaluated under the SHINE nuclear criticality safety program as described in TS 5.5.7, "Nuclear Criticality Safety."

Process or design changes that could affect NCS limits or controls are evaluated using the facility change process requirements of 10 CFR 50.59. Prior to implementing the change, the NCSE is reviewed and updated, if needed, to determine that the entire process will be subcritical under both normal and credible accident scenarios.

SHINE Response

SHINE confirms the requested language will be incorporated into the next FSAR update. SHINE has initiated an Issues Management Report (IMR) to track the requested incorporation.

RCI 13-19

SHINE Safety Analysis (SSA) Control FSAR Update

Addition to FSAR Section 13a2, "Irradiation Facility Accident Analysis"

The SSA also identifies the programmatic administrative controls that are required to be implemented to ensure that safety-related SSCs will be capable of performing their intended functions. Section 5.0 of the technical specifications, Administrative Controls, includes the programmatic administrative controls identified in the SSA (e.g., maintenance of safety-related SSCs) and requires that those programs are established, implemented, and maintained. Section 5.0 additionally requires the development and use of procedures that implement the specific administrative controls identified in the SSA. Section 5.0 also includes discussion of the configuration management program, which provides oversight and control of design information, safety information, and records of modifications that might impact the ability of safety-related SSCs to perform their intended functions.

In the SHINE configuration management program as described in TS 5.5.4, "Configuration Management," SHINE will address:

- *Chemical exposure consequences*
- *Changes that alter any safety-related control (engineered control or SAC) that is the sole safety-related control preventing or mitigating an accident sequence*
- *Changes that remove, without at least an equivalent replacement of safety function, a safety-related control (engineered control or SAC), including changes to its reliability management measures*

The limits to use for evaluation of changes in consequences, likelihoods, and frequencies are the SHINE Safety Criteria in Section 3.1 of the FSAR.

The configuration management program also lists SSA *Summary Report, as updated*-identified controls not otherwise included in Sections 3.0, 4.0, or 5.0 of the technical specifications that will be maintained under the configuration management program and will not be modified as described in the technical specifications without prior NRC approval.

Other Technical Specification Changes

TS 5.5.4, "Configuration Management" – Table 5.5.4

- Criticality Safety: Engineered controls *and specific administrative controls* are identified in the criticality safety evaluations to prevent criticality in the SHINE facility, excluding the TSVs.
- Isotope Production System (1st line): The target solution staging system (TSSS) process tanks are seismically qualified *to maintain their pressure boundary integrity*.

SHINE Response

SHINE confirms the requested language will be incorporated into the next FSAR update and revision of the Technical Specifications. SHINE has initiated an IMR to track the requested incorporation.

References

1. NRC electronic mail to SHINE Technologies, LLC, “SHINE Technologies, LLC – Request for Confirmatory Information Related to Final Safety Analysis Report and Technical Specifications Updates (EPID No. L-2019-NEW-0004),” dated December 22, 2022

2. SHINE Medical Technologies, LLC letter to the NRC, “SHINE Medical Technologies, LLC Application for an Operating License,” dated July 17, 2019 (ML19211C143)