

From: [Holly Cruz](#)
To: [Jeffrey Bartelme](#)
Cc: [Josh Borromeo](#); [Michael Balazik](#)
Subject: RCI for FSAR and TS updates
Date: Thursday, December 22, 2022 11:43:00 AM

Dr. Gregory Piefer, Chief Executive Officer
SHINE Technologies,
LLC 3400 Innovation Court
Janesville, WI 53546

SUBJECT: SHINE TECHNOLOGIES, LLC - REQUEST FOR CONFIRMATORY INFORMATION RELATED TO FINAL SAFETY ANALYSIS REPORT AND TECHNICAL SPECIFICATIONS UPDATES (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System Accession No. ML19211C044), as supplemented, SHINE Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which confirmatory information is needed. The enclosed request for confirmatory information (RCI) identifies information needed for clarity in the specific technical areas of Chapter 6, "Engineered Safety Features", Chapter 13, "Accident Analysis", and Technical Specifications.

It is requested that SHINE provide responses to the enclosed RCI within 30 days from the date of this letter. For clarity, please confirm the below updates will be made in the next final safety analysis report (FSAR) update and revision of the Technical Specifications. To facilitate a timely and complete response to the enclosed RCI, the NRC staff is available to meet with SHINE to clarify the scope of information and level of detail expected to be included in the RCI response. SHINE may coordinate the scheduling and agendas for any such meetings with the responsible project manager assigned to this project.

In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Following receipt of the confirmatory information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE's operating license application, additional RCIs for other chapters and technical areas may be developed. The NRC staff will

transmit any further questions to SHINE under separate correspondence.

If SHINE has any questions, or needs additional time to respond to this request, please contact me at 301-415-2856, or by electronic mail at Holly.Cuz@nrc.gov.

OFFICE OF NUCLEAR REACTOR REGULATION
REQUEST FOR CONFIRMATORY INFORMATION
REGARDING OPERATING LICENSE APPLICATION FOR
SHINE TECHNOLOGIES, LLC
CONSTRUCTION PERMIT NO. CPMIF-001
SHINE MEDICAL ISOTOPE PRODUCTION FACILITY
DOCKET NO. 50-608

By letter dated July 17, 2019 (Agencywide Documents Access and Management System Accession No. ML19211C044), as supplemented, SHINE Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which confirmatory information is needed. The enclosed request for confirmatory information (RCI) identifies information needed for clarity in the specific technical areas of:

- Chapter 6, "Engineered Safety Features,"
- Chapter 13, "Accident Analysis," and
- Technical Specifications

For clarity, please confirm the below updates will be made in the next final safety analysis report (FSAR) update and revision of the Technical Specifications.

Applicable Regulatory Requirements and Guidance Documents

Section 50.34, "Contents of applications; technical information," paragraph (b) of 10 CFR states, in part, that "[t]he final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole." Section 50.34, subparagraph (b)(4) of 10 CFR states, in part, that final analysis and evaluation of the design and performance of structures, systems, and components with the

objective stated in paragraph (a)(4) of this section and taking into account any pertinent information developed since the submittal of the preliminary safety analysis report.

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.

RCI 13-10 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 Systems (1st line): The target solution staging system (TSSS) process tanks are seismically qualified *to maintain their pressure boundary integrity*.

Thanks,

Holly

Holly Cruz, Senior Project Manager
Non-power Production and Utilization Facility Licensing Branch (UNPL)
Division of Advanced Reactors and Non-power Production and Utilization Facilities
Office of Nuclear Reactor Regulation, USNRC
Phone: (301) 415-1053
Location: O-6A56; M/S: O-6A51
email: holly.cruz@nrc.gov