UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

December 15, 2022

The Honorable Christopher T. Hanson
Chair
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: REPORT ON THE SAFETY ASPECTS OF THE SHINE MEDICAL TECHNOLOGIES, LLC, OPERATING LICENSE APPLICATION REVIEW

Dear Chair Hanson:

During the 701st meeting of the Advisory Committee on Reactor Safeguards (ACRS), November 29 – December 2, 2022, we completed our review of the SHINE Technologies, LLC (SHINE or the applicant), operating license (OL) application for its Medical Isotope Production Facility and the staff's associated Safety Evaluation Report (SER) with no open items.

During our review, we had the benefit of interactions with representatives of the Nuclear Regulatory Commission staff and the applicant. This included a visit to the SHINE construction site in Janesville, Wisconsin, in August 2022. We also benefited from the documents referenced. Appendix I lists the chronology of Full Committee and Subcommittee meetings on this topic. Appendix II contains the list of our memoranda on SER chapter reviews. This letter report fulfills the ACRS review requirement in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards."

CONCLUSION AND RECOMMENDATION

1. The staff SER provides a comprehensive review of important safety aspects of the design and operation of the SHINE facility.

2. The OL for the SHINE Medical Isotope Production Facility should be issued.

BACKGROUND

When operational, the SHINE Medical Isotope Production Facility will provide a domestic, reliable supply of molybdenum-99 (Mo-99) for medical applications. Not utilizing highly enriched uranium for medical isotope production supports U.S. national security interests and nuclear non-proliferation policy objectives.

Facility Description

SHINE submitted an OL application for the SHINE Medical Isotope Production Facility to produce Mo-99 in accordance with the requirements contained in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," on July 17, 2019. The facility would be licensed as a non-power utilization and production facility (NPUF), as defined in 10 CFR 50.2, "Definitions." Issuance of the OL would authorize SHINE to operate this facility for 30 years. The facility includes an irradiation facility and a radioisotope production facility. The irradiation facility consists of eight subcritical operating assemblies (or irradiation units). The radioisotope production facility consists of hot cell structures for the processing of the irradiated solution.

The Mo-99 production process begins in an irradiation unit where accelerator-driven deuterons bombard tritium gas to create a fusion reaction, producing neutrons. This neutron flux is enhanced by a neutron multiplier and induces fission in the low-enriched uranyl sulfate target solution, creating Mo-99 as a byproduct. The Mo-99 is extracted and purified in the radioisotope production facility.

Construction Permit Application

During the 628th meeting of the ACRS, October 7 - 10, 2015, we reviewed the construction permit (CP) application for the SHINE Medical Isotope Production Facility. After completing our review, we recommended the CP for this facility be approved. The SHINE CP was issued on February 29, 2016, and construction commenced in September 2019.

During the OL review, the applicant proposed a "phased approach" that allows operation of some irradiation units while the remaining units were being installed. The staff determined that this approach did not pose an impact to safety. We concur.

Operating License Review Approach

We conducted our review of the Final Safety Analysis Report (FSAR) and draft SER with no open items on a chapter-by-chapter basis. Individual members were assigned chapters or topics for detailed technical review. The entire SHINE Subcommittee participated in chapter briefings with the staff and applicant. The cognizant member summarized findings in a memorandum reflecting subsequent Full Committee deliberation. This approach provided a comprehensive, in-depth review of the SHINE submittal. The overall process significantly reduced the number of presentations required of the staff and applicant for our review.

Our review identified a number of items not thoroughly addressed in the initial FSAR and SER. Concerns relative to the OL were resolved during subsequent meetings. Beyond that, the Appendix II memoranda expand upon several other noteworthy points, including:

- The importance of human factors and actions in the conduct of operations of an irradiation and radioisotope production facility

- Coordination with local community resources to respond to low-frequency hazards (e.g., fire, chemical, and aircraft impact)

- Broadening of cyber security assessments to all critical digital assets required for mission critical system operation

DISCUSSION

The staff review followed NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Parts 1 and 2, supplemented by guidance in the associated Interim Staff Guidance document. In our review of this first-of-a-kind facility, we identified the following three noteworthy attributes that characterize the innovativeness of the design and the completeness of this application.

SHINE Safety Characteristics

The SHINE facility incorporates several important safety features. The low power density irradiation units are designed to automatically shut down the irradiation process and place the target solution into a safe stable passively cooled condition without immediate operator actions. Criticality during the dissolving and filling processes is largely precluded by the engineering design. Additionally, critically safe vessels or double contingency controls are used for fissile solutions in the production facility.

SHINE Safety Analysis Approach

Using common hazard evaluation methods, such as Hazard and Operability Analysis and Failure Modes and Effects Analysis, the SHINE Safety Analysis (SSA) methodology provides a systematic approach to identify, evaluate, and group credible accident sequences. Both internal and external events were considered. Results were ranked using a risk matrix. Design Basis Accidents (DBAs) were identified as those events with maximum consequences for each accident sequence grouping. The DBAs were used to identify those structures, systems, and components (SSCs) and procedural controls required to prevent unacceptable consequences. As a result, these SSCs are categorized as safety-related.

SHINE hazard analysis documents were not provided on the docket but were made available to us. These documents are thorough, well structured, and reflect an in-depth, systematic approach for the selection of DBAs used in accident analyses. The applicant did not rely on pre-conceived notions or tabulated lists to identify DBAs, satisfying our generic concern about licensing basis event identification.

SHINE used the concept of maximum hypothetical accident (MHA) to demonstrate compliance with acceptable limits for both radiological and chemical consequences. SHINE's evaluation indicates that the MHA is a large break in the top of the Target Solution Vessel Off-gas System which allows all radioactive gases to escape into the confinement. Consequences of exposure to facility staff and the public were evaluated to be within regulatory acceptance criteria. The DBA analysis identified that the limiting accident not involving the irradiation facility is a tritium purification system failure; this accident results in consequences similar to those of the MHA (and within the acceptance criteria).

Our review also explored the adequacy of assumed sensor response times to mitigate accident sequences because they affect the margins for proposed setpoints. In response to our questions and an audit completed by the staff, the applicant revised the FSAR to explicitly list

these response times. Subsequently, the staff completed independent evaluations of the associated margins. The additional input from SHINE and the staff addressed our concerns.

Technical Specifications Justifications

SHINE's proposed Technical Specifications (TSs) address relevant safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation (LCOs), and surveillance requirements (SRs). The staff assessed these TSs as well as design features that affect SSC function, availability, or reliability, and administrative controls to ensure their required availability.

The processes associated with SHINE isotope production include several interrelated irradiation and chemical processes that must be controlled by TSs. A key example of this is the prevention of uranyl peroxide precipitation. Uranyl peroxide can form and precipitate from the target solution if the concentration exceeds the temperature dependent solubility limit. The equilibrium uranyl peroxide concentration and precipitation limit are functions of temperature (power), uranium concentration, pH, and catalyst concentration.

The applicant provided extensive details related to the basis for the TSs for each of the LCOs and the SRs related to uranyl peroxide precipitation. We find the bases for these LCOs and SRs to be extremely detailed and easy to follow.

SUMMARY

The staff SER provides a comprehensive review of important safety aspects of the design and operation of the SHINE facility. The OL for the SHINE Medical Isotope Production Facility should be issued.

Sincerely,

Signed by Rempe, Joy
on 12/15/22

Joy L. Rempe
Chairman ACRS

APPENDICES:
Appendix I: Chronology of the ACRS Review of the SHINE, LLC, Operating License Application

Appendix II: Lead Member Memoranda on SER Chapters with no Open Items, SHINE Medical Technologies, LLC, Operating License Application

REFERENCES

1. SHINE Medical Technologies, LLC, “Application for an Operating License,” July 17, 2019 (ML19211C143).

2. SHINE Medical Technologies, LLC, “General and Financial Information,” Enclosure 2, July 17, 2019 (ML19211C089).

3. SHINE Medical Technologies, LLC, “Overview of Phased Approach to Initial Facility Operations,” February 26, 2021 (ML21057A340).

4. SHINE Medical Technologies, LLC, “Final Safety Analysis Report, Application for an Operating License, Supplement No. 30,” August 31, 2022 (ML22249A148).

5. SHINE Technologies, LLC, “Application for an Operating License Supplement No. 15, Submittal of the Phased Startup Operations Application Supplement,” January 27, 2022 (ML22027A353).

6. SHINE Technologies, LLC, “Application for an Operating License Supplement No. 31, Revision to the Phased Startup Operations Application Supplement,” September 28, 2022 (ML22271A962).

7. United States Nuclear Regulatory Commission, Safety Evaluation Report for SHINE Technologies, LLC, Operating License Application, November 29, 2022 (ML22314A132).

8. Advisory Committee on Reactor Safeguards, “Report on the Safety Aspects of the Construction Permit Application for SHINE Medical Technologies, Inc. Medical Isotope Production Facility,” October 15, 2015 (ML15286A426).

9. NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 28, 1996 (ML042430055).

10. NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 29, 1996 (ML042430048).

11. “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ML12156A069).

12. “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ML12156A075).

APPENDIX I

Chronology of the ACRS Review of the SHINE Medical Technologies, LLC, Operating License Application

The following table lists ACRS interactions on the SHINE Operating Licensing Application Review

Subcommittee (SC)/Full Committee (FC) Meetings	**Date**	**Subject**	**Transcript ML#**
Non-power production or utilization facility (NPUF) Subcommittee (SC)	October 22, 2020	NPUF Subcommittee Review Approach	ML20339A634
NPUF SC	November 4, 2020	Overview of SHINE Medical Isotope Production Facility	ML20345A277
NPUF SC	January 12, 2021	NPUF Subcommittee Review Approach	ML21055A548
NPUF SC	February 16, 2022	Overview of SHINE Medical Isotope Production Facility and Phased Approach	ML22060A150
NPUF SC	March 17, 2022	Chapters 1, 2, 4, 5, & 6	ML22095A053
694th ACRS FULL COMMITTEE (FC)	April 6-8, 2022	Review of memorandums for Chapters 2, 4, 5, & 6	N/A[1]
SHINE SC (previously the NPUF SC)	May 6, 2022	Chapters 3, 8, 9 & 11	ML22158A263
SHINE SC	May 17-18, 2022	Chapter 6, Section 6b.3, Chapter 12, Section 12.7, Chapter 12, Section 12.13 & Chapter 13	ML22172A022 ML22172A025
696th ACRS FC	June 1, 2022	Review of memorandums for Chapters 1, 2, 4, 5, & 6	N/A
SHINE SC	June 21, 2022	Review of technical issues identified in memorandums for Chapters 4, 8, 9, 11, 12.7, 12.13, & 13	ML22193A110
SHINE SC	July 19-20, 2022	Chapter 3, Section 3.1 (Design Criteria), Chapter 7 (Instrumentation and Control Systems), Chapter 9, Section 9a.3 (Fire Protection), Chapter 12, Section 7.9 (Human Factors Engineering), Chapter 12, Section 12.10 (Operator Training/Requalification) & Chapter 12, Section 12.11 (Startup Plan)	ML22243A210 ML22243A217

[1] Transcription does not exist. Committee deliberations are reflected in the associated review memorandum. See Appendix II of this letter report.

698th ACRS FC	September 7, 2022	Review of memorandums for Chapter 3, Section 3.1 (Design Criteria), Chapter 9, Section 9a.3 (Fire Protection), Chapter 12, Section 7.9 (Human Factors Engineering), Chapter 12, Section 12.10 (Operator Training/Requalification) & Chapter 12, Section 12.11 (Startup Plan)	ML22278A065
698th ACRS FC	September 9, 2022	Chapter 14, Technical Specifications, Cybersecurity, & Programmable Lifecycle Overview.	ML22278A068
SHINE SC	October 21, 2022	Chapter 7, Section 7.4.3 (Process Integrated Systems) & Phased Startup Operations	ML22334A138
SHINE SC	November 15, 2022	Review of memorandums for Chapters 7, 14, Cybersecurity, & Programmable Lifecycle Overview and discussion of Draft Final Letter Report.	N/A
701st ACRS FC	November 29 – December 2, 2022	Report on the Safety Aspects of the SHINE Medical Technologies, LLC, Operating License Application Review	ML22348A105

APPENDIX II

Lead Member Memoranda on SER Chapters with no Open Items
SHINE Medical Technologies, LLC, Operating License Application

Subject	Date	ADAMS Accession Number
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 2, "Site Characteristics"	April 29, 2022	ML22111A049
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 3, "Design of Structures, Systems, & Components"	September 26, 2022	ML22258A308
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 4, "Facility Description"	April 27, 2022	ML22111A143
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 5, "Cooling Systems"	April 27, 2022	ML22111A169
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 6, "Engineered Safety Features"	May 4, 2022	ML22111A177
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 6, "Engineered Safety Features," Section 6B.3, "Criticality Safety"	July 8, 2022	ML22175A188
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 7, "Instrumentation and Control Systems"	November 16, 2022	ML22319A217
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 7, "Instruments & Control Systems," Section 7.4.9, "Human Factors Engineering"	September 26, 2022	ML22258A305
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 8, "Electrical Power Systems"	July 12, 2022	ML22175A192
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 9, "Auxiliary Systems"	July 11, 2022	ML22164A915
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 9, "Auxiliary Systems," Section 9A.2.3, "Fire Protection Systems & Programs"	September 23, 2022	ML22258A307

Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 11, “Radiation Protection Program and Waste Management”	July 12, 2022	ML22164A913
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 12, “Conduct of Operations (Operator Training and Requalification, and Startup Plan)”	September 27, 2022	ML22258A310
Input for ACRS Review of SHINE Operating License Application – Safety Evaluation Report for Chapter 12, “Conduct of Operations,” Section 12.4.14, “Cybersecurity”	November 17, 2022	ML22321A191
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 12, “Conduct of Operations,” Section 12.7, “Emergency Plan”	July 11, 2022	ML22164A914
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 12, “Conduct of Operations,” Section 12.13, “Material Control and Accountability”	July 8, 2022	ML22164A917
Input for ACRS Review of SHINE Operating License – Safety Evaluation for Chapter 13, “Accident Analysis”	July 8, 2022	ML22175A182
Input for ACRS Review of SHINE Operating License Application – Software Life Cycle	November 16, 2022	ML22321A210
Input for ACRS Review of SHINE Operating License Application – Safety Evaluation Report for Chapter 14, “Technical Specifications”	November 17, 2022	ML22321A139

December 15, 2022

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