



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

September 27, 2022

MEMORANDUM TO: Ronald G. Ballinger, Lead
SHINE License Application Review Subcommittee
Advisory Committee on Reactor Safeguards

FROM: Matthew W. Sunseri, Member
Advisory Committee on Reactor Safeguards

SUBJECT: INPUT FOR ACRS REVIEW OF SHINE OPERATING LICENSE APPLICATION – SAFETY EVALUATION REPORT FOR CHAPTER 12, “CONDUCT OF OPERATIONS (OPERATOR TRAINING AND REQUALIFICATION, AND STARTUP PLAN)”

Matthew W. Sunseri
Digitally signed by Matthew W. Sunseri
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In response to the Subcommittee’s request, I have reviewed the Nuclear Regulatory Commission (NRC) staff’s safety evaluation report (SER) with no open items, and the associated section of the applicant’s final safety analysis report (FSAR), for Chapter 12, “Conduct of Operations.” In addition, representatives from SHINE Medical Technologies, LLC (SHINE) met with the SHINE subcommittee on July 19-20, 2022, to discuss conduct of operations. The following is my recommended course of action concerning further review of this chapter and the staff’s associated safety evaluation.

Background

The SER documents the staff’s review of the final design of SHINE’s conduct of operations as presented in FSAR Chapter 12 and supplemented by the applicant’s responses to staff requests for additional information. Specifically, Chapter 12 includes: organization structure, responsibilities, staffing and selection and training of personnel. This discussion is included in SHINE FSAR Sections; Review and Audit activities; Procedures; Required Actions; Reports; Records; Emergency Planning; Security Planning; Quality Assurance (QA); Operator Training and Requalification; Startup Plan; and Material Control and Accounting Plan. Separate committee memoranda have been prepared for Emergency Planning and Material Control and Accounting Plan. Security Planning is outside the scope of our review.

Summary

Organization

The organization structure provides for the appropriate level of accountability for the control of radioactive material and radiation safety. A “nuclear safety program” is discussed with appropriate lines of accountability. The quality assurance organization has sufficient independence from production activities. Although the quality assurance organization is described sufficiently, the function does not get high visibility on the corporate organization chart. When SHINE was asked, they reported that the reporting lines are prescribed in the QA

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program document. A review of the QA program has the QA manager listed as a position on an organization chart that is buried in an enclosure. Even then, the indirect reporting channel to the Chief Executive Officer (CEO) was not indicated. Having the QA organization prominently displayed on organization charts sends a message to the entire organization of the importance of this function. Lack of visibility potentially diminishes the role of QA.

Review and Audit

The review and audit functions are described with sufficient lines of accountability to provide for oversight of plant operations including the review and approval of procedures.

Procedures

SHINE proposes a set of activities and operations that will be covered by written procedures in accordance with the quality assurance program. The proposed list is commensurate with the scope of activities for operation of the plant.

Required Actions

SHINE proposes a set of required actions in the event of a safety limit violation and other occurrences requiring special reports per technical specifications. These actions are appropriate for the SHINE facility.

Reports

SHINE proposes an annual report to the NRC covering operations of the facility and other special reports as noted above under Required Actions. The reports are appropriate for the type of activities conducted at the facility.

Records

SHINE's conduct of operations provides for a records management program that includes the identification, generation, authentication, maintenance, and disposition of records appropriate for facility operation.

Quality Assurance

SHINE has prepared and implemented a quality assurance program consistent with ANSI/ANS 15.8-1995 and Regulatory Guide 2.5, revision 1. The program parallels Title 10 of the *Code of Federal Regulations* (10 CFR Part 50) Appendix B and NQA-1.

Operator Training and Requalification

SHINE has created an initial operator training program that conforms with 10 CFR Part 55 as it pertains to non-production facilities and ANSI/ANS 15.4-2016 for research reactors. This program, while not stated as such, appears to follow a systems approach to training that is consistent with good industry standards.

SHINE has created a requalification program in accordance with 10 CFR 55.59 designed to maintain knowledge, skills and proficiency of licensed operators. The program provides an appropriate requalification cycle of two years and follows a systems approach to training consistent with good industry standards.

Startup Plan

The startup program is important because it validates the plant design, validates the construction of the plant to the design, provides an opportunity to exercise newly developed operational procedures, and identifies weaknesses or problems with the design before radioactive material is introduced or created. An effective startup program is a necessary element to ensure the safety of the plant. A detailed startup plan is particularly important for a first of a kind facility such as SHINE.

No formal startup plan was available for review. The applicant summarized several important elements and systems that they expect to perform and test. It is understood that the scope of the SHINE facility is not as large as a commercial nuclear power plant; however, a rigorous, comprehensive and coordinated set of testing activities assembled into a complete startup plan would be beneficial to validate design and construction of the plant. Typical phases of a startup plan are prerequisite testing, system and component level testing and integrated testing. During the prerequisite phase, wiring continuity testing, system flushing, and instrument calibrations are called out and conducted. The system and component level testing phase normally includes functional testing of the systems and components against their design specifications and performance level testing in accordance with technical specifications for the plant conditions that are available. The integrated testing phase is conducted to ensure that, as much as possible prior to introducing radioactive material, the plant is tested to ensure the systems work together properly.

Regulatory Guide 1.68, although not applicable to the SHINE facility, provides a good bases for an initial testing program.

Staff acknowledges the actual startup activities referenced by the high-level discussion of the SHINE initial test program will need careful oversight during initial operation of the plant. Staff has plans for a few inspections to validate the effectiveness of the startup program. I would emphasize that these inspections will need careful development and oversight to ensure they are adequate compensation for the less detailed startup plan used for the license decision.

The activities described by the FSAR, staff's SER and presentations made by staff and applicant are appropriate and necessary. It is not possible to draw a conclusion on the quality of the initial startup program without a formal documented startup plan.

Concerns

During review of documents and presentations by SHINE, the QA function is not very visible. Having the QA organization prominently displayed on organization charts sends a message to the entire organization of the importance of this function. Lack of visibility potentially diminishes the role of QA.

No formal startup plan was available for review. The startup plan activities described by the FSAR, staff's SER and presentations made by staff and applicant are appropriate and necessary. It is not possible to draw a conclusion on the quality of the initial startup program without a formal documented startup plan. It is likely that a well-developed startup program will be developed as construction progresses to a more complete state. Staff will need to carefully develop their startup inspections to ensure the inspections are adequate compensation for the high-level startup plan accepted for the license decision. I recommend that this item be included in the final letter report on the SHINE application.

I did not identify any other specific deficiencies in my review. I observe that, except for the startup plan information discussed above, the application was well documented, and the staff's evaluation thorough.

Recommendation

As lead reviewer for SHINE Chapter 12, "Conduct of Operations," review, I recommend that no further review of conduct of operations is necessary.

References

1. U.S. Nuclear Regulatory Commission, "Conduct of Operations," Chapter 12, Staff Safety Evaluation Report, July 12, 2022 (ML22193A279).
2. U.S. Nuclear Regulatory Commission, "Startup Plan," Chapter 12, Section 12.11, Staff Safety Evaluation Report, July 12, 2022 (ML22193A280).
3. U.S. Nuclear Regulatory Commission, "Operator training and Requalification," Chapter 12, Section 12.4.10, Staff Safety Evaluation Report, July 12, 2022 (ML22199A008).
4. SHINE Medical Technologies, LLC, Application for an Operating License, "Licensed Operator Continuing Training Program," Revision 2, December 16, 2021 (ML21350A191).
5. SHINE Medical Technologies, LLC, Application for an Operating License Supplement 14, Revision to Final Safety Analysis Report, Chapter 12, "Conduct of Operations," January 26, 2022 (ML22034A626).
6. U.S. Regulatory Commission, Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research and Test Reactors, Revision 1," June 30, 2010 (ML093520099).
7. U.S. Regulatory Commission, Regulatory Guide 1.68, "Initial Test Programs for Water-Cooled Nuclear Power Plants, Revision 4," May 31, 2013 (ML13051A027).
8. American Nuclear Society, ANSI/ANS 15.8-1995, "Quality Assurance Program Requirements for Research Reactors," reaffirmed September 2005.
9. American Nuclear Society, ANSI/ANS15.4-2016, "Selection and Training of Personnel for Research Reactors," April 19, 2016.

10. Title 10 of the *Code of Federal Regulations* (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities, Appendix B to Part 50 - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants Appendix B to Part 50 - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," January 1, 2002.

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