



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

November 17, 2022

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

FROM: Ronald Ballinger, Lead *R. G. Ballinger*
Advisory Committee on Reactor Safeguards

SUBJECT: INPUT FOR ACRS REVIEW OF SHINE OPERATING LICENSE
APPLICATION – SAFETY EVALUATION REPORT FOR
CHAPTER 14, “TECHNICAL SPECIFICATIONS”

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 14, “Technical Specifications.” In addition, representatives from SHINE Medical Technologies, LLC (SHINE), met with the Advisory Committee on Reactor Safeguards on September 9, 2022, to discuss this chapter. The following is my recommended course of action concerning further review of this chapter and the staff’s associated SER.

Background

The purpose of the technical specifications (TS) is to specify design specifications and limits to maintain system performance and safe operation. Limiting or enveloping conditions of design and operation ensure the safety of the public, the facility staff, and the environment. TSs are derived from the analyses and evaluation included in a facility’s FSAR.

From the SER:

Chapter 14 of the SHINE operating license application SER describes the review and evaluation of the NRC staff of the proposed TSs for the SHINE irradiation facility (IF) and radioisotope production facility (RPF), as presented in Chapter 14, “Technical Specifications,” of the SHINE FSAR and in SHINE’s proposed TSs and supplemented by the applicant’s response to the staff’s requests for additional information.

The regulatory basis for the review included the following regulatory requirements:

- 10 CFR 50.34, “Contents of applications; technical information”
- 10 CFR 50.36, “Technical specifications”
- 10 CFR 50.40, “Common standards”
- 10 CFR 50.57, “Issuance of operating license”

The guidance and acceptance criteria for the review were as follows:

NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content."

NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria."

Final Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 1 and Part 2, for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors.

ANSI/ANS-15.1-2007 (R2013), "The Devolvement of Technical Specifications for Research Reactors."

NUREG-1431, "Standard Technical Specifications – Westinghouse Plants, Volume 1."

SER Summary

Chapter 14 is organized in the following sections:

Section 1: Introduction

Section 2: Safety Limits and Limiting Safety System Settings

Section 3: Limiting Conditions for Operation and Surveillance Requirements

Section 4: Design Features

Section 5: Administrative Controls

The specific areas of review for this chapter were those TSs proposed for the SHINE irradiation facility (IF) and the radioisotope production facility (RPF). The NRC staff assessed whether SHINE's proposed TSs, including relevant safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation, surveillance requirements, design features that affect the function, availability, or reliability of structures, systems, or components (SSCs), and administrative controls would ensure the availability of SSCs.

It should be noted that the current version of the SER did not include a review of TS Section 3.2, "Instrumentation and Control Safety Systems," that was associated with digital instrumentation and controls. This review was conducted and reported in the review of Chapter 7, "Instrumentation and Control Systems."

Based on the above determinations, the staff found that the descriptions and discussions are sufficient and meet the applicable regulatory requirements, guidance, and acceptance criteria, for the issuance of an operating license.

In addition to a complete general review of both the SER as well as Chapter 14 of the FSAR, the author specifically focused on Section 3 of the FSAR. This section provided extensive details related to the basis for the TSs related to the basis for each of the limiting conditions for operation (LCOs) and the surveillance requirements (SRs). The reviewer found the bases for the LCOs and SRs to be extremely detailed and easy to follow. The results of this review provided additional confidence that the SHINE facility will be operated.

Recommendation

As lead reviewer for SHINE Chapter 14, "Technical Specifications," I did not identify any specific deficiencies not meeting requirements of the review criteria.

Concerns

I did not identify any concerns.

References

1. U.S. Nuclear Regulatory Commission, "Technical Specifications," Chapter 14, Staff Safety Evaluation Report, September 6, 2022 (ML22249A326).
2. SHINE Medical Technologies, LLC, Application for an Operating License Supplement 14, Revision to Final Safety Analysis Report, Chapter 14, "Technical Specifications," January 26, 2022 (ML22034A647).
3. SHINE Medical Technologies, LLC, Final Safety Analysis Report, Chapter 14, Revision 0, "Technical Specifications," August 31, 2022 (ML22249A134).
4. U.S. Nuclear Regulatory Commission, SHINE Medical Technologies, LLC Regulatory Report on Audit of Chapter 14, "Technical Specifications," Described in Operating License Application (EPID No. L-2019-New-0004), September 12, 2022 (ML22227A200).
5. NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," February 1996 (ML042430055).
6. NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," February 1996 (ML042430048).
7. NUREG-1537, "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," October 17, 2012 (ML12156A069).
8. NUREG-1537, "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, '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," October 17, 2012 (ML12156A075).
9. ANSI/ANS-15.1-2007 (Reaffirmed 2013), "The Devolvement of Technical Specifications for Research Reactors," April 24, 2013.
10. NUREG-1431, "Standard Technical Specifications, "Westinghouse Plants"," Volume 1, Revision 5, September 30, 2021 (ML21259A155).

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