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

April 27, 2022

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

FROM: Joy L. Rempe, Chairman
Advisory Committee on Reactor Safeguards

Joy L. Rempe Digitally signed by Joy L. Rempe Date: 2022.04.27 21:12:45 -04'00'

SUBJECT: INPUT FOR ACRS REVIEW OF OPERATING LICENSE – SAFETY EVALUATION FOR SHINE CHAPTER 4, "FACILITY DESCRIPTION"

In response to the Subcommittee's request, I reviewed the NRC staff's safety evaluation report (SER) with no open items for Chapter 4, "Facility Description" of the SHINE Final Safety Analysis Report (FSAR). The following is my recommended course of action concerning further review of this chapter and the staff's associated SER.

Background

Chapter 4 describes the SHINE facility, including its principal design features and characteristics as well as associated operating parameters for performing irradiations and radioisotope production. As part of their Chapter 4 review, the staff issued several Requests for Additional Information (RAIs).

The staff reviewed major structures, systems, and components (SSC) of the irradiation facility (IF), such as its neutron driver assembly system, the subcritical assembly system (SCAS), heat removal systems (the primary closed loop cooling system and light water pool), target solution vessel (TSV) off-gas system, and irradiation cell biological shielding. Of special interest were the nuclear and thermal hydraulic design and transient response of uranium-solutions within the SCAS and TSV. In their review of the radioisotope production facility (RPF), the staff considered SSCs for various processes, such as activities to receive and store source materials; to prepare the target solution; to extract, purify, and package molybdenum, iodine and xenon isotopes; and to process and store radioactive wastes. The staff review considered applicable Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 and Part 20 requirements, NUREG-1537 guidelines, interim staff guidance (ISG) augmenting NUREG-1537, and relevant industry standards. This guidance emphasizes that the FSAR must present the facility design bases and functions of the SSCs in sufficient detail to allow a clear understanding that the facility can be operated for its intended purpose within applicable regulatory limits. The guidance also states that the staff should consider items such as: the application relies on validated methods; the analyses are complete; and the assumptions are justified and consistent.

SER Summary

The staff found the FSAR Chapter 4 descriptions and discussions sufficient to conclude that SHINE meets the applicable regulatory requirements for the issuance of an operating license. Staff also found that the design bases and functions of the systems and components were presented in sufficient detail to assess that the RPF can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the operating staff and the public. Drawings and diagrams were provided to allow a clear and general understanding of the physical RPF features and of the processes involved. The SER notes that staff found much of the FSAR Chapter 4 information to be "descriptive in nature," serving as "background for more detailed descriptions and evaluations for later sections of the application." Hence, the staff review focused on ensuring Chapter 4 information was consistent with information found in other chapters of the FSAR and other information available in the literature. For example, FSAR Section 4b.1 contains a general description of the design basis and implementation of any critical safety features. The SER notes that the staff evaluation of the criticality safety program is found in Chapter 6 of the SER. Likewise, staff evaluations of engineered safety features, the adequacy of shielding materials, and the chemical safety programs are found in Chapter 13 of the SER. SHINE provided additional information in response to staff RAIs. In several cases, such as RAI 4a-15 regarding the facility description and RAI 4a-4 regarding the potential for fuel precipitation, staff RAIs led to changes in the SHINE Chapter 4 FSAR.

Concerns

Although the staff review was appropriate for this chapter, members raised several questions that we plan to address in subsequent chapter reviews for this application. During our discussions, we requested additional information related to the following items:

- *The methods the staff used to confirm that instrumentation setpoints (and calibration) are adequate to detect and notify operators of required actions to prevent adverse conditions (e.g., overheating, hydrogen buildup, and increases in reactivity)*. The FSAR indicates calibration of some detectors (TSV flux detectors, TSV level indicators, combustible gas management system hydrogen and oxygen concentration monitors, etc.) will be verified during startup and operation. We request information to clarify how staff verified the adequacy of proposed safety margins. Furthermore, we are interested in how staff addressed detector calibration before the first startup and detector aging issues.

- *The methods staff used to confirm the adequacy of the design's transient and accident response.* Although staff considered experience with aqueous homogenous reactors in their evaluation, it is not clear what methods the staff used to confirm results provided by the applicant and how the staff approach considered the limited amount of long-duration commercial operating experience with such facilities. It is also not clear what methods the staff used to confirm the quality assurance associated with experimental correlations used to support transient analyses.

- *The methods staff used to evaluate the process SHINE will use to verify void, power, and temperature coefficients with varying solution concentrations*. Given the limited experience with subcritical solution reactors, especially with the physical phenomena associated with radiolytic hydrogen production and coalescence, uncertainties may be larger than assumed because of "unknown unknowns". Describe whether any conservative penalties were imposed until these coefficients can be validated with measured data in the facility.

- *The measures staff imposed to ensure to preclude fabrication-induced component failures.* Although there is some operating experience with using Type 347 austenitic stainless steel, there is also experience to indicate that welding of this material could lead to fabrication-induced component failures. It is not clear what measures staff imposed to ensure such failures are minimized.

- *The process staff used to verify the adequacy of proposed startup safety margins*. SHINE startup procedures are informed by MCNP calculations, level measurements, and neutron count rate ("1/M method"). However, there are uncertainties in detector calibration and converting the 1/M critical volume estimate to a k-effective margin. We are interested in additional information that would clarify how staff determined that the safety margin to criticality is appropriate. In particular, we request information regarding what methods the staff used to determine that no additional safety margins on the critical volume for the first few operating cycles were needed until the facility is properly characterized. As noted above, this is of concern because of uncertainties regarding detector calibrations and effective power reactivity coefficients, which control the adequacy of criticality margins.

Finding(s) and Recommendation(s)

As lead reviewer for SHINE Chapter 4, I concur with the staff that the descriptions of the IF and RPF are adequate for this SHINE operating license application. Our discussions regarding the Chapter 4 SER information, however, led to several items that we plan to explore in our reviews of subsequent chapters of this application. We request that staff provide information to address these items. In summary, no additional actions from the staff or applicant are needed to complete our review of this chapter. The topics will be addressed in subsequent chapter or focused area reviews.

References

1. US NRC, "Irradiation Unit and Isotope Production Facility Description," Chapter 4, Staff Safety Evaluation Report, March 14, 2022 (ML22073A203).

2. SHINE Medical Technologies, LLC, Operating License Application Supplement 2, FSAR Chapter 4, "Irradiation Unit and Isotope Production Facility Description," August 28, 2020 (ML20255A054).

3. SHINE, Medical Technologies, LLC – Response to Request for Additional Information on Operating License Application (ML20188A307, ML20220A343, ML21127A051, ML21154A303, ML22028A223)

4. SHINE Safety Analysis Summary Report, TECRPT-2020-0016, Revision 5, last updated March 2022.

5. Geoffrey R. Bull, Jason O. Oakley & Michael L. Corradini (2015), "Effects of Bubble Injection on Heat Transfer from a Volumetrically Heated Water Pool," Nuclear Science and Engineering, 180:3, 301-311, DOI: 10.13182/NSE14-79.

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