

OFFICE OF NUCLEAR REACTOR REGULATION

REGULATORY AUDIT TOPICS

REGARDING FIRE PROTECTION AUDIT TOPICS DESCRIBED IN

OPERATING LICENSE APPLICATION

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Accession No. ML20357A084), and December 15, 2020 (ADAMS Accession No. ML21011A264), SHINE Medical 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."

To support the review of the SHINE operating license application, the NRC staff will conduct a virtual regulatory audit related to the SHINE fire protection topics on April 8, 2021. The specific topics below identify areas where additional information is needed for the NRC staff to continue its review of the SHINE fire protection topics and may become formal requests for additional information following the regulatory audit.

Regulatory Basis and Applicable Guidance Documents

SHINE fire protection topics, as described in the SHINE operating license application, is being evaluated using the following regulations in 10 CFR and guidance:

Paragraph (a)(1) of 10 CFR 20.1301, "Dose limits for individual members of the public," states, in part, that "[e]ach license shall conduct operations so that [t]he total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year...."

SHINE has also committed to implementing the elements of a fire protection plan described in 10 CFR 50.48, "Fire protection," paragraph (a).

SHINE has also presented the following design criterion in Chapter 3, "Design of Structures, Systems, and Components," of its FSAR:

Criterion 3 – Fire protection

Safety-related SSCs [structures, systems, and components] are designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.

Noncombustible and heat resistant materials are used wherever practical throughout the facility, particularly in locations such as confinement boundaries and the control room.

Fire detection and suppression systems of appropriate capacity and capability are provided and designed to minimize the adverse effects of fires on safety-related SSCs. Firefighting systems are designed to ensure that their rupture or inadvertent operation does not significantly impair the safety capability of these SSCs.

The audit topics that follow are intended to confirm that SHINE has provided and developed sufficient analyses applicable to and commensurate with the risks of releases of radioactive material associated with fire hazards in the unrestricted environment at the site, and any doses received by members of the public are within the regulatory limits of 10 CFR Part 20, "Standards for Protection Against Radiation," Additionally, the NRC staff is conducting this regulatory audit to confirm that SHINE's fire protection plan includes the applicable elements of 10 CFR 50.48 and satisfies its principle design criteria.

The NRC staff's review of the SHINE fire protection topics is also based on the following:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," issued February 1996 (ADAMS Accession No. ML042430055)
- 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 1996 (ADAMS Accession No. ML042430048)
- "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 (ADAMS Accession No. ML12156A069)
- "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 (ADAMS Accession No. ML12156A075)

Audit Topics and Supporting Questions

Audit Topic 1: Fire Protection Program and Fire Hazard Analysis

Based on the information provided in Section 9a2.3, "Fire Protection Systems and Programs," the NRC staff was unable to determine how the applicant complies with NUREG-1537, Part 1 and Part 2, Section 9.3, "Fire Protection Systems and Programs." Further, the information in the current FSAR and other docketed documents do not provide the information necessary for the NRC staff to make the regulatory findings on the appropriateness of the applicant's fire protection systems and programs. It is also unclear to the NRC staff whether the applicant's fire protection systems and programs reflect the as-to-be-built and as-to-be-operated facility, including all design changes since the issuance of the construction permit. Therefore, the NRC staff requests that the applicant:

- (a) Provide SHINE updated fire protection program.
- (b) Provide SHINE updated fire hazard analysis.
- (c) Confirm that the documents identified in items (a) and (b) above reflect the as-to-be-built and as-to-be-operated facility, including all design changes since the issuance of the construction permit.

Audit Topic 2: Fire Protection Program and Fire Hazard Analysis

The NRC staff notes that fire modeling was performed in support of the SHINE operating license application in the form of plant-specific fire scenarios. However, insufficient information is available for the NRC staff to decide on the appropriateness of and consequently, the results from the fire modeling.

- (a) Identify the fire modeling tools or methods used in the development of the fire hazard analysis including how these tools or methods were used.
- (b) Describe the process used to validate and verify the fire models (calculational and numerical methods) used in support of fire hazard analysis.
- (c) Discuss how the fire modeling uncertainties were accounted in the fire modeling calculations.
- (d) Describe how the installed cabling in the fire areas was characterized, specifically, the critical damage threshold temperatures and heat fluxes for thermoset and thermoplastic cables.
- (e) Explain how exposed temperature-sensitive equipment was treated in the fire modeling and justify the damage criteria that was used for such equipment.

Audit Topic 3: Safe Shutdown Analysis

Based on the information provided in the Section 9a2.3.4 "Safe Shutdown Analysis," the NRC staff was unable to determine how the applicant complies with NUREG-1537, Part 1 and Part 2, Section 9.3 for the fire safe shutdown analysis and the corresponding regulatory findings. In

order to support the NRC staff's regulatory finding on the acceptability of the applicant's fire safe shutdown analysis, additional information is needed.

- (a) Summarize the safe shutdown performance goals and the safe shutdown analysis methodology.
- (b) Identify the functions required for safe shutdown. Such functions may include items such as inventory control, process monitoring, and reactivity control. Include any auxiliary equipment or cables required to support a safe shutdown function, such as, for example, room cooling.
- (c) Identify any required safe shutdown function that has only a single train and justify how such a configuration can ensure safe shutdown in the event of a fire.
- (d) Identify the fire area(s) that contain equipment or cables from all trains of a required safe shutdown function. If such area(s) exist, describe how safe shutdown is ensured for a fire occurring in that fire area(s).
- (e) Identify any fire area(s) where fire damage could prevent safe shutdown. If such area(s) exist, justify how safe shutdown is ensured for a fire occurring in that fire area(s).

Audit Topic 4: Radiological Fire Hazard

Based on the information provided in the Section 9a2.3.8 "Radiological Fire Hazards," the NRC staff was unable to determine how the applicant complies with NUREG-1537, Part 1 and Part 2, Section 9.3 with respect to the requirements to meet 10 CFR Part 20 exposure limits from fire-fighting effluents and the corresponding regulatory findings. In order to support the NRC staff's regulatory finding on reasonable assurance of the applicant meeting the 10 CFR Part 20 exposure limits from fire-fighting effluents, additional information is needed.

Describe how it is assured that the release of radioactive material as a result of fire-fighting activities would not cause radiation exposures that exceed the requirements of 10 CFR Part 20. Include in the response a description of fire protection program elements, plant programs, (such as fire brigade training), and plant engineering controls, that result in reasonable assurance of containment of gaseous and liquid fire-fighting related effluents within station boundaries or an analysis that demonstrates that the 10 CFR Part 20 limits are met. This evaluation may be done on a fire area basis.

Audit Topic 5: Regulatory Commitments

Appendix A, "Regulatory Commitments Identified in Response to Requests for Additional Information," of NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc., Construction Permit Application for a Medical Radioisotope Production Facility," August 2016 ADAMS Accession No. [ML16229A140](#), contains a fire protection regulatory commitment.

Identify the location(s) in in the SHINE operating license application and/or its supplements that addresses the fire protection regulatory commitments listed in Appendix A of NUREG-2189.

Audit Topic 6: Fire Protection Change Control

Section 13 of the Fire Protection Program states that “Design of fire protection systems and equipment is in accordance with the facility design control process, design change control process, and the fire protection design criteria documents.” However, additional details and description of the identified change control processes is not available.

Provide a description of the facility design control process, design change control process, and the fire protection design criteria. The description should be in sufficient detail for the NRC staff to confirm that these processes provide reasonable assurance that fire protection related changes are made in accordance with all applicable regulatory requirements and that any changes to SSCs do not impact their ability to perform the intended function.

General Questions

- Are there any known National Fire Protection Association (NFPA) code and standard deviations?
- Are there any existing fire protection equivalency evaluations?
- What are the inspection, testing, and maintenance surveillance frequencies of fire protection systems going to be? Is NFPA 25, “Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems” going to be used?
- Are there any fire protection technical specifications?
- Is there a facility lightning protection system? If so, is NFPA 780, “Standard for the Installation of Lightning Protection Systems,” going to be followed?
- What are the design specifications for all fire protection systems? Fire protection systems of interest include the following (Note: This is a general list, some systems might not be applicable to the SHINE facility):
 - Clean agent fire extinguishing systems, agent concentration and soak time in various fire areas.
 - Inert gas fire (nitrogen, argon, carbon dioxide, or a mixture of these gases) suppression systems concentrations and soak time.
 - Incipient fire detection or very early warning air sampling smoke detection and gas monitoring systems.
 - VESDA air sampling detection system’s sensitivity settings.
 - Wet pipe sprinkler system water densities.
 - Fire pump rating.
 - Fire hydrant spacing, fire protection loop design characteristics.

- What is response of electrical cables to fire exposure?
- Are the electrical breakers in the safety-related power supply coordinated? Will fire damage cause losses of upstream power supplies due to overcurrent, etc.?
- Is there any fire protection for high-efficiency particulate air and charcoal filters?
- Are there any ventilation and smoke control systems?
- What is the fire protection provided for rooms, such as cable spreading room, switchgear room, facility computer room, resource building (boiler, fire pump, etc.)?
- What is the fire protection for oil-filled outdoor and indoor dry-type transformers?
- What is the fire protection diesel fuel oil storage area?
- Which flame spread and smoke development rating has been used for interior finish materials? Clarify is SHINE is using (1) flame spread and smoke development rating ≤ 50 , (2) flame spreading rating 200 or less and smoke development rating of 450 or less, or (3) flame-spread rating of 25 or less, and a smoke-developed rating of 50 or less?
- What are the types of fire-resistant coatings and electric raceway fire barriers systems used for the protection cable and structural steel?
- Does SHINE plan to propose acceptance criteria for making changes to the facility's fire protection program without prior NRC review and approval?

Safe Shutdown Analysis Discussion Topics

- Identify the "safe shutdown fire" entry conditions.
- Describe the timeline for completing (that is, closing) the open items in the Safe Shutdown Analysis.
- Describe the separation criteria for redundant trains of a safe shutdown function located in the same fire area.
- Identify the guidance that will be used to perform the circuit analysis.

Radiological Fire Hazard Discussion Topics

Identify the document referred to in the Fire Hazards Analysis that evaluates the consequences of a fire-related radiological release. In the Fire Hazards Analysis, potentially contaminated areas contain text like the following in Section 7.4.9.4, "Potential for Toxic or Radiological Incident Due to a Fire," "The consequences of a radiological release are evaluated in a separate document."