December 30, 2021

2021-SMT-0187
10 CFR 50.30

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)
(2) NRC letter to SHINE Medical Technologies, LLC, "SHINE Medical Technologies, LLC – Request for Additional Information Related to Fire Protection (EPID No. L-2019-NEW-0004)," dated June 23, 2021 (ML21162A318)

SHINE Technologies, LLC Application for an Operating License
Response to Request for Additional Information

Pursuant to 10 CFR Part 50.30, SHINE Technologies, LLC (SHINE) submitted an application for an operating license for a medical isotope production facility to be located in Janesville, Wisconsin via Reference 1. Via Reference 2, the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE operating license application.

Enclosure 1 provides the SHINE responses to the NRC staff's request for additional information (RAIs) with the exception of RAI 9-6 and RAI 9-9. The SHINE Response to these remaining RAIs will be provided by February 28, 2022.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on December 30, 2021.

Very truly yours,

DocuSigned by:
Jim Costedio
F52DB96989224FF...

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Technologies, LLC
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Technologies, LLC (SHINE) operating license application (Reference 2). The following information is provided by SHINE in response to the NRC staff's request.

Chapter 9 – Auxiliary Systems

RAI 9-3

Appendix A.2, "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" (ADAMS Accession No. ML16229A140), includes regulatory commitments that "are the responsibility of the applicant" and were not fulfilled at the time of issuance of the construction permit (CP). As stated in Appendix A.2 of NUREG-2189, "…the applicant should ensure that these items are fully addressed in the FSAR supporting the issuance of an operating license. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of a SHINE operating license application."

The NRC staff identified the following fire-protection-related regulatory commitments in NUREG-2189 for which it was unable to determine how they are fully addressed in the FSAR and consequently, verify their implementation:

a. Firefighting procedures for use in a moderation-controlled area evaluate the use of moderator material (from CP RAI 6b.3-28)

b. Specific guidance in Rock County 911 Communications Center's SHINE-specific response information binder on the use of firefighting foam at the SHINE facility (from CP RAI 9a2.3-7)

Provide a discussion of how each of the above-mentioned fire protection regulatory commitments in NUREG-2189 are fully addressed in the FSAR supporting SHINE's operating license application.

This information is necessary for the NRC staff to ensure that SHINE is satisfying the elements of 10 CFR 50.48(a) to which it has committed and to make the necessary evaluation findings described in NUREG-1537, Part 2, Section 9.3. Specifically, the requested information will support the NRC staff in concluding that the plans for preventing fires ensure that the facility meets local and national fire and building codes.

SHINE Response

a. Use of moderation as a controlled parameter, including firefighting procedure evaluation, is described in Section 6b.3 of the final safety analysis report (FSAR) and is in accordance with American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.22-1997, Nuclear Criticality Safety Based on Limiting and Controlling Moderators (Reference 3).

   Subsection 9a2.3.8 of the FSAR also states, "Fire response using water-based extinguishants [in the target solution preparation system (TSPS) and uranium receipt and storage system (URSS) rooms] is prohibited; elevated floors of the URSS and TSPS fire area are provided to prevent flooding of these rooms." Pre-fire plans, developed in accordance with the Fire Protection Program (FPP), note where water use is restricted due to a criticality hazard.

b. During the development of the FSAR, SHINE determined that discussion of the Rock County 911 Communications Center's SHINE-specific response information binder was beyond the level of detail required to be addressed in the FSAR, based on application content guidance applicable to medical isotope production facilities. However, the SHINE-specific response information binder to be provided to the Rock County 911 Communications Center will provide specific guidance on the use of firefighting foam at the SHINE facility. The response information binder will be developed and provided to the Communication Center as part of the development and implementation of the SHINE Emergency Plan Implementing Procedures (EPIPs). The SHINE EPIPs will be submitted to the NRC no less than 180 days before the scheduled issuance of the SHINE operating license in accordance with Section V of Appendix E to 10 CFR Part 50.

RAI 9-4

Section 9.3 of NUREG-1537, Part 2, identifies areas of NRC staff review for fire protection systems and programs to include the following:

- A discussion of fire protection plans and protective equipment used to limit the consequence of a fire;

- A list of the objectives of the fire protection program, as well as a discussion of the organizations, methods, and equipment for attaining the objectives;

- The source of facility fire protection brigades and their training and the summary of the more detailed discussions of these personnel and offsite fire protection forces in the facility emergency plan.

SHINE FSAR Section 9a2.3.1, "Fire Protection Plan and Program," identified elements of the SHINE's fire protection program, including references to lower tier documents maintained as part of the overall SHINE fire protection program. However, SHINE does not provide adequate discussions of how these lower tier documents are used to adequately protect the facility's safety-related SSCs against fires. Therefore, additional information is needed to give the NRC staff a clear understanding of how SHINE is implementing the programmatic elements of its fire protection program, consistent with the guidelines in NUREG-1537. Provide additional discussion of SHINE's fire protection program implementing procedures that ensure protection of safety-related SSCs and safe facility shutdown in the event of a fire. Examples of elements

and of implementing fire protection procedures to include in this discussion, as applicable to the SHINE design and facility, are as follows:

a. Fire protection organization, its staffing, and their responsibilities
b. Fire protection engineering design bases
c. Description of electrical cable construction
d. Fire brigade and fire brigade training program
e. General employee fire protection training program
f. Pre-fire planning and emergency planning considerations
g. Manual firefighting capability
h. Lighting and communications for operator actions
i. Applicability of corrective action program and compensatory measures
j. Fire testing, qualification reports, and data for fire rated systems, barriers, and assemblies
k. Fire protection features of the facility's emergency diesel generator room and battery room
l. Confirm that SHINE will follow 10 CFR 50.59 as the change control process for making changes to its fire protection features and program

This information is necessary for the NRC staff to ensure that SHINE is satisfying the elements of 10 CFR 50.48(a) to which it has committed and to make the necessary evaluation findings described in NUREG-1537, Part 2, Section 9.3. Specifically, the requested information will support the NRC staff in concluding the following:

- The plans for preventing fires ensure that the facility meets local and national fire and building codes;

- The systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time;

- The potential for radiological consequences of a fire will not prevent safe shutdown, and any fire-related release of radioactive material from the facility to the unrestricted environment has been adequately addressed in the appropriate sections of the facility emergency plan; and

- Any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20.

SHINE Response

a. Responsibilities related to the FPP are assigned as follows:

   Safety Analysis Manager

   The Safety Analysis Manager is responsible for the establishment, implementation, and administration of the FPP and fire protection engineering aspects of program implementation. This responsibility includes ensuring that plant design is maintained in accordance with the design and licensing basis as described in the FPP and sub-tier documents. The Safety Analysis Manager oversees the fire protection staff and ensures that the staff is comprised of competent, and qualified fire protection personnel. The Safety Analysis Manager also ensures that the program is periodically assessed to ensure its effectiveness and satisfaction of licensing basis commitments.

Operations Manager

The Operations Manager is responsible for ensuring that facility operations are conducted in accordance with the FPP and implementing procedures. This responsibility extends to assurance that fire protection systems and components are functional as required to support plant operations.

The Operations Manager also ensures that facility operating staff and designated technical support staff are trained in fire protection related operating procedures, maintenance of a fire safe workplace, manual fire suppression, and as assigned, conduct of Fire Response Team operations.

Maintenance Manager

The Maintenance Manager is responsible for the planning and executing of preventative maintenance that provides assurance that the fire protection systems are highly reliable. The Maintenance Manager ensures inspection, surveillance, and maintenance is conducted in accordance with, at a minimum, the appropriate codes and standards and the maintenance program. Maintenance, repair, or replacement of system components is conducted in accordance with system specifications by qualified individuals. The Maintenance Manager is directly responsible for periodic maintenance and testing of plant fire protection systems and equipment including:

- Development of code/program required system inspection, testing, and surveillance procedures; and
- Tracking of system performance trends.

Fire Protection Staff

The Fire Protection Staff is comprised of Engineering and Operations personnel responsible for the performance of inspection, surveillance, acceptance, and periodic testing, and implementation of design changes, as necessary, of fire protection systems.

Specific responsibilities of the Fire Protection Staff include:

- Resolution of day-to-day fire protection issues;
- Periodic update to the FPP and sub-tier documents;
- Conduct of fire protection engineering analyses;
- Conduct of fire related training;
- Performance of liaison activities with off-site firefighting organizations;
- Performance of periodic facility walkdowns to assess compliance with housekeeping, combustible loading, ignition control, and design requirements regarding fire prevention;
- Ensure facility compliance with fire protection design and licensing commitments, regulations, committed codes and standards, building code requirements and insurance requirements;
- Review of plant design changes to provide concurrence on fire protection aspects; and
- Reporting and investigation of fire occurrence and fire related losses.

Fire Response Team

The Fire Response Team is a group of facility employees that are qualified to provide response to plant fires. This team is responsible for verification of fire conditions, communication with control room operators, incipient stage fire suppression, and liaison with professional firefighting personnel.

b. Appendix A to 10 CFR Part 50, General Design Criterion 3, has been adopted and revised for application to the SHINE facility to define the design bases for fire protection engineering. SHINE Design Criterion 3 is defined in Table 3.1-3 of the FSAR.

c. Electrical cables selected for use, to the extent practicable, are constructed to recognized flame spread test criteria. Plant cabling is selected and routed to minimize its contribution to combustible loading.

d. SHINE does not employ a fire brigade, and consequently, does not have a fire brigade training program.

e. As part of the implementation of the FPP, general employee fire protection training will be provided to facility employees upon initial hire with refresher training performed periodically. This training covers general fire protection awareness, FPP introduction, fire prevention, fire reporting, and response to fire alarms.

f. Pre-Fire Plans are developed for the main production facility to provide information for trained facility personnel and responding professional firefighters. Pre-Fire Plans are designed to aid firefighting personnel in their response to fires through identification of hazards, process activities, access routes, and available firefighting equipment. Pre-Fire Plans provide the basis for development of firefighting strategies for responder training and incident command. Pre-Fire Plans contain the following information, as appropriate:

- Area Identification
- Fire Hazards
- Radiation Hazards
- Electrical Information (electrical disconnect)
- Hazardous Substances
- Physical Hazards
- Communications
- Access/Egress Routes
- Fixed Fire Systems
- Portable Firefighting Equipment
- Safe Shutdown Guidance

Off-site fire support is requested to respond to fires that progress beyond the incipient stage. SHINE has developed a memorandum of understanding (MOU) with the Rock County Sheriff's Office – Emergency Management Bureau, for incident response at the SHINE facility. This MOU is designed to facilitate periodic training, fire and emergency incident command protocol, and to identify key SHINE Emergency Response contacts, in accordance with the SHINE Emergency Plan.

g. Manual firefighting is not credited for safe shutdown or the protection of safety-related equipment in the event of a fire. However, the SHINE facility does have portable fire extinguishers throughout the facility for the use by SHINE personnel in the suppression of incipient-stage fires. In the radiologically controlled area (RCA), there are Class I standpipes where firefighters responding to an emergency can get water for their hoses. Exterior to the SHINE buildings, there are fire hydrants arranged around the fire water loop.

h. Operator actions are not required to put the facility in a safe shutdown state in the case of a fire. Lighting, including emergency lighting, is provided to illuminate means of egress in accordance with the International Building Code (IBC) (Reference 4) and National Fire Protection Association (NFPA) 101, Life Safety Code (Reference 5). Fire alarms throughout the facility will notify occupants of a detected fire. Alarm response is initiated by facility operators in accordance with site procedures. Additional communication systems in the facility include a public announcement system and sound-powered telephones for communication among operators in the facility.

i. The SHINE corrective action program applies to the FPP and fire protection related operations. Identified failures, malfunctions, deficiencies, deviations, defective components, uncontrolled combustibles, and non-conformances, are promptly identified and corrected in accordance with the corrective action program.

   Compensatory measures are used to provide an added level of safety for areas where fire protection systems or equipment are out of service or degraded. Compensatory measures, such as fire watches, are intended to be temporary measures and may not be permanently relied on for fire protection.

j. Installations of fire protection equipment are inspected by qualified personnel to validate critical parameters and provide assurance of construction/installation with design requirements. Personnel, independent of the activity performed are assigned inspection duties to verify:

   - Installation, maintenance, or modification of fire protection features, systems, or equipment.
   - Installation, maintenance, or modification of electrical raceway fire barrier systems, fire barrier features, fire barrier segments, penetration seals, fire retardant coatings.

   Acceptance procedures/instructions are documented in design control packages. Periodic inspection/surveillance, preventive maintenance, and system testing is conducted in accordance with approved plant administrative and maintenance procedures. Plant inspection and surveillance schedules are documented to demonstrate required surveillance, testing, and preventive maintenance is conducted within appropriate timeframes. These inspection, surveillance, maintenance, and system testing activities will be performed and documented in accordance with the requirements of the IBC (Reference 4) and NFPA 801, Standard for Facilities Handling Radioactive Materials (Reference 6).

k. The uninterruptible power supply system (UPSS) battery rooms and equipment rooms are separated from the rest of the facility by walls with a fire resistance rating of 3 hours. Additionally, these rooms are protected by an automatic clean-agent fire detection and suppression system.

The SHINE facility does not employ an emergency diesel generator. The nonsafety-related standby generator system (SGS) is described in Section 8a2.2 of the FSAR.

l. SHINE will follow 10 CFR 50.59 as the change control process for making changes to its fire protection features and program.

RAI 9-5

NUREG-1537, Part 1, Section 9.3, "Fire Protection Systems and Programs," states, in part, that "[t]he applicant should discuss passive design features required by the [facility] design characteristics. In addition, the objectives of the fire protection program should limit fire consequences and provide that the facility is designed, and protective systems exist to prevent the uncontrolled release of radioactive material should a fire occur. The acceptance criteria in NUREG-1537, Part 2, Section 9.3, state, in part, that the information on the fire protection systems and programs should include descriptions of the "[m]ethods to detect, control, and extinguish fires…."

SHINE FSAR Section 9a2.3.3, "Fire Hazards Analysis," does not adequately describe passive design features intended to limit fire consequences, fire protection systems, active and passive fire suppression systems, and fire detection and alarm systems. Therefore, additional information is needed for the NRC staff to confirm that SHINE has adequately addressed these elements of fire protection in the design of its facility and implementing procedures. Provide descriptions of the following, including key objectives and elements of design and implementation for the fire protection program:

a. Facility construction elements related to the fire protection program. Examples of elements include building codes (including any deviations); facility fire barriers, including fire barrier penetrations, intended to limit fire consequences, including features of the facility that could affect safe shutdown or release radioactive material in the event of a continuing fire

b. Facility life safety features related to the fire protection program. Examples of features include egress from the building in the event of fire and compliance with codes, such as National Fire Protection Association (NFPA)-101, "Life Safety Code"

c. Fire protection water supply systems

d. Active and passive fire suppression systems

e. Fire detection and alarm/signaling systems

f. The code of record (e.g., NFPA-780) for the facility lightning protection system, including justification for the choice of code and any deviations.

This information is necessary for the NRC staff to ensure that SHINE is satisfying the elements of 10 CFR 50.48(a) to which it has committed and to make the necessary evaluation findings described in NUREG-1537, Part 2, Section 9.3. Specifically, the requested information will support the NRC staff in concluding the following:

- The plans for preventing fires ensure that the facility meets local and national fire and building codes;

- The systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time;

- The potential for radiological consequences of a fire will not prevent safe shutdown, and any fire-related release of radioactive material from the facility to the unrestricted environment has been adequately addressed in the appropriate sections of the facility emergency plan; and

- Any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20.

SHINE Response

a. The SHINE facility consists of non-combustible construction, of IBC Type II-B (Reference 4). Fire-rated barriers separate the individual fire areas within the SHINE facility. Fire barriers in the SHINE facility have fire resistance ratings of 1, 2, or 3 hours. The fire resistance rating is determined by the Fire Hazards Analysis (FHA), and considers regulatory requirements (e.g., IBC fire barrier requirements) as well as assessments of fire area contents, means of egress considerations, and equipment separation considerations. The RCA is separated from the non-RCA portion of the building by a 3-hour-rated fire barrier. Exit stairways are protected by 2-hour-rated fire barriers. Fire barrier design and construction is in accordance with the IBC and NFPA 801, Standard for Fire Protection for Facilities Handling Radioactive Materials (Reference 6).

   Where fire-rated barriers are penetrated by pipes, ducts, conduits, raceways or other such penetrations, fire barrier penetration material is placed in and around the penetrations to maintain the fire-resistance rating of the barrier.

   Fire doors and dampers are rated commensurate with the fire barrier in which they are installed and comply with the requirements of NFPA 80, Standard for Fire Doors and Other Opening Protectives (Reference 7) and NFPA 90A, Standard for the Installation of Air-Conditioning and Ventilating Systems (Reference 8).

   The SHINE Response to RAI 9-8 provides a listing of building and fire codes (including deviations) applied to the design of the SHINE facility, as related to the development of the FPP and implementing procedures.

b. The SHINE facility life safety features are designed in accordance with NFPA 101, Life Safety Code (Reference 5) and the IBC (Reference 4).

   Automatic fire detectors are installed where required. In addition, manual pull stations are installed to allow personnel to activate the fire alarm system. Upon actuation of the fire alarm system, audible and visual indicating devices will provide notification to personnel to evacuate the building.

   Emergency exits are available from all areas of the facility within the IBC allowed maximum travel distance of 200 feet. Common path of travel does not exceed the allowed maximum of 100 feet per the IBC. Dead-end corridors do not exceed the allowed maximum of 50 feet per the IBC.

The illumination of means of egress is provided in accordance with the life safety code and IBC.

c. The fire water distribution subsystem provides firefighting water to the main production facility and those outbuildings requiring fire water service. The system draws water from the municipal water supply and directly supplies water to the building sprinkler systems, and fire hydrants. The municipal water supply provides suction for two 100 percent capacity fire pumps that supply water to a fire water distribution loop and water-based fire suppression systems installed in the facility, including the fire hose standpipes in the RCA and automatic fire sprinklers in the administrative areas. Multiple hydrants are arranged around the main production facility, and fire water supply is sufficient to supply the greatest single suppression system demand plus a 500 gallons per minute (gpm) hose stream allowance for a period of 1-1/2 hours.

   The fire water distribution supply loop is designed such that individual legs of the loop may be isolated for system maintenance or testing without interruption of supply to unaffected portions of the system. Fire hydrants are provided around the facility structures.

d. The main production facility contains a water-based, wet-pipe fire sprinkler subsystem, a standpipe subsystem, and a gaseous suppression subsystem.

   Automatic water-based, wet-pipe fire sprinkler systems are designed to provide fire suppression in several general/administrative areas of the facility. The system piping contains water provided by the fire water distribution subsystem at the static system pressure for the water distribution system. These systems maintain fire suppression water available at each sprinkler, with water spray provided immediately upon activation of a sprinkler. The minimum densities for automatic sprinkler piping design are provided in the SHINE Response to RAI 9-7.

   The standpipe system is provided to facilitate manual firefighting capability in the RCA by responding professional firefighters. A Class I standpipe system is installed to provide 2-1/2 inch (in.) (65 millimeter [mm]) hose line connections for fire use by fire department personnel. This system allows distribution of firefighting water to the interior of the RCA from the fire water distribution subsystem. Manual dry standpipes are arranged to allow admission of firefighting water to be piped into the RCA, as necessary, to support manual firefighting in these areas. Design criteria for manual dry standpipe coverage are provided in the SHINE Response to RAI 9-7.

   Gaseous suppression systems are used for fire hazards where a clean agent or inert gas is needed to protect sensitive electronic equipment or in areas where nuclear criticality or other hazards preclude the use of water for fire suppression. These areas include the URSS and TSPS rooms, the Supercell, the radioactive liquid waste immobilization (RLWI) enclosure, the facility control room, the uninterruptible power supply equipment and battery rooms, and certain small rooms containing electrical and information technology (IT) equipment. These systems discharge a gaseous fire suppression agent from pressurized storage tanks into the protected volume/room achieving a predetermined concentration of agent required to accomplish fire suppression. The system can be activated by a signal from the area fire detection and alarm system and/or manually. Local pre discharge alarm and delay allow personnel evacuation before the suppression system actuates. Design criteria for gaseous suppression systems are provided in the SHINE Response to RAI 9-7.

e. The main production facility fire detection and alarm subsystems are designed to detect and provide early warning/notification of fire. These systems detect fire through the placement of signal initiating devices (e.g., smoke/heat detectors, manual pull boxes, supervisory switches) throughout the protected portions of the facility. Detection devices communicate via a communications loop and local fire alarm panels with the master fire alarm panel located in the facility control room. Alarm, supervisory, and trouble signals are received at the facility control room and alarms are annunciated within the protected space for occupant notification. Alarm response is initiated by facility operators in accordance with site emergency or standard operating procedures.

f. The facility grounding and lightning protection (FGLP) system adheres to the requirements of NFPA 780, Standard for the Installation of Lightning Protection Systems (Reference 9), without deviation. Adherence to NFPA 780 is consistent with the guidance provided in Section 5.12 of NFPA 801 (Reference 6).

RAI 9-6

Section 9.3 of NUREG-1537, Part 1, states that discussions of the fire protection systems and program should include descriptions of "any possible effects of a fire on the safe shutdown of the [facility]." As part of its review, as described in Section 9.3 of NUREG-1537, Part 2, the NRC staff is to evaluate the "designs of [facility] systems that can ensure safe [facility] shutdown in the event of fire."

While the SHINE FSAR Section 9a2.3.4, "Safe Shutdown Analysis," states that a safe shutdown analysis is to be performed as part of the SHINE fire protection program and included in implementing procedures and reports, insufficient detail is included for the NRC staff to ensure that the design of systems and implementation of such procedures is sufficient to provide for the safe shutdown of the SHINE facility in the event of fire. Therefore, additional information is needed for the NRC staff to confirm that SHINE has adequately performed a safe shutdown analysis, such that the design of its facility and implementing procedures can ensure safe facility shutdown in the event of fire. Provide descriptions of the following, as applicable, including key objectives and elements of design and implementation for the fire protection program related to the SHINE safe shutdown analysis:

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 inventory control, process monitoring, and reactivity control. Include any auxiliary equipment or cables required to support a safe shutdown function (e.g., 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. Describe the separation criteria for redundant trains of a safe shutdown function located in the same fire area.

e. Describe and justify any deviations from the separation criteria described in item (d).

f. 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).

g. Identify any fire areas where fire damage could prevent safe shutdown. If such areas exist, justify how safe shutdown is ensured for a fire occurring in those fire areas.

h. Identify the entry conditions for the facility fire safe shutdown procedure.

i. Identify the guidance used to perform any safe shutdown-related circuit analysis.

This information is necessary for the NRC staff to ensure that SHINE is satisfying the elements of 10 CFR 50.48(a) to which it has committed and to make the necessary evaluation findings described in NUREG-1537, Part 2, Section 9.3. Specifically, the requested information will support the NRC staff in concluding the following:

- The plans for preventing fires ensure that the facility meets local and national fire and building codes;

- The systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time;

- The potential for radiological consequences of a fire will not prevent safe shutdown, and any fire-related release of radioactive material from the facility to the unrestricted environment has been adequately addressed in the appropriate sections of the facility emergency plan; and

- Any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20.

SHINE Response

The SHINE Response to RAI 9-6 will be provided by February 28, 2022.

RAI 9-7

NUREG-1537, Part 2, Section 9.3, states, in part, that "[t]he fire protection plan should discuss the prevention of fires, including limiting the types and quantities of combustible materials." Additionally, Section 9.3 of NUREG-1537, Part 2, states, in part, that the application should describe the "methods to detect, control, and extinguish fires…." SHINE FSAR Section 9a2.3.5, "Administrative Control," does not provide adequate information on SHINE's fire protection-related administrative controls intended to prevent and mitigate fires. Therefore, additional information is needed for the NRC staff to confirm that SHINE has adequately developed administrative controls for fire protection. Provide descriptions of the following administrative and design controls, as applicable, included as part of the SHINE fire protection program and implementing procedures to prevent and mitigate fires, including controls to limit the types and quantities of combustible materials:

a. Fire protection systems design criteria (e.g., sprinkler system design densities, fire pump capacities, etc.).

b. Ignition sources.

c. Fire prevention methods intended to control handling, use, and disposal of combustibles materials.

d. Fire protection procedures, instructions, and design drawings.

e. Manual fire suppression actions.

This information is necessary for the NRC staff to ensure that SHINE is satisfying the elements of 10 CFR 50.48(a) to which it has committed and to make the necessary evaluation findings described in NUREG-1537, Part 2, Section 9.3. Specifically, the requested information will support the NRC staff in concluding the following:

- The plans for preventing fires ensure that the facility meets local and national fire and building codes;

- The systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time;

- The potential for radiological consequences of a fire will not prevent safe shutdown, and any fire-related release of radioactive material from the facility to the unrestricted environment has been adequately addressed in the appropriate sections of the facility emergency plan;

- Any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20; and

- Acceptable TSs related to fire protection have been proposed and justified.

SHINE Response

a. Design criteria for the facility fire protection systems include:

   - Fire water loop system flow requirement: 1,500 gpm at 100 pounds per square inch (psi)
   - Manual dry standpipes are located such that they will provide 100 percent coverage of the RCA assuming a 100-foot (ft.) (30.5 meter [m]) hose and 30-ft. (9.1 m) hose stream.
   - Minimum Density for Automatic-Sprinkler Piping Design:
     - Light-Hazard Occupancy: 0.10 gpm over 1500 square foot (sq. ft.) area.
     - Ordinary-Hazard, Group 1 Occupancy: 0.15 gpm over 1500-sq. ft. area.

   In addition:

   - The fire detection and alarm systems are designed, installed, tested, and maintained in accordance with NFPA 72, National Fire Alarm and Signaling Code (Reference 10).
   - The automatic wet-pipe fire sprinkler system is designed, installed, tested and maintained in accordance with NFPA 13, Standard for the Installation of Sprinkler Systems (Reference 11).
   - The standpipe system is designed, installed, tested, and maintained in accordance with NFPA 14, Standard for the Installation of Standpipe and Hose Systems (Reference 12).

- The automatic gas-based fire suppression systems are designed, installed, tested, and maintained in accordance with NFPA 2001, Standard on Clean Agent Fire Extinguishing Systems (Reference 13).

b. Administrative controls are established to manage hot work (i.e., welding, cutting, grinding, and open flames) in facility areas that are not designated for such operations. These controls are developed in accordance with NFPA 51B, Standard for Fire Prevention During Welding, Cutting, and Other Hot Work (Reference 14). The procedure for hot work is designed to ensure hot work is adequately controlled to mitigate the potential for ignition of combustibles and to provide immediate response if a fire does occur.

   Locations designated for the performance of hot work are designated as permanent hot work locations in accordance with the ignition control procedures. Hot work performed outside of designated locations is conducted under permit and in accordance with the ignition control procedures.

c. Combustible loading of fire areas and fire zones that contain safety-related equipment are carefully managed to maintain combustible loading as low as reasonable without impeding normal facility operations. In accordance with SHINE Design Criterion 3, noncombustible and heat resistant materials are used wherever practical throughout the facility and particularly in locations containing safety-related equipment.

   Combustible loading control is managed in accordance with FHA-assigned fire load limits. Combustible loading for each area containing safety-related equipment is tracked in the combustible loading calculation. This calculation is used to determine the baseline (in-situ) combustible loading for each affected fire area or zone. The difference in the baseline loading and the maximum allowable loading for the fire loading category assigned in the FHA identifies the maximum available transient combustible loading for the area under consideration.

   The combustible control procedure identifies requirements and restrictions for the use, handling, storage, and disposal of combustible materials, including:

   - Spacing and separation requirements for transient combustible storage;
   - Housekeeping requirements, including disposal requirements for combustible wastes (supplementing the housekeeping procedure);
   - Requirements for the use, handling, and storage of lumber and plastic;
   - Requirements for the use, handling, and storage of combustible and flammable liquids and gases; and
   - Requirements for the use of transient combustible permits.

   The combustible control procedure requires an engineering evaluation to be performed when a variance from procedure requirements is needed, or work activities require significant amounts of flammable or combustible liquids outside of approved storage rooms or storage cabinets.

d. The FPP elements are controlled by administrative, engineering, maintenance, and operations procedures. The topics of these procedures include:

- Ignition control;
- Control of combustibles;
- Housekeeping;
- Surveillance, inspection, maintenance, and testing of fire protection systems;
- Compensatory measures for out of service or degraded fire protection systems;
- Fire watches; and
- Fire protection training, including general employee fire protection program awareness, fire watch personnel training, and SHINE Fire Response Team training.

General area drawings are prepared to depict important fire protection information. These fire protection drawings document general arrangement of fire areas, fire zones, fire barriers and ratings, extinguishers, fire suppression system coverage, fire detection system coverage, hose connections, fire doors, fire dampers, fire hydrants, and other key fire protection equipment. In addition to general area drawings, information on individual fire protection systems and components is depicted on detailed drawings (e.g., component drawings, piping and instrumentation diagrams [P&IDs]).

e. Incipient stage fire suppression is provided by trained SHINE personnel using fire extinguishers. For fires beyond the incipient stage, firefighting by professional firefighters is managed via pre-fire planning and interface with on-shift Operations personnel.

RAI 9-8

FSAR Section 9a2.3.6, "Regulatory and Code Requirements," states, in part, that "[t]he design, installation, testing, and surveillance of the facility fire protection features, and systems are based on applicable guidance from nationally recognized codes and standards. The codes and standards used, and the code-of-record is as defined in the FPP [fire protection program] and applicable design documentation." Consistent with the guidance in Section 9.3 of NUREG-1537, Parts 1 and 2, for the design of fire protection systems and features, the applicant should use local building fire codes, as applicable, to help ensure that fire damage to structures, systems and components at the facility would not cause or allow an uncontrolled release of radioactive material.

SHINE FSAR Section 9a2.3.6, does not identify the codes and standards used in the development of SHINE's fire protection program or any deviations from such codes and standards. Therefore, additional information is needed for the NRC staff to confirm that SHINE has adequately implemented appropriate codes and standards in the design of its fire protection systems and development of its fire protection program. Provide the following:

a. A list of the building and fire codes and standards that SHINE considered in the design of the facility as related to the development of the fire protection program and implementing procedures, including identification of the edition (year). For codes and standards where more than one edition is used, identify which edition pertains to which areas of the facility.

b. Identify and justify any deviations from the codes and standards for the design and installation of fire protection systems identified in item (a), above.

This information is necessary for the NRC staff to ensure that SHINE is satisfying the elements of 10 CFR 50.48(a) to which it has committed and to make the necessary evaluation findings described in NUREG-1537, Part 2, Section 9.3. Specifically, the requested information will support the NRC staff in concluding the following:

- The plans for preventing fires ensure that the facility meets local and national fire and building codes;

- The systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time;

- The potential for radiological consequences of a fire will not prevent safe shutdown, and any fire-related release of radioactive material from the facility to the unrestricted environment has been adequately addressed in the appropriate sections of the facility emergency plan; and

- Any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20.

SHINE Response

a. SHINE applies the following building and fire codes and standards in the design of the SHINE facility, as related to the development of the FPP and implementing procedures:

   - International Building Code (IBC), 2015 Edition (Reference 4), and codes listed therein, as amended by the Wisconsin Administrative Code
   - International Fire Code (IFC), 2015 Edition (Reference 15), as amended by the Wisconsin Administrative Code
   - NFPA 1, Fire Code, 2012 Edition (Reference 16), as amended by Wisconsin Administrative Code
   - NFPA 801, Standard for Fire Protection for Facilities Handling Radioactive Materials, 2014 Edition (Reference 6), and codes listed therein

   There are no instances where SHINE applies more than one edition of a code or standard to the design of the SHINE facility, as related to the development of the FPP and implementing procedures.

b. SHINE has identified the following deviation from those codes and standards applied in the design of the SHINE facility identified in the SHINE Response to Part a of RAI 9-8:

   Deviation: Section 903.2.4 of the IBC (Reference 4) requires an automatic sprinkler system for group F-1 occupancies; however, the SHINE facility does not provide an automatic sprinkler system in the RCA.

   Justification: SHINE will not install an automatic sprinkler system in the RCA because the release of water into the RCA could cause a nuclear criticality hazard or lead to the spread of radioactive contamination. Section 903.3.1.1.1 of the IBC provides exemption from the automatic sprinkler system requirements for certain rooms or areas protected by an approved automatic fire detection system where, in part, application of water, or flame and water, constitutes a

serious life or fire hazard. SHINE will seek approval of the exempted condition for the RCA as part of the fire protection plan review for the SHINE facility by the Wisconsin Department of Safety and Professional Services.

RAI 9-9

NUREG-1537, Part 1, Section 9.3, states, in part, that "[t]he applicant should discuss passive design features required by the [facility] design characteristics." In addition, the objectives of the fire protection program should limit fire consequences and provide that the facility is designed, and protective systems exist to prevent the uncontrolled release of radioactive material should a fire occur. Additionally, NUREG-1537, Part 2, Section 9.3, states, in part, that "[t]he fire protection plan should discuss the prevention of fires, including limiting the types and quantities of combustible materials."

SHINE FSAR Section 9a2.3.7, "Facility Fire Protection System Description," does not provide sufficient detail of the use of SHINE's fire hazards analysis and the results. Therefore, additional information is needed to ensure that the passive design features, including fire barriers and facility fire areas and zones, are adequate to limit fire consequences to prevent the uncontrolled release of radioactive material should a fire occur.

a. Discuss means of egress for fire areas and zones and means of egress protection.

b. Describe the types of combustibles found in each fire area.

c. Describe combustible loading in fire areas and zones.

d. Discuss fire hazards and ignition sources that were considered for facility fire areas.

e. Describe the types of fire-resistant coatings and electric raceway fire barriers systems used for the protection of electrical cables and structural steel.

f. Identify the fire modeling tools or methods used in the development of the fire hazard analysis including how these tools or methods were applied. Describe the process to validate and verify the fire models, including any calculational and numerical methods used, used in support of fire hazard analysis. Discuss how the fire modeling uncertainties were accounted in the fire modeling calculations.

g. Describe how the installed cabling in the fire areas was characterized. Specifically, describe the critical damage threshold temperatures and heat fluxes for thermoset and thermoplastic cables consistent with the use of these cables in the facility. Include an explanation of how exposed temperature-sensitive equipment was treated in the fire modeling and justify the damage criteria that was used for such equipment. Alternatively, justify why this information is not necessary.

This information is necessary for the NRC staff to ensure that SHINE is satisfying the elements of 10 CFR 50.48(a) to which it has committed and to make the necessary evaluation findings described in NUREG-1537, Part 2, Section 9.3. Specifically, the requested information will support the NRC staff in concluding the following:

- The plans for preventing fires ensure that the facility meets local and national fire and building codes;

- The systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time;

- The potential for radiological consequences of a fire will not prevent safe shutdown, and any fire-related release of radioactive material from the facility to the unrestricted environment has been adequately addressed in the appropriate sections of the facility emergency plan; and

- Any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20.

This information is also requested to ensure that SHINE is satisfying its Design Criterion 3, which provides that "noncombustible and heat resistant materials are used whenever practicable…."

SHINE Response

The SHINE Response to RAI 9-9 will be provided by February 28, 2022.

RAI 9-10

Paragraph (a)(1) of 10 CFR 20.1301 states, in part, that "[e]ach licensee 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 FSAR Section 9a2.3.8 "Radiological Fire Hazards," does not describe how SHINE will meet 10 CFR Part 20 exposure limits from fire-fighting effluents.

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 and/or bounded by the accident analysis provided in SHINE FSAR Chapter 13, as applicable. Include in the response a description of fire protection program elements, programs and design elements (e.g., fire brigade training and physical barriers), and engineering controls, that result in reasonable assurance of containment of gaseous and liquid fire-fighting related effluents within facility boundaries or an analysis that demonstrates that the 10 CFR Part 20 limits are met. In this context, "gaseous and liquid firefighting related effluents" means smoke and fire fighting agent (generally water). This evaluation may be done on a fire area basis.

This information is necessary for the NRC staff to ensure that SHINE is satisfying the elements of 10 CFR 50.48(a) to which it has committed and to make the necessary evaluation findings described in NUREG-1537, Part 2, Section 9.3. Specifically, the requested information will support the NRC staff in concluding the following:

- The plans for preventing fires ensure that the facility meets local and national fire and building codes;

- The systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time;

- The potential for radiological consequences of a fire will not prevent safe shutdown, and any fire-related release of radioactive material from the facility to the unrestricted environment has been adequately addressed in the appropriate sections of the facility emergency plan; and

- Any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20.

SHINE Response

Accident scenarios related to fire and internal flooding due to fire water are described in Subsections 13a2.1.11 and 13a2.2.11 of the FSAR. These scenarios are prevented or mitigated to an acceptable level of risk, in accordance with the SHINE Safety Criteria, including the limit on the total effective dose equivalent to an individual member of the public not exceeding 1 rem over the duration of the event.

A description of the internal flooding event is provided in Section 3.3 of the FSAR. Liquid firefighting related effluents are prevented from exiting the RCA through the use of 2-inch berms or ramps at each exit from the RCA.

The radiological ventilation (RV) systems include isolation dampers that close on radiation detection through the engineered safety features actuation system (ESFAS) and target solution vessel (TSV) reactivity protection system (TRPS). If the gaseous firefighting related effluents contain radiological materials, these systems automatically initiate an RCA Isolation, Supercell Area Isolation, Tritium Purification System (TPS) Process Vent Actuation, TPS Train Isolation, or Irradiation Unit (IU) Cell Actuation depending on the impacted region of the facility. These isolations provide confinement of gaseous effluents, including contaminated smoke, for as long as postulated accident conditions require. In this way, gaseous firefighting effluents, including smoke, that contain radiological materials are contained within facility boundaries and prevent accident consequences from exceeding the SHINE Safety Criteria.

The RV systems also contain smoke detectors downstream of the air filters and ahead of any branch connections in air supply systems, per NFPA 90A, Standard for the Installation of Air-Conditioning and Ventilating Systems (Reference 8). These smoke detectors automatically stop their respective fan(s) on detecting the presence of smoke.

References

1. NRC letter to SHINE Medical Technologies, LLC, “SHINE Medical Technologies, LLC – Request for Additional Information Related to Fire Protection (EPID No. L-2019-NEW-0004),” dated June 23, 2021 (ML21162A318)

2. SHINE Medical Technologies, LLC letter to the NRC, “SHINE Medical Technologies, LLC Application for an Operating License,” dated July 17, 2019 (ML19211C143)

3. American National Standards Institute/American Nuclear Society, “Nuclear Criticality Safety Based on Limiting and Controlling Moderators,” ANSI/ANS-8.22-1997 (R2016), La Grange Park, IL

4. International Code Council, Inc., “International Building Code,” IBC-2015, Country Club Hills, IL

5. National Fire Protection Association, “Life Safety Code,” NFPA 101-2012, Quincy, MA

6. National Fire Protection Association, “Standard for Fire Protection for Facilities Handling Radioactive Materials,” NFPA 801-2014, Quincy, MA

7. National Fire Protection Association, “Standard for Fire Doors and Other Opening Protectives,” NFPA 80-2013, Quincy, MA

8. National Fire Protection Association, “Standard for the Installation of Air-Conditioning and Ventilating Systems,” NFPA 90A-2012, Quincy, MA

9. National Fire Protection Association, “Standard for the Installation of Lightning Protection Systems,” NFPA 780-2014, Quincy, MA

10. National Fire Protection Association, “National Fire Alarm and Signaling Code,” NFPA 72-2013, Quincy, MA

11. National Fire Protection Association, “Standard for the Installation of Sprinkler Systems,” NFPA 13-2013, Quincy, MA

12. National Fire Protection Association, “Standard for the Installation of Standpipe and Hose Systems,” NFPA 14-2013, Quincy MA

13. National Fire Protection Association, “Standard on Clean Agent Fire Extinguishing Systems,” NFPA 2001-2012, Quincy, MA

14. National Fire Protection Association, “Standard for Fire Prevention During Welding, Cutting, and Other Hot Work,” NFPA 51B-2014, Quincy, MA

15. International Code Council, Inc., “International Fire Code,” IFC-2015, Country Club Hills, IL

16. National Fire Protection Association, “Fire Code,” NFPA 1-2012, Quincy, MA