From:	Lynch, Steven
To:	Jeff Bartelme
Cc:	Smith - NRR, Brian; Casto, Greg; Balazik, Michael; Gran, Zachary; Smith, Micheal; Karipineni, Nageswara
Subject:	Issuance of Request for Additional Information Related to the SHINE Medical Technologies, LLC Operating License Application (EPID No. L-2019-NEW-0004)
Date:	Wednesday, January 27, 2021 10:01:59 PM
Attachments:	SHINE Request for Additional Information Related to FSAR Chapters 9 and 11.pdf

Jeff,

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), and August 28, 2020 (ADAMS Accession No. ML20255A027), 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."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted as part of the operating license application, and prepare a safety evaluation report. Specific chapters and technical areas of the SHINE operating license application covered by this RAI include the following:

- Chapter 9, "Auxiliary Systems"
- Chapter 11, "Radiation Protection and Waste Management"

It is requested that SHINE provide responses to the enclosed RAI within 60 days from the date of this electronic mail. In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Following receipt of the additional information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE's operating license application, additional RAIs for other chapters and technical areas may be developed. The NRC staff will transmit any further questions to SHINE under separate correspondence. If you have any questions, or need additional time to respond to this request, please contact me at 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Steve Lynch, Senior Project Manager

Non-Power Production and Utilization Facility Licensing Branch
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OFFICE OF NUCLEAR REACTOR REGULATION

REQUEST FOR ADDITIONAL INFORMATION

REGARDING OPERATING LICENSE APPLICATION FOR

SHINE MEDICAL TECHNOLOGIES, LLC

CONSTRUCTION PERMIT NO. CPMIF-001

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), and August 28, 2020 (ADAMS Accession No. ML20255A027), 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."

During the NRC staff's review of the SHINE operating license application, questions have arisen for which additional information is needed. This request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted as part of the operating license application, and prepare a safety evaluation report. Specific chapters and technical areas of the SHINE operating license application covered by this RAI include the following:

- Chapter 9, "Auxiliary Systems"
- Chapter 11, Radiation Protection and Waste Management"

Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE operating license application, which describes the SHINE irradiation facility, including the irradiation units, and radioisotope production facility , using the applicable 10 CFR regulations, as well as the guidance contained in 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), and 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). The NRC staff is also using the "Final Interim Staff Guidance [ISG] 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), and "Final Interim Staff Guidance [ISG] 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). As applicable, additional guidance cited in SHINE's FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE operating license application.

For the purposes of this review, the term "reactor," as it appears in NUREG-1537, the ISG Augmenting NUREG-1537, and other relevant guidance can be interpreted to refer to SHINE's "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate within the context of the application and corresponding with the technology described by SHINE in its application. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to refer to SHINE's "target solution."

Responses to the following RAI are needed to continue the review of the SHINE operating license application.

Chapter 9

RAI 9-1 SHINE FSAR Section 9a2.1, "Heating, Ventilation, and Air Conditioning (HVAC)," provides a description of the facility radiological ventilation (RV) systems including supply air, recirculating, and exhaust subsystems required to condition the air and provide the confinement and isolation needed to mitigate design basis accidents. It also includes a description of the HVAC systems serving the non-radiologically controlled areas. The SHINE facility utilizes three ventilation systems in the radiologically controlled area (RCA) to maintain the temperature and humidity of the RCA and to progress air from areas of least potential for contamination (Zone 3) to areas with the most potential for contamination (Zone 1). During its review of the application, the NRC staff determined that additional information is needed for to confirm that SHINE has satisfied the following regulations:

- In accordance with 10 CFR 20.1101, "Radiation protection programs," the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

- In accordance with 10 CFR 20 Subpart C, "Occupational Dose Limits," the licensee shall control the occupational dose to individual adults within dose limits.

- In accordance with 10 CFR 20 Subpart D, "Radiation Dose Limits for Individual Members of the Public," requires each licensee shall conduct operations so that the dose in any unrestricted area from external sources is maintained within specified limits.

- In accordance with 10 CFR 50.34(b)(2), the final safety analysis report shall include a description and analysis of structures, systems, and components (SSCs), with emphasis upon performance requirements, the bases upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

a. SHINE FSAR Section, 9a2.1.1.3, "System Operation," states that HEPA filters and carbon adsorbers are provided to remove airborne contaminants from the ventilation air stream. The filters and adsorbers capture airborne contaminants in Radiological Ventilation Zone 1 exhaust subsystem (RVZ1e) and Radiological Ventilation Zone 2 exhaust subsystem (RVZ2e) that may include radioactive material; however, it is not clear from the submittal how compliance with 10 CFR Part 20 will be maintained.

   Provide a discussion of how SHINE will assure compliance of the occupational dose requirements of 10 CFR Part 20 as a result of the concentration of radioactive material in the filters and adsorbers during all modes of operation and maintenance.

b. The SHINE application does not discuss potential failure modes for FVZ4, which could have adverse consequences. Specifically, the interface areas between the RCA and non-RCA areas (labyrinths, vestibule, and shipping/receiving) are supplied with ventilation air from RVZ2s. A failure of the FVZ4s (supply) subsystem with continued operation of the FVZ4e (exhaust) subsystem has the potential to lower the pressure in the non-RCA area below that in the interface areas. SHINE FSAR Figure 9a2.1-7, "Radiological Ventilation Zone 3 (RVZ3) Flow Diagram," shows makeup air from FVZ4. There does not appear anything to prevent the transfer of air from RVZ2s through the interface areas to the non-RCA through the FVZ4 makeup flow path.

   Provide a discussion of operational and equipment failure modes to confirm there are no failure modes which could cause an inadvertent release of radioactive airborne material to the unrestricted environment which could violate 10 CFR Part 20 occupational dose limits or dose limits to the general public.

   Confirm if non-RCA areas are included in the surveys required by 10 CFR 20.1501 in the event of an inadvertent release of radioactive airborne material from a HVAC subsystem or component failure.

c. Figure 9a2.1-2, "Radiological Ventilation Zone 1 Recirculating Cooling Subsystem (RVZ1r) Flow Diagram" shows condensate collected from the Irradiation Unit (IU) Cell cooling coil being sent to the light water pool. There is no discussion regarding the condensate from the target solution vessel off-gas system (TOGS) Cell cooling coil.

   Provide a discussion of the potential for condensate from the TOGS Cell cooling system to contain radioactive material, and if so, discuss how the condensate is monitored and disposed. This information is needed to ensure that there is not an inadvertent release of radioactive material to the unrestricted environment which could violate 10 CFR Part 20 occupational dose limits or dose limits to the general public.

d. The SHINE Application states that the RVZ2r recirculates, filters, and conditions air within the RCA. The system includes AHUs, filters, ductwork, and dampers. The RVZ2r units are located within the RCA. RVZ2r provides additional cooling for systems within ventilation zone 2. Figure 9a2.1-6, "Radiological Ventilation Zone 2 Supply Subsystem (RVZ2s) and Radiological Ventilation Zone 2 Recirculating Cooling Subsystem (RVZ2r) Flow Diagram," shows multiple RVZ2r recirculation units. The application does not discuss if the air from the RVZ2r subsystems is cooled by cooling coils.

   Discuss if condensate is collected from any of the RVZ2r units and if the condensate can contain radioactive material. Include in the discussion how the condensate is monitored and is disposed. This information is needed to ensure that there is not an inadvertent release of radioactive material to the unrestricted environment which could violate 10 CFR Part 20 occupational dose limits or dose limits to the general public.

e. Operating License Application Supplement No. 2 (ADAMS Accession Number ML20105A295) revised the tritium production method. The new method states that the Deuterium source gas exhaust is exhausted to the facility ventilation. There is no discussion in Section 3.4.5.2, "Explosion Hazards," or in Section 9a2.3.3, "Fire Hazard Analysis," regarding the potential for a combustible mixture of deuterium – air mixture.

   Provide a discussion regarding the potential for the formation of a combustible mixture of deuterium and air. Include in the discussion how a combustible mixture will be prevented, or if present, how ignition will be prevented under normal and anticipated degraded ventilation system operation. This information is needed to ensure that necessary safety functions will be accomplished in accordance with 10 CFR 50.34(b)(2).

RAI 9-2 Section 9b.7.2 "Material Handling System," of SHINE FSAR includes description of overhead cranes and hoists that are used to move or manipulate radioactive material within the radiologically controlled area.

The main emphasis in the material load handling system review is on critical load handling where inadvertent operations or equipment malfunctions, separately or in combination, could cause a release of radioactivity. In accordance with 10 CFR 50.34(b)(2), as appropriate, the final safety analysis report shall include a description and analysis of auxiliary and fuel handling structures, systems, and components (SSCs), with emphasis upon performance requirements, the bases upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

As discussed in Section 9b.7.2 "Material Handling System" of SHINE application, the ASME NOG-1 (Type I) overhead crane located in Irradiation Facility (IF) is designed to secure its load in place upon a loss of power and any fault condition. The hoisting machinery and wire rope system, in addition to other affected components, are designed to withstand the most severe potential overload, including two-blocking and load hang-up.

With use of a crane designed to the criteria of ASME NOG-1 for a Type 1 crane, a likelihood of failure is extremely low due to the single failure-proof handling features. In addition, Section 5.1.1 of NUREG-0612 provides certain guidance on slings and special handling devices. As indicated in NUREG-0612, the handling system for use with single-failure-proof design should include lifting devices that should be selected to satisfy either of the following criteria:

- A special lifting device that satisfies ANSI N14.6 should be used for recurrent load movements in critical areas (reactor head lifting, reactor vessel internals, spent fuel casks). The lifting device should have either dual, independent load paths or a single load path with twice the design safety factor specified by ANSI N14.6 for the load.

- Slings should satisfy the criteria of ASME B30.9 and be constructed of metallic material (chain or wire rope). The slings should be either (a) configured to provide dual or redundant load paths or (b) selected to support a load twice the weight of the handled load.

While SHINE commits to these ANSI and ASME codes, the staff is unable to locate any details or description of lifting devices, sling selection criteria, rigging design (i.e., redundant load path or double factor of safety), and sling attachment to the load.

In addition to above, the staff noted inconsistent versions of the ASME NOG-1 code were referenced in the application:

- Section 3.4.2.6.4.6 “Crane Load” of SHINE application, the building is evaluated for loads associated with two overhead bridge cranes, one servicing the IU cell area and one servicing the RPF area. Crane loading is evaluated in accordance with American Society for Mechanical Engineers (ASME) NOG-1, Rules for Construction of Overhead and Gantry Cranes (ASME, 2004).

- However, Section 9b.7.2 “Material Handling System” commits to single failure proof crane design in accordance with the ASME NOG-1, Rules for Construction of Overhead and Gantry Cranes (Top Running Bridge, Multiple Girder) (AMSE, 2015).

a. Provide additional details on special lifting devices, having redundant load paths or double the normal factors of safety, the particular components associated with special lifting devices, and details of the interfacing lift points for these components consistent with SHINE’s commitments applicable ANSI and ASME codes.

b. Verify which version of ASME NOG-1 code is applied to the SHINE design.

This information is necessary for the NRC staff to determine that systems, components, and methods for handling, moving, or storing components are adequately designed to prevent mechanical damage that could significantly decrease integrity of facility safety-related SSCs or release fission products.

Chapter 11 – Radiation Protection Program and Waste Management

RAI 11-1 Section 11.1, "Radiation Protection," of the NUREG-1537, Part 2, states that acceptance criteria for information concerning sources of radiation should include the following:

- Conservative best estimates of the predicted concentrations, locations, and quantities of airborne radionuclides during the full range of normal operation in areas occupied by personnel.

- Conservative best estimated of the predicted locations and magnitude of external radiation fields during the full range of normal operation in areas occupied by or accessible to personnel.

Section 11.1.1, "Radiation Sources" of the SHINE FSAR, page 11.1-3 states that, "Shielded vaults, cells, and rooms designated as high radiation areas or very high radiation areas as denoted in Figure 11.1-1..." However, it appears that Figures 11.1-1 and 11.1-2 do not have room designations (labels for rooms) that inform the staff of what equipment may be in the rooms.

Provide updated versions of Figures 11.1-1 and 11.1-2 in the FSAR with labeled rooms with identified equipment that are sources for designation as high and very high radiation areas.

RAI 11-2 10 CFR 50.34(b)(3) states that the FSAR shall include the kinds and quantities of radioactive material expected to be produced in the operation of the facility as it relates to tracking the amount of radioactive material contained in the various facility components as well as the anticipated radionuclides inside and outside the plant environment. In addition, NUREG-1537 Part 2, Section 11.1.1, "Radiation Sources," states that applicant should identify the "quantities and concentrations expected to be released." 10 CFR 20.1101(b) states that the applicant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Section 11.1.1, "Radiation Sources," of the SHINE FSAR, page 11.1-2 states that the normal operation internal facility radiation dose rates are consistent with ALARA principles and that the "dose rates were calculated using the maximum specified shield plug gap sizes, minimum density shielding materials, and the nominal inventories for full power operation."

a. In order for NRC staff to determine whether SHINE's dose rate estimates are appropriate for meeting 10 CFR 20.1101(b) and consistent with ALARA principles, provide a summary of the calculations/evaluations, assumptions, methodology, and input parameters that resulted in the estimated dose rates. The current information provided in FSAR section 11.1 tables generically provides a total curie content for components but does not provide enough details for the staff to perform an independent evaluation. Provide FSAR tables that provide the expected activities by isotope, in the components located in the SHINE facility to demonstrate compliance with 10 CFR

50.34(b)(3). The tables that staff are referring to include: Tables 11.1-5, 11.1-9, and 11.1-10. In addition, the staff requests the applicant provide a table that summarizes the volumes in components such as tanks and systems assumed for dose calculations and provide thickness for tanks and pipes to allow staff to verify the stated radiation zoning in FSAR section 11.1. If other assumptions were necessary for the dose calculations provide that information within the response to this question.

Section 11.1.1.1, "Airborne Radioactive Sources," of the SHINE FSAR, page 11.1-4 states that SHINE maintains airborne radioactive material at very low concentrations in normally occupied areas and that systems are designed to protect workers in keeping with the ALARA principles of 10 CFR Part 20.

b. In order for NRC staff to determine whether SHINE airborne doses to occupational workers are consistent with the ALARA principles, provide a summary of the calculations/evaluations, assumptions, methodology, and input parameters for the calculated expected doses rates, include DAC estimates, from gaseous radioactive sources presented in Section 11.1.1.1.

Section 11.1.1.1., "Airborne Radioactive Sources," of the SHINE FSAR, page 11.1-5 states only nuclides with greater than 1 Ci/year released are included in Table 11.1-8.

c. Describe why SHINE limited the nuclides in Table 11.1-8 to only nuclides with greater than 1 Ci/year, which appears contrary to 10 CFR 50.34 and the guidance in NUREG-1537. Update the FSAR and Table 11.1-8 to include the quantities expected to be released, as necessary.

Consistent with the evaluation findings in Section 11.1.1 of NUREG-1537, Part 2, the information requested in parts a., b., and c. of this RAI is necessary for the NRC staff to confirm that the FSAR identifies potential radiation safety hazards associated with the SHINE facility and conduct an independent review of the SHINE radiation protection program.

RAI 11-3 FSAR Table 3.1-3 "SHINE Design Criteria," Criterion 35 – "Control of releases of radioactive materials to the environment" specifies that the facility is designed to include means to suitably control the release of radioactive materials in gaseous and liquid effluents and to handle radioactive solid wastes produced during normal operation, including anticipated transients. Sufficient holdup capacity is provided for retention of radioactive gases.

The NRC staff noted that SHINE has performed a dose analysis to demonstrate that the off-site doses to individuals through direct exposure and potential environmental pathways, such as leafy vegetable ingestion, meat ingestion, and milk ingestion from the release of airborne radionuclides will not exceed the limits of 10 CFR Part 20, "Standards for Protection Against Radiation." The results of this analysis are in Section 11.1.1.1, "Airborne Radioactive Sources," of the SHINE FSAR, page 11.1-5 and state that the "estimated annual doses at the MEI and the nearest resident are 3.9 mrem and 0.3 mrem, respectively, which are less than the limit in 10 CFR Part 20." The current version of the SHINE FSAR

lacks enough information for the NRC staff to determine whether SHINE annual doses to the public comply with 10 CFR Part 20.

a. Provide a summary of the assumptions, methodology, and input parameters used to estimate annual doses to the MEI and nearest resident. Specifically, include FSAR tables with the input parameters used to perform the dose calculations that determined the above referenced doses to the MEI. This includes the base radionuclides (listed by isotope) used for analysis, along with those assumptions made in regard to radionuclide filtration, consumption rates, food yields, and any other inputs necessary for the staff to perform an independent evaluation.

The limits in 10 CFR Part 20 are specified in terms of TEDE and mrem because the regulations in 10 CFR Part 20 are based on the International Commission on Radiation Protection's (ICRP) recommendations in ICRP Reports 26 and 30. Dose conversion factors acceptable to the NRC staff are derived from data and methodologies provide in ICRP Publication 30, "Limits for Intakes of Radionuclides by Workers" and can be found in Federal Guidance Report (FGR) No. 11, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," and FGR No. 12, "External Exposure to Radionuclides in Air, Water, and Soil," for exposure to radionuclides in air, water, and soil.

As stated above the estimated annual doses at the maximum exposed individual and the nearest resident are 3.9 mrem and 0.3 mrem which are less than the limits in 10 CFR Part 20. However, the FSAR does not specify if the estimated doses are in terms of total effective dose equivalent (TEDE) which is defined as the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent. It is not clear in the FSAR whether the dose coefficients used in the analysis are consistent with the regulations in 10 CFR Part 20 and ICRP Reports 26 and 30.

b. Clarify if the dose estimates were performed using the appropriate dose conversion factors based on ICRP 26/30 methods. If not, re-compute the radiological dose estimates to the MEI and nearest resident in terms of TEDE to be consistent with the regulations in 10 CFR Part 20.

Consistent with the evaluation findings in Section 11.1.1 of NUREG-1537, Part 2, the information requested in parts a. and b. of this RAI is necessary for the NRC staff to confirm that the FSAR identifies potential radiation safety hazards associated with the SHINE facility and conduct an independent review of the SHINE radiation protection program.

RAI 11-4 NUREG-1537 Part 2, Section 11.1, states that acceptance criteria for applicant’s analysis for doses in unrestricted areas should “contain conservative best estimates of the predicted annual total doses to at least the following in the unrestricted areas: (1) the maximum exposed individual, (2) the nearest permanent residence, and (3) any location of special interest, such as a classroom or campus dormitory.”

Section 11.1.7.2.1, “Direct Radiation Monitoring,” of the SHINE FSAR states that “dosimeters are stationed off site at special interest areas.” However, no analysis for special interest areas appears in the SHINE FSAR which is inconsistent with the acceptance criteria in NUREG-1537.

Provide clarification as to whether the “special interest areas” referred to in Section 11.1.7.2.1 of the SHINE FSAR are meant to be “locations of special interest” as discussed in the acceptance criteria in NUREG 1537 Part 2. If so, provide the associated public dose analysis for these locations of special interest or a justification for why a separate dose analysis is not necessary.

RAI 11-5 10 CFR 20.2003, “Disposal by release into sanitary sewerage,” and 10 CFR 20.2007, “Compliance with environmental and health protection regulations” as it relates to the applicant’s description of their potential liquid releases pathways and ensuring that liquid releases are done in accordance with NRC as well as other federal, state, and local regulations.

Section 11.1.7.2 of the SHINE FSAR states that “There are no routine radioactive liquid effluent discharges from the RCA” and that “There are no piped liquid effluent pathways from the RCA to the sanitary sewer.” Based on this information the staff understands that the only release of liquid radioactive material from the facility will be via the sewer.

If there are no piped liquid effluent pathways from the RCA to the sanitary sewer, clarify in the FSAR how SHINE intends to perform sewer discharges in accordance with 10 CFR 20.2003, “Disposal by release into sanitary sewerage,” and 10 CFR 20.2007, “Compliance with environmental and health protection regulations,” and how often the sewer discharges are expected to be performed. This additional information is necessary to ensure NRC staff and the public understand how SHINE intends to operate the facility while protecting the public and environment. In addition, section 11.1.4, “Radiation Monitoring and Surveying, of the SHINE FSAR states that “liquid effluent releases are collected and sampled prior to release.” In the context of this section, clarify if liquid effluent releases meant to be understood as liquid releases via sewer as discussed in 11.1.7.2.

RAI 11-6 NUREG-1537, Part 2, Chapter 11 of the standard review plan and acceptance criteria, as augmented by the interim staff guidance (ISG) for licensing radioisotope production facilities is applicable to reviewing a description of the radiation protection program and waste management for the licensing of a radioisotope production facility. The acceptance criteria in Chapter 11 of the ISG states that the application should identify a controlled area as defined in 10 CFR 20.1003. 10 CFR 20.1003 defines “controlled area” as “an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.”

Section 11.1.5.1 of the SHINE FSAR defines “controlled access area” in the first sentence but later states that “Facility visitors include delivery people, tour guests, and service personnel who are transient occupants of the controlled area.”

Provide a definition for “controlled area” and provide clarification as to the difference between “controlled access area” and “controlled area” when used in Section 11.1.5 of the SHINE FSAR.

RAI 11-7 FSAR Table 3.1-3 “SHINE Design Criteria,” Criterion 38, “Monitoring Radioactivity Releases,” specifies that means are provided for monitoring the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material. Potential effluent discharge paths and the plant environs are monitored for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents. In addition, NUREG-1537 Part 2, Section 11.1.1, “Environmental Monitoring,” has acceptance criteria that states the environmental monitoring program should provide confidence that a significant radiological impact on the environment from the facility would be detected and the type and magnitude of the radiological impact would be determined.

Section 11.1.7.2, “Effluent Release Pathways,” of the SHINE FSAR presents the pathways that represent plausible public exposure scenarios from airborne effluents, one of which is the “Ingestion exposure pathway.” However, Section 11.1.7.2.3, “Ingestion Pathway (Biota Monitoring),” states that “biota monitoring is not routinely included in the REMP.” However, given that Section 11.1.7.1 states that Regulatory Guide (RG) 4.1, “Radiological Environmental Monitoring for Nuclear Power Plants,” was considered when developing the radiological environmental monitoring program for the SHINE facility the staff requests the following information:

a. Provide a summary of the evaluation and data that was used to justify that routine biota monitoring is not necessary for SHINE and how this conclusion meets the objectives of RG 4.1, as applicable, and explain this in the SHINE FSAR.

b. If monitoring of this pathway will not be performed prior to start up or during operations, describe if evaluations will be performed in the future to determine if biota monitoring may become necessary after start-up.

RAI 11-8 FSAR Table 3.1-3 “SHINE Design Criteria,” Criterion 38, “Monitoring Radioactivity Releases,” specifies that means are provided for monitoring the primary confinement boundary, hot cell, and glovebox atmospheres to detect potential leakage of gaseous or other airborne radioactive material. Potential effluent discharge paths and the plant environs are monitored for radioactivity that may be released from normal operations, including anticipated transients, and from postulated accidents. In addition, NUREG-1537 Part 2, Section 11.1.1, “Environmental Monitoring,” has acceptance criteria that states the environmental monitoring program should provide confidence that a significant radiological impact on the environment from the facility would be detected and the type and magnitude of the radiological impact would be determined.

However, Section 11.1.7.2.4, “Groundwater Monitoring,” states that surface waters are not expected to accumulate detectable levels of radioactivity as such surface water will not be included in the radiological environmental monitoring program.

Provide a summary of the evaluation and assumptions that support the justification that surface water sampling is not needed in the radiological environmental monitoring program and provide this discussion in the SHINE FSAR. If monitoring of surface water will not be performed prior to start up or during operations, clarify if evaluations will be performed in the future to determine if surface water sampling may become necessary after start-up.

RAI 11-9 10 CFR 50.34(b)(3) states that the FSAR will include the kinds and quantities of radioactive material expected to be produced in the operation of the facility as it relates to tracking the amount of radioactive material contained in the various facility components as well as the anticipated radionuclides inside and outside the plant environment. Section 11.2 of the FSAR states that "the material storage building is used for interim storage of wastes for decay and for preparation for shipment. Wastes are not stored for more than five years." Section 11.2.2.2 states, "At least 5,600 square feet (ft^2) of the material staging building is for temporary storage to allow for decay." Section 11.2.2.2 also states that "drums may be stored in multiple layers." However, the SHINE FSAR does not provide anticipated activities of waste stored within the material storage building.

Provide additional detail regarding the anticipated activities of waste stored within the material storage building so that the staff can determine compliance with 10 CFR 50.34(b)(3) in defining the annual amount of radionuclides generated as waste at the SHINE facility. In addition, this source term information will be used by the staff to perform an independent evaluation for direct dose to determine compliance with 10 CFR 20.1301 dose limits. Specifically, provide information on the activity by isotope, the volumes of the barrels that the applicant plans to use for stored waste, shielding thickness credited in the analysis and any other assumptions the applicant used to determine that "The material staging building design evaluated the shielding provided by the building to ensure 10 CFR 20 site dose limits are met and ALARA principles are followed," as described in FSAR section 11.2.2.

RAI 11-10 Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," of 10 CFR Part 20, "Standards for Protection Against Radiation," specifies the conditions under which respiratory protection equipment may be used and lists the procedural requirements that must be met by a licensee when using respirators to limit intakes of radioactive material or to take credit for the protection assigned to a respirator in limiting and estimating intakes of airborne radioactive materials.

Section 11.3 of the SHINE FSAR briefly describes the respiratory protection program and states that the program is "in accordance with 10 CFR 20, Subpart H." Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection" describes a respiratory protection program that is acceptable to the NRC staff. Regulatory Guide 8.15 also provides guidance on performing evaluations to determine whether the use of respirators optimizes the sum of internal and external dose and other risks. The NRC staff uses RG 8.15 to evaluate respiratory protection programs for compliance with Subpart H of 10 CFR

Part 20, except in those cases where an applicant proposes an acceptable alternative method for complying with specific portions of the regulations.

Clarify if SHINE intends to conform their program to RG 8.15 or if SHINE intends to apply their own methods when using respiratory protection. If SHINE's program will not conform with RG 8.15, further describe SHINE's methods in the FSAR. For example, describe:

- the respiratory protection training program,
- industry standards used as basis for program,
- TEDE-ALARA evaluations,
- fit-testing program,
- types of respirators to be used,
- use of assigned protection factors,
- air sampling bioassays,
- qualifications of respirator wearers,
- safety precautions,
- breathing air quality management,
- maintenance, repair, testing, QA and storage of respiratory equipment, and
- whether respirators will be used for mixed hazards (airborne radioactive material and nonradioactive hazardous material).

RAI 11-11 Section 5.8.1, "Operating Reports," of the SHINE Technical Specifications requires SHINE to submit an annual report providing "A summary of exposures received by facility personnel and visitors where such exposures are greater than 25 percent of that allowed or recommended." However, 10 CFR 20.2206, "reports of individual monitoring," requires licensees who fall under one of the categories listed in 10 CFR 20.2206(a) to submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by 10 CFR 20.1502.

Justify why SHINE does not meet the category described in 10 CFR 20.2206(a)(7) and why the current technical specification annual report requirement is appropriate for SHINE.

RAI 11-12 Section 11.1.2, "Radiation Protection Program" describes the SHINE radiation protection program which is intended to protect the radiological health and safety of workers and members of the public. Section 5.1.3, "Facility Staffing Required" of the SHINE technical specifications provides the required minimum staffing for when the facility is not secured. The staffing plan does not specifically include radiation safety personnel but states that radiation safety personnel should be included on a telephone number list readily available in the control room.

Considering the types, quantities and concentrations of radioactive material that will be handled at the SHINE facility, describe the staffing expectations for radiation safety personnel when the facility is secured and not secured. In addition, confirm if radiation safety personnel work will still be handled by the radiation safety personnel, as defined in Chapter 11, during a secured condition.

This information is necessary for the NRC staff to verity that SHINE has developed, documented, and implemented a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.