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11.0 RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

The purposes of the radiation protection program and waste management provisions are to ensure safety of the SHINE Medical Technologies, Inc. (SHINE) irradiation facility (IF) and radioisotope production facility (RPF) and protection of the public. The radiation protection program and waste management provisions, identified by the analyses in the SHINE Preliminary Safety Analysis Report (PSAR), should be conducted using the appropriate methods and engineering design criteria.

This chapter of the SHINE construction permit (CP) safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) of the preliminary design of the SHINE radiation protection program and waste management provisions as presented in Chapter 11, "Radiation Protection Program and Waste Management," of the SHINE PSAR, as supplemented by the applicants responses to requests for additional information (RAIs).

11.1 Areas of Review

SHINE PSAR Chapter 11, "Radiation Protection Program and Waste Management," identifies the aspects of the radiation protection program and waste management provisions considered to ensure facility safety and protection of the public. SHINE PSAR Chapter 11 is applicable to both the SHINE IF and RPF.

The staff reviewed PSAR Chapter 11 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design criteria of the SHINE facility radiation protection program and waste management provisions. As part of this review, the staff evaluated descriptions and discussions of the SHINE facility radiation protection program and waste management provisions, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the SHINE facility radiation protection program and waste management provisions were evaluated to ensure the design criteria; design bases; and information relative to construction is sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design.

Areas of review for this section included both the SHINE IF and RPF program. Within these review areas, the staff assessed the following:

- The capability of the program to identify and discuss all expected radiation and radioactive sources, to include airborne, liquid, solid sources, and radioactive wastes
- The design and effectiveness of the radiation protection program required by 10 CFR 20.1101
- The ability to maintain worker and public doses and radiological releases through an As Low As Reasonably Achievable (ALARA) program, including 1) a description of the methods to establish, change, and manage policy for the ALARA program; and 2) a description of how the ALARA program is implemented for all activities at the facility to

maintain radiation doses of all personnel and releases of effluents to the unrestricted area ALARA

- The procedures and equipment at the facility for routinely monitoring and sampling workplaces and other accessible locations to identify and control potential sources of radiation exposure and release
- The design bases for the equipment and procedures utilized for controlling radiation exposures to personnel and releases of radioactive materials from the facility
- The capability of the dosimetry and other methods to effectively assess exposure to radiation and radioactive materials
- The capability of the program for contamination control to meet all applicable requirements of the regulations and the facility ALARA program
- The capability of the environmental monitoring program to: 1) comply with any commitments made in environmental reports or other documents (e.g. standards the applicant used in the environmental monitoring program); 2) establish preoperational baselines used to ascertain natural background so that the radiological impact of facility operation on the environment can be determined; 3) promote compliance with environmental quality requirements through the facility policy, the bases for procedures implementing the facility policy, the overall program, and technical specifications or internal requirements of the applicant; 4) ensure that the written plans and the bases of procedures for implementing the environmental monitoring operations, including changes, are reviewed for adequacy and approved by authorized personnel and are distributed to and used at the appropriate locations throughout the facility; and 5) establish the environmental surveillance program, including information on the identification of possible and probable radioactive contaminants resulting from operation of the facility, selection of sampling materials and locations (include maps), sample collection methods and frequency, sampling and counting equipment, and sample analysis techniques, sensitivities, and detection limits
- The capability to manage radioactive wastes to include: philosophy of and approach to management of the wastes; organization of the management function; program staffing and position descriptions, and program personnel responsibilities and qualifications as discussed in the format and content guide; any review and audit committees related to radioactive waste management; training for staff; plans for shipping, disposal, and long-term storage; program documentation and records, including availability and retention; audits of the effectiveness of the program; bases of procedures; and bases of technical specifications
- The effectiveness of the radioactive waste control plans at the facility to include methods to decrease and eventually minimize the formation of radioactive wastes
- The methods of characterizing the possible effluents, references to the applicable regulations that establish limits for release, descriptions of the identities and amounts of radionuclides in the effluents, the release points, and the characteristics of the environment to which they are released

11.2 Summary of Application

As stated above and described in SHINE PSAR Chapter 11, the radiation protection program and waste management provisions are established to ensure facility safety and protection of the public.

PSAR Section 11.1.1.1, "Airborne Radioactive Sources," notes that gaseous activity from the TSV will be handled by the Tritium Purification System (TPS) and the TSV Off Gas System (TOGS). Located in the RPF, the noble gas removal system (NGRS), and the process vessel vent system (PVVS) will also be used to contain and control airborne activity. In addition to the major airborne activity source term within the IUs, an estimated 15 Ci of Ar-41 ($T_{1/2}$ = 1.8 hours) is also produced To ensure containment of these airborne radioactive materials, the heating, ventilation, and air conditioning (HVAC) systems described in PSAR Chapter 9a2.1 consist of three stages (designated RVZ1, RVZ2, and RVZ3) to remove airborne activity from areas of the facility having the lowest concentration (RVZ3) and cycle it to the increasingly higher concentration areas (RVZ2 and RVZ1, respectively). Exhaust air from these zones will be pulled through HEPA filters and carbon adsorbers to minimize the potential for airborne contamination. In addition the above-mentioned sources of airborne activity, N-16 ($T_{1/2}$ = 7.1 seconds) is produced through neutron activation of natural nitrogen in the primary coolant loops. The N-16 is contained within the coolant loops; however, its decay, accompanied by 6.1 and 7.1 MeV gamma rays, requires shielding design consideration for worker safety. Gaseous activity released from the TSV and process operations will be collected and sent to the NGRS which consists primarily of five 100 gallon decay tanks and is located in a shielded cell. The gasses will be held for 40 days post irradiation to allow short lived fission and activation products to decay to levels that meet regulatory limits for release to the environment. The estimated annual dose from airborne effluent releases is below 10 mrem. The processes will be remotely controlled, manually controlled, or performed with telemanipulators, with minimal automated sequences. Radiation monitors and alarms will be used to monitor for release of radiological materials and ambient exposure rates. Gases and liquids that contain potentially-radiological material will be transferred through shielded pipe chases to limit the exposure of individuals to radiation.

PSAR Section 11.1.1.2, "Liquid Radioactive Sources," states with the exception of two sources (N-16 production and fresh, unirradiated uranyl sulfate solution) all liquid wastes are associated with irradiated uranyl sulfate as a target solution. The values in Table 11.1-5 related to IF operation show an estimated [redacted] of fission products to be present in the Subcritical Assembly System. Slightly lower activities [redacted] are estimated in the Uranyl Nitrate Convesion System (UNCS) that will be handled in the RPF portion of the SHINE facility with other sources being either lower in activity or were not estimated pending completion of the FSAR. [redacted]. This contains the majority of byproduct material within the facility; specifically, the fission products generated in the TSV. Each of the two waste storage tanks can hold a maximum of 21 TSV batches of raffinate. The PSAR states that certain details, such as concentrations and solubilities of major liquid sources will be provided in the FSAR. The PSAR also states that there will be no radioactive liquid discharges to the environment from the SHINE facility.

PSAR Section 11.1.1.3, "Solid Radioactive Sources," identifies several categories of solid radioactive sources expected during operations. On the low end of this activity spectrum is enriched uranium feed material. It is converted from a metallic form to an oxide and then to uranyl sulfate where it enters the irradiation process. The other end of the activity spectrum includes spent extraction columns, spent filters, solidified liquid waste and irradiated components. To identify options for disposal, licensed radioactive waste disposal sites that can take receipt and dispose of solid radioactive waste are identified.

PSAR Section 11.1.2, "Radiation Protection Program," addresses the following the radiation protection program elements: responsibilities of key program personnel; staffing of the radiation

protection program; radiation protection program independence; radiation safety committee; written radiation protection procedures; radiation protection training; radiation safety audits.

PSAR Section 11.1.3, "ALARA Program," states the radiation protection manager (RPM) is responsible for implementing the ALARA program and ensuring that adequate resources are committed to make the program effective. The RPM will prepare an annual ALARA program evaluation report that will review trends in radiation exposures and effluent release data; reviews the results of audits and inspections; the use, maintenance, and surveillance of equipment used for exposure and effluent control; and other issues that may influence program effectiveness. The program will facilitate interactions between radiation protection and operations personnel, particularly through use of the Radiation Safety Committee where both organizations are represented. The applicant committed to the ALARA principles as applied to plant design, where designs are reviewed, updated, and modified as experience is gained. Specifically included in these reviews will be shielding, ventilation, and monitoring instrument designs as they relate to traffic control, security, access control, and health physics. Additionally, the location of equipment and routing of piping containing radioactive fluids is reviewed as part of the design effort to ensure that significant sources are adequately shielded and properly routed to minimize exposure of personnel. SHINE has indicated that lessons-learned from industry practices and operating experience shared by the NRC in the form of generic communications are incorporated into the facility design. The design considerations noted in PSAR Section 11.1.3 emphasize remote handling capabilities, use of high reliability of components as a means of reducing maintenance requirements, and reducing component access and removal times to reduce radiation exposure. Specific examples cited by SHINE that assist in maintaining exposures ALARA include:

- Design provisions for maintenance of target solution and light water pool chemistry conditions, such that corrosion and resulting activation product source terms are minimized.
- Features to allow draining, flushing, and decontaminating equipment and piping.
- Design of equipment to minimize the creation and buildup of radioactive material and to ease flushing of crud traps.
- Shielding for personnel protection during maintenance or repairs and during decommissioning.
- Means and adequate space for the use of movable shielding.
- Separation of more highly radioactive equipment from less radioactive equipment and separate shielded compartments for adjacent items of radioactive equipment.
- Shielded access hatches for installation and removal of plant components.
- Design features, such as the means to provide surface decontamination within hot cells.
- Means and adequate space for the use of remote operations, maintenance, and inspection equipment.
- Separating clean areas from potentially contaminated ones.
- Locating equipment, instruments, and sampling stations that require routine maintenance, calibration, operation, or inspection, to promote ease of access and minimize occupancy time in radiation areas.
- Laying out plant areas to allow remote or mechanical operation, service, monitoring, or inspection of contaminated equipment.
- Providing, where practicable, for movement of equipment or components requiring service to a lower radiation area.

PSAR Section 11.1.4, "Radiation Monitoring and Surveying," discusses the applicant's plan to use continuous air monitors (CAMs) to provide indications of airborne activity levels in the RCA. The CAMs will be supplemented when needed by a portable air sampler followed by laboratory analysis. Tritium sampling will be conducted in each IU, the TPS glovebox room, and from stack effluent. Continuous monitoring of the plant stack releases will be annunciated in the control room. SHINE proposes that the MIPF will be a zero liquid release facility; however, continuous monitoring of closed loop systems will be performed. Radiation area monitors will be located at unspecified areas and provide indications of exposure rates to the control room. At each control point (entrance/exit to the RCA), SHINE has proposed having one or more of the following available: a portal monitor, a frisker, a hand and foot monitor, and a small article monitor, the latter being used to conduct free-release surveys of tools and similar equipment. Additionally, criticality accident and alarm system (CAAS) monitors (gamma and neutron detectors with local and control room annunciation) will be provided (locations to be included in the FSAR). Also in PSAR Section 11.1.4, the applicant states that radiation surveys will be performed to ascertain radiation levels and concentrations that may be present in the facility and to detect releases of radioactive material from facility equipment and operations. Specific surveillance program details were not provided in the PSAR. It was noted, however, that survey and monitoring programs will be consistent with the guidance provided in Regulatory Guides 8.2, 8.7, 8.9, 8.24, and 8.34.

PSAR Section 11.1.5, "Radiation Exposure Control and Dosimetry," defines a Restricted Area (defined in 10 CFR 20) to primarily include the RCA and that most other restricted areas are within the physical structure of the SHINE facility; however, the PSAR notes that radioactive material may be temporarily stored in areas outside of the main facility such as the waste staging and shipping building. The applicant has also defined a Controlled Area (also defined in 10 CFR 20) to include any area beyond the main reception area, but outside of the Restricted Area. The applicant also states that members of the public cannot directly enter the Controlled Area and must be processed by security and given authorization to enter. SHINE has defined an Unrestricted Area for which no access control is exercised and access is not limited in any way. This includes all areas outside of the Controlled Area. SHINE recognized that the dose in an Unrestricted Area from external sources may not exceed 0.02 mSv (2 mrem) in any one hour and that doses to members of the public may not exceed 100 mrem/year above background. The PSAR includes definitions for a Radiation Area, Airborne Radioactivity Area, and a High Radiation Area as contained in 10 CFR 20. Also defined by SHINE (but not in 10 CFR 20) is a Contaminated Area. Such an area is defined by the presence of removable surface contamination of 0.33 Bq/100 cm^2 (20 dpm/100 cm^2) of alpha activity or 16.7 Bq/100 cm^2 (1000 dpm/100 cm^2) of beta activity. Access to the Restricted Area occurs via one of the Control Points where dosimetry and protective clothing and equipment are issued. All personnel entering the Restricted Area must be properly trained unless they are escorted by someone who has been trained. Within the Restricted Area, a number of High Radiation Areas (HRAs) exist. Access to HRAs will be controlled by a combination of administrative methods and a combination of active and passive barriers. PSAR Section 11.1.5 also states that any personnel entering the Restricted Area will be required to wear a beta-gamma dosimetry device in a manner consistent with the manufacturer's directions. Devices with be exchanged quarterly. Exposure control includes performing an investigation (and documentation) of any individual exposure greater than 25% of the SHINE administrative limits. The RPM is informed of such exposures. PSAR Section 11.1.5 also addresses internal dose assessments, where the applicant proposes to use a combination of air concentration measurements, measurements for intake of radionuclides in the body, and radionuclides in excreta. SHINE will assume that the measured air concentration is equal to the inhaled concentration unless respiratory protective equipment is used in accordance with 10 CFR 20.1703 or the intake is determined based on

excreta sample measurements or whole body counting. PSAR Section 11.1.5 also discusses additional facilities, including: locker and change rooms for male and female employees to change into clothing suitable for RCA entry, a first aid station to treat injured personnel, a personnel decontamination area, and storage areas for anti-contamination clothing, respiratory protective equipment, and radiation protection supplies.

PSAR Section 11.1.6, "Contamination Control Equipment and Facility Layout General Design Considerations for 10 CFR 20.1406," addresses design considerations to prevent spread of contamination to the facility and the environment for the following: (1) Shielded compartments and hot cells; (2) Monitoring and controlled entry/egress to the Restricted Area; (3) Piping considerations; (4) A light water pool; and (5) Process tanks.

PSAR Section 11.1.7, "Environmental Monitoring," discusses the applicant's proposed radiological environmental monitoring program (REMP) that routinely includes direct exposure monitoring, air sampling and groundwater sampling. Provisions are included for sampling of other environmental media (termed biota sampling) when triggered by pre-defined off-normal releases, should they occur. A preoperational REMP will be conducted and include TLD, air, groundwater, and biota in order to establish baseline values which can be referenced by the operational REMP.

PSAR Section 11.2.1, "Radioactive Waste Management Program," defines the goals of the waste management program as: minimizing waste generation, minimizing exposure of personnel, and protecting the general public and environment. The applicant discusses the following aspects of the program: 1) responsibilities of management and supervisory positions; 2) operating procedures; 3) record keeping and document controls; and 4) waste management audits.

PSAR Section 11.2.2, "Radioactive Waste Controls," contains a commitment to describe the operational procedures to be used to identify, characterize, and separately treat the different waste streams in the FSAR. PSAR Section 11.2.2.1 states that a waste minimization program will exist within the radioactive waste management program. PSAR Section 11.2.2.2 presents the preliminary identification of waste streams and the proposed controls.

PSAR Section 11.2.3, "Release of Radioactive Waste," describes "release" as processing and packaging wastes as required to meet the waste acceptance criteria at an established disposal facility. Processes are utilized to segregate specific radionuclides important to waste classification so to reduce the waste classification of the larger volume of wastes. Several of the solid waste streams are packaged then stored in the waste staging and shipping building to allow decay of the contents to occur, reducing the waste classification as well as the radiation level of the packages at final disposal. PSAR Section 11.2.3 restates that there are no liquid radioactive effluent discharges from the facility. Liquid wastes are processed by ion exchange to remove specific radionuclides important to waste classification and by evaporation to concentrate the bottoms prior to solidification and disposal. Gaseous wastes from the NGRS are held for a minimum 40 days of decay, sampled and evaluated against release criteria and - if sufficiently below the limits - released through a monitored stack.

PSAR Section 11.3, "Respiratory Protection Program," states that a respiratory protection program will be used only when the HVAC or other engineering controls cannot be applied to control the intake of radioactive material. The applicant first made reference to these engineered controls represented by the heating, ventilation, and air conditioning (HVAC) system described in Section 9a2.1 of the PSAR. The respiratory protection program includes the

following elements: 1) air sampling; 2) surveys and, when necessary, bioassays; 3) performance testing of respirators for operability; 4) written procedures for all key program elements; and 5) determination by a physician that the individual user is medically fit to use respiratory protection equipment. The applicant also references applicable regulations, industry standards, and provides additional information regarding elements of the proposed respiratory protective equipment fit testing program.

Additionally, the following PSAR tables provide information on the radiation protection program and waste management provisions:

- Tables 11.1-1 through Table 11.1-3 lists the Target Solution Vessel (TSV) source term parameters, limiting and bounding radionuclide inventories, and activity for select radionuclides following shutdown.
- Table 11.1-4 through Table 11.1-6 lists various airborne, liquid, and solid radioactive sources that are expected to be associated with plant operation, including the IF and RPF components
- Table 11.1-7 provides administrative radiation exposure limits
- Table 11.1-8 provides the proposed environmental thermoluminescent dosimeters locations
- Table 11.1-9 shows the radionuclides being released with Xe-133 comprising more than 94% of the emissions by activity
- Table 11.2-1 provides a summary of waste types, the waste classification at the time of generation, and anticipated volume
- Table 11.2-2 through 11.2-7 provides waste methodology for various components and waste streams
- Table 4b.4-1 of the PSAR lists estimated SNM inventory in the RPF

11.3 Regulatory Basis and Acceptance Criteria

As previously stated and described in SHINE PSAR Chapter 11, the radiation protection program and waste management provisions are established to ensure facility safety and protection of the public. Therefore, the regulatory basis and acceptance criteria provided below applies to both the IF and RPF.

The staff reviewed SHINE PSAR Chapter 11 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design of the SHINE radiation protection program and waste management provisions in support of the issuance of a construction permit. In accordance with paragraph (a) of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.35, “Issuance of Construction Permits,” a construction permit authorizing SHINE to proceed with construction may be issued once the following findings have been made:

(1) SHINE has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.
(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

(3) Safety features or components, if any, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.
(4) On the basis of the foregoing, there is reasonable assurance that (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility and (ii) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

The staff's evaluation of the preliminary design of the SHINE radiation protection program and waste management provisions does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE radiation protection program and waste management provisions as described in the FSAR as part of SHINE's operating license application.

11.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE radiation protection program and waste management provisions are as follows:

10 CFR Part 20, "Standards for Protection Against Radiation."

10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."

11.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated the SHINE radiation protection program and waste management provisions against the applicable regulatory requirements listed above primarily using the guidance and acceptance criteria contained in Chapter 11, "Radiation Protection Program And Waste Management," of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Agencywide Documents Access and Management System [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), as well as 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 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 appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers [IEEE] standards, American National Standards Institute/American Nuclear Society [ANSI/ANS] standards) has been utilized in the review of the SHINE's radiation

protection program and waste management provisions. The use of additional guidance is based on the technical judgement of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG Augmenting NUREG-1537, Parts 1 and 2; and the SHINE PSAR.

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 11.4, "Review Procedures and Technical Evaluation," of this SER. Additional guidance documents used to evaluate the SHINE radiation protection program and waste management provisions are provided as references at the end of this chapter.

11.4 Review Procedures, Technical Evaluation, and Evaluation Findings

As described in SHINE PSAR Chapter 11, the radiation protection program and waste management provisions are established to ensure facility safety and protection of the public. Therefore, the regulatory basis and acceptance criteria provided below applies to both the IF and RPF.

The staff performed an evaluation of the technical information presented in SHINE PSAR Chapter 11, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the radiation protection program and waste management provisions in support of the issuance of a construction permit, in accordance with 10 CFR 50.35(a). Sufficiency of the radiation protection program and waste management provisions is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 11.3, "Regulatory Basis and Acceptance Criteria," of this SER. The results of this technical evaluation are described in SER Section 11.5, "Summary and Conclusion."

For the purposes of issuing a CP, the radiation protection program and waste management provisions may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the radiation protection program and waste management provisions based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of the SHINE radiation protection program and waste management provisions does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE radiation protection program and waste management provisions, as described in the FSAR, as part of SHINE's operating license application.

11.4.1 Radiation Sources

The staff evaluated the information provided on the radiation sources, as described in SHINE PSAR Section 11.1.1, "Radiation Sources," using the guidance and acceptance criteria from Section 11.1.1, "Radiation Sources," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG 1537, Part 2, Section 11.1.1, the staff evaluated the discussion of potential sources of radiation in the facility, as presented in SHINE PSAR Section 11.1.1 and other relevant chapters of the PSAR. The staff compared the description of the types of radioactive materials present with the applicable process description, including radionuclide inventories and mass balances and chemical and physical forms, to verify that all radioactive materials associated with the process have been identified. The staff reviewed the description and discussion of all sources of radiation to verify that they are

described in sufficient detail to provide the bases for the design and assessment of personnel protective measures and dose commitments. The staff confirmed that all solid sources of radiation at the facility are described and discussed in sufficient detail to permit evaluation of all significant radiological exposures related to normal operation, utilization, maintenance, and radioactive waste management including processing and shipment.

Although technically it is a part of the Chapter 4 material that describes features of the IU, RAI 4a2.5-1 and its response are discussed in this section because of the impact of shield thickness on occupational radiation exposures.

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.4, "Biological Shield," Acceptance Criteria, states that "[t]he principal objective of the shield design should be to ensure that the projected radiation dose rates and accumulated doses in occupied areas do not exceed the limits of 10 CFR Part 20, 'Standards for Protection Against Radiation,' and the guidelines of the facility's ALARA (as low as reasonably achievable) program discussed in Chapter 11 of the SAR."

SHINE PSAR, Section 4a2.5.2.2, "Geometry and Configuration," states that the side wall of the IU cell biological shield consists of standard density concrete that is 6.0 feet (1.8 meters) thick and that the dose rates on the external surface of the shield wall is expected to be less than 1.0 millirem/hour. PSAR Section 4a2.5.3.1, "Shielding Calculations," notes that the Monte-Carlo N-Particle (MCNP) Transport Code was used to determine the required shield thickness. PSAR Section 4a2.5.4, "Analysis," states, in part, that analysis is performed to: 1) give detailed results of both neutron and gamma-ray dose rates at locations that could be occupied as well as to the unrestricted environment; and 2) include shield penetrations and voids, such as beamports, thermal columns, and irradiation rooms or vaults, as well as the shielding of piping and other components that could contain radioactive materials or allow radiation streaming.

Therefore, in RAI 4a2.5-1, the staff asked the applicant to provide a list of the components inside the irradiation unit cell that are considered significant contributors (and the magnitude of these contributions) to the gamma and neutron flux and dose rates impinging on the interior shield wall. For each component describe the key assumptions included in the MCNP (or other computer code) radiation transport modeling used to determine shield wall thickness.

In response to RAI 4a2.5-1, the applicant stated the components inside the IU cell that are considered to be significant contributors to the gamma and neutron fluxes are the neutron driver and the Subcritical Assembly System. The interior surface of the IU shield wall was partitioned into two foot by two foot sections above the light water pool, and the neutron and gamma flux and dose rates in each section were calculated. The doses below the light water pool are not required for shielding purposes as this portion of the IU cell is below grade and there are no areas where personnel would normally be present below grade near the IU cell. The applicant provided key assumptions, inputs, neutron and gamma dose rates, and fluxes impinging in the 1.8 m thick shield wall to support the assertion that the dose rate at the exterior of the wall was <1 mrem/hr.

The staff was able to determine through its assessment that concrete shielding provided for the IU cells was sufficient to reduce the average and peak dose rates at the interior of the shield wall from the neutron driver during operation to <1 mrem/hr at the wall exterior. A dose rate of 1 mrem/hr is below the limit in 10 CFR 20.1301(a)(2) of 2 mrem in any hour for an unrestricted area. From a radiation protection perspective, members of the public could

occupy such areas without restriction. The 1 mrem/hr dose rate was therefore acceptable from a design perspective for occupational exposure considerations. Therefore, the staff finds this response satisfies the acceptance criteria of ISG Augmenting NUREG-1537, Part 2, Section 4a2.4 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of the SHINE FSAR.

10 CFR 50.34(a)(3)(i) requires that preliminary design information provided for the facility include principal design criteria. SHINE PSAR, Section 11.1.1.1, "Airborne Radioactive Sources," presents information on the management of airborne radioactive sources. It states that predicted personnel dose rates (including maintenance activity) due to airborne radioactivity and associated methodology will be presented in the Final Safety Analysis Report for the SHINE facility.

Therefore, in RAI 11.1-1, the staff asked the applicant to provide design information in sufficient detail (including key assumptions) to demonstrate the manner in which airborne radioactive material concentrations to which workers may be exposed (especially during maintenance activities) will be controlled in order to meet the derived air concentrations contained in 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage." The staff further clarified the request by specifically asking the applicant to provide the following: a) The expected airborne radioactive material concentrations (partitioned into noble gases, radioiodines, and particulates) associated with normal operations of the facility compared to their respective derived air concentrations in various areas that could be occupied by workers. Use definitions for airborne radioactivity areas similar to the following in terms of the derived air concentrations: Zone 1 (<0.01 – 1.0 derived air concentration), Zone 2 (1.0 - 10 derived air concentrations), and Zone 3 (>10 derived air concentrations); b) The expected airborne radioactive material concentrations associated with facility accidents compared to their respective derived air concentrations in various areas that could be occupied by workers; and c) Key assumptions associated with (a) and (b) above, including: (i) The basis for the production rate data in PSAR, Table 11.1-9, "Target Solution Vessel (TSV), Noble Gas and Iodine Production Rates, Annual Releases, and Effluent Concentration Limits (ECL) Fraction at the Site Boundary after 960 Hours of Noble Gas Removal System (NGRS) Holdup; (ii) A description of leakage pathways (including holdup and filtration/adsorption) from the point of production to the point of worker exposure; and (iii) For the ventilation system: Key parameters and assumptions associated with the estimates of airborne radioactive material concentrations in work areas.

In response to RAI 11.1-1(a), the applicant stated that the facility design maintains airborne radioactive material concentrations very low in normally occupied areas. Confinement and ventilation systems are designed to protect workers from sources of airborne radioactivity during normal operation and minimize worker exposure during maintenance activities, keeping with the as low as reasonably achievable (ALARA) principles outlined in 10 CFR 20. The applicant also stated that they have qualitatively assessed anticipated derived air concentrations for airborne radioactive material (noble gases, radioiodines, and particulates), above grade and within the RCA at the SHINE facility, during normal operations. The applicant provided PSAR Figure 11.1-1-1 as an illustrative depiction of this assessment Partitioning of airborne radioactive material concentrations associated with normal operations into noble gases, radioiodines, and particulates will be provided in the FSAR. An IMR has been initiated to track the inclusion of this information in the FSAR. The staff estimated the dose equivalent associated with the Zone 1 concentrations (up to 1.0 DAC) was 5 rem/yr. Although this dose

equivalent meets the annual occupational dose limits in 10 CFR 20.1201, it is not clear that such concentrations, if allowed to persist on a regular basis, would be considered ALARA. The upper limit for Zone 1 concentrations needs to be further evaluated at the FSAR stage to determine if additional measures, such as occupancy limitations, need to be applied as ALARA measures.

In response to RAI 11.1-1(b), the applicant provided Table 11.1-1-1, showing the expected airborne radioactive material concentrations associated with facility accidents compared to their respective derived air concentrations (DACs). The occupational airborne concentration for each radionuclide was compared to the DAC contained in Appendix B to 10 CFR 20. A sum of fractions method was used to calculate values for noble gases, radioiodines, and particulates for each accident scenario. The DAC values are for areas that could be occupied by workers and are applicable throughout the RCA of the SHINE production facility building. Evacuation of the workers is to be completed within 10 minutes, as described in PSAR Tables 13a2.2.1-2 and 13b.2.1-2. The staff notes the maximum expected concentrations under accident conditions would result in a maximum dose that is within 10 CFR 20 limits and EPA Protective Action Guidelines.

In response to RAI 11.1-1(c), the applicant indicated Table 11.1-9 provides the basis for the production rate data which consists of a single TSV operating at the licensed power limit. Cumulative fission yields were used to account for both instantaneous fission products and decay chain products that would be produced over the course of the entire operational cycle. All fission was assumed to occur by thermal neutrons in U-235. Fission of transmuted Pu-239 and fast neutron fission of U-238 were assumed to be negligible in comparison to U-235 fission rates. A total energy yield for neutron-induced fission of 200 MeV/fission was used. Decay constants for individual isotopes were used to convert the generation rate (atoms/sec) to a fission product activity generation rate (Ci/sec) for each radionuclide. The annual releases provided in Table 11.1-9 assume eight TSVs are in operation.

Further, the applicant states that during normal operation, there are no significant anticipated leakage pathways for worker exposure in normally occupied areas to airborne radioactive material. Normally occupied areas within the RCA are serviced by RVZ2 and RVZ3. Positive pressure is maintained in normally occupied areas relative to RVZ1 areas, which potentially contain airborne radioactive materials. See PSAR Subsection 9a2.1.1 and the discussion of key parameters of the ventilation system below for additional information on the RV within the SHINE facility. For the leakage pathway to workers during accident events, excluding the TPS DBA, the applicant assumed that a maximum of 10 percent of the airborne release would escape from the confinement area (e.g., TOGS shielded cell, IU cell, noble gas storage cell, hot cells) penetrations prior to the evacuation. Also, for the releases involving target solution and the release from the TOGS, the applicant assumed that only 25 percent of the available source term is released from the TSV, piping, or TSV dump tank prior to evacuation of the facility ($0.1 \times 0.25 = 0.025$). This assumption is made based on the systems operating near atmospheric pressure, leading to non-energetic releases, the slow pumping rate of the solution from the TSV dump tanks, and the maximum evacuation time for the facility being 10 minutes. For the TPS DBA, no reduction was credited for confinement features for workers, resulting in a leak path factor of 1.0. Regarding key parameters of the ventilation system during normal operations, the applicant states that ventilation within the SHINE facility is a once-through system with cascading ventilation zones designed to protect workers from exposure to airborne radioactive material. RVZ2 areas receive outside air through the RVZ2SA air handling units and exhaust through the RVZ2 exhaust header, which is maintained at a negative pressure relative to outside air. RVZ2 areas also receive a small fraction of air from RVZ3, which also receives

its supply air from the RVZ2SA air handing units. Areas serviced by RVZ1 (e.g., IU cells, hot cells) are maintained at a negative pressure in relation to RVZ2 to prevent leakage of airborne radioactive material into normally occupied areas. See Subsection 9a2.1.1 of the PSAR for additional information on the RV. Regarding key parameters of the ventilation system during accident conditions, the applicant states that during an accident event in areas of the facility serviced by RVZ1, bubble-tight isolation dampers in the RVZ1 exhaust will close. No components of the RV (e.g., dampers or filters) are credited with reducing worker exposure during accident events.

While the staff finds that SHINE's preliminary analysis of expected airborne radioactivity concentrations meet the dose requirements of 10 CFR Part 20 and EPA Protective Action Guidelines and are sufficient to proceed with construction, due to the significant source term in the liquid waste storage system and operator presence near the Molybdenum Extraction and Purification System (MEPS), additional research and development is necessary to confirm the adequacy of the design of SHINE's supercells and liquid waste storage tanks. Specifically, SHINE's design must sufficiently shield personnel from the materials contained within the liquid waste storage tanks and MEPS to meet the proposed administrative limits for dose rate in normally occupied areas. Therefore, the staff recommends the inclusion of the following condition in the SHINE construction permit:

> **Prior to the construction of the RPF supercells, as well as the installation of the liquid waste storage tanks and Molybdenum Extraction and Purification System, SHINE shall provide sufficient design information demonstrating adequate construction, shielding, and occupancy times consistent with ALARA practices and dose requirements of 10 CFR Part 20."**

As required by 10 CFR 50.34(a)(3)(i), the preliminary design information provided for the facility should include principal design criteria. As specified in 10 CFR 20.1101(d): "[t]o implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to § 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions." As stated, in part, in 10 CFR 20.1301, each licensee shall conduct operations so that the 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 PSAR Section 11.1.1.1, "Airborne Radioactive Sources," presents information on the public doses to the Maximally Exposed Individual (MEI). Consistent with the guidance in NRC Regulatory Guide 4.20, the effluent concentration values are compared with the effluent concentration limits in 10 CFR Part 20, Appendix B, Table 2 for showing compliance with the requirements of 10 CFR 20.1101(d). These concentration limits, however, only account for environmental pathway doses attributed to the inhalation pathway. Other environmental pathways, such as for radioiodine accumulation via the air-pasture grass-milk pathway, merit evaluation in the calculation of the total effective dose equivalent to individual members of the public. NRC Regulatory Guide 1.109 may be used as a reference for evaluating environmental pathway doses, as needed.

In order for the NRC staff to determine the adequacy of SHINE's conduct of operations and implementation of ALARA requirements, additional information was needed on the total effective

dose equivalent to individual members of the public, considering all environmental pathways, to demonstrate compliance with 10 CFR 20.1301.

Therefore, in RAI 11.1-9, the staff asked the applicant to provide design basis dose calculations for the MEI, considering all age groups and all applicable pathways, examining, in particular, the closest recipients in each of the sixteen (16) meteorological sectors. The environmental pathway dose assessment should include, but not necessarily be limited to, the cow and goat milk from the two dairy operations noted in PSAR Section 11.1.7.2.3.

In response to RAI 11.1-9, the applicant prepared an analysis of the total effective dose equivalent (TEDE) to individual members of the public, considering possible environmental pathways for airborne releases, to demonstrate compliance with 10 CFR 20.1301, as well as 10 CFR 20.1101(d). The applicant stated that the facility does not have liquid effluent pathways from the Radiologically Controlled Area (RCA). The applicant provided the design basis dose calculation for the maximally exposed individual (MEI) and the nearest full-time resident for normal operations in an attachment to the response titled, "Assessment of Dose to the Public due to Normal Gaseous Effluent Releases (ATKINS-NS-DAC-SHN-15-01, Revision 0)." The assessment analyzed releases using the GENII2 computer code, version 2.10.1. The analysis considered doses in each of the 16 meteorological sectors. Within five miles of the SHINE facility, there are both dairy and goat production. The analysis considered consumption of goat and cow milk and determined goat milk consumption was more limiting; therefore, the total doses are reported for the consumption of only goat milk. As shown in the calculation, the annual doses for the MEI and nearest full-time resident were calculated to be 9.0 mrem and 0.6 mrem, respectively. GENII was developed under Quality Assurance (QA) plans based on the American National Standards Institute (ANSI) standard NQA-1, as implemented in the Pacific Northwest National Laboratory (PNNL) Quality Assurance Manual. The steps of the code development have been documented and tested, and hand calculations have verified the code's implementation of major transport and exposure pathways for a subset of the radionuclide library. A comprehensive test plan also was developed and tests completed and documented. The code has been reviewed by the Environmental Protection Agency (EPA) Science Advisory Board and a separate EPA-sponsored, independent peer review panel. The Department of Energy (DOE) reviewed QA for GENII Version 1.485 and Version 2. As described in the SHINE Response to RAI 11.1-7, although there is no regulatory requirement for SHINE to perform regular biota monitoring, SHINE will include routine milk sampling in the Community Environmental Monitoring Program (CEMP). As noted in RAI 11.1-9, the effluent concentration limits (ECL) in 10 CFR 20, Appendix B, Table 2 only account for environmental pathway doses attributed to the inhalation pathway. The GENII2 computer code accounts for this pathway and other pathways, such as the meat ingestion, milk ingestion, and leafy vegetable ingestion pathways. As described in 10 CFR 20.1302(b), it is acceptable to demonstrate compliance with the annual dose limit in 10 CFR 20.1301 by calculating the TEDE to the individual likely to receive the highest dose from the licensed operation and comparing this to the annual dose limit. The applicant used this method to demonstrate compliance with the annual dose limit in 10 CFR 20.1301. The applicant also provided updates to PSAR Chapter 11 and 19 as a result of the response.

The staff finds this response sufficiently provided design basis dose calculations of the MEI and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

10 CFR 20.1101, "Radiation protection programs," Item (b) requires licensees to "…use, to the extent practical, procedures and engineering controls…to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." NUREG-1537, Part 2, Section 11.1.1 states, in part, that maximum annual dose and collective doses for major radiological activities shall be shown to be within the applicable limits of 10 CFR Part 20.

SHINE PSAR Section 11.1.1.1, "Airborne Radioactive Sources," states that "[t]he tritium purification system and neutron driver are designed such that the estimated annual doses to the maximally exposed individual (MEI) and the nearest resident are below the regulatory limits specified in 10 CFR 20.1101(d)." Additional information is needed for the NRC staff to determine the adequacy of SHINE's implementation of the applicable limits of 10 CFR Part 20.

Therefore, in RAI 11.1-11, the staff asked the applicant to clarify that all the activities in the SHINE Radioisotope Production Facility are designed to meet the requirements of 10 CFR 20.1101(d), as the current statement in the SHINE PSAR only applies to the tritium purification system and neutron driver.

In response to RAI 11.1-11, the applicant stated that, in addition to the design of the Tritium Purification System (TPS) and the neutron driver, all activities in the IF and RPF are designed to meet the dose constraint specified in 10 CFR 20.1101(d). SHINE has revised PSAR Section 11.1.1.1 to clarify that activities in the IF and RPF are designed such that the estimated annual doses to the MEI and the nearest resident are below the dose constraint specified in 10 CFR20.1101(d).

The staff finds this response sufficiently clarified the intent to comply with dose constraints in 10 CFR 20.1101(d) and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," states, in part, that "[a]ll sources of radiation should be discussed by the applicant, [including] the physical and chemical form…"

SHINE PSAR Section 11.1.1 (page 11-2), states that special nuclear material inventories are tabulated in Tables 4b.4-1 and 4b.4-13 for the SHINE Radioisotope Production Facility (RPF). The amount of U-235 represented in Table 4b.4-1 (based on the inventory of special nuclear material and the level of enrichment) does not seem to agree with the amount of U-235 process inventory specified in Table 4b.4-13.

Therefore, in RAI 11.1-14, the staff asked the applicant to specify the quantity of special nuclear material and U-235 processed at one time in the RPF, ensuring that the values in Tables 4b.4-1 and 4b4-13 are consistent.

In response to RAI 11.1-14, the applicant provided the RPF inventory of SNM, which includes: storage, preparation processes, awaiting reuse in the TSV or other processing/adjustment, active extraction processes, Uranyl Nitrate Conversion System (UNCS) processes, and waste streams and packaged waste. The applicant discussed how Table 4b.4-1 represents an estimate of the total SNM inventory within the RPF at one time. The applicant then discussed that the values in Table 4b.4-13 of the PSAR specify only a per batch quantity of the fissile isotopes uranium-233, uranium-235, and plutonium-239, rather than a total inventory (e.g., eight batches of recycled target solution can be contained within the eight target solution hold tanks).

Based on this information, the applicant stated that the values in Table 4b.4-1 and Table 4b.4-13 provide alternate means to estimate the quantity of SNM in the RPF, and are not inconsistent.

The staff finds this response clarified the values in Tables 4b.4-1 and 4b.4-13 and demonstrates an adequate methodology in support of a preliminary design.

NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," states in part that, "The applicant should present the best estimates of the maximum annual dose and the collective doses for major radiological activities during the full range of normal operations for facility staff and members of the public. The doses shall be shown to be within the applicable limits of 10 CFR Part 20."

SHINE PSAR Section 11.1.1, (page 11-2) contains a commitment to implement sufficient shielding to ensure direct exposure rates do not exceed 0.25 mrem/hr, except during tank transfers. Additional information is needed on the dose rates that will occur during the tank transfers to ensure consistency with ALARA and the dose limits.

Therefore, in RAI 11.1-15(a), the staff asked the applicant to explain why dose rates during tank transfers that exceed 0.25 mrem/hr are acceptable and consistent with ALARA principles. Explain why shielding will not be used for the tank transfers.

In response to RAI 11.1-15(a), the applicant states that they are committed to an operating philosophy that maintains occupational exposures to radiation consistent with ALARA principles. These ALARA principles include limiting exposure through temporary and permanent shielding of radioactive material, providing sufficient distance between personnel and radioactive material, and limiting the time personnel are exposed to radioactive material. ALARA principles are maintained through commitment by SHINE management to maintain exposures ALARA, as well as through vigilance of means to reduce exposures by RP staff. Shielding is used for tank transfers as part of SHINE's ALARA operating philosophy. Target solution transfer piping is contained within shielded trenches with thick (at least three feet) concrete shield plugs. The SHINE facility will be designed to the goal of 0.25 mrem/hr for normally occupied locations during normal operations, which includes routine, planned tank transfers. For example, the shielding requirements for the operator workstation of the Mo-99 extraction Supercell have been evaluated assuming target solution is being transferred through the cell for the extraction process. Shielding thickness was set to meet the goal of 0.25 mrem/hr during this process. Some areas in the SHINE facility, such as areas where target solution piping transitions into a hot cell, may have dose rates that locally exceed 0.25 mrem/hr during some solution transfers. However, these local increases are not expected to significantly affect doses in the normally occupied areas. The increased dose rates will be monitored by Radiation Protection (RP) staff and the areas will be posted appropriately. Given that sufficient shielding is used for tank transfers and the dose rate goal for shielding in normally occupied areas is 0.25 mrem/hr, including during routine, planned tank transfers, the design is acceptable and consistent with ALARA principles.

The staff finds this response clarified tank transfer shielding design and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," states in part that, "The applicant should present the best estimates of the maximum annual dose and the collective doses for

major radiological activities during the full range of normal operations for facility staff and members of the public. The doses shall be shown to be within the applicable limits of 10 CFR Part 20."

SHINE PSAR section 11.1.1.1 provides annual dose estimates for the maximum exposed member of the public, but does not state whether the dose rate limit in 10 CFR 20.1301 will also be met.

Therefore, in RAI 11.1-15(b), the staff asked the applicant to demonstrate that in addition to meeting the annual dose limit, the dose rate limit in 10 CFR 20.1301 will also be met.

In response to RAI 11.1-15(b), the applicant states that annual doses to the public were calculated and were determined to be below the annual dose limit from airborne effluents in 10 CFR 20.1301 of 0.1 rem/yr and below the 10 CFR 20.1101 ALARA air emissions annual dose constraint of 0.01 rem/yr. Exposures are due to the periodic release of decayed noble gases in the Noble Gas Removal System (NGRS) to the PVVS and normal continuous releases of Ar-41 from IU cells. PVVS and the IU cells are connected to RVZ1, which exhausts to the atmosphere through the facility exhaust stack. The radioactive gases are held in NGRS at least 40 days before being released to the stack. Releases from NGRS will occur throughout the year, with the activity expected to be distributed among at least 10 small quantity releases per year. Additionally, the releases from the NGRS tanks are expected to occur in a slow, controlled manner over a significant period of time (e.g., several hours). The Ar-41 releases are continuous during operation and were calculated to result in less than 1 mrem TEDE to the MEI over the course of a year. Total dose to the MEI is estimated at 9.0 mrem over an entire year (which includes dose due to long-term ingestion pathways, as well). By conservatively assuming that all of the releases are due to NGRS gas releases, and given the information above, the unrestricted area dose rate will be less than 0.0009 rem in any one hour. Therefore, the dose in any unrestricted area from external sources will be well below the 10 CFR 20.1301 dose rate limit of 0.002 rem in any one hour.

The staff finds this response meets the requirements in 10 CFR 20.1301 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.1 states, in part, that "[l]iquid effluent volumes and radionuclide concentrations should be shown to be within the requirements of 10 CFR Part 20."

SHINE PSAR Section 11.1.1.2, (page 11-3 and 11-4) "Liquid Radioactive Sources," describes liquid radioactive sources at the SHINE facility. Additional information is needed for the NRC staff to determine the adequacy of the design of the SHINE facility to protect workers and the public from radiation exposures due to liquid radioactive sources.

Therefore, in RAI 11.1-16, the staff asked the applicant to provide a description of the safety features in place to prevent exposures to liquid radioactive sources, (e.g., regular maintenance, shielding, berms).

In response to RAI 11.1-16, the applicant stated there are safety features in place to prevent exposures to liquid radioactive sources. The primary barriers to preventing worker exposure to liquid radioactive sources are prevention of leakage and shielding. The systems that contain radioactive liquids will be made from corrosion resistant materials, based on the chemical composition of the materials they contain, to minimize the potential for leaks. Piping, tanks, and

valves that contain radioactive liquids at SHINE will be of robust construction, and will be made of appropriate grades of stainless steel (e.g., 316L) and other corrosion-resistant materials, which will greatly reduce the potential for leakage of liquid radioactive sources. The applicant stated that they will have a Preventive Maintenance Program for components such as valves to identify, prevent, and correct leakage. Significant radioactive liquid sources (e.g., the irradiated target solution material, UREX process, and raffinate waste liquid from UREX) are located in shielded cells, underground vaults, and trenches. These cells, vaults, and trenches have significant amounts of shielding to decrease exposure to liquid radioactive sources. The exterior dose rates from these shielded cells are provided in PSAR Table 11.1-5. Furthermore, should a leakage occur, SHINE has a Radioactive Drain System (RDS), which has drains and a collection tank to divert and collect leakage of vessels, pipes, and valves containing significant quantities of fissile material. The floors are sloped towards the drains, and the RDS has the capability to detect leakage and initiate alarms to alert the operators. The RDS is also located within substantial (e.g., three feet thick) concrete shielding. Berms will be used as needed in conjunction with other leak collection safety features to direct and contain radioactive liquid leak flows and reduce potential for personnel exposure should a leak occur.

The staff finds this response meets the acceptance criteria in NUREG-1537 Section 11.1.1 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

Review of other aspects of the gaseous, liquid, and solid source information presented in Chapter 11.1.1 demonstrated that the information provided was sufficiently complete to support an assessment by the staff that the expected doses to workers would meet the limits contained in 10 CFR 20.1201.

On the basis of its review, the staff finds that the level of detail provided demonstrates adequately established design criteria in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.1, allowing the staff to make the following relevant findings: 1) potential radiation sources and associated doses including the inventories, chemical and physical forms, and locations of radioactive materials, and other facility radiation and operational parameters related to radiation safety presented in the PSAR have been sufficiently described; 2) the bases for identifying potential radiation safety hazards with the process and facility descriptions have been compared to verify that such hazards were accurately and comprehensively identified; 3) the PSAR identifies the potential radiation safety hazards associated with the SHINE facility and provides an acceptable basis for the development of the radiation protection program.

Therefore, with the exception of the aforementioned construction permit condition, the staff finds that the radiation sources of the SHINE facility meets the applicable regulatory requirements and acceptance criteria of NUREG-1537 in support of the issuance of a construction permit in accordance with 10 CFR 50.35.

11.4.2 Radiation Protection Program

The staff evaluated the information provided on the radiation sources, as described in SHINE PSAR Section 11.1.2, "Radiation Protection Program," using the guidance and acceptance criteria from Section 11.1.2, "Radiation Protection Program," of NUREG 1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 11.1.2, the staff evaluated (1) the roles, responsibilities, authorities, organization, and staffing of the radiation protection organization; (2) the roles, responsibilities, authorities, staffing, and operation of committees responsible for the review and audit of the radiation protection program; (3) the effectiveness and comnprehensiveness of the radiation protection training program; (4) radiation protection plans and information that form the bases of procedures and the management systems employed to establish and maintain them; (5) the effectiveness and comprehensiveness of the program for independent oversight review's and audits of the radiation protection program; (6) the effectiveness and comprehensiveness of the process to evaluate the iradiation protection program to improve the program and the process to examine problems and incidents at the facility, and (7) the management of records relating to the radiation protection program.

Although it is also a part of the Chapter 9 material that discusses RCA material handlng, RAI 11.1-2 and its response are discussed in this section because of the importance of having appropriately training radiation workers.

The ISG Augmenting NUREG-1537, Part 2, Section 11.1, “Radiation Protection,” states that the application should identify trained radiation workers.

SHINE PSAR, Section 9b.7.2, “RCA Material Handling,” provides information on the equipment used to move or manipulate radioactive material within the RCA, but there is no discussion or reference to the training/qualification of personnel who operate the equipment. In addition, as required by 10 CFR 71.5, “Transportation of licensed material,” any facility that ships or receive shipments from across state lines must assure that its personnel, who are expected to handle radioactive materials, are adequately trained and qualified in accordance with U.S. Department of Transportation regulations in 49 CFR Part 172, “Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, And Security Plans,” Subpart H, “Training.”

Therefore, in RAI 11.1-2, the staff asked the applicant to provide additional information clarifying whether the training and qualification program for radiation workers will include elements to assure that personnel who are expected to handle radioactive materials are adequately trained and qualified in accordance with 49 CFR Part 172, Subpart H.

In response to RAI 11.1-2, the applicant responded that, in accordance with 10 CFR 71.5, the SHINE Training Program will include elements to assure that radiation workers expected to handle radioactive materials are adequately trained and qualified in accordance with Subpart H of 49 CFR Part 172.

The staff finds this response sufficiently provided the applicant’s intent to ensure radiation workers will be appropriate training and qualified in accordance with Subpart H of 49 CFR Part 172 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE’s FSAR.

NUREG-1537, Part 2, Section 11.1.2, “Radiation Protection Program,” states, in part, that “[p]rocedures should be organized and presented for convenient use by operators and technicians at the appropriate locations, and should be free of extraneous material.”

SHINE PSAR Section 11.1.2.1.5, (pg 11-8) “Commitment to Written Radiation Protection Procedures,” states that radiation work permits (RWPs) will be used for both routine and non-routine activities. Additional information is needed for NRC staff to determine the adequacy of the organization of SHINE’s radiation protection program procedures. The description of RWPs appears contradictory because it requires RWPs for routine activities which should already be covered by existing operating procedures.

Therefore, in RAI 11.1-17, the staff asked the applicant to clarify the conditions under which RWPs will be used and clarify under what conditions routine activities, typically covered by existing operating procedures, would also require RWPs.

In response to RAI 11.1-17, the applicant stated that all work in the RCA will be performed under a RWP, including any activity in the RCA covered by an existing operating procedure. The applicant also revised PSAR Section 11.1.2.1.5 to clarify that all work performed in the RCA is performed in accordance with an RWP.

The staff finds this response sufficiently provided the applicant’s intent to conduct work under a RWP and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE’s FSAR.

On the basis of its review, the staff finds that the level of detail provided on the radiation protection program is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.2, allowing the staff to make a finding that the applicant’s commitments to develop and conduct a radiation protection program as presented in the PSAR: 1) will likely comply with applicable requirements; and 2) gives reasonable confidence that management's commitment to radiation protection in all activities will protect the facility staff the environment, and the public from unacceptable exposure to radiation.

Therefore, the staff finds that the radiation protection program is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35.

11.4.3 ALARA Program

The staff evaluated the sufficiency of the provisions at the facility for maintaining worker and public doses and radiological releases ALARA, as described in SHINE PSAR Section 11.1.3, “ALARA Program,” using the guidance and acceptance criteria from Section 11.1.3, “ALARA Program,” of NUREG-1537, Part 2.

In accordance with the review procedures of Section 11.1.3 of NUREG-1537, Part 2, the staff considered the elements of the ALARA program to ensure: 1) radiation doses received by facility staff and members of the public are maintained as low as reasonably achievable; 2) the highest levels of facility management are committed to the ALARA program; 3) exposure records are periodically reviewed, analyzed for trends and factors, and methods evaluated for reducing exposures; and 4) sufficient emphasis and resources are given to ALARA considerations during design, construction, operation, maintenance, and disposal activities.

The staff's review determined that the ALARA program proposed by SHINE consisted of two primary components: (1) overall program considerations (including design, construction, and operations policies), and (2) program design considerations. In terms of ALARA policies, the PSAR states that SHINE will update and modify facility design and layout as experience is gained related to plant design and layout regarding traffic control, security, access control and health physics. Regarding program design considerations, the PSAR notes that key operational elements of equipment and facility design to maintain exposures ALARA have been considered, for example: (1) locating equipment, instruments, and sampling stations that require routine maintenance such that easy access is promoted and occupancy time is minimized; (2) locating redundant component containing radioactive material in separate compartments so that the operating component does not cause significant radiation exposure to individuals performing maintenance on the shutdown component; and (3) providing adequate space to store and utilize mobile shielding when needed.

10 CFR 20.1101, "Radiation protection programs," Item (b) requires licensees to "…use, to the extent practical, procedures and engineering controls…to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." NUREG-1537, Part 2, Section 11.1.3, "ALARA Program" Acceptance Criteria, states, in part: "The highest levels of facility management should be committed to the ALARA program."

SHINE PSAR, Section 11.1.2, "Radiation Protection Program," and Section 11.1.3, "ALARA Program," discuss SHINE's commitment to the radiation protection program implementation and the proposed content of the ALARA program. Responsibilities of the plant manager and the environment, safety and health manager (and his subordinate, the radiation protection manager) are outlined with regard to the control of occupational radiation exposure. Both individuals report to the chief operating officer, providing the needed separation of the radiation protection component from the operating component. The staff notes that missing from the PSAR, however, is the commitment to develop a management policy statement(s) that demonstrates SHINE's commitment to maintaining occupational and public radiation exposures ALARA.

Therefore, in RAI 11.1-3, the staff asked the applicant to provide such a commitment to develop an ALARA policy statement(s).

In response to RAI 11.1-3, the applicant stated that the SHINE Radiation Protection Program will include a management policy statement, demonstrating SHINE's responsibility to maintain occupational and public radiation exposures ALARA. An IMR has been initiated to track the inclusion of an ALARA policy statement in the Radiation Protection Program. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds this response meets the acceptance criteria in NUREG-1537, Part 2, Section 11.1.3 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.3, "ALARA Program," states, in part that "[f]acility management should ensure that sufficient emphasis is placed on and sufficient resources are given to ALARA considerations during design, construction, and operation of facilities…"

SHINE PSAR Section 11.1.3.2.1, "General Design Considerations for ALARA Exposures," indicates that ALARA is applied to the general design considerations and methods without any

explanation. Additional information is needed for the NRC staff to determine that sufficient emphasis is placed on ALARA considerations for the design of the SHINE facility.

Therefore, in RAI 11.1-12, the staff asked the applicant to describe how ALARA is applied to the general design considerations and methods.

In response to RAI 11.1-12, the applicant states that general design considerations and methods to maintain in-plant radiation exposures ALARA at the SHINE facility are consistent with the recommendations of Regulatory Guide 8.8. ALARA design considerations are described in PSAR Section 11.1.3.2.1, in a bulleted list entitled, "Examples of features that assist in maintaining exposures ALARA." Additional ALARA design considerations are described in PSAR Sections 11.1.3.2.2 and 11.1.3.2.3.

The staff finds this response meets the acceptance criteria in NUREG-1537, Part 2, Section 11.1.3 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.3, "ALARA Program," states, in part that "[f]acility management should ensure that sufficient emphasis is placed on and sufficient resources are given to ALARA considerations during design, construction, and operation of facilities…"

SHINE PSAR Section 11.1.3.2, "ALARA Program Design Considerations," states in part, that "[t]he basic management philosophy guiding the SHINE facility design effort so that radiation exposures are ALARA can be expressed as: [d]esign structures, systems and components to reduce the radiation fields and control streaming, thereby reducing radiation exposure during operation, maintenance, and inspection activities." Additional information is needed for the NRC staff to determine whether the design of structures, systems, and components to reduce radiation fields and control streaming are designed to meet ALARA requirements.

Therefore, in RAI 11.1-13, the staff asked the applicant to describe how the ALARA concepts of time, distance and shielding are incorporated into the design of structures, system and components for employee work stations.

In response to RAI 11.1-13, the applicant stated that employee work stations within the RCA will be designed using the ALARA concepts of time, distance, and shielding to minimize employee exposures. The applicant further described how time, distance and shielding concepts would be integrated into employee work stations. The applicant also provided PSAR Section 11.1.1 which states that the goal for the normal operations dose rate for normally occupied locations in the facility is 0.25 mrem/hr at the surface, which is inconsistent with Subsections 3.5a.10.2.2 and 3.5b.1.9.2.2 with respect to the design dose rate of 0.25 mrem/hr at 12 in. from the surface. An IMR has been initiated to address the inconsistency. SHINE has revised PSAR Section 11.1.1 to state that the goal for the normal operations dose rate for normally occupied locations in the facility is 0.25 mrem/hr at 12 in. from the surface of the shielding.
The staff finds this response meets the acceptance criteria in NUREG-1537, Part 2, Section 11.1.3 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on the ALARA program damage is adequate and supports the preliminary design and satisfied the applicable

acceptance criteria of NUREG-1537, Part 2, Section 11.1.3, and is consistent with guidance contained in Regulatory Guides 8.8 (as applicable) and 8.10, allowing the staff to make the following relevant findings: (1) the applicant has clearly defined an ALARA program that has guided the design of plant features to ensure occupational and public exposures will be maintained at the lowest practicable level; 2) the applicant has designated a responsible individual for developing the ALARA program and formally evaluating its effectiveness annually; and, 3) a number of ALARA features have been included in plant design, such as attention to shielding to avoid radiation streaming situations, inclusion of maintenance features that provide for remote handling and flushing of components, features that minimize build-up of radioactive material in pipes, tanks, and other components, and separation of components and use of shielding whenever practical.

Therefore, the staff finds that the ALARA program is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35.

11.4.4 Radiation Monitoring and Surveying

The staff evaluated the sufficiency of the radiation monitoring equipment and the performance of radiation surveys, as described in SHINE PSAR Section 11.1.4, “Radiation Monitoring and Surveying,” using the guidance and acceptance criteria from Section 11.1.4, “Radiation Monitoring and Surveying,” of NUREG-1537, Part 2.

In accordance with the review procedures of Section 11.1.4 of NUREG-1537, Part 2, the staff considered the design of the instrumentation systems used for both routine and special radiation monitoring and sampling to ensure compliance with the acceptance criteria. The staff evaluated the positions of air sampling or monitoring equipment to measure airborne concentrations of radioactive material to which people are exposed. The staff considered whether radiation monitoring and alarms, as described in the PSAR, provide adequate warning and coverage and are of sufficient sensitivity to ensure that any significant increase in radiation exposure rates or concentration of airborne radioactive material within the restricted area, controlled area (if present), or in the unrestricted area would be detected and would initiate appropriate annunciation or action. The staff coordinated this review with the Chapter 7 review and should evaluate the design of the radiation instrumentation systems used for radiation monitoring and dosimetly to verify compliance with the acceptance criteria. The staff also considered whether these radiation monitors and alarm systems will be maintained, operated, calibiated, andsubjected to surveillance in compliance with the appropriate standards and are addressed in the technical specifications. Finally, the staff reviewed the facility warning and annunciator systems to ensure they are designed to alert personnel to a radiological hazard or abnormal condition in sufficient time to enable them to respond in a planned appropriate manner. The staff also confirmed that the interface between the radiation monitoring system and the engineered safety features (as discussed in Chapter 6) and the discussion of the radiation monitoring system in the emergency plan are appropriate.

The applicant has stated that several different types of sampling and monitoring equipment will be located at points within the RCA, at control points where exits from the RCA occur, and at the plant stack where effluents may be released. The applicant notes that continuous air monitors (CAMs) will be used in the controlled and restricted areas of the facility; however, the specific locations and number of such CAMs were not provided. Airborne tritium sampling is proposed in PSAR 11.1.4.1 each IU cell, and the tritium purification system glovebox room. The

stack release monitor will provide continuous monitoring of noble gases and continuous sampling of radioiodines, particulates and tritium. Control point monitoring will be performed using a combination of portal monitors, friskers, hand/foot monitors, and small article (hand tools) monitors. The staff notes that details vary in terms of their level of specificity; however, the commitments and general descriptions are sufficient for the PSAR and, therefore, are acceptable.

Regarding radiation surveys, the applicant has stated that written procedures will be developed to orchestrate the surveillance program and that it will ensure compliance with the requirements of Subparts C, F, L, and M of 10 CFR Part 20. The applicant has also stated that the guidance of several Regulatory Guides (8.2, 8.7, 8.9, 8.24, and 8.34) will be met when the program is implemented. These commitments and general descriptions are viewed as sufficient for the PSAR and, therefore, are acceptable.

NUREG-1537, Part 2, Section 11.1.4, "Radiation Monitoring and Surveying," states, in part, that the "procedures and equipment should be designed to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary."

SHINE PSAR Section 11.1.4.1, "Radiation Monitoring," indicates that radiation area monitors (RAMs) will be used at the SHINE facility. However, there is no information on the location or conditions that will be present for these monitors to be installed. Additional information is needed for NRC staff to determine the adequacy of the design of the SHINE facility ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

SHINE PSAR Section 11.1.4, provides a general overview of the survey and monitoring program. However, there is no indication of the facility function/program responsible for overseeing and implementing this program or the plan to use written procedures. Additional information is needed for NRC staff to determine that the radiation protection program will oversee the adequacy of the design of the SHINE facility to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

SHINE PSAR Section 7a2.7.4.3, (page 7a2-45), "Audible and Visual Alarm Devices," states that radiation alarms have present activation levels. Additional information is needed for NRC staff to determine that radiation alarms have the appropriate oversight to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

SHINE PSAR section 11.1.4.1(g), (page 11-18), "Control Point Monitoring," states the radiological monitoring equipment will be calibrated and maintained. Additional information is needed for NRC staff to determine that radiation monitoring equipment will have the appropriate calibration and maintenance to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

Therefore, in RAI 11.1-18, the staff asked the applicant to: a) provide additional information on the location and conditions that will result in the instillation of RAMs and provide sufficient information to determine if RAMs will be used in locations where exposures may exceed administrative limits under normal operations or credible accident conditions, as determined by the Integrated Safety Analysis or equivalent means; b) describe the function or program (e.g., radiation protection program) that is responsible for implementing the radiation survey and monitoring program and will have written procedures that specify the types, times, and methods for radiation sampling and monitoring; c) specify the alarm levels or identify the function or

program (e.g., radiation protection program) responsible for setting these limits and the methodology to be used to establish these values (e.g., administrative limits; and, d) provide additional information to clarify which group (e.g., the radiation protection program) is responsible for maintaining and checking the radiological monitoring equipment.

In response to RAI 11.1-18, the applicant will provide the requested information in the radiation protection program and in the FSAR as part of detailed design. Following receipt of the FSAR, the staff will confirm that this issue has been resolved.

The staff finds submitting this information in the radiation protection program with the FSAR is acceptable and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.4, "Radiation Monitoring and Surveying," states, in part, that "[i]n coordination with the information presented in Chapter 6, 'Engineered Safety Features,' the applicant should describe the interface between the radiation monitoring system and the engineered safety features."

SHINE PSAR Section 6b.2.1.2, (page 6b-5) "Confinement System and Components," and Table 6b.1-1, "Summary of RPF Design Basis Events and ESF Provided for Mitigation," indicate that the confinement systems for the hot cell and the radiological integrated control system (RICS) are considered safety-related systems, structures and components (SSCs). Additional information is needed for the NRC staff to determine that the radiation monitoring systems are adequate to remain available and reliable to support the engineered safety features.

Therefore in RAI 11.1-19, the staff asked the applicant to: 1) clarify whether the items used to support the RICS for the hot cells and other potentially high radiation areas are safety-related systems, structures and components (SSCs); and, 2) demonstrate that radiation monitors (e.g., CAMS and RAMS) used as SSCs or to support SSCs have appropriate controls (e.g., management measures) to ensure they remain available and reliable.

In response to RAI 11.1-19, the applicant stated the RICS initiates engineered safety features (ESF) actuation for RPF hot cells and other isolable areas (e.g., noble gas shielded cell, RVZ2 isolation) that require isolation upon measured parameters exceeding setpoints as determined in the safety analysis. Safety-related confinement isolation actuation by RICS is described in PSAR Section 6b.2.1. The Radiation Area Monitoring System (RAMS) supplies information to RICS to determine if confinement isolation is required due to high radiation levels. RICS compares the measured values provided by RAMS with the isolation actuation setpoints. Should actuation setpoints be exceeded due to high radiation levels, RICS generates a confinement isolation signal, which closes the corresponding bubble-tight isolation dampers and isolation valves on piping systems. RAMS is a safety-related system. The components of RAMS necessary to support the RICS safety-related confinement isolation function are safety-related. Safety-related structures, systems, and components (SSCs), including RAMS, have the appropriate controls through the Technical Specifications (TS) to ensure that they remain available and reliable. Proposed parameters for TS for the radiation monitoring systems are provided in Item 3.7 of PSAR Table 14a2-1. While the Continuous Air Monitoring System (CAMS) is expected to provide radiation level information to RICS, it is not credited with providing safety-related information for confinement isolation actuation. Therefore, CAMS is not required to be safety-related, and is a nonsafety-related system in the SHINE facility. The applicant revised PSAR Sections 7a2.7.4.3 and 7b.1.3 of the PSAR to remove the reference to

CAMS providing input to RICS for ESF functions. Following receipt of the FSAR, the staff will confirm that this issue has been resolved.

The staff finds the response meet the acceptance criteria in NUREG-1537 Section 11.1.4 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on radiation monitoring and surveying is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.4, allowing the staff to make the following relevant findings: 1) the fixed and portable equipment used for radiation monitoring and sampling inside the facility are appropriate for the tasks needed to be performed; 2) the general types of monitoring and surveillance equipment appear appropriate to the facility; and 3) the commitments to implement a program consistent with the Regulatory Guides noted above give reasonable assurance that radioactive material and associated radiation exposures will be detected, monitored, and sampled consistent with 10 CFR Part 20 requirements and the facility ALARA program.

Therefore, the staff finds that the design of radiation monitoring and surveying provisions is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35.

11.4.5 Radiation Exposure Control and Dosimetry

The staff evaluated the sufficiency of the radiation exposure control and dosimetry provisions, as described in SHINE PSAR Section 11.1.5, "Radiation Exposure Control and Dosimetry," using the guidance and acceptance criteria from Section 11.1.5, "Radiation Exposure Control and Dosimetry," of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

In accordance with the review criteria of NUREG-1537, Part 2, Section 11.1.5, the staff examined the facility exposure control and dosimetry programs for both external exposures and internal exposures to facility personnel, the environment, and the public to confirm that plans and the bases of procedures for the control of external dose to workers and the public consider equipment and equipment design, shielding, radiation monitors and alarms, personnel protective equipment, and external radiation monitoring dosimetry. The staff also considered whether procedures for the control of internal exposure consider equipment and equipment design, engineered controls, personnel protective equipment, radiation monitors, alarms and samplers, bioassay methods, frequency, and action levels, and the models and methods used for internal dose evaluation. The staff reviewed the engineered controls used to ensure radiation protection safety for each of the sources of radiation and radioactive material described in Section 11.1.1. The staff considered whether radiation protection measures have been implemented for sources of radiation and radioactive material. The staff confirmed that the radiation dose limits and bases are identified and the plans and programs to control doses are documented. The staff reviewed the descriptions of facility exposure conditions and methods used to derive administrative radiation dose limits. The staff evaluated whether the radiation protection engineered controls (e.g., the provisions of shielding, ventilation systems, remote handling systems) have been designed to reduce the potential for uncontrolled exposure or release and have been incorporated in the facility. The staff also considered how records will be kept to establish the conditions under which individuals were exposed to radiation.

10 CFR 20.1101, "Radiation protection programs," Item (b) requires licensees to "…use, to the extent practical, procedures and engineering controls…to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." NUREG-1537, Part 2, Section 11.1.3, "ALARA Program" Acceptance Criteria, states, in part: "The highest levels of facility management should be committed to the ALARA program."

SHINE PSAR, Section 11.1.3, "ALARA Program," states, in part, that the "ALARA concept is also incorporated into the design of the facility. The plant is divided into radiation zones with radiation levels that are consistent with the access requirements for those areas. Areas where on-site personnel spend significant amounts of time are designed to maintain the lowest dose rates reasonably achievable." Additional information is needed on the radiation zones for the NRC staff to determine their consistency with ALARA principles.

Therefore, in RAI 11.1-4, the staff asked the applicant to provide the radiation zone designations based on a consideration of neutron and gamma dose rates for locations that could be occupied, as well as the unrestricted environment as referenced in SHINE PSAR, Section 4a2.5.4. Use definitions for radiation zones similar to the following: Zone 1 (background – 2 millirem/hour); Zone 2 (2 - 100 millirem/hour); and Zone 3 (>100 millirem/hour). Additionally, using the preceding radiation zone definitions (or equivalent), provide a tabulation of radiation zone designations that could be occupied by radiation workers, even on a transient basis. Finally, include doses resulting from anticipated operational occurrences and accidents.

In response to RAI 11.1-4, the applicant stated that they will use the following radiation area designations, as defined in 10 CFR 20, including consideration for neutron and gamma dose rates: unrestricted area, radiation areas, high radiation areas (HRAs), and very high radiation areas (VHRAs).

The applicant stated that the facility will be design and constructed so that the measurable dose rate in the normally occupied and unrestricted area due to activities at the plant will be less than the limits of 10 CFR 20.1301(a)(2). PSAR Subsection 11.1.1 states the goal for the normal operations dose rate for normally occupied locations in the facility is 0.25 mrem/hr at the surface, and facility shielding is designed to meet this goal. Procedures for transient access to the IU cells, hot cells, and other shielded vaults; cells; and rooms will ensure doses are maintained ALARA by addressing the following: job planning; radiation protection coverage; survey techniques and frequencies; training of workers; pre-work briefing; frequency for updating radiation work permits or their equivalent; and placement of measuring and alarming dosimeters. The IU cells, hot cells, and other shielded vaults; cells; and rooms designated as HRAs or VHRAs will not normally be occupied when those conditions exist. Administrative procedures will address the management oversight and specific control measures needed for entry into HRAs and VHRAs, if it is ever necessary to do so. The procedures will include the process for gaining entry to these areas, such as the control and distribution of keys. Typical transient access to the IU cells, hot cells, and other shielded vaults; cells; and rooms that are usually HRAs or VHRAs for maintenance or other necessary work will normally be performed after dose rates have been reduced to at least the level of a radiation area. This will be done by removing the radioactive materials or changing the conditions (such as shutting down the accelerator in an IU cell), and waiting some time period for decay. The applicant provided a tabulation of normally and transient-occupied areas, dose rates, and designations in Table 11.1-4-1. The applicant also provided the probable radiation area designations, above grade, within the RCA at the SHINE facility in Figure 11.1-4-1.

The staff finds this response meets the acceptance criteria in NUREG-1537, Part 2, Section 11.1.3 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

10 CFR 20.1902, "Posting requirements," defines the manner in which various radiological control areas should be demarcated. Included therein are requirements for Radiation Areas, High Radiation Areas, Very High Radiation Areas and Airborne Radioactivity Areas.

SHINE PSAR, Section 11.1.5.1.1, "Radiological Zones," Item b, "Restricted Area," defines the types of restricted areas to be used for the purpose of radiological control. All of the posting requirements noted above have been included except for a Very High Radiation Area.

Therefore, in RAI 11.1-5, the staff asked the applicant to provide either (a) a commitment that all Very High Radiation Areas included in the plant design will meet the requirements of 10 CFR Part 20, Subpart G, "Control of Exposure From External Sources in Restricted Areas," or (b) Provide a basis for not including Very High Radiation Areas in the plant design (i.e., why such controls will not be necessary).

In response to RAI 11.1-5, the applicant stated that, in addition to those types of restricted areas defined in Subsection 11.1.5.1.1.b of the PSAR, very high radiation areas included in the facility design will be posted in accordance with the requirements of 10 CFR 20. Specifically, very high radiation areas will meet the requirements of 10 CFR 20, Subpart G. The FSAR will be updated to include a definition of very high radiation areas in the list of restricted area types provided in Subsection 11.1.5.1.1.b. An IMR has been initiated to track the inclusion of very high radiation areas in the list of restricted area types. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds this response complies with the requirements of 10 CFR 20.1902 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.5, "Radiation Exposure Control and Dosimetry," states, in part, that the "[d]esign of the facility…should prevent uncontrolled radiation releases to the environment or to the work areas during normal operations."

SHINE PSAR 11.1.5.1.1, (page 11-19) "Radiological Zones," describes radiation zones that have varied definitions and span of control. Additional information is needed for the NRC staff to understand how these radiological zones operate and are used to (1) control the spread of contamination, (2) control personnel access to avoid unnecessary exposure of personnel to radiation, and (3) control access to radioactive sources present in the facility.

Therefore in RAI 11.1-20, the staff asked the applicant to provide additional information describing how the radiological zones are defined, how they work, how each zone is physically separated from other zones, and how the zones are maintained.

In response to RAI 11.1-20, the applicant referenced the response to RAI 9a2.1-3, which provides additional information describing how the RCA ventilation zones are defined, how they work, how each zone is physically separated from other zones, and how the zones are maintained. Additionally, the applicant referenced PSAR Subsection 11.1.5.1.1, which

describes radiation areas in the RCA with respect to varying radiation levels and varying contamination levels. Anticipated radiation areas in the facility are described in the response to RAI 11.1-4. Anticipated airborne radioactive material concentration zones are described in the response to RAI 11.1-1.

The staff finds this response meets the acceptance criteria of NUREG-1537 Section 11.1.5 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.5, states, in part, that the "design of entry control devices…should alert workers to, or prevent unauthorized entry into, high radiation areas and very high radiation areas, as appropriate."

SHINE PSAR 11.1.5.2, "Access and Egress Control," refers to active and passive engineered safeguards to control access to high radiation areas. Additional information is needed for NRC staff to determine the adequacy of the design of entry control devices to alert workers to, or prevent unauthorized entry to specified radiation areas, as appropriate.

Therefore, in RAI 11.1-21, the staff asked the applicant to: a) provide a description of the active and passive safety systems that are used to control access to high radiation areas; and b) clarify whether the "engineered safeguards" discussed in PSAR Section 11.1.5.2, are security-related, consistent with the guidance in NUREG-1537, Section 12.8, "Security Planning."

In response to RAI 11.1-21(a), the applicant stated active and passive safety features will be provided to control access to high radiation areas in accordance with 10 CFR 20.1601. These safety features include: personnel access door interlocks, audible and visual warnings, and shielding in the form of engineered physical barriers. The applicant revised PSAR Section 11.1.5.2 to include the safety features used to control access to high radiation areas described above.

In response to RAI 11.1-21(b), the applicant referenced PSAR Section 11.1.5.2, which states:

> "Because there are high radiation areas in the facility, access to those areas is physically prevented due to radiation level. Access control is by a combination of administrative methods and active as well as passive engineered safeguards."

The applicant stated that the term "engineered safeguards" discussed above is not security-related, consistent with the guidance provided in NUREG-1537 Section 12.8, Regulatory Guide 5.59, and Regulatory Issue Summary 2005-31. The applicant further provided that the access control program, described in PSAR Section 11.1.5.2, ensures that: (a) signs, labels, and other access controls are properly posted and operative; (b) restricted areas are established to prevent the spread of contamination and are identified with appropriate signs; and (c) step-off pads, change facilities, protective clothing facilities, and personnel monitoring instruments are provided in sufficient quantities and locations.

The staff finds this response meets the acceptance criteria of NUREG-1537 Section 11.1.5 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.5, states, in part, that the "design bases of radiation shielding, ventilation, and remote handling and decontamination equipment should be planned so radiation doses are maintained ALARA and should be within the regulatory limits."

SHINE PSAR Section 9a2.1.1, (page 9a2-2) "Radiologically Controlled Area Ventilation System," indicates the automatic cell ventilation dampers are safety-related. Additional information is needed for the NRC staff to determine the adequacy of the design basis for the SHINE automatic cell ventilation dampers to ensure ALARA considerations are maintained.

Therefore, in RAI 11.1-22(a), the staff asked the applicant to identify the management measures required to ensure the safety-related dampers remain available and reliable to ensure radiation doses are maintained ALARA and within regulatory limits.

In response to RAI 11.1-22(a), the applicant stated that isolation damper operability will be controlled by TS, as specified by Item 3.5 of PSAR Table 14a2-1. The SHINE Quality Assurance Program, Preventive Maintenance Program, and TS surveillance activities will ensure the dampers remain available and reliable to ensure radiation doses are maintained ALARA and within regulatory limits.

The staff finds this response meets the acceptance criteria of NUREG-1537 Section 11.1.5 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.5, states, in part, that the "design bases of radiation shielding, ventilation, and remote handling and decontamination equipment should be planned so radiation doses are maintained ALARA and should be within the regulatory limits."

SHINE PSAR section 9a2.1.1, (page 9a2-3) "Radiologically Controlled Area Ventilation System," indicates flow control valves will maintain constant pressure for the fume hoods. Additional information is needed for the NRC staff to determine that appropriate minimum pressure gradient will be maintained across the fume hood threshold.

Therefore, in RAI 11.1-22(b), the staff asked the applicant to demonstrate that a minimum pressure gradient will be maintained across the fume hood threshold consistent with guidance in Regulatory Guide 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication." Show that, if the gradient drops below this level, the pressure drop will be identified and corrected.

In response to RAI 11.1-22(b), the applicant stated they will follow the guidance provided in Regulatory Guide 8.24 for fume hood operations and maintenance involving uranium-235 processing. Issues identified during fume hood surveys, operations, and maintenance will be placed in the SHINE Corrective Action Program. Fume hood work will be terminated if parameters are found to be below acceptable levels, as specified in Regulatory Guide 8.24.

The staff finds this response meets the acceptance criteria of NUREG-1537 Section 11.1.5 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The ISG Augmenting NUREG-1537, Part 2, Section 11.1, "Radiation Protection," states, in part:

> "[I]ndividuals who are not workers, as defined in 10 CFR 70.4, may be permitted to perform ongoing activities…in the controlled areas if the licensee…[p]rovides training that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the ISA…"

While SHINE PSAR Section 13b.2.1.2, "Identification of Initiating Events and Causes," discusses a rupture of five noble gas storage tanks, it does not identify the credible accident events that could initiate this accident sequence. Additional information is needed for the NRC staff to determine whether SHINE has ensured that individuals are aware of the risks associated with accidents involving licensed activities.

Therefore, in RAI 11.1-23, the staff asked the applicant to identify the potential credible accident sequences that could result in the radiological maximum hypothetical accident (MHA). Provide sufficient information to describe the initiating events and demonstrate that the consequences are calculated for both the credible unmitigated conditions (without SSCs) and mitigated conditions (with SSCs).

In response to RAI 11.1-23, the applicant responded that they have identified a Maximum Hypothetical Accident (MHA) consistent with the guidance provided in Parts 1 and 2 of NUREG-1537, and Parts 1 and 2 of the Interim Staff Guidance (ISG) augmenting NUREG-1537. The guidance on the MHA is primarily described in Chapter 13 of NUREG-1537 and Sections 13a2 and 13b of the ISG. In Section 13a2 of Part 1 of the ISG, it is stated that the MHA selected should bound all credible potential accidents at the facility and that the MHA may be a non-mechanistic failure assumed to establish outer limit consequence, but the scenario need not be entirely credible. In Section 13b.1.2 of Part 2 of the ISG, under the evaluation findings for the MHA, it is stated that the MHA is not considered a credible event for the facility. The applicant considers the rupture of five noble gas storage tanks simultaneously to not be an entirely credible event and is a means to establish an outer limit consequence. Therefore, the applicant did not identify potential credible accident sequences that could result in the radiological MHA. Choosing an event that bounds the other identified credible events at the facility and demonstrating acceptable consequences from this event helps to demonstrate that the facility is designed in an acceptable manner. Mitigated dose consequences calculated for the MHA are provided in Subsection 13b.2.1.7 of the PSAR. The availability of mitigators is discussed in Part b of the SHINE Response to RAI 11.1-24, below. The applicant did not calculate the MHA dose consequences for both the worker and the off-site public excluding mitigation because there is no regulatory requirement. In addition, the SHINE Response to RAI 13b.1-3 (Reference 13) provides a detailed accident sequence description for the MHA, from the initiating event through the sequence's mitigated consequences.

The staff finds this response meets the acceptance criteria of ISG Augmenting NUREG-1537, Part 2, Section 11.1 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The ISG Augmenting NUREG-1537, Part 2, Section 11.1, "Radiation Protection," states, in part:

> "[I]ndividuals who are not workers, as defined in 10 CFR 70.4, may be permitted to perform ongoing activities…in the controlled areas if the licensee…[p]rovides

> training that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the ISA…"

Additional information is needed for the NRC staff to determine whether SHINE has ensured that individuals are aware of the risks associated with accidents involving licensed activities.

As required by 10 CFR 50.34(a)(4), the preliminary safety analysis report shall include "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

As set forth in ISG Augmenting NUREG-1537, Part 1, Section 13b, "Radioisotope Production Facility Accident Analyses," the NRC staff has determined that the "use of ISA methodologies, as described in 10 CFR Part 70, ["Domestic Licensing of Special Nuclear Material,"] and NUREG-1520, ["Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,"] application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS [items relied on for safety], and establishment of management measures are acceptable ways of demonstrating an adequate margin of safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features. As used in the ISG, the term "performance requirements," when referencing 10 CFR Part 70, subpart H, is not intended to mean that the performance requirements of subpart H are required for a radioisotope production facility license, only that their use as accident consequence and likelihood criteria may be found acceptable by NRC staff.

SHINE PSAR section 13b.2.1.4, page 13b-5 identifies mitigating structures, systems, and components that should not be included in the unmitigated accident analysis. The mitigating structures, systems, and components cannot be credited during the unmitigated portion of the accident analysis. The MHA, under unmitigated conditions, could be bound by a 100 percent release of the contents of the five noble gas storage tanks to the environment.

Therefore, in RAI 11.1-24, the staff asked the applicant to:

> a. Recalculate the MHA for both the worker and the public excluding mitigation, assuming credible accident conditions consistent with the rupture of the five noble gas storage tanks. In addition, safety systems used to prevent or mitigate a credible event must remain available and reliable under the credible accident conditions. For example, a credible accident (e.g., seismic event, fire, explosion, airplane crash) that can result in rupture of the five noble gas storage tanks may also result in failure of the fail-safe bubble-tight isolation dampers, etc.
>
> b. Provide justification for the assumptions in PSAR Section 13b.2.1.7, "Radiological Consequence Analysis," used to mitigate the MHA. Provide justification that the safety related systems, structures, and components relied on to mitigate the MHA will remain available and reliable under credible accident conditions.

In response to RAI 11.1-24(a), the applicant stated that the basis for the selection of the MHA was described in the response to RAI 11.1-23. The applicant stated they did not calculate the MHA dose consequences for both the worker and the off-site public excluding mitigation because there is no regulatory requirement. In addition, the response to RAI 13b.1-3 provides a detailed accident sequence description for the MHA, from the initiating event through the sequence's mitigated consequences.

In response to RAI 11.1-24(b), the applicant stated that safety-related SSCs that mitigate the event include RVZ1 (including isolation dampers), RVZ2, the structure and confinement seals of the noble gas shielded cell (as part of the confinement boundary), and the RAMS. PSAR Section 13b.2.1.7 describes specific assumptions with regards to mitigating the event, including: the NGRS storage cell confines the release; RVZ1 confines and directs releases through the exhaust filter housings; radiation detectors (i.e., RAMS) detect the high radiation levels; and RVZ1 limits the release through the closing of the isolation dampers. The applicant stated they did not identify potential credible accident sequences that could result in the MHA. However, the mitigators described above are also used as mitigators for the rupture of a single NGRS tank, which is considered credible and is described in PSAR Section 13b.2.4. The portions of the SSCs described above that are necessary in order for the SSC to perform its safety function are safety-related, and will be designed, procured, installed, and maintained in accordance with Quality Level 1 (QL-1) requirements, as required by the SHINE Quality Assurance Program Description (QAPD). These safety-related components will be controlled under a configuration management program, and periodically tested in accordance with TS surveillance requirements. These components will be Seismic Category I components, and will be protected from credible external events. Furthermore, these components will be qualified to perform their function in the post-accident environment, as described in PSAR Section 3.5a.4, and will be designed to meet the single failure criterion, as described in PSAR Section 3.5. Therefore, the mitigating SSCs will remain available and reliable to perform their safety function, and the assumptions presented in PSAR Section 13b.2.1.7 are correct.

The staff finds this response meets the acceptance criteria of ISG Augmenting NUREG-1537, Part 2, Section 11.1 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The ISG Augmenting NUREG-1537, Part 2, Section 11.1, "Radiation Protection," states, in part:

> "[I]ndividuals who are not workers, as defined in 10 CFR 70.4, may be permitted to perform ongoing activities…in the controlled areas if the licensee…[p]rovides training that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the ISA…"

Additional information is needed for the NRC staff to determine whether SHINE has ensured that individuals are aware of the risks associated with accidents involving licensed activities.

As required by 10 CFR 50.34(a)(4), the preliminary safety analysis report shall include "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and

components provided for the prevention of accidents and the mitigation of the consequences of accidents."

As set forth in ISG Augmenting NUREG-1537, Part 1, Section 13b, "Radioisotope Production Facility Accident Analyses," the NRC staff has determined that the "use of ISA methodologies, as described in 10 CFR Part 70, ["Domestic Licensing of Special Nuclear Material,"] and NUREG-1520, ["Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,"] application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS [items relied on for safety], and establishment of management measures are acceptable ways of demonstrating an adequate margin of safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features. As used in the ISG, the term "performance requirements," when referencing 10 CFR Part 70, subpart H, is not intended to mean that the performance requirements of subpart H are required for a radioisotope production facility license, only that their use as accident consequence and likelihood criteria may be found acceptable by NRC staff.

SHINE PSAR Section 13b.2.1.1, (page 13b-5) "Initial Conditions and Assumptions," identifies systems that are mitigative without designating them as IROFS or safety-related structures, systems, and components.

Therefore, in RAI 11.1-25, the staff asked the applicant to designate all mitigative or preventive systems relied on to meet the performance requirements of 10 CFR 70.61 (or equivalent) as safety-related structures, systems, and components or IROFS, as applicable, and designate appropriate management measures. Provide a commitment to evaluate all credible accidents under unmitigated conditions and implement safety-related structures, systems, and components or IROFS, as applicable, and management measures to ensure intermediate and high consequence events comply with the performance requirements of 10 CFR 70.61 (or equivalent).

In response to RAI 11.1-25, the applicant stated the SSCs which are required to mitigate the MHA described in PSAR Section 13b.2.1 to meet the dose requirements specified in 10 CFR 20 include RVZ1 (including isolation dampers), RVZ2, the structure and confinement seals of the noble gas shielded cell (as part of the confinement boundary), and the RAMS. As described in the response to RAI 13b.1-3, the SSCs credited to perform a preventative function are the process tanks and piping (i.e., the integrity of the NGRS storage tanks and interconnecting piping), and the administrative control credited with helping to prevent this event (i.e., Conduct of Operations Program). The portions of the SSCs described above that are necessary in order for the SSCs to perform their safety functions are safety-related, and will be designed, procured, installed, and maintained in accordance with QL-1 requirements, as required by the SHINE QAPD. The basis for the selection of the MHA with respect to credibility is described in the response to RAI 11.1-23. Evaluated unmitigated consequences for this event are described in the response to RAI 11.1-23, and unmitigated consequences for other accident sequences are described in the response to RAI 13b.1-3. Safety-related SSCs and administrative controls required to prevent and mitigate the events are described in the response to RAI 13b.1-1.

The staff finds this response meets the acceptance criteria of ISG Augmenting NUREG-1537, Part 2, Section 11.1 and demonstrates an adequate methodology in support of a preliminary

design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The addition of the above-mentioned area controls and zoning designations allows a completion of this portion of the evaluation. As a result, the staff is able to determine that the proposed definitions for Unrestricted Areas, Restricted Areas, and Controlled Areas are appropriate and consistent with 10 CFR 20. The staff is also able to determine that the definition of Radiation Area and other area posting requirements contained in 10 CFR 20.1902 have been met. SHINE has committed to implement the requirements of Subpart G of 10 CFR 20 for HRAs and VHRAs that will be included in facility design.

The applicant has proposed an approach to the control of external exposures that includes a trigger point for investigating off-normal exposures at 25% of their administrative limit (10% of the occupational limits in Subpart C of 10 CFR 20). The investigation level thus becomes: 5 rem/yr x 10% x 25% = 125 mrem. The investigation process that is proposed by SHINE when this trigger point is reached should ensure that an adequate review process takes place and lessons-learned developed. The staff determined that this investigative process was adequate.

Regarding internal exposure assessment, the applicant proposes to use a mixture of air sampling and bioassay determinations that are prescribed by 10 CFR 20.1204. This process, coupled with the necessary sampling, monitoring, and analysis processes, should be adequate for quantification of internal exposure. The staff notes, however, that in order to implement the aspects of internal dose evaluations that are described in PSAR Sections 11.1.5.6.c – 11.1.5.6.e, prior NRC approval is required as stated in 10 CFR 20.1204(c).

Additionally, the staff reviewed the support facilities (locker and change rooms, first aid area, and a personnel decontamination area) proposed by SHINE, which should be adequate to support operational needs.

On the basis of its review, the staff finds that the level of detail provided on radiation exposure control and dosimetry provisions, is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 11.1.5, allowing the staff to make the following relevant findings: 1) program for posting and access control regarding Restricted Area, Controlled Area, and Unrestricted Area definitions, proposed access controls, and area radiological posting methodology is sufficient to meet the requirements of 10 CFR 20; 2) proposed dosimetry program meets the requirements of 10 CFR Part 20 and is acceptable, provided that prior NRC approval is received for internal dose evaluations that use the provisions of 10 CFR Part 20.1204(c); and 3) the provisions incorporated for locker and change rooms, a decontamination facility, and storage areas for radiation protection equipment and supplies, although discussed in conceptual terms, are considered acceptable for design purposes.

Therefore, the staff finds that the facility design features for radiation exposure control and dosimetry provisions is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration.

11.4.6 Contamination Control

The staff evaluated the sufficiency of the radiation exposure control and dosimetry provisions, as described in SHINE PSAR Section 11.1.6, “Contamination Control Equipment and Facility Layout General Design Considerations for 10 CFR 20.1406,” using the guidance and acceptance criteria from Section 11.1.6, “Contamination Control,” of NUREG-1537, Part 2.

In accordance with the review criteria of NUREG-1537, Part 2, Section 11.1.6, the staff considered the elements of the contamination control program to ensure: 1) the program scope demonstrates understanding of problems caused by radioactive contamination; 2) procedures will be established to prevent radioactive contamination; 3) the bases of procedures show that routine monitoring of locations, equipment, and personnel for contamination will be established and maintained; 4) bases of procedures show that no materials, equipment, or personnel will be permitted to leave an area known to be or suspected of being contaminated without being appropriately monitored; 5) contamination control program includes provisions to avoid, prevent, and remedy the occurrence and the spread of contamination; 6) contamination control training is established as part of comprehensive radiation protection and radioactive waste management training, as needed; and 7) contamination control program includes provisions for recordkeeping in accordance with 10 CFR Part 20 regarding occurrence and spread of contamination, sufficient in content and retention to support cleanup of contamination, maintenance, and planning for eventual decommissioning of the facility.

The staff notes that the design features described in PSAR Section 11.1.6 emphasized containment of radioactive material and leak detection. Design features included in PSAR Section 11.1.3 included examples that would also assist in meeting the requirements of 10 CFR 20.1406. Specifically, PSAR Section 11.1.3 described features that: (1) allowed draining, flushing, and decontaminating equipment and piping; and (2) design of equipment to minimize the creation and buildup of radioactive material and to ease flushing of crud traps. The applicant proposed procedures to be used for contamination control and monitoring of personnel and equipment leaving the Restricted Area is consistent with industry practice and should enable an adequate contamination control program to be implemented. The design features related to radioactive material containment and periodic decontamination when necessary, together with the proposed contamination control and monitoring program, are acceptable.

On the basis of its review, the staff finds that the level of detail provided on contamination control is adequate and supports the preliminary design and satisfies the applicable acceptance criteria of NUREG 1537, Part 2, Section 11.1.6, allowing the staff to make the following relevant findings: the description and level of detail on the contamination control program will acceptably meet the requirements of 10 CFR 20.1406.

Therefore, the staff finds that the design of radiation monitoring and surveying provisions is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35

11.4.7 Environmental Monitoring

The staff evaluated the sufficiency of the radiation exposure control and dosimetry provisions, as described in SHINE PSAR Section 11.1.7, “Environmental Monitoring,” using the guidance

and acceptance criteria from Section 11.1.7, "Environmental Monitoring," of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

In accordance with the review criteria of NUREG-1537, Part 2, Section 11.1.7, the staff evaluated whether the documentation discussed the environmental quality commitments that the program should address and the standards that were used in development of the program. The staff reviewed the the methods used to establish the preoperational baseline conditions. The staff evaluated the sufficiency of the methods and techniques to sample and analyze the radiological effect of facility operation. The staff considered if the environmental monitoring program would be capable of detecting and assessing a significant radiological impact on the environment from the facility.

NUREG-1537, Part 2, Section 11.1.7, "Environmental Monitoring," Acceptance Criteria, states, in part, that "[t]he methods and techniques to sample and analyze the radiological effect of facility operation should be complete, applicable, and of sufficient validity that the environmental impact can be unambiguously assessed."

SHINE PSAR, Section 11.1.7.2.2.1, "Air Sampling Locations," discusses the proposed air monitoring program. When discussing the equipment that will be used for air sampling, the applicant uses the term CAM (continuous air monitor). The conventional use of the term "continuous air monitor" denotes equipment that both samples and quantifies the activity on the sample media (i.e., real-time monitoring). Normally, CAMs are not used for such purposes and the NRC guidance document, NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors," that the applicant cites, does not specify CAMs for environmental air sampling.

Therefore, in RAI 11.1-6, the staff asked the applicant to clarify whether the term "air monitoring" is intended to refer to sample collection followed by laboratory analysis or real-time air monitoring.

In response to RAI 11.1-6, the applicant stated that they inappropriately used the term "CAM" to refer to a continuous air sampler in PSAR Subsection 11.1.7.2.2.1. SHINE will employ continuous air samplers at the stated locations, with the samples collected and analyzed in a laboratory. SHINE will correct the terminology in PSAR Subsection 11.1.7.2.2.1, Table 11.1-8, and Figure 11.1-3 in the FSAR. An IMR has been initiated to track the correction Subsection 11.1.7.2.2.1, Table 11.1-8, and Figure 11.1-3. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds this response complies with the guidance in NUREG-1301 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.7, "Environmental Monitoring," Acceptance Criteria, states, in part, that "[t]he methods and techniques to sample and analyze the radiological effect of facility operation should be complete, applicable, and of sufficient validity that the environmental impact can be unambiguously assessed."

SHINE PSAR, Section 11.1.7.2.3, "Ingestion Pathway (Biota Monitoring)," discusses the proposed monitoring program for the ingestion pathway. This section notes that because radioiodine and particulate activity is not expected to be present in measureable quantities in effluent releases, biota sampling will only be included if certain conditions are met. These

conditions include: (a) The presence of radioiodine or particulates on an environmental air sample, or (b) Effluent releases of radioiodine or particulates that would result in a dose at the property line of 1 millirem/year or more. The PSAR also notes that dairy production takes places 0.5 miles from the facility and goat milk production occurs 0.7 miles from the facility. Given the presence of cow and goat milk production so close to the SHINE facility, it is apparent that routine milk sampling as part of the radiological environmental monitoring program is warranted becuase: (1) the proposed sampling of effluents and the environment may not result in timely recognition of an environmental impact issue if an off-normal release occurs in the beginning of a sample period (presumably a one-week interval), considering the remaining collection period and subsequent laboratory analysis; (2) milk, especially goat milk, is a more sensitive indicator of radioiodine impact on the environment; and (3) routine milk sampling could also demonstrate the adequacy of inplant controls. Beyond the regulatory requirements aspect, milk pathway sampling provides an opportunity to establish a relationship with neighboring dairies that can foster confidence in plant operations.

Therefore, in RAI 11.1-7, the staff asked the applicant to provide additional information regarding exclusion of ingestion pathway monitoring and determine whether it is appropriate to add milk sampling to the radiological environmental monitoring program.

In response to RAI 11.1-7, the applicant stated that there is no regulatory requirement for SHINE to perform biota monitoring to assess doses due to particulate and iodine ingestion. However, the applicant stated that they acknowledge the benefits of demonstrating the adequacy of in-plant controls through radiological environmental monitoring programs. The applicant has determined it is appropriate to add routine milk sampling to the environmental monitoring program for a five year monitoring period. Continued sampling beyond the initial five year period will be determined based upon the results of the sampling program.

The staff finds this response meets the acceptance criteria in NUREG-1537, Part 2, Section 11.1.7 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.1.7, "Environmental Monitoring," Acceptance Criteria, states, in part, that "[t]he methods and techniques to sample and analyze the radiological effect of facility operation should be complete, applicable, and of sufficient validity that the environmental impact can be unambiguously assessed."

The large number (40) of direct exposure monitoring stations (e.g., thermoluminescent dosimeter) recommended in NRC guidance documents for nuclear power plants is noted in SHINE PSAR, Section 11.1.7.2.1, "Direct Radiation Monitoring," as well as a statement regarding why that number of monitoring stations does not appear warranted for the SHINE facility. As a result, the applicant proposed nine direct radiation-monitoring locations, based on the smaller source term compared to nuclear power plants. Additional information is needed for the NRC staff to determine whether the number of direct monitoring locations should not be based on source term alone or whether consideration should also be given to the variability of wind direction and the expected "signal-to-noise ratio" (plant contribution versus background). The ability to demonstrate the SHINE facility's impact on the environment is enhanced by having additional direct monitoring stations that increase the statistical power of the analysis. The applicant proposed only four direct monitoring locations at the site boundary (north, east, south, and west). The staff notes that such a relatively small number of monitoring locations

decreases the probability of detecting the impact of effluent releases associated with normal and off-normal operations, and accidents.

Therefore, RAI 11.1-8, the staff asked the applicant to provide additional information further justifying use of only four direct monitoring locations, or propose additional monitoring locations at the site boundary and special interest areas, such as population centers and nearby residences and schools.

In response to RAI 11.1-8, the applicant stated that the requirement to make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public is specified in 10 CFR 20.1302(a). However, the applicant states there is no regulatory requirement to use a specific number of direct exposure monitoring stations. The applicant acknowledged the benefits of demonstrating the adequacy of in-plant controls through radiological environmental monitoring programs. Therefore, the applicant SHINE has determined that it is appropriate to add 15 direct radiation-monitoring stations to the 9 proposed in PSAR Subsection 11.1.7.2.1, for a total of 24 direct radiation-monitoring stations. The applicant stated PSAR Figure 11.1-3 and Table 11.1-8 will be updated in the FSAR to include the additional direct radiation-monitoring stations described above. An IMR has been initiated to track the update to Figure 11.1-3 and Table 11.1-8 in the FSAR. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The proposed Radiological Environmental Monitoring Program (REMP), as described in the PSAR and amended by the RAI responses cited above, is generally consistent with NRC guidance that includes the following (as principal examples):

- Regulatory Guide 4.1, "Radiological Environmental Monitoring For Nuclear Power Plants,"
- Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Inception Through Normal Operations to License Termination)—Effluent Streams and the Environment"
- NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors," (and the companion NUREG-1302 on the same subject for Boiling Water Reactors)

The term "generally consistent" is used due to the fact that all of the above-cited references relate to the development and conduct of REMPs for nuclear power plants. As recognized by the applicant, many of the REMP elements had to be adjusted to be more applicable to SHINE's medical isotope production facility. The staff finds these adjustments, as noted in the above discussion, to be acceptable.

On the basis of its review, the staff finds that the level of detail provided on environmental monitoring is adequate and supports the preliminary design and satisfies the applicable acceptance criteria of NUREG 1537, Part 2, Section 11.1.7, allowing the staff to make the following relevant findings: 1) the environmental monitoring program described is appropriate to the facility and its projected impact; and 2) the proposed REMP meets the aforementioned regulatory guidance.

Therefore, the staff finds that the design of environmental monitoring is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35

11.4.8 Radioactive Waste Management Program

The staff evaluated the sufficiency of the radioactive waste management program, as described in SHINE PSAR Section 11.2.1, "Radioactive Waste Management Program," using the guidance and acceptance criteria from Section 11.2.1, "Radioactive Waste Management Program," of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

In accordance with the review criteria of NUREG-1537, Part 2, Section 11.2.1, the staff evaluated how the radioactive waste management program fits into the facility's overall management structure, how such wastes are identified and segregated effectively, how the management and radiation protection organization will ensure that radioactive wastes are continuously controlled from formation to ultimate safe disposal, and what organizational entities are assigned responsibilities in the radioactive waste management program.

The staff review of PSAR Section 11.2.1 included review of PSAR Chapter 12 Conduct of Operations to assure consistent integration, and review of applicable parts of Sections 9b to assure the systems design included features needed to sample waste streams to obtain the information required by the regulations.

The staff notes the introductory paragraph in PSAR Section 11.2 contains a commitment to comply with all applicable local and national regulations for managing radioactive wastes. The waste management program described in SHINE PSAR Section 11.2.1 describes a sufficient administrative structure to assure releases of gaseous and solid wastes are in accordance with the regulations. The requirements contained in 10 CFR 20, Subpart K focus primarily on the information needed to adequately identify and characterize radioactive material for transportation and disposal. PSAR Sections PSAR Section 9b.7.3.1.2 identifies sampling capabilities needed to obtain data required by the regulations. PSAR Section 11.2.1.3 assigns responsibilities to Waste Management/Operations Management for maintaining working knowledge of waste disposal requirements and for the procedures and processes needed to ship wastes for disposal.

PSAR Section 11.2.1 contains a commitment to develop an official charter describing the authority, duties, and responsibilities of personnel in the waste management organization for the FSAR. PSAR Chapter 12, Appendix 12 D commits to describing the Conduct of Operations program in the FSAR. Following the receipt of SHINE's FSAR, staff will confirm that these issues have been resolved.

NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," states, in part, that the "SAR should contain a commitment to comply with applicable regulations for managing radioactive wastes." Additional information is needed for NRC staff to determine the adequacy of SHINE's commitment to comply with applicable regulations for managing radioactive wastes.

SHINE PSAR Section 11.2, "Radioactive Waste Management," states that SHINE is committed to comply with all applicable local and national regulations for managing radioactive wastes.

Therefore, in RAI 11.2-6, the staff asked the applicant to provide a summary list of the regulations and any standards or guidance that SHINE intends to follow to demonstrate its commitment to complying with applicable regulations for managing radioactive wastes.

In response to RAI 11.2-6, the applicant stated that they will comply with the following federal regulations related to radioactive wastes: 10 CFR 20, "Standards for Protection Against Radiation"; 10 CFR 61, "Licensing Requirements for Land Disposal of Radioactive Waste"; 10 CFR 71, "Packaging and Transportation of Radioactive Material"; 40 CFR, Chapter I, Subchapter F, "Radiation Protection Programs"; 40 CFR, Chapter I, Subchapter I, "Solid Wastes"; and, 49 CFR, Chapter I, Subchapter C, "Hazardous Materials Regulations." The applicant also stated that they are regulated by the NRC and not by the State of Wisconsin pertaining to matters involving the management of radioactive wastes per Wisconsin Statutes Chapter 254.365(1) and Wisconsin Administrative Code Chapter DHS 157.02(1). The applicant stated that they will comply with Wisconsin regulations relating to the transportation and disposal of hazardous waste per Wisconsin Administrative Code Chapter NR 662. The State of Wisconsin will regulate radioactive waste once it leaves the SHINE facility and is transported. The State of Wisconsin implements the Department of Transportation (DOT) radioactive waste transportation regulations. The applicant also stated they will meet the DOT regulations contained in 49 CFR, Chapter I, Subchapter C, and therefore, will comply with the State of Wisconsin radioactive waste transportation requirements. The applicant stated that they will also comply with the waste acceptance criteria of the selected disposal facilities, including any local or state regulations specified in those criteria. The applicant also indicated that they will use the following regulatory guidance and industry standards related to managing radioactive wastes:

- ANSI/ANS-55.1-1992 (R2009), "Solid Radioactive Waste Processing System for Light-Water-Cooled Reactor Plants"
- ANSI/ANS-55.4-1993 (R2007), "Gaseous Radioactive Waste Processing Systems for Light Water Reactor Plants"
- ANSI/ANS-55.6-1993 (R2007), "Liquid Radioactive Waste Processing System for Light Water Reactor Plants"
- Regulatory Guide 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants"
- Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other than Power Reactors"
- Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations will be As Low As Reasonably Achievable"
- Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable"
- NUREG/BR-0204, "Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest"
- Information Notice No. 90-09, "Extended Interim Storage of Low Level Radioactive Waste by Fuel Cycle and Materials Licensees"
- Regulatory Issue Summary 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees"
- Regulatory Issue Summary 2011-09, "Available Resources Associated with Extended Storage of Low-Level Radioactive Waste"

The staff finds this response meets the acceptance criteria of NUREG-1537 Section 11.2.1 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," states, in part, that the "SAR should contain a commitment to comply with applicable regulations for managing radioactive wastes."

SHINE PSAR Section 11.1.1.2, (page 11-4) "Liquid Radioactive Sources" indicates that solid waste will be sent to disposal facilities. Additional information is needed for NRC staff to determine the adequacy of SHINE's commitment to comply with applicable regulations for managing radioactive wastes.

Therefore, in RAI 11.2-7, the staff asked the applicant to provide additional information indicating that these disposal facilities will have appropriate licenses for managing radioactive wastes (i.e., licensed disposal facilities).

In response to RAI 11.2-7, the applicant stated that the disposal facilities referred to in PSAR Subsection 11.1.1.2 will have appropriate licenses for managing radioactive waste (i.e., licensed disposal facilities).

The staff finds this response meets the acceptance criteria of NUREG-1537 Section 11.2.1 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," states, in part, that the "SAR should contain a commitment to comply with applicable regulations for managing radioactive wastes."

SHINE PSAR Sections 11.2.3.1, 11.2.3.2, and 11.2.3.3, (pages 11-49 through 11-49) describe the control of solid, liquid and gaseous waste streams. Additional information is needed for NRC staff to determine the adequacy of SHINE's commitment to comply with applicable regulations for managing radioactive wastes.

Therefore, in RAI 11.2-8, the staff asked the applicant to provide a description of the survey or monitoring equipment [e.g., continuous air monitoring system (CAMS) and radiation area monitoring system (RAMS)] and program that will be used to ensure wastes remain in these designated controls/processes and identify any loss of control or unplanned releases.

In response to RAI 11.2-8, the applicant stated that the CAMS equipment is described in PSAR Section 7a2.7.4.1, and the RAMS equipment is described in PSAR Section 7a2.7.4.2. The RP Program will ensure wastes remain in these designated controls/processes, and identify any loss of control or unplanned releases.

The staff finds this response meets the acceptance criteria of NUREG-1537 Section 11.2.1 and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on the radioactive waste management program supports the preliminary design and satisfies the applicable acceptance criteria of NUREG 1537, Part 2, Section 11.2.1, allowing the staff to make the following relevant findings: 1) personnel will likely be appropriately structured to perform functions under the program in accordance with the requirements; and 2) facility systems are designed in a manner that will provide the capability to obtain the data needed to comply with the requirements.

Therefore, the staff finds that the design of environmental monitoring is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35. Further evaluation of the waste management program and its integration into the overall conduct of operations will occur following the receipt of the FSAR submitted with the OL application.

11.4.9 Radioactive Waste Controls

The staff evaluated the sufficiency of the radiation exposure control and dosimetry provisions, as described in SHINE PSAR Section 11.2.2, “Radioactive Waste Controls,” using the guidance and acceptance criteria from Section 11.2.2, “Radioactive Waste Controls,” of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

In accordance with the review criteria of NUREG-1537, Part 2, Section 11.1.5, the staff examined how all processes and procedures that could produce radioactive waste material will be evaluated. The staff considered whether appropriate monitoring and sampling will be performed and sufficient analyses will be completed to assess the extent of the radiation exposure from waste products. The staff reviewed whether the applicant sufficiently described methods to: 1) avoid inadvertent exposure of personnel or uncontrolled escape of the radioactive materials; 2) define and maintain continuous control of radioactive materials that require treatment and management as waste; and 3) reduce the quantities of radioactive waste.

The staff notes the purpose of the SHINE facility is to produce Mo-99 by fissioning uranium in a liquid uranium sulfate solution and extracting Mo-99 from the resulting fission products. Because both the volume and the radioactivity content of fission products, other than Mo-99, far exceeds that of the Mo-99 product, waste management activities and control are an important aspects of the overall operation. Regarding waste minimization, inspection of PSAR Section 11.2.1 confirms that waste minimization programmatic efforts are part of annual audits of the waste management program. The staff reviewed the description of the waste streams presented in SHINE PSAR Section 11.2.2.2 and the evaluations contained therein identifying the required capabilities for adequate packaging of the wastes for transportation and disposal. The evaluations of the systems generating these waste streams and processing them through packaging are presented in SER Chapters 4 and 9.

The Mo-99 extraction columns are a frequent (400 target solution volumes per year) and initially highly radioactive solid waste generated by the proposed SHINE facility. As a supplement to material presented in SHINE PSAR, Section 9b.7.2, “RCA Material Handling,” and Section 11.2, “Radioactive Waste Management,” additional information is needed on criteria for the handling of this waste stream and the handling of the extraction column in and from the supercells to the shielded vaults and further to packaging and shipping for disposal. This information is needed for the NRC staff to ascertain safety, as well as SHINE’s ability to meet the regulatory

requirement regarding hazardous material identification in shipping papers (10 CFR 20, Subpart K, "Waste Disposal"), and conformance with ALARA goals.

Therefore, in RAI 11.2-1, the staff asked the applicant to provide the following information so that staff may assess compliance with the ALARA requirement of 10 CFR Part 20: a) Describe the inlet and outlet connections of the Mo-99 columns that permit frequent remote replacement while providing leak-tightness and preventing the spread of contamination during replacement. Provide the estimated dose rate from an extraction column at time of removal and after 2 weeks storage in the supercell; b) Provide information on the material handling methods of moving shielded containers of an extraction column from the supercell to the shielded vaults at the other end of the facility from the supercells. If this material handling includes movement by crane, include a load drop in the accident analyses or justify why such an event need not be considered; c) Clarify how long extraction columns are maintained in shielded vault storage. SHINE PSAR, Table 11.2-3, "Waste Methodology for Columns," says approximately 400 days of decay are required to be Class A; PSAR, Section 9b.7.5.4.2, "Solid Radioactive Waste Handling Hot Cell," says they are transferred to the storage vault for an additional 6 months.; d) Provide information on the transfer of an extraction column into one of the six separate shielded storage vaults shown on figures presented in SHINE PSAR, Chapter 1, "The Facility"; and, e) Clarify, whether there are any differences between the handling of the Mo-99 columns.

In response to RAI 11.2-1(a), the applicant stated that the inlet and outlet connectors are a quick-disconnect style specifically designed for use with remote manipulators in hot cell environments. Radiation and wear-resistant seals provide leak tightness. Automatic valves built into the connectors close when the connector is separated, which significantly reduces the leakage of contaminated fluids from the process lines and columns. As the target solution is washed from the extraction column (by an acid wash, water wash, and strip solution) prior to the column being removed, there will be significantly lower levels of contamination present in the column and lines during disconnection than during extraction steps. Means will be provided to capture the small leakage of liquid that will occur during the disconnection of the connectors. The estimated dose rate for an extraction column at the time of removal is approximately 6,700 rem/hr at 3 feet unshielded. The peak dose rate drops to approximately 340 rem/hr at 3 feet unshielded after 2 weeks of storage in the supercell.

In response to RAI 11.2-1(b), the applicant stated that the material handling methods involved in the transfer of an extraction column from the supercell to the shielded vaults are described in Part d of the SHINE Response to this RAI. The applicant stated that they will ensure safe load handling guidance is applied to the movement, as described in the SHINE Response to RAI 9b.7-1.

In response to RAI 11.2-1(c), the applicant stated following storage in the supercell for no less than two weeks after use, the extraction columns will be maintained in shielded vault storage for approximately six months. The columns will then be transferred to the solid radioactive waste handling hot cell for packaging in approved containers. The containers will be transferred to the Waste Staging and Shipping Building for storage until they reach the requirements for Class A waste and can be shipped for disposal. Preliminary calculations indicate that a total decay time of approximately 400 days will be needed for the columns to reach the requirements for Class A waste. At least two weeks of this time will be spent in the supercell, approximately six months in shielded vaults, and the

remaining time (approximately 200 days) will be spent in the Waste Staging and Shipping Building.

In response to RAI 11.2-1(d), the applicant stated that they plans to perform the following steps for the transfer of an extraction column from a supercell to a shielded storage vault:

> After removing an extraction column from the process, it is decayed for a minimum of two weeks in the supercell on a decay storage rack. Several extraction columns that have decayed for a minimum of two weeks are planned to be transported out of the cell in one transfer to reduce personnel exposure and the number of transfer operations. The number of extraction columns transferred will be limited based on transfer container capacity. The transfer container will be shielded to ensure personnel doses are maintained ALARA and within procedural limits during the transfer.
>
> When several extraction columns are to be transferred, a transfer container will be placed on a transfer cart. The radiation levels in the supercell will be checked to ensure they are below procedural limits that permit opening the supercell shield door. The shield door, which opens to the lower section of the extraction cell, will then be opened. The transfer cart will be moved into the extraction area of the supercell. The transfer container will then be raised to the transfer system hatch and sealed to reduce the potential for contamination of the lower section of the extraction cell.
>
> The supercell shield door will then be closed, and the hatch will be opened. The supercell manipulators will be used to move several extraction columns to the transfer container and the hatch will be closed. The radiation levels in the supercell will be checked to ensure they are below procedural limits that permit opening the supercell shield door. The shield door will be opened, and the transfer container will be detached and lowered from the hatch. The transfer cart will then be removed from the supercell and the shield door will be closed. Before leaving the contaminated area boundary, the transfer cart and the exterior surfaces of the transfer container will be checked to ensure surface contamination is below procedural limits. If contamination is found, the transfer container and cart will be decontaminated in accordance with health physics procedures before being released.
>
> The transfer cart will then be moved to the shielded storage vault. Any checks required prior to removing the storage vault shield plug, such as radiation level, will be made and verified within procedural limits. The overhead crane will then be used to remove the shield plug. An engineered lifting device will then be used to lower the shielded container into the shielded cell.
>
> The overhead crane will then be used to replace the shielded storage vault shield plug, and the transfer cart will be returned to its storage location.

In response to RAI 11.2-1(d), the applicant states all of the columns will be handled in the same manner: 1) stored in the supercell for no less than two weeks after use; 2) transferred to the storage vault for additional decay time, currently planned for six months; 3) transferred to the solid radioactive waste handling hot cell in approved containers; 4) transferred to the waste staging and shipping building prior to being shipped offsite.

The staff finds this response complies with the requirements in 10 CFR Part 20, Subpart K and demonstrates an adequate methodology in support of a preliminary design. The staff will

confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

SHINE PSAR, Section 4b.4.1.1.4.1, "Uranyl Nitrate Preparation Process Sequence," explains part of the process for reusing target solution and states that the solid salts discharged from the centrifuge are moved to solid radioactive waste packaging in a 55-gallon drum. PSAR, Section 11.2.2.2.6, "Target Solution Clean-up," identifies that this waste stream is Class B. There is no discussion of the radiation levels emanating from these drums, no discussion of sealing the drums during handling to prevent spills, and no discussion of design features implemented to assure doses to workers are ALARA during these evolutions. PSAR, Table 11.2-6, "Waste Methodology for [ ]" (the rest of the table name is withheld as proprietary information) identifies that the waste stream must be sampled for waste characterization prior to solidification, but there is no discussion of how this is accomplished in an ALARA manner.

Therefore, in RAI 11.2-2, the staff asked the applicant to provide discussion of the design features and design review procedures used to assure that the ALARA considerations committed to in SHINE PSAR, Section 11.1.3, "ALARA Program," are effectively implemented for each of the identified waste streams and the handling operations required during their processing.

In response to 11.2-2, the applicant states PSAR Subsection 11.1.2.1 discusses SHINE's commitment to the implementation of an ALARA program. The applicant also provided the preliminary design features of the Uranyl Nitrate Preparation (UNP) waste streams. The applicant also stated they will more fully specify waste handling for the UNP subsystem with respect to design features used to assure that ALARA considerations are effectively implemented during detailed design, and provide those details in the FSAR. An IMR has been initiated to track the inclusion of this information in the FSAR. Further, the applicant states that while the SRWP system design has not been finalized, the design of the radiation shielding for tanks, walls, hot cells, and the drums will ensure the dose rates are within the regulatory limits of 10 CFR 20.1201 and 10 CFR 20.1301, and that the dose rates in normally occupied areas meet (to the extent practicable) the facility goal of 0.25 mrem/hr. These design features will also ensure that ALARA objectives to minimize exposure to facility workers during waste handling and transfer operations are met. Radiation monitors will be located at operations areas to detect and warn of changes in radiation levels. A design review of the final SRWP system design will be performed to ensure that transfer and processing of the sulfate sludge will be done in an ALARA manner. The design review will be proceduralized, and these procedures will evaluate general design considerations and methods to maintain radiation exposures ALARA consistent with the recommendations of Regulatory Guide 8.8. Following the receipt of SHINE's FSAR, staff will confirm that these issues have been resolved.

The staff finds this response demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The staff identified some errors and inconsistencies regarding liquid waste quantities and generation in Tables 11.2-1 and 11.2-5 and, in RAIs 11.2-3 and 11.2-4, asked the applicant to correct or justify the inconsistent values. In response to RAI 11.2-3 and 11.2-4, the applicant committed to revise Tables 9b.7-7, 11.2-1 and 11.2-5 with corrected values. Additionally, the applicant provided a liquid waste process flow diagram and discussed the liquid waste streams. The staff finds these responses demonstrate an adequate methodology in support of a

preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 2, Section 11.2.2, "Radioactive Waste Controls," Evaluation Findings, states, in part: "The descriptions of the plans and procedures provide reasonable assurance that radioactive wastes will be controlled at all times in a manner that protects the environment and the health and safety of the facility staff and public."

PSAR Chapter 11 states that disposal sites have established waste acceptance criteria. The inputs to the consolidated radioactive liquid waste tanks are a mixture of strong acids and bases, chemicals in solution, and water, all containing fission products. This chemical mixture is then concentrated through evaporation to reduce the volume of waste to be solidified for packaging and disposal.

Therefore, in RAI 11.2-5, the staff asked the applicant to provide references that support the validity of the assumption that the evaporator concentrates of the consolidated liquid waste stream can be solidified on Portland cement to meet the waste acceptance criteria of the potential disposal sites. Alternatively, commit to conducting a solidification testing program during construction of the facility to be able to define the requirements of the solidification Process Control Program in the PSAR.

In response to RAI 11.2-5, the applicant states that they plan to adjust the pH of the consolidated radioactive liquid waste prior to evaporation and solidification using Portland cement as the solidification agent. The Electric Power Research Institute (EPRI) has addressed the issue of cement solidification in Topical Report NP-2900. Table F-1 of EPRI NP-2900 presents the type and amount of solidification agent to be used with various types of waste streams found in the nuclear power industry. The table specifically addresses the use of Portland cement as a solidification agent and addresses solidification of sodium sulfate waste streams which typically are generated by the neutralization of sodium hydroxide with sulfuric acid prior to solidification. Appendix D of EPRI NP-2900 discusses leach rate tests of solidified waste. Appendix D provides significant data on leach rate tests of cement solidified sodium sulfate waste streams. Figure 1 of Appendix D indicates that if the weight percent of sodium sulfate in the solidified waste is eight weight percent or less, then leaching is in compliance with federal regulations, even for samples immersed in water. The applicant states that the facility design is for waste streams with low concentrations of solid species that are below eight weight percent, as shown in the modified Table 9b.7-7 provided in the SHINE Response to RAI 11.2-4. Even after a volume reduction factor of 1.5, the contents of species other than water are not expected to exceed eight weight percent. Therefore, the applicant anticipates that the solidification process with cement will be successful and meet the acceptance criteria of potential waste disposal sites. The guidance included in EPRI NP-2900 will be employed in detailed design and in developing facility operating procedures for pre-treatment and cement solidification of liquid radwaste. The operating procedures will implement the requirements of the facility solidification Process Control Program (PCP). The PCP will ensure that the solidified product will have no detectable free liquid, consistent with nuclear power industry guidance contained in Branch Technical Position 11-3. During the SHINE facility commissioning, solidification demonstration test runs will be performed using non-licensed materials.

The staff finds this response meets the acceptance criteria of NUREG-1537, Section 11.2.2, and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The staff notes that descriptions of the plans and procedures to provide reasonable assurance that radioactive wastes will be controlled at all times in a manner that protects the environment and the health and safety of the facility staff and the public will be presented in the FSAR. The staff finds this can reasonably be left for later consideration when it will be supplied in the FSAR.

On the basis of its review, the staff finds that the level of detail provided on the radioactive waste controls supports the preliminary design and satisfies the applicable acceptance criteria of NUREG 1537, Part 2, Section 11.2.2, allowing the staff to make the following relevant findings: 1) appropriate controls are described for radioactive waste management on the waste streams and products designed to prevent uncontrolled exposures or escape of radioactive waste; 2) the applicant has described programmatic measures to evaluate the generation of radioactive wastes at the facility to define actions to maintain and control waste generation.

Therefore, the staff finds that the design of radioactive waste controls is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35. Further evaluation of the radioactive waste controls plans and procedures will occur following the receipt of the FSAR submitted with the OL application.

11.4.10 Release of Radioactive Waste

The staff evaluated the sufficiency of the radioactive effluents, as described in SHINE PSAR Section 11.2.3, “Release of Radioactive Waste,” using the guidance and acceptance criteria from Section 11.2.3, “Release of Radioactive Waste,” of NUREG-1537, Part 2 and the ISG Augmenting NUREG-1537, Part 2.

In accordance with the review criteria of NUREG-1537, Part 2, Section 11.2.3, the staff evaluated the discussions on radioactive effluents for compliance with the regulations in Subpart K of 10 CFR Part 20.

The staff notes the evaluation of the adequacy of controls on gaseous releases is presented in SER Section 11.4.4 and Section 11.4.7. According to PSAR Section 11.2.3, there will be no liquids containing radioactive effluents discharged to the sanitary sewer. Further, several liquid waste streams will be solidified on-site to meet shipping and waste acceptance criteria.

The applicant has identified the requirements for adequate packaging of solid wastes for disposal and has committed to comply with 10 CFR 20, Subpart K and the waste acceptance criteria for the potential waste disposal sites. The description of procedures to be implemented to assure compliance with the requirements will be discussed in the FSAR. Review of the tables in PSAR Section 11.2 reveals acknowledgement of the requirements for waste characterization. Review of the system designs and capabilities for sampling necessary for waste characterization is presented in SER Section 9b.7.

On the basis of its review, the staff finds that the level of detail provided on the release of radioactive waste supports the preliminary design and satisfies the applicable acceptance criteria of NUREG 1537, Part 2, Section 11.2.3, allowing the staff to make the following relevant findings: 1) radionuclides have been sufficiently identified by quantities, other relevant characteristics, release points, and relevant environmental parameters; and, 2) releases of radioactive effluents will likely be sufficiently be managed, controlled, and monitored so that limits in applicable regulations would not be exceeded.

Therefore, the staff finds that the design for release of radioactive waste is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35. Further evaluation of the release of radioactive waste procedures will occur following the receipt of the FSAR submitted with the OL application.

11.4.11 Respiratory Protection Program

The staff evaluated the sufficiency of the respiratory protection program, as described in SHINE PSAR Section 11.3, "Respiratory Protection Program," using the guidance and acceptance criteria from Section 11.3, "Respiratory Protection Program," of the ISG Augmenting NUREG-1537, Part 2.

In accordance with the review criteria of NUREG-1537, Part 2, Section 11.3, the staff examined whether the respiratory protection program provides adequate protection of personnel from airborne concentrations exceeding the limits of Appendix B to 10 CFR Part 20. The staff reviewed the proposed radiation protection equipment for providing the appropriate degree of personal protection. The staff evaluated the description of respirator selection, training, fit testing, storage, maintenance, repair, and quality assurance.

The staff notes the respiratory protection program proposed by SHINE is consistent with the hierarchy of protection intended by Subpart H of 10 CFR 20, i.e., HVAC system considerations first, followed by the use of respiratory protective equipment only when HVAC controls are not practical or are ineffective. The applicant stated that only NIOSH-certified respiratory equipment will be used and that written procedures will be prepared for all key program elements. The program will include a review by a physician to certify that an individual is medically fit to wear respiratory protective equipment and that quantitative fit testing will be performed. Regarding respirator quantitative fit testing, PSAR Section 11.3 states that "…a minimum fit factor of at least 10 times the … assigned protection factor (APF) for negative pressure devices, and….at least 500 times the APF for any positive pressure, continuous flow, and pressure-demand devices…" Because the APF is typically 1000 for the latter devices, to require demonstration of a fit APF of 500,000 (i.e., 500 x 1000) may be beyond the capabilities of most quantitative fit testing methods. This matter needs to be reviewed in light of the guidance contained in Regulatory Guide 8.15 and related documents and appropriate clarification included in the FSAR.

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, "Respiratory Protection Program," states, in part, that the applicant should "[i]nstall appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed occupational derived air concentration values in 10 CFR Part 20."

PSAR Section 9a2.1.1 indicates that air which passes from radiation controlled area ventilation Zone 2 (RVZ2) to radiation controlled ventilation Zone 1 (RVZ1) is first passed through HEPA filtration. This appears to imply that the zones are isolated from each other and that air is filtered between each zone. Additional information is needed for NRC staff to determine the adequacy of the ventilation system at the SHINE facility.

Therefore, in RAI 11.3-1, the staff asked the applicant to provide additional information to clarifying whether each zone can be isolated from the other zones automatically using the automatic isolation dampers and whether the air is filtered between each zone.

In response to RAI 11.3-1, the applicant stated that RVZ1 areas draw supply air from adjacent RVZ2 spaces. RVZ1 area air inlets are equipped with automatic isolation dampers (fail closed), manual isolation dampers, and non-credited HEPA filters. The air inlet HEPA filter ensures that if an RVZ1 area were to see a flow reversal, the air stream would be filtered. Should high radiation levels be detected within an RVZ1 area, ESFAS (IF) or RICS (RPF) generate a confinement isolation signal, which closes the corresponding bubble-tight isolation dampers on the air inlet and exhaust outlet for each affected RVZ1 area. This automatic isolation does provide isolation between the affected RVZ1 area and the adjacent RVZ2 space. Confinement barrier penetrations are sealed, as necessary, to reduce leakage. However, some leakage between zones is expected to occur even after the isolation described above, and potential leakage is accounted for in safety analysis calculations, as described in PSAR Chapter 13. RVZ1 exhaust can also be isolated downstream of the filter trains on high radiation levels in RVZ1. This point of RVZ1 isolation does not isolate RVZ1 from the other zones; however, it provides an additional means to reduce releases to the environment. Also, should high radiation levels be detected within RVZ2, RICS generates a signal for confinement isolation at the RCA boundary, which closes bubble-tight isolation dampers in the supply duct at the RCA boundary and in the RVZ2 exhaust duct downstream of the final filters. This automatic isolation does not isolate RVZ2 from other zones directly; however, it reduces the potential releases to the environment. There are no automatic isolations necessary or provided for RVZ3 or FVZ4.

The staff finds this response meets the acceptance criteria of the ISG Augmenting NUREG-1537, Section 11.3, and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, "Respiratory Protection Program," states, in part, that the applicant should "[i]nstall appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed occupational derived air concentration values in 10 CFR Part 20."

SHINE PSAR Section 9a2.1.1 (page 9a2-2) indicates that the ventilation air in the exhaust header is tested before being exhausted to the stack. Additional information is needed for NRC staff to determine the adequacy of the ventilation system at the SHINE facility.

Therefore, in RAI 11.3-2, the staff asked the applicant to provide additional information to demonstrate that the tests will verify some pre-defined differential pressure gradient across the filters and measure the level of contamination following the filters. Additionally, indicate the type of action that will be taken (e.g., a notification will be sent to the control room or other appropriate facility for action) if a specified differential pressure or contamination level is exceeded.

In response to RAI 11.3-2, the applicant referenced PSAR Section 9a2.1.1, which states:

> "The exhaust from the cells collects in an RVZ1 system duct header and then draws through final, testable, HEPA filters and carbon adsorbers prior to discharge into the exhaust stack."

And

> "The exhaust air from these spaces collects in an RVZ2 exhaust header and then draws through final, testable, HEPA filters and carbon adsorbers prior to discharge into the exhaust stack."

The applicant provides that PSAR Section 9a2.1.1 is stating that HEPA filters and carbon adsorbers are testable, not that ventilation air in the exhaust header is tested before being exhausted to the stack. The applicant stated that they will test the pressure differential across HEPA filters and decontamination efficiencies of carbon adsorbers to ensure adequate operation and minimize the potential for contamination downstream of the exhaust filter housings. The applicant also stated they will test the HEPA filters and carbon adsorbers in accordance with vendor recommendations and applicable regulatory guidance. The applicant also indicated they will ensure differential pressure instruments are installed to allow for filter monitoring. The applicant's operators will periodically monitor differential pressure and compare the measurement to a pre-defined allowed pressure gradient. If monitoring or testing indicate filter or charcoal adsorber replacement is necessary, an IMR will be issued to ensure corrective actions are taken (e.g., filter replacement).

The staff finds this response meets the acceptance criteria of the ISG Augmenting NUREG-1537, Section 11.3, and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, "Respiratory Protection Program," states, in part, that the applicant should "[i]nstall appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed occupational derived air concentration values in 10 CFR Part 20."

SHINE PSAR Section 9a2.1.1 (page 9a2-3) states that fume hood exhaust ducts are controlled automatically to compensate for changes in pressure drops for loading of filters. Additional information is needed for NRC staff to determine the adequacy of the ventilation system at the SHINE facility.

Therefore, in RAI 11.3-3, the staff asked the applicant to justify that an acceptable differential pressure will be maintained across facility air filters. Indicate whether this will be done through monitoring or some other process. Describe any notification that may be generated to change the filters if a set-point is exceeded.

In response to RAI 11.3-3, the applicant stated that they will monitor fume hood exhaust for adequate airflow in accordance with the ventilation survey guidance provided in Regulatory Guide 8.24. If monitoring indicates deficient airflow, an IMR will be issued to initiate corrective actions (e.g. filter replacement). The requirements for monitoring will be included in the RP Program.

The staff finds this response meets the acceptance criteria of the ISG Augmenting NUREG-1537, Section 11.3, and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, (pages 11-57 through 11-59) states, in part, that the applicant should "[d]escribe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used."

SHINE PSAR Sections 9a2.1.1 and 11.3, "Respiratory Protection Program," do not provide the minimum flow velocity at openings, maximum differential pressure across filters, or types of filters to be used. Additional information is needed for NRC staff to determine the adequacy of SHINE design criteria for the ventilation and containment systems.

Therefore, in RAI 11.3-4, the staff asked the applicant to describe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used. In addition, state which safety function is responsible for maintaining the respiratory program (e.g., the radiation protection program).

In response to RAI 11.3-4, the applicant stated that the facility does not have a containment feature, but uses confinement to minimize the release and spread of radioactive contamination. The design basis for confinement is described in PSAR Section 6a2.2.1. The applicant added that they will follow the ventilation survey guidance in Regulatory Guide 8.24 for fume hood and glovebox operations and maintenance involving uranium-235 processing. This guidance includes monthly surveys to determine that airflow velocities in hoods preclude the escape of airborne uranium and to minimize potential intake by workers, as well as surveys of negative pressure maintained in gloveboxes. The specific criteria for the ventilation systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used will be determined in detailed design and provided in the FSAR. An IMR has been issued to track inclusion of this information in the FSAR. Respiratory protection programmatic requirements are included in the RP Program, and implemented through SHINE procedures. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds this response meets the acceptance criteria of the ISG Augmenting NUREG-1537, Section 11.3, and demonstrates an adequate methodology in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on the respiratory protection program, with the exception of the APF issue mentioned above, supports the preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 11.2.2, allowing the staff to make the following relevant findings: 1) the program is generally consistent (given the level of detail available at the facility design stage) with Regulatory Guide 8.15 and Subpart H and Appendix A of 10 CFR 20.

Therefore, the staff finds that the design of respiratory protection program is sufficient and meets the applicable regulatory requirements and guidance to support issuance of a construction permit in accordance with 10 CFR 50.35. Further evaluation of the respiratory protection program and quantitative fit testing will occur following the receipt of the FSAR submitted with the OL application.

11.4.12 Probable Subjects of Technical Specifications

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications for the radiation protection program and waste management provisions, with special attention given to those items which may significantly influence the final design.

Based on the information provided in Table 14a2-1 of the SHINE PSAR, the staff finds that identification and justification of the proposed conditions related to radiation protection or waste management (e.g. LCOs for the Radiation Monitoring Systems and Effluents, conditions related to design features of the noble gas decay tank storage cell) are sufficient and meet the applicable regulatory requirements to support the issuance of construction permit in accordance with 10 CFR 50.35. A complete evaluation of technical specifications, LCOs, and surveillance requirements will be performed during the review of SHINE's operating license application.

11.5 Summary and Conclusion

The staff evaluated the descriptions and discussions of the SHINE facility radiation protection program and waste management provisions, as described in PSAR Chapter 11 and supplemented by the applicant's responses to RAIs, and finds that the preliminary design criteria of the radiation protection program and waste management provisions, including the principle design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions (1) provides reasonable assurance that the final design will conform to the design basis and (2) meets all applicable regulatory requirements and acceptance criteria in NUREG-1537 and the ISG augmenting NUREG-1537. Based on these findings, the staff has made the following conclusions to support the issuance of a construction permit in accordance with 10 CFR 50.35:

(1) SHINE has described the proposed design criteria of radiation protection program and waste management provisions, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Further technical or design information required to complete the safety analysis of the radiation protection program and waste management provisions may reasonably be left for later consideration the FSAR.

(3) On the basis of the foregoing, there is reasonable assurance that the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

APPENDIX 11A REFERENCES

American National Standards Institute/American Nuclear Society (ANSI/ANS)

ANSI/ANS 15.1-2007 (R2013), "The Development of Technical Specifications for Research Reactors," Reaffirmed April 24, 2013.

U.S. Code of Federal Regulations

Title 10, Energy, Part 20, "Standards for Protection Against Radiation."
Title 10, Energy, 50.34(a), "Preliminary safety analysis report."
Title 10, Energy, 50.35, "Issuance of construction permits."

U.S. Nuclear Regulatory Commission (NRC)

Interim Staff Guidance

"Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," October 17, 2012 (ADAMS Accession No. ML12156A069).

"Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," October 17, 2012 (ADAMS Accession No. ML12156A075).

NUREG-Series Reports

NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," February 1996.

NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," February 1996.