11.0 RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

The principal purpose of the radiation protection program and waste management is to ensure the safety of the SHINE Medical Technologies, LLC (SHINE, the applicant) facility and the public. The radiation protection program and waste management, identified by the analyses in the SHINE Final Safety Analysis Report (FSAR), should be conducted using the appropriate methods and engineering design criteria.

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE radiation protection program and waste management as presented in Chapter 11, "Radiation Protection Program and Waste Management," of the SHINE FSAR, as supplemented by the applicant's response to NRC requests for additional information (RAIs).

11.1 Areas of Review

SHINE FSAR Chapter 11, "Radiation Protection Program and Waste Management," identifies the aspects of the radiation protection program and waste management considered to ensure facility safety and the protection of the public. SHINE FSAR Chapter 11 is applicable to both the SHINE irradiation facility (IF) and radioisotope production facility (RPF). The NRC staff reviewed SHINE FSAR Chapter 11 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design of the SHINE facility radiation protection program and waste management.

11.2 Summary of Application

Chapter 11 of the SHINE FSAR describes all of the relevant aspects of the applicant's radiation protection program and how the radiation protection program meets the NRC requirements in 10 CFR Part 20, "Standards for Protection Against Radiation." The description of the radiation protection program identifies the sources of radiation and radioactive material that will be received, used, or generated in the applicant's facility; the sources and nature of the airborne, liquid, and solid radioactive materials; and the types of radiation that could be emitted by these radiation sources. With the consideration of the radiation sources identified by the applicant, the FSAR also describes the applicant's programs and processes for maintaining occupational and public doses as low as is reasonably achievable (ALARA); radiation monitoring and surveying; radiation exposure control and dosimetry; facility contamination control; and radiological environmental monitoring. In addition, Chapter 11 of the SHINE FSAR describes the applicant's radioactive waste management program, controls, and disposal pathways that will be established to comply with all applicable federal regulations for radioactive wastes and ensure proper identification, classification, control, processing, and packaging for the applicable radioactive waste streams that will be generated by the facility.

11.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR Chapter 11 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the

sufficiency of the bases and the information provided by SHINE for the issuance of an operating license.

11.3.1 Applicable Regulatory Requirements

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

10 CFR 19.12, “Instruction to workers.”

10 CFR 19.13, “Notifications and reports to individuals.”

10 CFR 20.1101, “Radiation protection programs.”

10 CFR 20.1201, “Occupational dose limits for adults.”

10 CFR 20.1202, “Compliance with requirements for summation of external and internal doses.”

10 CFR 20.1203, “Determination of external dose from airborne radioactive material.”

10 CFR 20.1204, “Determination of internal exposure.”

10 CFR 20.1206, “Planned special exposures.”

10 CFR 20.1208, “Dose equivalent to an embryo/fetus.”

10 CFR 20.1301, “Dose limits for individual members of the public.”

10 CFR 20.1302, “Compliance with dose limits for individual members of the public.”

10 CFR 20.1406, “Minimization of contamination.”

10 CFR 20.1601, “Control of access to high radiation areas.”

10 CFR 20.1602, “Control of access to very high radiation areas.”

10 CFR 20.1901, “Caution signs.”

10 CFR 20.1902, “Posting requirements.”

10 CFR 20.1903, “Exceptions to posting requirements.”

10 CFR 20.1904, “Labeling containers.”

10 CFR 50.34, “Contents of applications; technical information,” paragraph (b), “Final safety analysis report,” subparagraph (3).

10 CFR 50.40, “Common Standards.”

10 CFR 50.57, “Issuance of operating license.”

10 CFR Part 61, “Licensing Requirements for Land Disposal of Radioactive Waste.”

10 CFR Part 71, “Packaging and Transportation of Radioactive Material.”

40 CFR, Chapter I, Subchapter F, “Radiation Protection Programs.”

40 CFR, Chapter I, Subchapter I, “Solid Wastes.”

49 CFR, Chapter I, Subchapter C, “Hazardous Materials Regulations.”

11.3.2 Applicable Regulatory Guidance and Acceptance Criteria

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

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

“Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

“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.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used 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, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment 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 FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in Appendix B, “References,” of this SER.

11.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the technical information presented in SHINE FSAR Chapter 11, as supplemented, to assess the sufficiency of the radiation protection program and waste management for the issuance of an operating license. The sufficiency of the radiation protection program and waste management is determined by ensuring that it meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 11.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in SER Section 11.5, "Review Findings."

11.4.1 Radiation Protection

The SHINE facility is designed to produce molybdenum-99 (Mo-99) for use as a medical isotope. The SHINE facility produces Mo-99 along with other radioactive fission and activation products by irradiating a uranyl sulfate target solution inside the target solution vessel (TSV) with a low-energy, accelerator-based neutron source. After the completion of an irradiation cycle, the target solution is pumped through an extraction column, which separates the Mo-99 from the rest of the target solution. The rest of the target solution is then returned for re-use in the irradiation process. The separated Mo-99 is purified via a chemical process. As a result of this process, the radioactive materials produced during the cycle are transferred, by means of piping in shielded trenches, through various locations and systems throughout the facility.

The major radioactive sources that could become airborne during the production process are primarily tritium and other radioactive gases that are byproducts of the Mo-99 production process. The systems that would primarily handle the gaseous radioactive materials include the TSV off-gas system (TOGS) and tritium purification system (TPS), which are located in the IF area; and the process vessel vent system (PVVS) and vacuum transfer system (VTS), which are located in the RPF area. The primary liquid radioactive sources in the facility, which are contained in closed systems (piping and tanks), are primarily byproducts of the uranyl sulfate target solution and exist in the primary cooling water. As for major solid radioactive sources, they exist in several locations within the facility. The major solid radioactive sources include fresh low enriched uranium, spent Mo-99 extraction columns, spent filters, and solidified liquid waste. These solid radioactive sources are contained in irradiation unit (IU) cells, shielded cells, hot cells, and/or preparation areas within the radiologically control area (RCA) of the facility.

11.4.1.1 Radiation Sources

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

This section contains the NRC staff's review of the sources of radiation that are monitored and controlled by the radiation protection and radioactive waste programs. In general, the sources of radioactivity are categorized as airborne, liquid, or solid.

The applicant provided two radionuclide inventory scenarios with the assumptions in FSAR Table 11.1-1, "Parameters Applicable to Target Solution Radionuclide Inventories." The applicant described the two scenarios as nominal and safety basis values. The nominal parameter values are reflective of the applicant's best estimate of the facility's normal, full-power

operating conditions. The safety basis parameter values define the bounding radionuclide inventories for the TSV, TSV dump tank, and supercell.

Operation of the TSV produces radioactive fission products and actinides through the neutron capture in uranium. FSAR Table 11.1-2, "Nominal Versus Safety Basis Radionuclide Inventories in Target Solution," summarizes the results for the total activities from actinides and fissions products contained within the TSV. FSAR Table 11.1-3, "Irradiated Target Solution Activity for Select Radionuclides Pre-Extraction," provides the curie content by nuclide using NUREG/CR-4467, "Relative Importance of Individual Elements to Reactor Accident Consequences Assuming Equal Release Fractions," as a basis for providing a radionuclide listing.

The values contained in FSAR Table 11.1-3 are stated to be the bounding values. The NRC staff's review of the applicant's listed activities as provided in FSAR Table 11.1-3 determined that sufficient information is provided to detail the applicant's anticipated source terms for use in evaluating what source terms will be contained in downstream systems. The staff finds that the SHINE FSAR demonstrates compliance with 10 CFR 50.34(b)(3) by providing a list of radionuclides that reflects the anticipated source terms contained in each system.

Airborne Radioactive Sources

SHINE FSAR Section 11.1.1.1, "Airborne Radioactive Sources," states that the primary forms of airborne radiation at the SHINE facility are tritium and radioactive gases produced by the Mo-99 production process. Ar-41 is produced in the IU during irradiation. N-16 is produced within the primary cooling loop and the light water pool due to the neutron activation of oxygen. The systems that handle the airborne radioactivity are the TPS, the TOGS, the VTS, and the PVVS. The TPS and the TOGS are in the IF, and the VTS and the PVVS are in the RPF. FSAR Table 11.1-5, "Airborne Radioactive Sources," provides information on the location of airborne radioactive sources in various plant areas. The information contained in this table allowed the NRC staff to review and understand the airborne sources when evaluating the dose impacts to workers.

Gaseous activity collected from the TSV and process operations is routed through the PVVS. The PVVS includes carbon delay beds, which are used to delay airborne radioactive sources, primarily krypton and xenon isotopes, to acceptable levels prior to release to the environment. Another pathway for gaseous activity is through the RVZ1 hot cell ventilation and RVZ2 general area ventilation. The RVZ1 and RVZ2 do not have carbon delay beds but do include HEPA filtration. These flow paths to the environment all exit to the facility stack, which has the stack release monitor to monitor the radiological releases to the environment. The flow path for these pathways is provided in SHINE FSAR Figure 9a2.1-8 and Figure 9b.6-1.

SHINE FSAR Table 11.1-6, "Estimated Derived Air Concentrations," provides estimated Derived Air Concentrations (DAC) for different areas in the facility. FSAR Figure 11.1-2 provides a map of the DAC zone categorization for the facility. The NRC staff finds the zoning acceptable given the information provided about the airborne source terms and the potential for leakage from the facility systems in the FSAR tables.

SHINE FSAR Table 11.1-8, "Estimated Annual Releases from Normal and Maintenance Operations," provides the source term for use in the gaseous release dose calculations. This table is used in conjunction with metrological data to assess the doses to the nearest residents

and the maximally exposed individuals. The NRC staff's assessment of the airborne effluent doses is contained in the gaseous waste streams section of this chapter of the SER.

The NRC staff's review of the airborne radioactive sources determined that SHINE provided sufficient details about the airborne radioactive sources. These source terms allow the staff to perform confirmatory analyses for dose calculations to confirm that SHINE is meeting ALARA objectives and 10 CFR 20.1101(d).

Liquid Radioactive Sources

SHINE FSAR Section 11.1.1.2 states that the liquid sources of radioactivity within the SHINE facility are generally derived from the irradiated uranyl sulfate target solution as it is processed by the facility. The primary coolant and the low activity fresh uranyl sulfate target solution are identified as additional liquid sources of radioactivity in the plant. The liquid sources of radioactivity in the plant are contained in closed systems. The summary of the sources of liquid radioactivity is provided in FSAR Table 11.1-9, "Liquid Radioactive Sources." Based on the FSAR, there are no piped direct radioactive liquid discharges from the SHINE facility. Liquid waste generated by the applicant is solidified and shipped to a disposal facility. Non-radioactive liquid waste is also generated during normal operations. This waste is collected and sampled prior to disposal into the sanitary sewers or disposed of as low-level waste if sampling determines that it cannot be released through the sanitary sewer. FSAR Table 11.2-1, "Estimated Annual Waste Stream Summary," provides information on the volumes of waste generated by the SHINE facility.

The NRC staff's review of the liquid radioactive sources finds that there are no doses attributed to liquid effluent releases. In review of the information contained in FSAR Table 11.1-9, the staff finds that SHINE provided sufficient details to allow the staff to perform dose calculations to understand the radiation environment in the plant and to ensure that doses for plant workers are ALARA and within regulatory limits.

Solid Radioactive Sources

SHINE FSAR Section 11.1.1.3 states that the solid sources of radioactivity include the low enriched uranium, which undergoes processing to be converted into uranyl sulfate, spent extraction columns from the Mo-99 extraction process, spent filters, and solidified liquid waste. FSAR Table 11.1-10, "Solid Radioactive Sources," provides information on the locations, types, and sources of solid radioactivity. The radionuclide inventory is a function of the TSV system operation. FSAR Table 11.2-1 provides information on the quantities of waste generated by the SHINE facility.

The NRC staff's review of the solid radioactive sources finds that SHINE provided sufficient details about the solid radioactive sources to allow the staff to perform dose calculations to understand the radiation environment in the plant and to ensure that doses for plant workers are ALARA and within regulatory limits. The staff reviewed the description of potential radiation sources and associated doses including the inventories, chemical and physical forms, and locations of radioactive materials, as well as other facility radiation and operational parameters related to radiation safety presented in the FSAR. This review included a comparison of the bases for identifying potential radiation safety hazards with the process and facility descriptions to verify that such hazards were accurately and comprehensively identified. This review and evaluation confirmed that the FSAR identifies the potential radiation safety hazards associated

with the SHINE facility and this provides an acceptable basis for the development and independent review of the radiation protection program.

11.4.1.2 Radiation Protection Program

The NRC staff evaluated the information provided on the radiation protection program, as described in SHINE FSAR Section 11.1.2, “Radiation Protection Program,” using the guidance and acceptance criteria from Section 11.1.2, “Radiation Protection Program,” of NUREG-1537, Part 2.

The NRC staff reviewed the information provided in the SHINE FSAR regarding radiation protection program personnel in FSAR sections 11.1.2.1.1 and 11.1.2.1.2. The staff finds that the applicant’s description of radiation protection personnel is consistent with the guidance contained in Regulatory Guide (RG) 8.2, “Administrative Practices in Radiation Surveys and Monitoring,” and RG 8.10, “Operating Philosophy for Maintaining Operational and Public Radiation Exposures As Low As Is Reasonably Achievable.” The staff finds that the roles for plant personnel are adequately defined in FSAR section 11.1.2.1.1, and that the commitment to follow RG 8.2 and RG 8.10 is appropriate.

SHINE FSAR section 11.1.2.1.6 provides information related to the commitment to radiation protection training. The applicant stated that the program will comply with the requirements of 10 CFR 19.12. The applicant also stated that the radiation protection training program will be consistent with the guidance provided in RG 8.10, RG 8.13, “Instruction Concerning Prenatal Radiation Exposure,” RG 8.29, “Instruction Concerning Risks from Occupational Radiation Exposure,” and American Society for Testing and Materials (ASTM) E1168-95, “Radiological Protection Training for Nuclear Facility Workers.” The NRC staff finds that the inclusion of these guidance documents is appropriate for a radiation protection program. The staff also finds that the FSAR demonstrates compliance with 10 CFR 19.12 and 10 CFR 19.13 by providing a description of the program implemented at SHINE to keep workers informed about the storage, transfer, and use of radioactive material and the requirements for monitoring radiation exposures in the SHINE facility.

SHINE FSAR section 11.1.2.1.7 provides information related to the applicant’s ability to review and determine the effectiveness of the radiation protection program. The applicant stated that audits will be conducted on an annual basis to meet the requirements of 10 CFR 20.1101(c). The NRC staff finds that this is consistent with 10 CFR 20.1101(c), which requires that audits are to be conducted at least annually.

SHINE FSAR section 11.1.2.1.8 addresses the applicant’s management of records by stating that the radiation protection program will meet the requirements of 10 CFR Part 20, Subpart L, “Records.” The NRC staff finds that this is appropriate as Subpart L details the NRC requirements for what documentation needs to be retained.

SHINE provided the anticipated administrative exposure limits in FSAR Table 11.1-11, “Administrative Radiation Exposure Limits.” This table provides a comparison of the 10 CFR Part 20 limits to the specified SHINE administrative limits. The SHINE administrative limits are approximately a factor of 2.5 less than the limits in 10 CFR Part 20.

The NRC staff has reviewed the radiation protection program presented in the FSAR for the SHINE facility. This review included an evaluation of (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 comprehensiveness 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 reviews and audits of the radiation protection program; (6) the effectiveness and comprehensiveness of the process to evaluate the radiation 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. The staff finds that the radiation protection program presented in the FSAR both complies with applicable requirements and provides reasonable assurance 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.

11.4.1.3 As Low As Is Reasonably Achievable Program

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

The NRC staff's review focused on the description of the ALARA program, ensured that plant management is engaged with the ALARA program, and how the ALARA program would be used to reduce radiation exposures. The applicant stated that its ALARA program will be compliant with RG 8.2, RG 8.13, and RG 8.29. The applicant also stated that the operation of the facility will be consistent with RG 8.10. SHINE FSAR Section 11.1.3 also identifies the responsibilities of the Radiation Protection Manager in implementing the ALARA program and identifies ALARA program evaluation reports that are evaluated by the Radiation Safety Committee (RSC).

The NRC staff reviewed the ALARA design considerations in SHINE FSAR section 11.1.3.2. The staff determined that the design considerations as described by the applicant are consistent with RG 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable." Examples of the applicant's design considerations include the remote handling of material, where possible, in hot cells to greatly reduce radiation exposures. In addition, the applicant discussed the use of features to allow for draining, flushing, decontamination of equipment and piping, shielding for personnel during repair work, and separation of highly radioactive equipment from less radioactive equipment. The applicant provided additional features for maintaining exposures ALARA in FSAR section 11.1.3.2. The staff finds that the applicant follows the guidance in RG 8.8 to meet the ALARA guidelines in accordance with 10 CFR 20.1101(b).

The NRC staff reviewed the ALARA program at the facility. The policies and the bases for procedures give reasonable assurance that doses to occupational workers and the public will be maintained below regulatory limits and ALARA. The controls and procedures for limiting access and personnel exposure (including allowable doses, effluent releases, ALARA goals, and criteria used for the action levels in radiation alarm systems) meet the applicable radiation protection program requirements and provide reasonable assurance that radiation doses to the environment, the public, and facility personnel will be ALARA. The ALARA program is adequately supported at the highest levels of management for the facility.

11.4.1.4 Radiation Monitoring and Surveying

The NRC staff evaluated the sufficiency of the radiation monitoring equipment and the performance of radiation surveys, as described in SHINE FSAR 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 SHINE FSAR Section 11.1.4, the applicant provided information about the monitors and survey equipment that will be used within the facility. SHINE FSAR Section 7.7 "Radiation Monitoring Systems," contains the system descriptions for the various radiation monitors used in the facility.

The applicant stated that there will be monitoring for tritium within each IU, the TPS glovebox room, and at the facility stack. In addition, the applicant stated that there will be continuous monitoring of noble gases, aerosols, and iodine at the facility stack. The facility stack monitor is used to demonstrate that the gaseous releases from the plant are below the regulatory limits. For liquid effluents, there are no radioactive liquid effluent discharges from the facility and, therefore, the applicant stated that there will be no liquid effluent monitors. In the scenario where liquid waste is collected, SHINE stated that the effluent will be transported outside of the RCA, sampled to ensure that it meets the release limits, and then disposed of through the sanitary sewer. SHINE FSAR Section 11.2.3 states that the effluent will be disposed of as low-level waste if sampling determines that it cannot be released through the sanitary sewer.

SHINE FSAR Table 11.1-12, "Radiation Monitoring Equipment," provides a summary of the radiation monitoring equipment used at the site, along with the anticipated locations and functions of the monitors being provided.

The applicant stated that its gaseous effluent monitoring will be capable of continuous monitoring for noble gas releases, generating real time data for control room display and recording. In SHINE FSAR Section 7.7.5, the applicant provided the anticipated ranges for the noble gas radiation monitor and tritium monitors. The NRC staff's review of the information contained in FSAR Sections 7.7.5 and 11.1.4 finds that the ranges listed are appropriate to monitor and track the releases from the facility and that the description and ranges of these effluent monitors are acceptable. Iodine and particulate monitoring at the SHINE facility is performed through collection onto filter cartridges which are then analyzed. In addition, the facility's environmental monitoring program ensures that the releases are also being adequately tracked.

Within the facility, there will be continuous air monitors (CAM) and radiation area monitors (RAM). SHINE FSAR section 11.1.4 provides general descriptions with more detailed descriptions provided in FSAR Section 7.7.3, "Area Radiation Monitoring," and Section 7.7.4, "Continuous Air Monitoring." FSAR Tables 7.7-2 and 7.7-3 provide information describing where the CAMs and RAMs are located within the facility. The NRC staff's review of the locations of the CAMs and RAMs determined that the applicant provided sufficient descriptions and placed monitoring equipment in areas that allow the applicant to understand the radiation environment of the facility.

The applicant stated that it will follow ANSI N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments," for the calibration of portable radiological monitoring equipment used to document survey results. The applicant also stated that it will use ANSI N13.1-1999, "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities," for the

effluent stack monitors to ensure representative sampling of the radioactive effluents. In addition, the applicant stated that it will develop procedures to specify the methods and frequency for which monitoring equipment will need to be calibrated. The NRC staff's review of these sampling and calibration methods determined that the information provided by the applicant is acceptable to ensure appropriate calibrations and representative sampling necessary to monitor the radiological conditions of the facility and the releases to the environment.

As stated in the SHINE FSAR, radiation surveys are performed to understand the radiation levels, concentrations, and the radiological hazards that could be present in the facility, and to understand the potential releases from plant equipment. Furthermore, the surveys performed will be compliant with 10 CFR Part 20, Subparts C, "Occupational Dose Limits," F, "Surveys and Monitoring," L, and M, "Reports." The applicant also referenced RG 8.2, RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," RG 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," RG 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication," and RG 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," for demonstrating compliance with NRC regulations. The NRC staff finds that the inclusion of these RGs is acceptable in demonstrating an adequate radiation survey program.

The NRC staff reviewed the design of radiation monitoring and sampling provisions at the SHINE facility. The fixed and portable equipment used for radiation monitoring and sampling inside the facility is selected, located, calibrated, tested, and maintained in accordance with guidance contained in recognized national standards and the manufacturers' instructions, and with applicable regulations. The methods and bases of procedures used to determine the placement of the equipment, the circumstances under which the equipment is used, and the selection of the equipment function and sensitivity are appropriate to the facility and give reasonable assurance that appropriate types of radiation in significant intensities will be detected, monitored, and sampled consistent with 10 CFR Part 20 requirements and the facility ALARA program.

11.4.1.5 Radiation Exposure Control and Dosimetry

The NRC staff evaluated the sufficiency of the radiation exposure control and dosimetry provisions, as described in SHINE FSAR 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.

SHINE FSAR section 11.1.5 provides information related to the established controls at the SHINE facility. The applicant provided information on the radiological zoning, access controls, radiological postings, protective clothing and equipment, monitoring of external doses, and the evaluation of doses in general.

The NRC staff's review determined that the applicant provided adequate information related to the radiological boundaries that are defined for the SHINE facility. The applicant followed those definitions in 10 CFR Part 20 for establishing the unrestricted area, restricted area, and radiologically controlled areas. The applicant provided additional information related to the posting of radiological areas in SHINE FSAR Table 11.1-13, "Radiological Postings."

As stated in the SHINE FSAR, the applicant will establish a program that ensures the appropriate use of signs and postings, will establish restricted areas that will prevent the spread

of contamination, and will provide those controls necessary when working in contaminated areas. Furthermore, the postings will be done in accordance with 10 CFR 20.1902. The FSAR also provides information on how the applicant will limit access to high radiation areas and describes those controls and interlocks that will prevent access to the high radiation areas. Specifically, hot cells have interlocks that prevent the doors from being open during times with excessive radiation fields and during target solutions transfers. In addition, the neutron driver service cell and the hot cells are equipped with audible and visual warnings to inform individuals that they are entering a high radiation area or the area is controlled by locked entry. Lastly, the use of radiological shielding and engineered physical barriers are provided to limit access to high radiation areas. The NRC staff finds that the use of these features is in accordance with the requirements in 10 CFR 20.1601, and that the information provided in the FSAR to control access to high radiation areas is acceptable.

The NRC staff reviewed the engineered radiation exposure controls employed at the facility. The staff finds that the applicant provided sufficient information related to the design of the confinement, radiological shielding, ventilation, remote handling, decontamination equipment, and entry control devices to allow for an assessment of the design of these radiological protection features. The entry control devices employed are adequate to alert workers to, or prevent entry into, radiological areas, including high or very high radiation areas. The confinement system design provides reasonable assurance that uncontrolled radiological releases to the unrestricted environment, controlled area (if present), or the restricted work area will not occur during any anticipated normal operations.

Personnel monitoring at the SHINE facility is through personal dosimetry worn by those individuals that enter and work in the restricted areas of the facility. SHINE FSAR Section 11.1.5.5, “Personnel Monitoring for External Exposures,” provides information related to the procedures for use of personal dosimetry at the facility. Provisions have been made for external and internal radiation monitoring of all individuals required to be monitored. The NRC staff determined that the proposed dosimetry program meets the requirements of the regulations in 10 CFR Part 20. In addition, the staff determined that the provisions incorporated for personal dosimetry, shielding, ventilation, remote handling, and decontamination equipment provide reasonable assurance that radiation doses are maintained ALARA and within applicable regulations.

The NRC staff reviewed the calculational files to understand the assumptions and models used for the dose calculations. The applicant provided various source term information for the SHINE facility in SHINE FSAR Tables 11.1-5, 11.1-9, and 11.1-10. Shielding details are also in FSAR Chapter 4 describing IU shielding, super cell shielding, shield plug shielding, and various other shielding in the facility that are assumed in the SHINE analysis. The applicant performed shielding calculations using the Monte Carlo N-Particle (MCNP) computer code. The staff’s review of the applicant’s calculations determined that the approach and models used in the analysis were reasonable and should accurately model the radiation areas within the SHINE facility. To verify the calculations, the staff performed independent verifications using the MicroShield computer code and found that the results detailed by SHINE’s estimated dose maps in FSAR Figures 11.1-1 and 11.1-2 are acceptable.

The applicant discussed the procedures for use of personal dosimetry at the SHINE facility. Provisions have been made for external and internal radiation monitoring of all individuals required to be monitored. The proposed dosimetry program meets the requirements of the regulations in 10 CFR Part 20. The NRC staff finds that the provisions incorporated for personal dosimetry, shielding, ventilation, remote handling, and decontamination equipment provide

reasonable assurance that radiation doses are maintained ALARA and within applicable regulations.

11.4.1.6 Contamination Control

The NRC staff evaluated the sufficiency of the contamination control provisions, as described in SHINE FSAR 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.

SHINE FSAR Section 11.1.6 provides information on the design features managing the levels of contamination at the SHINE facility to demonstrate compliance with 10 CFR 20.1406.

Shielded compartments and hot cells are provided in the SHINE facility to minimize the spread of contamination for components that do not require local operator actions and when handling material during processing activities. The SHINE FSAR details that piping is in shielded compartments or hot cells. The transfer areas for pipes are in pipe trench areas to contain the radioactive liquid and gases. The FSAR describes the use of inspection ports to allow for visual inspections of the pipes in these shielded areas. In addition, the FSAR describes how the design considered the spread of contamination by implementing means of controlling ventilation air flow patterns from areas of low radioactivity to areas of higher activity.

Furthermore, monitoring of personnel access to areas is employed as a means of reducing the levels of contamination in the SHINE facility and personal protective equipment is used to minimize the contamination of plant personnel. CAMs are also located within the facility to detect the spread of airborne contamination in plant restricted areas. The RAMs within the facility are used to identify increased background radiation levels within the facility.

The NRC staff reviewed the information provided in the SHINE FSAR related to contamination control features and finds the features consistent with the requirements in 10 CFR 20.1406 for the minimization of contamination. The staff’s review determined that the applicant has controls and design features in place to limit the spread of contamination at the SHINE facility.

11.4.1.7 Environmental Monitoring

The NRC staff evaluated the sufficiency of the environmental monitoring provisions, as described in SHINE FSAR Section 11.1.7, “Environmental Monitoring,” using the guidance and acceptance criteria from Section 11.1.7, “Environmental Monitoring,” of NUREG-1537, Part 2.

SHINE FSAR Section 11.1.7 provides information related to the environmental monitoring program and effluent monitoring program at the SHINE facility. The applicant stated that it followed RG 4.1, “Radiological Environmental Monitoring for Nuclear Power Plants,” and NUREG-1301, “Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors,” in the development of the SHINE radiological environmental monitoring program (REMP).

The applicant identified that direct radiation exposure, inhalation, and ingestion pathways are monitored from the SHINE facility. These pathways are from direction radiation and gaseous effluent releases. As previously identified, there are no liquid effluent releases from the SHINE facility. However, as stated in SHINE FSAR Section 11.1.7, any releases to the sanitary sewer will be made in accordance with 10 CFR 20.2003, “Disposal by release into sanitary sewerage,”

and 20.2007, “Compliance with environmental and health protection regulations,” which require compliance with 10 CFR Part 20, Appendix B, Table 3 and other Federal, State, and local environmental regulations.

SHINE FSAR Table 11.1-14, “Environmental Monitoring Locations,” provides a list of the environmental monitors that will be set up by the applicant. The applicant also provided a map of the environmental dosimeter locations in FSAR Figure 11.1-4, “Environmental Dosimeter Locations.”

The SHINE facility will establish direct radiation monitoring and air sampling locations based on the guidance contained in NUREG-1301. This guidance describes the rationale for placing monitoring and establishing the necessary background data for the measurement. This air sampling program around the site allows the applicant to verify the effectiveness of the air effluent monitoring program.

As stated in SHINE FSAR Sections 11.1.7.2.3 and 11.1.7.2.4, surface water and biota monitoring are not anticipated at this time due to the environment in which the facility is located. Specifically, there are no nearby biota that require monitoring since surface waters are not expected to be contaminated given that there are no direct liquid releases to the environment. The NRC staff finds this acceptable given that the REMP is evaluated annually to verify the effectiveness of the program.

The NRC staff reviewed the applicant’s environmental monitoring program. The staff reviewed the monitoring locations and pathways for doses from effluent and direct sources. The staff concludes that the applicant appropriately included air sampling and dosimeters that would appropriately track effluent releases to demonstrate compliance with SHINE Design Criteria Criterion 38, as described in SHINE FSAR Section 3.1, “Design Criteria.” In addition, the staff reviewed the locations for proposed offsite monitoring and concludes that the applicant provided enough information to conclude that the proposed offsite monitoring is sufficient to observe offsite dose impacts. The staff finds that the SHINE FSAR demonstrates compliance with 10 CFR 20.1301 by providing for the monitoring of the expected gaseous releases to the environment. The applicant showed that the releases will result in doses to members of the public below the limits contained in 10 CFR 20.1301.

11.4.2 Radioactive Waste Management

SHINE FSAR Section 11.2 states that the production of medical isotopes creates liquid, gaseous, and solid radioactive wastes. The applicant described the management program, controls, and disposal pathways established to ensure proper identification, classification, control, processing, and packaging for each generated waste stream. All radioactive wastes generated at the SHINE facility are prepared for shipment in approved shipping containers and shipped offsite using carriers in compliance with applicable regulations. The state of Wisconsin is a part of the Midwest Interstate Low-Level Radioactive Waste Compact. The waste disposal sites available for SHINE’s use are Energy*Solutions* in Clive, UT and Waste Control Specialists in Andrews, TX.

11.4.2.1 Radioactive Waste Management Program

The NRC staff evaluated the sufficiency of the radioactive waste management program, as described in SHINE FSAR 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.

In SHINE FSAR Section 11.2.1, the applicant described the overall structure of the radioactive waste management program including, in detail, the authority, duties, and responsibilities of the Director of Corporate Support, Radiation Protection Manager, Training Manager, Quality Manager, and shipping personnel, and how this allows the program to comply with federal and state regulations. FSAR Section 11.2.1 states that the SHINE facility Radioactive Waste Management Program is coordinated with the Radiation Protection Program, under the Director of Corporate Support, and designates disposal pathways and controls necessary to ensure proper identification, classification, control, processing, and packaging for the anticipated radioactive waste streams generated by the facility. The goal of this program is to minimize waste generation, minimize radiation exposure to personnel, and protect the public and environment. The program is committed to complying with all applicable local (State of Wisconsin) and federal regulations for managing radioactive wastes.

The NRC staff reviewed the radioactive waste management program as presented in SHINE FSAR Section 11.2.1. This review included an evaluation of: (1) the authority, duties, and responsibilities of the Director of Corporate Support and Radiation Protection Manager; (2) the roles and responsibilities of the Training Manager and Quality Manager; (3) implementing procedures applicable to waste management; (4) the management of records pertaining to the radioactive waste management program; and (5) the program’s provisions for reviews, audits, and assessments.

The NRC staff finds that the applicant’s description of the Radioactive Waste Management Program presented in SHINE FSAR section 11.2.1 provides reasonable assurance that radioactive wastes will be adequately controlled by the facility and will not pose any risk of undue radiation exposure to the facility staff, the environment, or the public. The staff also finds that the program provides reasonable assurance that radioactive waste released from the facility will not exceed the limits in 10 CFR Part 20 or endanger the public or the environment.

11.4.2.2 Radioactive Waste Controls

The NRC staff evaluated the sufficiency of the radioactive waste controls provisions, as described in SHINE FSAR 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.

SHINE FSAR Section 11.2.2 states that the SHINE Radiation Protection Program and ALARA Program apply to radioactive waste management, including, but not limited to, control of materials, monitoring and surveys, RCA access control, contamination control, and personnel monitoring. In addition, the radioactive waste management operating procedures will ensure proper identification, characterization, and separate treatment of radioactive wastes. For the purposes of meeting the ALARA principle, radioactive waste at the SHINE facility may be categorized as either contact handled or handled remotely. The primary forms of radioactive waste generated at the SHINE facilities are all classified as low-level waste (LLW) and do not include spent nuclear fuel, high-level waste, or the paragraphs (2), (3), and (4) definitions of byproduct material in 10 CFR 20.1003. The neutron multipliers are designed for the life of the facility and will be disposed of as greater-than Class C (GTCC) waste during decommissioning. When transporting radioactive waste, the waste may be categorized as low specific activity (LSA) requiring Type A packaging or requiring Type B packaging. The material staging building

is used for the interim storage of radioactive waste for decay and preparation for transportation. The building is designed to ensure that the dose limits in 10 CFR Part 20 are not exceeded while maintaining doses ALARA. Radioactive waste stored in the staging building is not stored for more than five years.

Radioactive Waste Minimization

SHINE FSAR Section 11.2.2.1 states that waste minimization and pollution prevention are key elements of the SHINE Radiological Waste Management Program. The implementing procedures for waste minimization and pollution address: (1) employee training and education on environmental activities and hazards regarding the SHINE facility, operations, pollution prevention, and waste minimization goals and accomplishments; (2) goals for reducing the volume of radioactivity in each waste stream; (3) sorting and compacting waste to reduce overall volume; (4) segregation of non-radiological and radiological wastes to reduce the volume of contaminated waste; (5) process controls that minimize generation of wastes; and (6) periodic program assessments. The NRC staff finds that the FSAR describes adequate efforts to reduce and minimize the amount of waste produced when feasible.

Waste Stream Sources

SHINE FSAR section 11.2.2.2 states that waste management operations occur in the RPF and the material staging building. SHINE will use approximately 5,600 square feet of the material staging building for temporary storage of radioactive waste to allow time for decay. Drums that are being stored in the material staging building may be stored in multiple layers if the waste drum design, building design, and programmatic controls allow for the drums to be stored safely. The equipment and design features used for the containment and/or packaging, storage, and disposal of solid, liquid, and gaseous radioactive waste include the radioactive liquid waste immobilization (RLWI) system, the radioactive liquid waste storage (RLWS) system, and the solid radioactive waste packaging (SRWP) system. Detailed descriptions of these systems are contained in SHINE FSAR Chapter 9.

The anticipated waste streams, characteristics, generation rates, and shipment categories for the SHINE facility are detailed in FSAR Table 11.2-1 and Sections 11.2.2.2.1 through 11.2.2.2.12.

Based on its review of SHINE FSAR Section 11.2.2, the NRC staff concludes that the radioactive waste controls are acceptable. The FSAR provides sufficient details by discussing the high-level function of the waste systems and the anticipated waste streams generated. Included in these discussions, the applicant described details such as the anticipated radionuclides, cleanup systems involved with the waste streams, and the expected waste output classification for each waste stream. As described in the FSAR, the facility provides methods by which waste products will be monitored and assessed for radioactive material contents, has controls established for waste streams and products to prevent uncontrolled exposures or release of radioactive waste, has descriptions of the plans and procedures for controlled radioactive wastes to protect the environment and the health and safety of the facility staff and public, and has described efforts to reduce and minimize the amount of waste produced when feasible.

11.4.2.3 Release of Radioactive Waste

The NRC staff evaluated the sufficiency of the release of radioactive waste provisions, as described in SHINE FSAR 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.

SHINE FSAR Section 11.2.3 states that prior to the release of radioactive waste, the SHINE facility ensures that the wastes are adequately processed and packaged as required to meet the waste acceptance criteria for the disposal facility that the waste is being transported to. Processing at the SHINE facility can be comprised of one or more operations. These operations can include compaction, solidification, adsorption onto a solid medium (elemental iodine onto activated carbon filters), interim storage for decay of radionuclides, consolidated handling and processing, extraction and consolidation of radionuclides by segregation, and mixing waste streams so that the bulk volume of waste is readily disposable. The final determinations of waste classification and management will be made in accordance with the SHINE Radioactive Waste Management Program.

Gaseous effluent waste streams at the SHINE facility are monitored by the main facility stack release monitor (SRM) and the carbon delay bed effluent monitors (CDBEM) located at the exhaust of the PVVS carbon delay beds. The SRM is used to monitor gaseous effluent releases from the facility to demonstrate that the releases are within the limits of 10 CFR Part 20. The CDBEM monitors provide the ability to monitor the safety-related effluent release pathway when it is in use to demonstrate that gaseous effluent releases from the facility are within regulatory limits.

At the SHINE facility, there are no piped liquid effluent pathways from the RCA to the sanitary sewer. During operations at the SHINE facility, liquid effluents are not expected to be routinely discharged from the RCA. Prior to liquid discharges to the sanitary sewer, sampling will be performed to determine suitability for release and compliance with 10 CFR Part 20.

Solid Wastes

SHINE FSAR Section 11.2.3.1, “Solid Wastes,” describes the methodology that the facility will use for the eventual release of major solid wastes that may be generated at the facility. For all shipments of solid waste for disposal, SHINE’s processing requirements will be in accordance with the receiving facility’s waste acceptance criteria. If the receiving facility’s acceptance criteria change, SHINE will modify its practices to account for any changes. FSAR Table 11.2-1, “Estimated Annual Waste Stream Summary,” provides the details for the wastes generated, the class of the waste generated, the amount of the waste generated, and the destination for disposal.

SHINE FSAR Sections 11.2.3.1.1 through 11.2.3.1.6 provide the sources of expected solid waste generation at the SHINE facility. The applicant detailed the waste forms and expected handling for the various solid waste types.

The NRC staff reviewed the description of solid wastes generated at the SHINE facility and finds that the applicant adequately described the expected forms and quantities of solid waste generated at the facility. In addition, the applicant provided details regarding wastes that will be shipped to and disposed of at either Waste Control Specialists or Energy*Solutions*.

Liquid Waste Streams

As discussed in Section 11.2.2.2 of this SER, the consolidated liquid waste stream once solidified is expected to be Class A waste at Energy*Solutions*. Liquid waste that remains is disposed of through the sanitary sewer outside of the RCA, consistent with applicable limits.

The estimated generated volumes of radioactive liquid waste are provided in SHINE FSAR Table 11.2-1. The radioactive liquid waste presented in the table are collected and processed separately, then blended prior to solidification. Blending of the wastes will be performed without exceeding the maximum uranium concentrations allowed by the disposal site that will be receiving the waste. For the purposes of the transportation of the material to a disposal site, certain fissile material may be exempted in accordance with 10 CFR 71.15.

SHINE FSAR Section 11.1.1.2 states that while liquid wastes generated at the SHINE facility will generally be solidified and then shipped, the facility does have the ability to dispose of liquid waste through the sanitary sewer. FSAR Section 11.2.3 states that there are no piped pathways from the RCA to the sanitary sewer, therefore, liquid discharge has no pathway from the RCA to the sanitary sewer. SHINE estimates that around 40 gallons per week of liquid waste are planned to be disposed of through the sanitary sewer. This liquid waste is expected to have no sources of radioactivity and is produced from the facility's cooling and air handling system operations. Liquid waste generated in this manner will be sampled for radioactivity prior to disposal through the sanitary sewer.

The NRC staff reviewed the description of liquid wastes generated at the SHINE facility and finds that the applicant will adequately control the liquid radioactive waste generated and that radioactive liquid waste disposal is not anticipated at the site.

Gaseous Waste Streams

The estimated generated release of airborne radioactive materials is provided in SHINE FSAR Section 11.2.3.3 and the airborne sources are discussed in FSAR Section 11.1.1.1. FSAR Table 11.1-5 provides information on the airborne radioactive sources. The gaseous release path for the SHINE facility is from the facility exhaust stack. The facility exhaust stack is continuously monitored for noble gases, particulates, iodine, and tritium to ensure compliance with effluent release limits.

The NRC staff reviewed the information contained in FSAR Table 11.1-8 and the annual average relative atmospheric concentration (χ/Q) information provided in FSAR Section 11.1.1.1, and performed a confirmatory calculation using the GENII computer code. The applicant's dose calculation determined that the estimated annual doses were 4.6 mrem to the maximum exposed individual and 0.3 mrem to the nearest resident. The staff's confirmatory calculation determined that the airborne releases from SHINE would be less than 10 mrem per year. 10 CFR 20.1101(d) requires that air emissions shall have a dose limit of 10 mrem per year. The applicant provided the estimated gaseous activity production rates for a single TSV in FSAR Table 11.1-8, "Estimated Annual Releases from Normal and Maintenance Operations," to support the dose analysis for demonstrating compliance with 10 CFR 20.1101(d). Based on the information provided, the staff finds that the facility's gaseous releases will be compliant with the dose limits contained in 10 CFR 20.1101(d).

11.4.3 Respiratory Protection Program

The NRC staff evaluated the sufficiency of the respiratory protection program, as described in SHINE FSAR 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.

The NRC staff examined whether the respiratory protection program provides adequate protection of personnel from airborne concentrations exceeding the limits in 10 CFR Part 20, Appendix B. Given that the SHINE facility will conform to the NRC guidance contained in RG 8.15, “Acceptable Programs for Respiratory Protection,” the staff determined that the SHINE facility will have a program that supports a respiratory protection program capable of protecting its personnel from airborne concentrations exceeding the limits of 10 CFR Part 20, Appendix B.

The NRC staff finds that SHINE has committed to an acceptable radiation protection program that includes a program to control airborne concentrations of radioactive material with engineering controls and a respiratory protection program.

11.4.4 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant’s proposed technical specifications (TSs) for the SHINE facility.

The proposed TS 3.7, “Radiation Monitoring Systems and Effluents,” Limiting Condition for Operation (LCO) 3.7.1 and Surveillance Requirement (SR) 3.7.1, states the following:

LCO 3.7.1	Radiation monitoring instruments listed in Table 3.7.1-a shall be Operable. Note – Any single SFM [safety function module] may be bypassed for up to 2 hours while in the condition of applicability for the purpose of performing a Channel Calibration.
Applicability	According to Table 3.7.1-a
Action	According to Table 3.7.1
SR 3.7.1	1. A Channel Check shall be performed for radiation monitors monthly. 2. A Channel Calibration shall be performed for radiation monitors annually.

The proposed Table 3.7.1-a, “Safety-Related Radiation Monitoring Instruments,” states the following:

	Monitored Location	**Setpoint and Monitored Material**	**Required Channels**	**Applicability (per IU, TPS train, or monitored location)**	**Action**
a.	RVZ1 supercell exhaust ventilation (PVVS hot cell)	≤ 5x background Fission products	3	Facility not Secured	1, 2, 3

b.	RVZ1 supercell exhaust ventilation (Extraction and IXP hot cells)	≤ 5x background Fission products	2 (per hot cell)	Target solution or radioactive process fluids present in the associated hot cell	4, 5
c.	RVZ1 supercell exhaust ventilation (Purification and Packaging hot cells)	≤ 5x background Fission products	2 (per hot cell)	Radioisotope products or radioactive process fluids present in the associated hot cell	4, 5
d.	RVZ1 RCA exhaust	≤ 5x background Fission products	3	Facility not Secured	1, 6, 7
e.	RVZ2 RCA exhaust	≤ 5x background Fission products	3	Facility not Secured	1, 6, 7
f.	RVZ1e IU cell exhaust	≤ 5x background Fission products	3 (per IU)	Associated IU in Mode 1, 2, 3, or 4	1, 8
g.	TPS confinement A/B/C	≤ 927 Ci/m^3 Tritium	2 (per TPS train)	Tritium in associated TPS process equipment not in storage	9
h.	TPS exhaust to facility stack	≤ 0.96 Ci/m^3 Tritium	3	Tritium in any TPS process equipment not in storage	1, 10
i.	MEPS heating loop extraction area A/B/C	≤ 1000 mR/hr Fission products	2 (per hot cell)	Target solution or radioactive process fluids present in the associated hot cell	11, 12

LCO 3.7.1 requires the radiation monitoring equipment listed in Table 3.7.1-a to be operable. The NRC staff finds that this LCO limits the spread of contamination and effluent releases by ensuring that appropriate setpoints are in place to monitor the radionuclides of concern for each area the monitors are in. The staff finds that the LCO will ensure that elevated levels of radiation that may result in radiation exposure to workers or individual members of the public are detected. The staff also finds that LCO 3.7.1 is consistent with the information contained in SHINE FSAR Sections 7.7.1 and 7.7.5 in establishing setpoints and channel requirements. Therefore, the staff finds the LCO acceptable. Additional staff review of LCO 3.7.1, Table 3.7.1, and Table 3.7.1-a is discussed in Chapter 7, “Instrumentation and Control Systems,” of this SER.

SR 3.7.1 requires monthly channel checks and annual channel calibrations for radiation monitors. The NRC staff finds that the SR will ensure that radiation monitoring instruments are operable to detect elevated levels of radiation that may result in radiation exposure to workers or individual members of the public. The NRC staff also finds that the monthly periodicity of channel checks and the annual periodicity of channel calibrations are consistent with applicable guidance. Therefore, the NRC staff finds the SR acceptable.

The proposed TS 3.7, LCO 3.7.2 and SR 3.7.2, states the following:

LCO 3.7.2	The annually averaged concentration of radioactive material released in gaseous effluents to unrestricted areas shall be limited to 2800 times the concentrations specified in 10 CFR 20, Appendix B, Table 2, Column 1.
Applicability	Facility not Secured
Action	According to Table 3.7.2
SR 3.7.2	1. Total curies released shall be assessed monthly.

The proposed Table 3.7.2, "Gaseous Effluents Actions," states the following:

	Action	**Completion Time**
1.	If the curie assessment exceeds the established limit, Submit a Special Report as described in Section 5.8.2.	As described in Section 5.8.2

LCO 3.7.2 requires gaseous effluents released to the environment to be below the effluent concentration limits found in 10 CFR Part 20, Appendix B, Table 2, Column 1. The NRC staff finds that this condition for operation will limit the releases of gaseous effluents to concentrations below the effluent concentration limits found in 10 CFR Part 20, Appendix B, Table 2, Column 1. The staff also finds that if the curie assessment exceeds the established limit, submitting a special report not later than the following working day by telephone to be followed by a written report within 14 days, as described in TS 5.8.2, "Special Reports," is consistent with applicable guidance. Therefore, the staff finds the LCO acceptable.

SR 3.7.2 requires the total curies released to be assessed monthly. The NRC staff finds that this SR will ensure that gaseous effluents released to the environment are within the allowable limits. The staff also finds that assessing the total curies released monthly will ensure that monthly and annual releases are appropriately monitored and evaluated. Therefore, the NRC staff finds the SR acceptable.

The proposed TS 4.1, "Site and Facility Description," Design Feature (DF) 4.1.2, part 4 states the following:

DF 4.1.2	4. The normal effluent release height is 67 feet above grade.

DF 4.1.2, part 4 states the normal effluent release height. SHINE FSAR Section 2.1.1.2 states that the free-standing exhaust stack is at 67 feet above grade. The NRC staff finds that the stack and release height information is sufficiently described in the FSAR. The staff also finds that the SHINE facility's normal effluent releases will be compliant with the dose limits contained in 10 CFR Part 20. Therefore, the NRC staff finds the DF acceptable.

The proposed TS 5.3, "Radiation Safety," states the following:

> The Radiation Protection Manager (RPM) shall be responsible for the implementation of the radiation protection program. The requirements of the radiation protection program are established by 10 CFR Part 20. The program shall use the guidelines of ANSI/ANS 15.11-1993, Radiation Protection at Research Reactor Facilities. Furthermore, SHINE is committed to ensuring that radiation exposures are ALARA and in maintaining and [sic] effective ALARA Program.
>
> The radiation protection department is independent of facility operations. This independence ensures that the radiation protection department maintains its objectivity and is focused only on implementing sound radiation protection principals [sic] necessary to achieve occupational doses and doses to members of the public that are ALARA.
>
> Radiation protection staff maintain the ability to raise safety issues with the review and audit committee or executive management.

TS 5.3 requires the RPM to be responsible for the implementation of the Radiation Protection Program. The requirements of the Radiation Protection Program are established in 10 CFR Part 20. The TS also states that the SHINE Radiation Protection Program uses the guidelines of ANSI/ANS 15.11-1993, "Radiation Protection at Research Reactor Facilities." The NRC staff finds that the TS identifies the responsible person for the implementation of the Radiation Protection Program. The staff also finds that this TS is consistent with the guidance in NUREG-1537, Part 2 and ANSI/ANS 15.11-1993. Therefore, the staff finds TS 5.3 acceptable.

The proposed TS 5.5.3, "Radiation Protection," states the following:

> The SHINE radiation protection program is provided to protect the radiological health and safety of workers and the public. The program meets the requirements of 10 CFR 20, Subpart B, and is consistent with the guidance provided in ANSI/ANS 15.11-2016, Radiation Protection at Research Reactor Facilities, and Regulatory Guide 8.2, Revision 1, Administrative Practices in Radiation Surveys and Monitoring. In addition, SHINE has established this program to maintain occupational radiation exposures and releases to the environment ALARA.

TS 5.5.3 requires that the Radiation Protection Program be established, implemented, and maintained. The TS states that the Radiation Protection Program meets the requirements in 10 CFR Part 20 and that the program uses the guidelines of ANSI/ANS 15.11-2016 and RG 8.2. The NRC staff finds that this TS and the referenced guidance are appropriate for the establishment of the radiation protection program and are consistent with NUREG-1537. Therefore, the staff finds TS 5.5.3 acceptable.

11.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE facility radiation protection program and waste management, as described in SHINE FSAR Chapter 11, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the FSAR and independent confirmatory review, the NRC staff determined that:

(1) SHINE described the radiation protection program and waste management and the respiratory protection program and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 19, 10 CFR Part 20, 10 CFR Part 50, 10 CFR Part 61, 10 CFR Part 71, 40 CFR, Chapter I, and 49 CFR, Chapter I, and that the health and safety of the public will be protected.

(3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's radiation protection program and waste management are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.