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9.0 AUXILIARY SYSTEMS

The preliminary design description of the auxiliary systems in the PSAR focuses on those structures, systems, components, and associated equipment that constitute the auxiliary safety systems and includes the overall design bases, system classifications, functional requirements, and system architecture. The auxiliary systems are designed to support operation of the SHINE Medical Technologies, Inc. (SHINE), irradiation facility (IF) and radioisotope production facility (RPF).

This chapter of the SHINE construction permit (CP) safety evaluation report (SER) describes the review and evaluation by the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) of the preliminary design of the SHINE auxiliary systems as presented in Chapter 9, "Auxiliary Systems," of the SHINE Preliminary Safety Analysis Report (PSAR), and supplemented by the applicant's responses to requests for additional information (RAIs).

9a Irradiation Facility Auxiliary Systems

SER Section 9a, "Irradiation Facility Auxiliary Systems," provides an evaluation of the preliminary design of SHINE's IF auxiliary systems as presented in SHINE PSAR Section 9a2, "Irradiation Facility Auxiliary Systems."

9a.1 Areas of Review

The staff reviewed SHINE PSAR Section 9a2 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of SHINE's irradiation facility auxiliary systems. As part of this review, the staff evaluated descriptions and discussions of SHINE's auxiliary systems, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of SHINE's auxiliary systems was evaluated to ensure the sufficiency of principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions, 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. The following sections of the SER describe the areas reviewed.

Section 9a.4.1, "Heating, Ventilation, and Air Conditioning Systems," provides an evaluation of SHINE's radiologically controlled area and non-radiological area ventilation systems. Within these review areas, the staff assessed the characteristics and functions of the systems, the sources of radioactive materials that could become airborne during the full range of reactor operation, and the way the systems are designed to affect the distribution and concentration of those materials, the features of the systems designed to limit exposures of personnel to radiation in the restricted area as a result of the full range of facility operation, the features of the HVAC system and associated facility structure designed to prevent inadvertent or uncontrolled release of airborne radioactive material to areas outside the reactor room and to the unrestricted environment.

Section 9a.4.2, "Handling and Storage of Target Solution," provides an evaluation of SHINE's program for handling and storage of special nuclear material (SNM) and byproducts within the

target solution and within the irradiation facility. Within this review area, the staff assessed the equipment, systems, methods, and administrative procedures for receipt of new target solution, the systems and methods for movement, physical control, and storage of target solution within the facility, including analyses to prevent criticality, the systems, components, and methods-used to prepare and ship target solution off site in accordance with applicable regulations.

Section 9a.4.3, "Fire Protection Systems and Programs," provides an evaluation of SHINE's fire protection system. Within this review area, the staff assessed the potential causes and consequences of fires at the facility, the fire protection plans and protective equipment used to limit the consequences of a fire, including defense in depth in the event of escalation of a fire, the passive designs or protective barriers planned to limit fire consequences, including features of the facility that could affect a safe facility shutdown or release radioactive material in the event of a continuing fire, the source of facility fire protection brigades and their training and the summary of the more detailed discussions of these personnel and offsite fire protection forces in the facility emergency plan, and compliance with local and national fire and building codes applicable to fire protection.

Section 9a.4.4, "Communication Systems," provides an evaluation of SHINE's communication systems between essential areas of the SHINE facility, as well as locations remote to the facility. Within this review area, the staff assessed the methods of communication between all necessary locations during the full range of facility operations and during emergencies.

Section 9a.4.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," provides an evaluation of SHINE's auxiliary systems within the IF that normally interact with byproduct, source, and SNM. Within this review area, the staff assessed the types and quantities of radionuclides authorized, the general types of processing, or packaging for shipments, the provisions for controlling and disposing of radioactive wastes, including special drains for liquids and chemicals, and air exhaust hoods for airborne materials, and the provisions for radiation protection, including shielding materials and radiation survey methods.

The applicant has deferred submittal of Section 9a.4.6, "Cover Gas Control in Closed Primary Coolant Systems," which will be provided and will be reviewed in the FSAR.

Section 9a.4.7, "Other Auxiliary Systems," provides an evaluation of SHINE's other auxiliary systems in the IF that are not described in other chapters of SHINE PSAR. Within this review area, the staff assessed the systems description, including drawings and specifications of principal components and any special materials, operational analysis and safety function, and instrumentation and control requirements not described in SHINE PSAR Chapter 7, "Instrument and Control Systems."

9a.2 Summary of Application

Section 9a2.1, "Heating, Ventilation, and Air Conditioning Systems," of SHINE PSAR describes the radiologically controlled area (RCA) and non-radiological area ventilation systems. The heating, ventilation, and air conditioning (HVAC) systems provide ventilation to three areas in the radiologically controlled area (RCA) called RVZ1 (i.e., RCA ventilation zone 1), RVZ2, and RVZ3. RVZ1 includes the irradiation unit (IU) cells and the hot cells. RVZ2 includes operating areas, workrooms, and fume hoods. RVZ3 includes areas where contamination is not expected to occur under normal operating conditions. Thus, RVZ1 encompasses those areas with the highest potential for contamination with RVZ2 and RVZ3 encompassing areas of lesser potential

contamination (RVZ3 being the least). Therefore, RVZ3 is maintained at a higher pressure than RVZ2, which is maintained at a higher pressure than RVZ1 so that airflow is toward areas of increasing contamination potential.

The HVAC system also provides ventilation to the non-RCA called FVZ4 (facility ventilation zone 4).

The facility chilled water supply and distribution system (FCHS), is a closed-loop air-cooled chilled water system that provides cooling water to the cooling coils that are located outside the RCA boundary. The FCHS also supplies water to the radioisotope production facility cooling system (RPCS) heat exchangers.

The facility heating water system (FHWS) provides heated water (via a gas-fired boiler) to the RCA and non-RCA of the SHINE facility.

Testing of the HVAC systems will be done as appropriate. Technical specifications are discussed in PSAR Chapter 14, "Technical Specifications."

Section 9a2.2, "Handling and Storage of Target Solution," of SHINE PSAR describes the handling and storage of SNM and byproducts in the target solution within the IF. The preparation of the target solution is located outside of the IU cell. The piping used for transfer of the target solution to the IF cell includes penetrations of the cell through redundant sets of isolation valves. Target solution must meet the chemical property requirements discussed in PSAR Section 4a2.2.1 before it is transferred from the target solution hold tank to the target solution vessel. If the target solution is not within the required chemical specifications, operators make appropriate adjustments while the target solution is being prepared in the Target Solution Preparation System (TSPS). The storage and process tanks in the TSPS use double-contingency, criticality-safe controls.

Section 9a2.3, "Fire Protection Systems and Programs," of SHINE PSAR provides a description of the facility fire protection system (FFPS), which includes systems for early detection and notification of a fire, and provides the capability to extinguish fires in any SHINE facility area, to protect SHINE facility personnel and limit fire damage. The SHINE fire hazards analysis (FHA) is discussed in SHINE PSAR Section 9a2.3.4, "Fire Hazards Analysis." SHINE Fire Protection Training Plan and Emergency Plan will be submitted with the SHINE FSAR. Technical specifications are discussed in SHINE PSAR Chapter 14.

Section 9a2.4, "Communication Systems," of SHINE PSAR provides a description of the communication systems, which includes a normal communication system with paging, alarming, and party-line-type voice communications. A private exchange line, which is powered separately from the normal communications system, serves as a backup to the normal communications system. The communication system also includes a sound-powered phone system which operates without a power source and is not affected by loss of power to the facility, and a radio system operating on ultra-high frequency bands. The applicant stated that the SHINE FSAR will provide more detailed descriptions of the communication systems, including drawings and specifications. The applicant also stated that the systems will be tested, as appropriate, and that it has been determined that the communications systems will not be in the technical specifications for the SHINE facility.

Section 9a2.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," of SHINE PSAR provides a description of the byproduct, source, and SNM used in the IF. The

review of the TPS is provided in SER Section 9a2.2.7, "Other Auxiliary Systems." The byproduct material present in the TSPS and the Target Solution Vessel (TSV) are fission products. The review of the TSPS is provided in SER Section 9b.2.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," and the review of the TSV is provided in SER Section 4a2.3, "Target Solution Vessel and Light Water Pool." [redacted]
The review of the SCAS in provided in SER Chapter 4. The SNM is the small amount of Pu produced in the [redacted] in during the neutron irradiation. The review of the SCAS is provided in SER Chapter 4.

In SHINE PSAR Section 9a2.6, "Cover Gas Control in Closed Primary Coolant Systems," the applicant stated that the primary closed loop cooling system (PCLS) is a closed loop cooling system that provides cooling to the TSV. Details for the cover gas control will be provided in the SHINE FSAR.

Section 9a2.7, "Other Auxiliary Systems," of SHINE PSAR describes the Tritium Purification System (TPS), whose purpose is to remove impurities in the tritium, after it has been used in the neutron driver assembly system (NDAS) so that it can be reused. The TPS process steps are conducted inside of two gloveboxes that are sized such that one glovebox can accommodate the process needs of all eight NDAS neutron drivers. Since tritium is hydrogen and is flammable, the glovebox atmosphere is 100-percent nitrogen during TPS operation. The glovebox atmosphere is cooled via a water chiller system. The glovebox atmosphere is monitored/alarmed for oxygen. The area around the gloveboxes and the TPS piping is monitored/alarmed for tritium to detect any leaks. In addition, TPS piping is maintained at sub-atmospheric pressures.

SHINE PSAR Section 9b contains a summary description of the RPF auxiliary systems. It describes the design of the RPF auxiliary systems and the processes employed within it, includes the principal safety considerations that were factored into the RPF design, construction, and operation.

9a.3 Regulatory Basis and Acceptance Criteria

The regulatory basis and acceptance criteria provided below apply to both the IF and the RPF.

The staff reviewed SHINE PSAR Sections 9a.2 and 9b against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of SHINE's auxiliary systems 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 SHINE's auxiliary systems 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 SHINE's auxiliary systems as described in the FSAR as part of SHINE's operating license application.

9a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's auxiliary systems are as follows:

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

9a.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated SHINE's organization against the applicable regulatory requirements listed above primarily using the guidance and acceptance criteria contained in Chapter 9, "Auxiliary Systems," of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 4), 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 (Reference 5), 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 (Reference 6), 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 (Reference 7).

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 SHINE's auxiliary systems. The use of additional guidance is 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 PSAR.

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 9.4, "Review Procedures and Technical Evaluation," of this SER. Additional guidance documents used to review SHINE's organization are provided as references at the end of this chapter.

9a.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed a section-by-section evaluation of the technical information presented in SHINE PSAR Section 9a2, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of SHINE's auxiliary systems in the IF in support of the issuance of a CP, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance of SHINE's auxiliary systems is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 9a.3, "Regulatory Basis and Acceptance Criteria," of this SER. The results of this section-by-section technical evaluation are described in SER Section 9a.5, "Summary and Conclusion."

For the purposes of issuing a CP, the preliminary design of the SHINE auxiliary systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the SHINE auxiliary systems 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 SHINE's auxiliary systems 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 SHINE's auxiliary systems, as described in the FSAR, as part of SHINE's operating license application.

9a.4.1 Heating, Ventilation, and Air Conditioning Systems

The staff evaluated the sufficiency of the preliminary design of SHINE's heating, ventilation, and air conditioning (HVAC) systems, as described in SHINE PSAR Section 9a2.1, in part, by reviewing the radiologically controlled and non-radiological areas ventilation system, the chilled water supply and distribution system, the heating water system, using the guidance and acceptance criteria from Section 9.1, "Heating, Ventilation, and Air Conditioning Systems," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.1, the staff evaluated SHINE's HVAC system for all operations and functions during the full range of facility operations. The staff compared the design bases with requirements from other chapters of the PSAR, including Chapters 4, "Irradiation Unit And Radioisotope Production Facility Description," Chapter 6, "Engineered Safety Features," Chapter 7, "Instrumentation and Control Systems," Chapter 11, "Radiation Protection Program and Waste Management," and Chapter 13, "Accident Analysis," to determine whether the HVAC system designs agree with the acceptance criteria for the full range of facility operations.

NUREG-1537, Part 2, Section 9.1, "Heating, Ventilation, and Air Conditioning Systems," Acceptance Criteria, states, in part: "The design and operating features of the system should ensure that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur."

SHINE PSAR, Section 9a2.1.1, "Radiologically Controlled Area Ventilation System," states that RCA Zone 2 Supply Air supplies air to RCA Ventilation System Zone 2 and RCA Ventilation System Zone 3, but there is no mention of where RCA Ventilation System Zone 1 gets its supply air from. SHINE PSAR, Figure 9a2.1-2, has an arrow after the supply fans that states: "Supply Air Flows to Additional Rooms, but provides no clarification as to what rooms/areas receive the

air. PSAR, Figure 9a2.1-1 has an arrow going into the irradiation unit cell and an arrow going into the hot cell. Both arrows have the following statement: "Transfer Air from Zone 2." It is not clear if the supply to the irradiation unit and hot cells is via dedicated ductwork or from ambient air drawn from the room. The staff also noted that while SHINE Section 9a2.1.2, "Non-Radiological Area Ventilation System," discusses the Facility Ventilation Zone 4 (FVZ4) system and further states that this is a non-radiological controlled area ventilation system, additional information, on the potential for contamination in this area, was needed to determine the adequacy of the FVZ4 ventilation system.

Therefore in RAI 9a2.1-1 (Reference 14), the staff requested that PSAR Section 9a2, and the flow diagrams (Figures 9a2.1-1 and 9a2.1-2) be revised to clarify the ambiguities with respect to the operation of RCA Ventilation System Zone 1 (RVZ1) and RCA Ventilation System Zone 2 (RVZ2), and provide an additional flow diagram for RCA Ventilation System Zone 3 (RVZ3).

In response to RAI 9a2.1-1 (Reference 21), the applicant provided some additional details of the operation of RVZ1, RVZ2, and RVZ3, but did not provide updated flow diagrams that removed the ambiguities. In addition, the applicant did not provide a flow diagram for RVZ3, but rather stated that this would be provided in the FSAR.

The staff noted that while Section 9a2.1.2, "Non-Radiological Area Ventilation System," discusses the Facility Ventilation Zone 4 (FVZ4) system and further states that this is a non-radiological controlled area ventilation system, the staff needed additional information on the potential for contamination in this area to determine the adequacy of the FVZ4 ventilation system. Therefore in RAI 9a2.1-2 (Reference 14), the staff requested additional information on the FVZ4 ventilation system, including information on where the system exhausts, whether there are any radiation detectors on the exhaust, and a FVZ4 flow diagram.

In RAI 9a2.1-3 (Reference 17), the staff delineated how the applicant's response to RAI 9a2.1-2 does not supply sufficient information about the configuration and function of RVZ1, RVZ2, and RVZ3. In response (Reference 26), the applicant provided the necessary information with descriptions of each system, a revised flow chart of the RCA HVAC showing the interrelationship between RVZ1, RVZ2, and RVZ3 and a marked-up general arrangement showing the areas ventilated by RVZ1, RVZ2, RVZ3, and FVZ4.

Included in the response was the pressure relationship between the four HVAC zones and ambient atmospheric pressure as follows:

$$P_{RVZ1} < P_{RVZ2} < P_{RVZ3} < P_{ambient} < P_{FVZ4}$$

The applicant also clarified that RVZ3 consisted of only the airlocks, provided a list of the airlocks, and provided the location (including labeling) of the airlocks on the marked-up general arrangement, which clearly showed that the airlocks are within the Seismic Category I RCA boundary. Finally, the applicant stated that the airlocks do not have fans to maintain their air pressure, but rather airflow control valves that are supplied by the RVZ2 air-handling units with the RVZ3 exhausted air being transferred into the RVZ2 ventilated area. The applicant further clarified their function by stating that the airlocks are the tertiary confinement zone for the RCA.

While the applicant's responses to the above RAIs are sufficient, there are still the issues of control room habitability and RVZ3 safety classification as discussed in SER Section 3.5. The staff will confirm that the final design conforms to the design basis of NUREG-1537, Part 2, Section 9.1, during the evaluation of SHINE's FSAR.

Pending the resolution of the above concerns, the staff finds that the level of detail provided on SHINE's heating, ventilation, and air conditioning systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.2, allowing the staff to make the following relevant findings:

A review of the design bases and functional and safety characteristics of the HVAC systems shows that the proposed systems are adequate to control the release of airborne radioactive effluents during the full range of facility operations in compliance with the regulations.

The applicant has discussed all sources of radioactive material that could become airborne in the facility from a full range of facility operations. The analyses demonstrate that the radioactive material is controlled by the HVAC system and could not inadvertently escape from the RCA. They show that the distributions and concentrations of the airborne radionuclides in the facility are limited by operation of the HVAC system so that during the full range of facility operations, no potential occupational exposures would exceed the design bases derived in Chapter 11 of SHINE PSAR.

The applicant has considered the height and flow rate of the stack that exhausts facility air to the unrestricted environment for the design-basis dose rates derived in Chapter 11 of SHINE PSAR for the maximum exposed personnel in the unrestricted environment.

The HVAC system is an integral part of a confinement system at the reactor facility. The design of the confinement system and analysis of its operation ensure that it will function to limit normal airborne radioactive material to the extent analyzed in this chapter and Chapter 11 of SHINE PSAR. The potential radiation doses will not exceed the limits of 10 CFR Part 20 and are consistent with the facility as low as reasonably achievable (ALARA) program.

Therefore, the staff finds that the preliminary design of the SHINE heating, ventilation, and air conditioning systems, as described in SHINE PSAR Section 9a2.2, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. However, the discussion and commitments (including Table 9a2.1-3-1, and Figures 9a2.1-2-1, 9a2.1-3-1, and 9a2.1-3-2) in the applicant's responses to RAIs 9a2.1-1 through 9a2.1-3, will need to be incorporated into the SHINE FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

9a.4.2 Handling and Storage of Target Solution

The staff evaluated the sufficiency of the preliminary design of SHINE's handling and storage of the target solution, as described in SHINE PSAR Section 9a2.2, in part, by reviewing the preparation, storage and handling of the target solution, the equipment used for loading/unloading the TSV with target solution, and the storage of SNM, using the guidance and acceptance criteria from Section 9.2, "Handling and Storage of Reactor Fuel," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.2, the staff evaluated the systems and methods used to handle and store new and irradiated target solution, compared the design bases with requirements in this and other chapters of the PSAR (such as Chapters 4, 6, 11, and 13) and the requirements of 10 CFR 50.34(a) and 10 CFR Part 20, and focused on the design features that control radiation and prevent criticality.

On the basis of its review, the staff finds that the level of detail provided on SHINE's handling and storage of the target solution demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.2, allowing the staff to make the following relevant findings:

(1) As evaluated in SER Section 6b3, the analyses show that fuel storage features will ensure that criticality cannot occur. Plans to implement the applicable requirements of 10 CFR 70.24 for criticality monitoring are acceptable.

(2) Tanks, pumps, and procedures for inserting and removing target solution from the TSVs are specially designed to avoid loss or damage to target solution.

(3) As evaluated in SER Chapter 11, methods for assessing irradiated fuel radioactivity and potential exposure rates are adequate to avoid overexposure of the staff. Methods for shielding and storing irradiated fuel give reasonable assurance that potential personnel doses will not exceed the regulatory limits of 10 CFR Part 20 and are consistent with the facility ALARA program.

Therefore, the staff finds that the preliminary design of the SHINE handling and storage of the target solution in the IF, as described in SHINE PSAR Section 9a2.2, is sufficient and meets the applicable regulatory requirements and guidance to support the 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. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR and that technical specifications will contain limitations on storage conditions necessary to ensure sub-criticality and to administratively and physically control the target solution.

9a.4.3 Fire Protection Systems and Programs

The staff evaluated the sufficiency of the preliminary design of SHINE's fire protection systems and programs, as described in SHINE PSAR Section 9a2.3, in part, by reviewing the design bases, components of the system, and the fire hazard analysis, using the guidance and acceptance criteria from Section 9.3, "Fire Protection Systems and Programs," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.3, the staff evaluated the discussions of potential fires; provisions for early detection, including during those times when areas are not occupied; methods for isolating, suppressing, and extinguishing fires; passive features designed into the facility to limit fire consequences; response organization training and availability to fight fires as detailed in the emergency plan; designs of facility systems that can ensure safe reactor shutdown in the event of fire; and potential radiological consequences to the public, the staff, and the environment if firefighting efforts are unsuccessful.

The Fire Protection Training Plan and the Emergency Plan will be reviewed when the SHINE FSAR is submitted.

As part of its evaluation, the staff issued RAIs to the applicant. The RAIs and applicant's responses are summarized below.

In RAI 9a2.3-1 (Reference 14), the staff requested that the applicant identify which fire detection and suppression systems are necessary to prevent or mitigate high or intermediate

consequence accidents and describe and commit to applying management measures that will assure that these systems and components are constructed, procured, installed, and tested to ensure that they will be available and reliable to perform their intended functions when needed.

In response to RAI 9a2.3-1 (Reference 21), the applicant stated that there are no fire detection or suppression systems that are credited with prevention and/or mitigation of potential accident scenarios. The applicant went on to state that the fire protection program will be designed, constructed, and maintained in accordance with the applicable National Fire Protection Association (NFPA) standards. Finally, the applicant stated that the fire protection program will be included in the Administrative Controls section of the SHINE technical specifications, and that the fire protection system components are subject to the SHINE Quality Assurance Program, as described in the SHINE Quality Assurance Program Description (QAPD).

Because of the configuration of Fire Area 6 (a long "L" shaped corridor), in RAI 9a2.3-2 (Reference 14) the staff requested additional information on personnel evacuation.

In response to RAI 9a2.3-2 (Reference 21), the applicant responded that the corridor has fire detection and water suppression and the egress distances meet the requirements of the International Building Code (IBC) and the Life Safety Code (LSC).

The staff noted that Fire Areas (FA) 1 and 3 utilize gaseous fire suppression systems, which could result in asphyxiation during a release. Therefore, in RAI 9a2.3-3 (Reference 14), the staff requested that the applicant provide clarification on how potential asphyxiation during a release of the gaseous suppression systems has been addressed.

In response to RAI 9a2.3-3 (Reference 21), the applicant responded that automatic gaseous fire suppression systems will be equipped with a pre-discharge alarm system and a discharge delay to permit personnel egress. In addition, warning signs will be affixed in appropriate locations for areas protected by an automatic gaseous fire suppression system.

The staff noted that in radiation areas, the smoke detection capability of ionization detectors could be adversely affected and that photoelectric smoke detector capability can be affected in areas of dust/particulates. Therefore, in RAI 9a2.3-4 (Reference 14), the staff requested clarification on the basis of choosing detectors, and what maintenance program will be used to assure that the detectors function properly.

In response to RAI 9a2.3-4 (Reference 21), the applicant stated that fire detection systems are designed, installed, located, inspected, tested, and maintained in accordance with NFPA 72, "National Fire Alarm and Signaling Code." The applicant further stated that it would ensure that appropriate fire detection equipment is placed in radiation areas and areas of dust/particulates.

The staff noted that the neutron moderation capability of firefighting foam is not discussed in the SHINE PSAR. Therefore, in RAI 9a2.3-5 (Reference 14), the staff requested information on the moderation capabilities of firefighting foams because local fire departments may use foam as part of their firefighting repertoire. The staff also requested information on foam, if any, that can or will be used in the facility and what training is proposed for the fire brigade and for offsite fire departments that may provide assistance.

In response to RAI 9a2.3-5 (Reference 21), the applicant responded that there are no firefighting foam systems within the RCA in the current design of the facility. The applicant added that discussions have been initiated with Rock County Emergency Management. The

Rock County 911 Communications Center will have a response information binder specific to emergency response at the SHINE facility. The applicant also stated that it will ensure that the response information binder specific to emergency response at the SHINE facility does not allow off-site fire support organizations to use firefighting foam within the SHINE RCA, and will ensure that the Rock County 911 Communications Center's SHINE-specific response information binder provides specific guidance on the use of firefighting foam at the SHINE facility. Finally, the applicant stated that periodic training will be provided to both SHINE fire brigade members and off-site fire support organizations regarding permitted manual fire suppression techniques at the SHINE facility.

The staff noted that the Boiler Room (FA-17), which has a natural gas pipeline supplying the boiler, is adjacent (i.e., shares a common wall) to the Fire Brigade/Hazmat Room (FA-16) that contains the Fire Zone Panels. Therefore, in RAI 9a2.3-6 (Reference 14), the staff requested additional information on the potential for a fire in the Boiler Room and address the effects of the pipeline gas combustible load (until the pipeline can be shut off outside the Boiler Room) on the FA-17 and on the rest of the building.

In response to RAI 9a2.3-6 (Reference 21), the applicant responded that the walls, floors, and ceilings of the FA-17 boundary have a 3-hour fire resistive rating as required by a high combustible loading in the room and where an adjacent room contains equipment or systems from a different safety train. The 3-hour fire barrier provides adequate time for operators to manually isolate the natural gas supply, if required. The applicant further stated that the potential release of natural gas into FA-17 will be limited by the installation of safety controls, as required by Wisconsin Administrative Code Chapter SPS 341.

While the above response is sufficient for the issuance of a construction permit, at the OL stage, the effects of the pipeline gas combustible load (until the pipeline can be shut off outside the boiler room) on the boiler room and adjacent fire areas needs to be discussed in the FSAR.

The staff noted that SHINE PSAR Figure 9a2.3-1 indicates that there are fire zones inside of FA-1 and FA-2. However, the fire zones are not numbered. In RAI 9a2.3-7 (Reference 14), the staff requested information indicating whether the fire zones will be numbered, and whether the fire zone numbers will be unique. Additionally, the staff requested that the applicant provide information indicating whether the FHA will provide assessments of each fire zone.

In response to RAI 9a2.3-7 (Reference 21), the applicant stated that each fire zone will be uniquely numbered and as the detailed design is completed, the FHA will be revised and updated. Also, the final FHA will provide an assessment of each fire zone.

On the basis of its review, the staff finds that the level of detail provided on SHINE's fire protection systems and programs demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.2, allowing the staff to make the following relevant findings: (1) the fire protection plan for preventing fires ensure that the facility meets local and national fire and building codes, (2) the systems designed to detect and combat fires at the facility can function as described and limit damage and consequences at any time, (3) the potential radiological consequences of a fire will not prevent safe facility shutdown, and (4) any release of radioactive material as a result of fire would not cause radiation exposures that exceeded the requirements of 10 CFR Part 20.

Therefore, the staff finds that the preliminary design of the SHINE fire protection systems and programs, as described in SHINE PSAR Section 9a2.3, is sufficient and meets the applicable

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

9a.4.4 Communication Systems

The staff evaluated the sufficiency of the preliminary design of SHINE's communication systems, as described in SHINE PSAR Section 9a2.4, in part, by reviewing the on-site and off-site communication systems, using the guidance and acceptance criteria from Section 9.4, "Communication Systems" of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.4, the staff evaluated the design bases; system description; operational analysis and safety function; and required technical specifications and their bases, including testing and surveillance.

On the basis of its review, the staff finds that the level of detail provided on SHINE's communication systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.4, allowing the staff to make the following relevant findings: (1) the facility communication systems are designed to provide two-way communication between the control room and all other locations necessary for safe facility operation, (2) the communication systems allow the operator on duty to communicate with supervisory and health physics personnel, and (3) the communication systems allow a facility-wide announcement of an emergency and have provisions for summoning emergency assistance from designated personnel.

Therefore, the staff finds that the preliminary design of the SHINE communications systems, as described in SHINE PSAR Section 9a2.4, is sufficient and meets the applicable regulatory requirements and guidance to support the 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. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

9a.4.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

The staff evaluated the sufficiency of the preliminary design of SHINE's program for possession and use of byproduct, source, and special nuclear material in the IF, as described in SHINE PSAR Section 9a2.5, in part, by reviewing how byproduct materials, source material, and SNM are generated and processed, using the guidance and acceptance criteria from Section 9.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.5, the staff evaluated the design bases; system description; operational analysis and safety function; and required technical specifications and their bases, including testing and surveillance.

On the basis of its review, the staff finds that the facility design with respect to the byproduct, source, and SNM used in the IF demonstrates an adequate design basis in support of a

preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.5, allowing the staff to make the following relevant findings:

(1) The auxiliary facilities and systems are designed for the possession and use of byproduct materials produced by the facility. The design bases include limits on potential personnel exposures that are in compliance with 10 CFR Part 20 and are consistent with the facility ALARA program.

(2) To ensure that radiation exposures are acceptably limited, the design features specify upper limits on source strengths of radionuclides authorized for possession or use in the facility under the 10 CFR Part 50 license. The applicant has described the authorized spaces for use of the material.

(3) Design features provide reasonable assurance that uncontrolled release of radioactive material to the unrestricted environment will not occur.

Therefore, the staff finds that the preliminary design of the SHINE program for the possession and use of byproduct, source, and SNM in the IF, as described in SHINE PSAR Section 9a2.5, is sufficient and meets the applicable regulatory requirements and guidance to support the 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. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

9a.4.6 Cover Gas Control in Closed Primary Coolant Systems

The applicant has deferred submittal of this section, which will be provided and will be reviewed in the FSAR.

9a.4.7 Other Auxiliary Systems

In accordance with SHINE PSAR Section 9a2.7, the Tritium Purification System (TPS) is the only other auxiliary system in the IF. The staff evaluated the sufficiency of the preliminary design of SHINE's TPS, as described in SHINE PSAR Section 9a2.7, in part, by reviewing the TPS process, and off-normal and accident scenarios, using the guidance and acceptance criteria from Section 9.7, "Other Auxiliary Systems," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.7, the staff compared the design and functional descriptions of TPS with the design bases. In addition, the staff reviewed the discussion and analyses of the functions and potential malfunctions with respect to safe facility operation and shutdown, the effect on facility safety systems, and the potential for TPS to initiate or affect the uncontrolled release of radioactive material.

The applicant performed an analysis of the TPS and determined that the system design, function, and potential malfunctions would not result in an uncontrolled release of radioactivity. The TPS was reviewed as part of the development of the ISA for potential as design basis accidents (DBAs) or initiating events (IEs). The guidance in NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1 (Reference 60)), and NUREG-1537, Part 1, was used in this evaluation. The results of this evaluation (TPS accident analysis) are discussed in PSAR Chapter 13. The staff evaluation of the TPS accident analysis is provided in SER Chapter 13.

On the basis of its review, the staff finds that the level of detail provided on SHINE's other auxiliary system demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7, allowing the staff to make the following relevant findings: (1) the system has been designed to perform the functions required by the design bases, (2) the functions and potential malfunctions, that could affect facility operations or initiate uncontrolled release of radioactive material, have been considered in the design of the system, and (3) the technical specifications and their bases proposed in the PSAR give reasonable assurance that the system will be operable, as required by the design bases.

Therefore, the staff finds that the preliminary design of SHINE auxiliary systems, as described in SHINE PSAR Section 9a2.7, is sufficient and meets the applicable regulatory requirements and guidance to support of the 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. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

9a.4.8 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 SHINE IF auxiliary systems, with special attention given to those items which may significantly influence the final design. The evaluation of the technical specifications is provided in SER Chapter 14.

9a.5 Summary and Conclusion

The staff evaluated the descriptions and discussions of SHINE's irradiation facility auxiliary systems, as described in SHINE PSAR Section 9a2 and supplemented by the applicant's responses to RAIs, and finds that the preliminary design of SHINE's IF auxiliary systems, including the principal design criteria, design bases, and information relative to materials of construction, general arrangements, provides reasonable assurance that the final design will conform to the design basis and meets all applicable regulatory requirements and acceptance criteria in or referenced in NUREG-1537.

On the basis of 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 of the auxiliary systems, including, but not limited, 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 compete the safety analysis of the auxiliary systems may be reasonably left for later consideration in the FSAR;

(3) 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.

9b Radioisotope Production Facility Auxiliary Systems

SER Section 9b, "Radioisotope Production Facility Auxiliary Systems," provides an evaluation of the preliminary design of SHINE's RPF auxiliary systems as presented in SHINE PSAR Section 9b, "Radioisotope Production Facility Auxiliary Systems."

9b.1 Areas of Review

The staff reviewed SHINE PSAR Section 9b against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of SHINE's radioisotope production facility auxiliary systems. As part of this review, the staff evaluated descriptions and discussions of SHINE's auxiliary systems, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of SHINE's auxiliary systems was evaluated to ensure the sufficiency of principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions, 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. The following sections of the SER describe the areas reviewed.

Section 9b.4.1, "Heating, Ventilation, and Air Conditioning Systems," provides . . . The SHINE facility has one heating, ventilation, and air conditioning system which serve both the IF and the RPF. Therefore, the review and evaluation described in SER Section 9a.4.1 "Heating, Ventilation, and Air Conditioning," is applicable to both the SHINE IF and RPF.

Section 9b.4.2, "Handling and Storage of Target Solution," provides an evaluation of SHINE's program for handling and storage of special nuclear material (SNM) and byproducts within the target solution and within the radioisotope production facility. Within this review area, the staff assessed the equipment, systems, methods, and administrative procedures for receipt of new target solution, the systems and methods for movement, physical control, and storage of target solution within the facility, including analyses to prevent criticality, the systems, components, and methods-used to prepare and ship target solution off site in accordance with applicable regulations.

Section 9b.4.3, "Fire Protection Systems and Programs,"……. The SHINE fire protection systems and programs serve both the IF and the RPF. Therefore, the review and evaluation described in SER Section 9a.4.3 "Fire Protection Systems and Programs," is applicable to both the SHINE IF and RPF.

Section 9b.4.4, "Communication Systems." The communication system is common to both the IF and the RPF. Therefore, the review and evaluation described in SER Section 9a.4.4 "Communication Systems," is applicable to both the SHINE IF and RPF.

Section 9b.4.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," provides an evaluation of SHINE's auxiliary systems within the RPF that normally interact with byproduct, source, and SNM. Within this review area, the staff assessed the types and quantities of radionuclides authorized, the rooms, spaces, equipment, and procedures to be used, the general types of uses, such as research and development, processing, or packaging for shipment, the provisions for controlling and disposing of radioactive wastes, including special

drains for liquids and chemicals, and air exhaust hoods for airborne materials, the relationship between these auxiliary facility designs and the physical security and emergency plans, and required technical specifications and their bases, including testing and surveillance.

Section 9b.4.6, "Cover Gas Control in Closed Primary Coolant Systems," provides an evaluation of SHINE's systems within the RPF that handle radioactive gases from process vessels. Within this area, the staff assessed the design bases, system description, including drawings and specifications of principal components and any special materials, operational analysis and safety function, instrumentation and control requirements not described in SHINE PSAR Chapter 7, "Instrument and Control Systems," and required technical specifications and their bases, including testing and surveillance.

Section 9b.4.7, "Other Auxiliary Systems," provides an evaluation of SHINE's other auxiliary systems in the RPF that are not described in other chapters of SHINE PSAR. Within this review area, the staff assessed the molybdenum isotope product packaging system and the radiologically controlled area material handling.

9b.2 Summary of Application

SHINE PSAR Section 9b.1, "Heating, Ventilation, and Air Conditioning Systems." The SHINE facility has one heating, ventilation, and air conditioning system which serve both the IF and the RPF. Therefore, the summary provided in SER Section 9a.2 is applicable to both the SHINE IF and RPF.

SHINE PSAR Section 9b.2 discusses the handling and storage of the target solution while it is in the RFP. This section includes the target solution lifecycle, dissolution of uranium metal, target solution preparation, shipment and receipt of SNM, target solution preparation and handling equipment, storage of SNM, and criticality control.

SHINE PSAR Section 9b.3, "Fire Protection Systems and Programs." The SHINE facility has one fire protection systems and programs. Therefore, the summary provided in SER Section 9a.3 is applicable to both the SHINE IF and RPF.

SHINE PSAR Section 9b.4, "Communication Systems." The SHINE facility has a common communication system which serve both the IF and the RPF. Therefore, the summary provided in SER Section 9a.4 is applicable to both the SHINE IF and RPF.

SHINE PSAR Section 9b.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," describes the generation of byproduct material by the fission and irradiation of target solution in the TSV and the systems that process byproduct material in the RPF. The eight auxiliary systems that process byproduct material in the RPF are as follows:

- Target Solution Preparation System (TSPS).
- Radioactive Drain System (RDS).
- Aqueous Radioactive Liquid Waste Storage System (RLWS).
- Radioactive Liquid Waste Immobilization System (RLWE).
- Process Vessel Vent System (PVVS).
- Molybdenum Isotope Product Packaging System (MIPS).
- Solid Radioactive Waste Packaging (SRWP).
- Noble Gas Removal System (NGRS).

SHINE PSAR Section 9b.6, “Cover Gas Control in Closed Primary Coolant Systems,” discusses systems that handle radioactive gases from process vessels. These are the PVVS and the NGRS. The PVVS collects and treats the off-gases from process vessels in the SHINE facility. The PVVS collects off-gases from each vented vessel containing a significant quantity of radioactive material in the RPF, and receives noble gases from the NGRS after a period of decay. The PVVS consists of an acid gas scrubber loop and a blower to vent treated gases out of the RCA. The NGRS receives the cover gas from the target solution vessel off gas system (TOGS), which consists of eight separate vessels. This gas is primarily air, with small quantities of krypton, xenon, and iodine radioisotopes. The gases are compressed and stored in one of five noble gas decay tanks for at least 40 days. This allows the short-lived radioisotopes to largely decay. The stored gases can then be vented through the PVVS to the RCA ventilation zone 1 (RVZ1) system for monitored release through the stack. There is no significant amount of SNM present in the off-gas sent to the NGRS; therefore, criticality requirements are not necessary for the NGRS equipment.

SHINE PSAR Section 9b.7, “Other Auxiliary Systems,” describes the auxiliary systems in the RPF not captured in other chapters of the PSAR. These include the Molybdenum Isotope Product Packaging System (MIPS) and the Radiologically Control Area Material Handling (RMHS). The MIPS receives the purified Mo-99 (now called the “Mo-99 product”) from the molybdenum extraction and purification system (MEPS). Once the Mo-99 product is in the MIPS shielded supercells, it undergoes assay and quality control procedures. The final Mo-99 product is then placed in a Mo-99 product shipping container. The RMHS includes overhead cranes, fork trucks, hand trucks, carts, and master-slave manipulators that are used to move or manipulate radioactive material within the RCA.

9b.3 Regulatory Basis and Acceptance Criteria

The regulatory basis and acceptance criteria provided in SER Section 9a.3, “Regulatory Basis and Acceptance Criteria,” applies to both the IF and RPF auxiliary systems.

9b.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed a section-by-section evaluation of the technical information presented in SHINE PSAR Section 9b, as supplemented by the applicant’s responses to RAIs, to assess the sufficiency of the preliminary design and performance of SHINE’s auxiliary systems in the RPF in support of the issuance of a CP, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance of SHINE’s auxiliary systems is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 9a.3, “Regulatory Basis and Acceptance Criteria,” of this SER. The results of this section-by-section technical evaluation are described in SER Section 9b.5, “Summary and Conclusion.”

For the purposes of issuing a CP, the preliminary design of the SHINE auxiliary systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the SHINE auxiliary systems 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 SHINE’s auxiliary systems 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 SHINE's auxiliary systems, as described in the FSAR, as part of SHINE's operating license application.

9b.4.1 Heating, Ventilation, and Air Conditioning Systems

As stated before, the review and evaluation described in SER Section 9a.4.1 "Heating, Ventilation, and Air Conditioning," is applicable to both the SHINE IF and RPF.

9b.4.2 Handling and Storage of Target Solution

The staff evaluated the sufficiency of the preliminary design of SHINE's handling and storage of the target solution, as described in SHINE PSAR Section 9b.2, in part, by reviewing the preparation, storage and handling of the target solution, the equipment used for loading/unloading the TSV with target solution, systems, components, and methods for radiation shielding and for protecting irradiated target solution from damage during removal from the IF, movement within the RPF, and the storage of SNM, using the guidance and acceptance criteria from Section 9.2, "Handling and Storage of Reactor Fuel," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.2, the staff evaluated the systems and methods used to handle and store new and irradiated target solution, compared the design bases with requirements in this and other chapters of the PSAR (such as Chapters 4, 6, 11, and 13) and the requirements of 10 CFR 50.34(a) and 10 CFR Part 20, and focused on the design features that control radiation and prevent criticality.

On the basis of its review, the staff finds that the level of detail provided on SHINE's handling and storage of the target solution within the RPF demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.2, allowing the staff to make the following relevant findings:

(1) As discussed in Section 6b.3 of this SER, the staff has determined that the design of systems, components, and methods for handling, moving, and storing target solution outside the IF will provide reasonable assurance that under normal and credible abnormal conditions, all nuclear processes will be subcritical, including use of an NRC-approved margin of sub-criticality for safety.

(2) The systems, components, and methods for handling, moving, and storing target solution, including insertion and removal from the IF, are designed to prevent damage.

(3) The design of systems, components, and methods for handling, moving, and storing target solution demonstrate that the facility staff and the public are protected from radiation and that radiation exposures do not exceed the requirements of 10 CFR Part 20 and are consistent with the facility ALARA program.

Therefore, the staff finds that the preliminary design of the SHINE handling and storage of the target solution in the RPF, as described in SHINE PSAR Section 9b2, is sufficient and meets the applicable regulatory requirements and guidance to support of the 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. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR and that technical specifications will contain limitations on storage conditions

necessary to ensure sub-criticality and to administratively and physically control the target solution.

9b.4.3 Fire Protection Systems and Programs

As stated before, the review and evaluation described in SER Section 9a.4.3 “Fire Protection Systems and Programs,” is applicable to both the SHINE IF and RPF.

9b.4.4 Communication Systems

As stated before, the review and evaluation described in SER Section 9a.4.4 “Communication Systems,” is applicable to both the SHINE IF and RPF.

9b.4.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

The staff evaluated the sufficiency of the preliminary design of SHINE’s program for possession and use of byproduct, source, and special nuclear material in the RPF, as described in SHINE PSAR Section 9b.5, in part, by reviewing how byproduct materials, source material, and SNM are generated and processed; the types and quantities of radionuclides authorized; the rooms, spaces, equipment, and procedures to be used; the general types of uses, such as research and development, processing, or packaging for shipment; the provisions for controlling and disposing of radioactive wastes, including special drains for liquids and chemicals, and air exhaust hoods for airborne materials; the relationship between these auxiliary facility designs and the physical security and emergency plans, required technical specifications and their bases, including testing and surveillance, using the guidance and acceptance criteria from Section 9.5, “Possession and Use of Byproduct, Source, and Special Nuclear Material,” of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.5, the staff evaluated the design bases, system description, operational analysis and safety function, and required technical specifications and their bases, including testing and surveillance.

The staff compared the design bases for the auxiliary systems that process byproduct material in the RPF with the commitments developed in other chapters of SHINE PSAR, especially Chapters 11, “Radiation Protection and Waste Management,” and 12, “Conduct of Operations,” and evaluated agreement with the acceptance criteria.

On the basis of its review, the staff finds that the facility design with respect to the byproduct, source, and SNM used in the RPF demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.5, allowing the staff to make the following relevant findings:

(1) The auxiliary facilities and systems are designed for the possession and use of byproduct materials produced by the facility. The design bases include limits on potential personnel exposures that are in compliance with 10 CFR Part 20 and are consistent with the facility ALARA program.

(2) The design features provide reasonable assurance that uncontrolled release of radioactive material to the unrestricted environment will not occur.

Therefore, the staff finds that the preliminary design of the SHINE program for the possession and use of byproduct, source, and SNM in the RPF, as described in SHINE PSAR Section 9b.5, is sufficient and meets the applicable regulatory requirements and guidance to support of the 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. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

9b.4.6 Cover Gas Control in Closed Primary Coolant Systems

SHINE PSAR Section 9b.6, "Cover Gas in Closed Primary Coolant Systems," states that there are no primary coolant system in the RPF and thus, this section of the PSAR discusses systems that handle radioactive gases from process vessels. The staff evaluated the sufficiency of the preliminary design of SHINE's cover gas control systems as described in SHINE PSAR Section 9b.6, in part, by reviewing the Process Vessel Vent System (PVVS) and the Noble Gas Removal System (NGRS), using the guidance and acceptance criteria from Section 9.6, "Cover Gas Control in Closed Primary Coolant Systems," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.6, the staff evaluated the cover gas control systems to ensure that:

- The design and functional description conforms with the design bases.
- The design, functions, and potential malfunctions of NGRS should not cause accidents to the facility or uncontrolled release of radioactivity.
- In the event radioactive material is released by the operation of NGRS, potential radiation exposures should not exceed the limits of 10 CFR Part 20 and should be consistent with the facility ALARA program.

The staff compared the design and functional descriptions of the PVVS and NGRS with the design bases. In addition, the staff reviewed the discussion and analyses of the functions and potential malfunctions with respect to safe facility operation and shutdown, the effect on facility safety systems, and the potential for uncontrolled release of radioactive material.

On the basis of its review, the staff finds that the level of detail provided on SHINE's cover gas control systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.2, allowing the staff to make the following relevant findings:

(1) The PVVS and NGRS are designed to capture and treat the expected off-gases at their anticipated concentrations of constituents under normal and accident conditions, and that the design-basis pressures can be maintained.

(2) Processing, storing, and recombining of radiolytic gases, as well as safe disposal of spent scrubber solutions, HEPA filters, and charcoal filters, have been acceptably incorporated into the design.

(3) The NGRS has been designed to perform the functions required by the design bases.

(4) Functions and potential malfunctions that could affect facility operations have been considered in the design of the system. No analyzed functions or malfunctions could

initiate a facility accident, prevent safe facility shutdown, or initiate uncontrolled release of radioactive material.

Therefore, the staff finds that the preliminary design of the SHINE cover gas control systems as described in SHINE PSAR Section 9b6, is sufficient and meets the applicable regulatory requirements and guidance to support of the 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. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR and that technical specifications will contain limitations on storage conditions necessary to ensure sub-criticality and to administratively and physically control the target solution.

9b.4.7 Other Auxiliary Systems

The staff evaluated the sufficiency of the preliminary design of SHINE other auxiliary systems in the RPF, as described in SHINE PSAR Section 9b.7, in part, by reviewing the following, using the guidance and acceptance criteria from Section 9.7, "Other Auxiliary Systems," of NUREG-1537, Parts 1 and 2:

- the Molybdenum Product Packaging System (MIPS),
- the RCA Material Handling System (RMHS),
- the Radioactive Liquid Waste Evaporation and Immobilization System (RWLE),
- the Aqueous Radioactive Liquid Waste Storage System (RLWS),
- the Solid Radioactive Waste Packaging System (SWRP),
- the Radioactive Drain System (RDS),
- the Material Handling System (MHS),
- the Facility Potable Water System (FPWS),
- the Facility Instrument Air System (FIAS),
- the Facility Compressed Air System (FCAS),
- the Facility Breathing Air System (FBAS),
- the Facility Inert Gas System (FIGS),
- the Facility Roof Drain Systems (FRDS),
- the Facility Sanitary Drains System (FSDS),
- the Facility Acid Reagent Storage and Distribution System (FARS),
- the Facility Alkaline Reagent Storage and Distribution System (FSRS),
- the Facility Organic Reagent Storage and Distribution System (FORS),
- the Organic Liquid Waste Storage and Export (OLWS), and
- Off-Normal and Accident Scenarios

In accordance with the review procedures of NUREG-1537, Part 2, Section 9.7, the staff compared the design and functional descriptions of other auxiliary systems with their design bases. In addition, the staff reviewed the discussion and analyses of the functions and potential malfunctions with respect to safe facility operation and shutdown, the effect on facility safety systems, and the potential for these auxiliary systems to initiate or affect the uncontrolled release of radioactive material.

As part of its evaluation, the staff issued the RAIs to the applicant. The RAIs and the applicant's responses are summarized below.

Due to the size and weight of the shields and equipment that need to be moved, and the inventory of tritium and uranium onsite, in RAI 9b.7-1 (Reference 14), the staff requested that the applicant provide additional assessments demonstrating the implementation of the requirements of ASME B30.2 and CMAA 70 to ensure that dropped, toppled, rolled or otherwise off-normal load events do not result in the loss of safety function or the release of radioactivity to the public. The applicant responded (Reference 21) that the guidance provided in NUREG-0612, "Control of Heavy Loads at Nuclear Power Plants: Resolution of Generic Technical Activity A-36" (Reference 78), would be utilized and that a heavy load will be defined as a load that, if dropped, may cause radiological consequences that challenge 10 CFR 20 limits. The heavy load limit, and the associated load drop analysis, will be determined during detailed design and provided in the FSAR.

With respect to the consequences that may result from inadvertent criticality during materials handling, in RAI 9b.7-2 (Reference 14), the staff requested that the applicant provide additional details on how the equipment will be designed to prevent inadvertent criticality and provide an assessment of why technical specifications are not needed or describe preliminary plans for technical specification safety limits and surveillance requirements. The applicant responded (Reference 21) that safety evaluations will be performed for systems that handle fissile material within the facility. In addition, the design for these systems will comply with the requirements for criticality safety detailed in ANSI/ANS-8.7-1998 (Reference 64) and the PSAR. The applicant further stated that administrative controls and maintenance will be applied to these systems to ensure reliability and availability. In addition, the applicant stated that in the FSAR, safety limits that are applicable for material handling activities will be included in the Technical Specifications (TS) and Surveillance Requirements (SR) will be developed to ensure criticality control is maintained during material handling activities.

On the basis of its review, the staff finds that the level of detail provided on SHINE's other auxiliary system demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7, allowing the staff to make the following relevant findings: (1) the system has been designed to perform the functions required by the design bases, (2) the functions and potential malfunctions, that could affect facility operations or initiate uncontrolled release of radioactive material, have been considered in the design of the system, and (3) the technical specifications and their bases proposed in the PSAR give reasonable assurance that the system will be operable, as required by the design bases.

Therefore, the staff finds that the preliminary design of SHINE auxiliary systems, as described in SHINE PSAR Section 9b.7, is sufficient and meets the applicable regulatory requirements and guidance to support of the 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. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

9b.4.8 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 SHINE RPF auxiliary systems, with special attention given to those items which may significantly influence the final design. The evaluation of the technical specifications is provided in SER Chapter 14.

9b.5 Summary and Conclusion

The staff evaluated the descriptions and discussions of SHINE's radioisotope production facility auxiliary systems, as described in SHINE PSAR Section 9b and supplemented by the applicant's responses to RAIs, and finds that the preliminary design of SHINE's RPF auxiliary systems, including the principal design criteria, design bases, and information relative to materials of construction, general arrangements, provides reasonable assurance that the final design will conform to the design basis and meets all applicable regulatory requirements and acceptance criteria in or referenced in NUREG-1537.

On the basis of 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 of the auxiliary systems, including, but not limited, 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 compete the safety analysis of the auxiliary systems may be reasonably left for later consideration in the FSAR;

(3) 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.