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13.0 ACCIDENT ANALYSES

The accident analysis shows that the health and safety of the public and workers are protected, potential radiological and nonradiological consequences have been considered in the event of malfunctions, and the Part 50 facility is capable of accommodating disturbances in the functioning of structures, systems, and components. Additionally, the accident analysis demonstrates that the facility design features, safety limits, limiting safety system settings, and limiting conditions for operation have been selected to ensure that no credible accident could lead to unacceptable radiological consequences to people or the environment.

The accidents analyzed range from such anticipated events as a loss of normal electrical power to a postulated fission-product release with radiological consequences that exceed those of any accident considered to be credible. This limiting accident is named the maximum hypothetical accident (MHA). Because the MHA is not expected to occur, the scenario need not be entirely credible. The initiating event and the scenario details need not be analyzed, but the potential consequences should be analyzed and evaluated.

The accident analysis establishes safety limits for facility operations and provides a technical basis for control of those limits through technical specifications.

This chapter of the SHINE construction permit (CP) safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) of the preliminary accident analysis of the SHINE irradiation facility (IF) and radioisotope production facility (RPF), as presented in Chapter 13, "Accident Analysis," of the SHINE Preliminary Safety Analysis Report (PSAR), as supplemented by the applicant's responses to requests for additional information (RAIs).

13a Irradiation Facility Accident Analyses

Section 13a, "Irradiation Facility Accident Analysis," provides an evaluation of the preliminary accident analysis of SHINE's IF as presented in PSAR Section 13a2, "Irradiation Facility Accident Analysis," within which, SHINE describes accident-initiating events and scenarios, as well as the accident analysis and determination of consequences.

13a.1 Areas of Review

The staff reviewed SHINE PSAR Section 13a2 against the applicable regulatory requirements described in NRC regulatory guidance and standards to assess the sufficiency of the preliminary accident analysis. As part of this review, the staff evaluated descriptions and discussions of SHINE's accident analysis, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary accident analysis 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 that are determined to be probable subjects of technical specifications for the facility, with special attention given to those items that may significantly influence the final design. Structures, systems, and components (SSCs) were also evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents. The staff considered the preliminary analysis and evaluation of the design and performance of the SSCs of the SHINE facility, including those SSCs shared by both the IF and RPF, with the objective of assessing the risk to public health and safety resulting from operation of the facility.

Areas of review for this section included accident-initiating events and scenarios, as well as the accident analysis and determination of consequences. Within these areas of review, the staff assessed the maximum hypothetical accident, target solution release into the irradiation unit (IU) cell, excess reactivity insertion accident, inadvertent criticality events, reduction in cooling, mishandling or malfunction of target solution, loss of off-site power, external events, mishandling or malfunction of equipment affecting the primary system boundary, large undamped power oscillations, detonation and deflagration in the primary system boundary, unintended exothermic chemical reactions other than detonation, primary system boundary system interaction events, and facility-specific events.

13a.2 Summary of Application

The SHINE IF design has features that are important for understanding the accident analysis. The SHINE IF contains eight Irradiation Units (IUs). Each IU contains a neutron driver, a Target Solution Vessel (TSV), a TSV dump tank, and a TSV off-gas system (TOGS) which are all surrounded by thick concrete shielding. The TSV and TSV dump tank sit in the light water pool. The light water pool is a large pool of water that is cooled by the light water pool system (LWPS). The LWPS removes heat from the neutron driver accelerator target chamber, the neutron multiplier, and any other heat load on the pool such as radiation energy deposition. The primary closed loop cooling system (PCLS) circulates water past heat transfer surfaces to cool the TSV. The TOGS is in a concrete shielded gas space. The TOGS circulates nitrogen gas through the gas space of the TSV. It recombines hydrogen and oxygen generated in the TSV by radiolysis and condenses water vapor from the TSV. The atmosphere in the gas space is connected by ducts to the radiologically controlled area (RCA) ventilation Zone 1 (RVZ1). These ducts are a path for airborne radiation to escape from the IU and move into the building atmosphere. There are isolation dampers on the ducts that close in the event of a high radiation signal. There are also penetrations in the IUs that can be leakage paths for airborne radioactivity in the IU atmosphere to the RCA where the IUs are located. The building atmosphere in RVZ1 is vented to the outside through high-efficenty particulate air (HEPA) and charcoal filters.

SHINE PSAR Section 13a2 describes accident-initiating events and scenarios, as well as the accident analysis and determination of consequences for the SHINE IF. The application provides details on event categories covering credible accidents related to the IF, including the target solution and the accelerator; the maximum hypothetical accident intended to bound all credible accidents; limiting accidents; target solution release into the irradiation unit (IU) cell; excess reactivity insertion accident; inadvertent criticality events; reduction in cooling; mishandling or malfunction of target solution; loss of off-site power; external events; mishandling or malfunction of equipment affecting the primary system boundary; large undamped power oscillations; detonation and deflagration in the primary system boundary; unintended exothermic chemical reactions other than detonation; primary system boundary system interaction events; and facility-specific events.

13a.3 Regulatory Basis and Acceptance Criteria

The staff reviewed SHINE PSAR Section 13a2 against applicable regulatory requirements, regulatory guidance, and standards, to assess the sufficiency of the preliminary accident analysis 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) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

The staff's evaluation of the preliminary accident analysis does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE facility as described in the FSAR as part of SHINE's operating license application.

13a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's preliminary accident analysis are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 20.1201, "Occupational dose limits for adults."
- 10 CFR 20.1301, "Dose limits for individual members of the public."

13a.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated SHINE's IF accident analysis against the applicable regulatory requirements listed above, primarily using the guidance and acceptance criteria contained in Chapter 13a2, "Aqueous Homogeneous Reactor Accident Analyses" of 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 preliminary accident analysis. The use of additional guidance is based on the technical judgement of the reviewer, as well as references in 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 13a.4, "Review Procedures, Technical Evaluation, and Evaluation Findings," of this safety evaluation report (SER). Additional guidance documents used to evaluate SHINE's preliminary accident analysis are provided as references in Appendix B.

13a.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 13a2, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of SHINE's accident analysis in the IF in support of the issuance of a CP, in accordance with 10 CFR 50.35(a). The sufficiency of the SHINE preliminary accident analysis is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 13a.3, "Regulatory Basis and Acceptance Criteria," of this SER. While the technical evaluation of preliminary accident analysis provided in this section is specific to the SHINE IF, the staff's review considers the interface of accident scenarios between the IF and RPF as part of a comprehensive technical evaluation. The results of this section-by-section technical evaluation are described in SER Section 13a.5, "Summary and Conclusions."

For the purposes of issuing a CP, the preliminary accident analysis may be adequately described at a conceptual level. The staff evaluated the sufficiency of the preliminary accident analysis 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 accident analysis does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE facility, as described in the FSAR, as part of SHINE's operating license application.

For SER Sections 13a.4.1 through 13a.4.14, the staff evaluated the sufficiency of the preliminary identification, analysis, and determination of consequences of accident-initiating events and scenarios, as described in SHINE PSAR Sections 13a2.1 and 13a2.2, in part, by reviewing the maximum hypothetical accident, inadvertent criticality events, reduction in cooling, mishandling or malfunction of target solution, loss of off-site power, external events, mishandling or malfunction of equipment affecting the primary system boundary, large undamped power oscillations, detonation and deflagration in the primary system boundary, unintended exothermic chemical reactions other than detonation, primary system boundary system interaction events, and facility-specific events, using the guidance and acceptance criteria from Sections 13a2, "Aqueous Homogeneous Reactor Accident Analyses," and 13a2.1, "Accident-Initiating Events and Scenarios," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

For SER Sections 13a.4.1 through 13a.4.14, in accordance with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Sections 13a2 and 13a2.1, the staff followed the sequence of events in each accident scenario from initiation to stabilization. The staff evaluated credible accidents; instruments, controls and automatic protective systems assumed to be operating normally before an initiating event; the identification of single malfunctions; the discussion of sequence of events and components and systems damaged during the accident scenario; mathematical models and analytical methods employed; radiation source term; and that potential radiation consequences to the facility staff and public were presented and compared with acceptable limits. Additionally, the staff assessed whether the integrity of the primary system boundary would be maintained under credible accidents analyzed, determined whether all analyzed credible accidents have been categorized, confirmed that the applicant analyzed potential power instabilities, and confirmed that loss of normal electrical power and consequent reduction in cooling would not challenge the primary system boundary. Also, as described in SHINE PSAR Sections 13a2.1.12 and 13a2.2.12, “Facility-Specific Events,” the applicant evaluated the SHINE facility for initiating events and possible design basis accidents that are possible because of the unique design features of the facility as specified by NUREG-1537 and the ISG. The applicant identified and analyzed possible events and accidents that fall under this category. The applicant analyzed the consequences of the facility-specific initiating events and accidents proposed in the accident-initiating events section of the PSAR. These events are presented in Sections 13a.4.12 – 13a.4.14 in this SER.

13a.4.1 Maximum Hypothetical Accident

As described in SHINE PSAR Sections 13a2.1.1, “Maximum Hypothetical Accident,” and 13a2.2.1, “Target Solution Release into the IU Cell,” SHINE considered an MHA for the IF as well as the RPF. While an evaluation of the MHA for the IF is provided below, the RPF postulated MHA, as described in SHINE PSAR 13b.2.1, “Maximum Hypothetical Accident in the RPF,” provides the bounding consequences to the public and is therefore considered the MHA for the SHINE facility. An evaluation of the RPF postulated MHA is provided in SER section 13b.4.3 of this SER.

SHINE postulated a non-specific large rupture of the TSV or dump tank for a single IU as the MHA for the Irradiation Facility (IF). Hypothetical causes for the rupture include corrosion, overpressure, maintenance or operational errors. However, as stated in SHINE PSAR, Section 13a2.1.1.1, “Initial Conditions and Assumptions,” “[b]ecause the SHINE facility is being designed to withstand external events … scenarios that involve multiple IUs are not analyzed further.” However, the staff noted that a group of similar systems or components failing together, as a result of a single external event, is still considered a single failure. Therefore, in RAI 13a2.1-1 (Reference 14), the staff requested that SHINE provide the basis for rejecting events that could affect multiple irradiation units. This information is necessary to satisfy the recommendation of the ISG Augmenting NUREG-1537, Part 2, Section 13a2.1, which recommends that external events affecting more than one unit be considered as a maximum hypothetical accident.

In response to this RAI (Reference 20) SHINE stated that the facility was designed as a robust structure to protect equipment contained within the seismic envelope from external events such as aircraft impact, tornado, flood, earthquake, or tornado missile, thus making an initiating event involving one or more irradiation units not credible. SHINE provided additional details on the robust design of the primary system boundary in response to RAI 13a.2.1-2 (Reference 20) by describing the application of relevant portions of American Society of Mechanical Engineers

(ASME) Boiler and Pressure Vessel Code (BPVC) sections to the design of TSV, TOGS, and TSV dump tank to prevent.
The staff finds these responses satisfy the recommendation of the ISG Augmenting NUREG-1537, Part 2, Section 13a2.1 and demonstrate an adequate design basis to protect the irradiation units from external events and to ensure the integrity of the primary system boundary in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

For the analysis of the MHA, the following initial conditions were assumed, among others: (1) the presence of the maximum radioisotope inventory in the TSV, (2) the IU cell penetrations are sealed to be within design specifications, and (3) deactivation of the neutron driver. In the MHA scenario, the inventory of the TSV is instantaneously dumped into IU cell and no credit is taken for light water pool scrubbing and the airborne material is released to the IU cell atmosphere. Fission products can be released to the environment through the facility stack through the RCA ventilation Zone 1 (RVZ1) flow path. The barriers to release are the filters in the RVZ1 and the inlet and outlet dampers of the IU. The isolation dampers close due to a high radiation signal after about 1 percent of the airborne activity is released to RVZ1. The RVZ1 exhaust is equipped with two trains of HEPA filters and carbon adsorber beds that have assumed efficiencies of 99 percent for particulates and 95 percent for halogens. These efficiencies are expected to be degraded values compared to filter design values. For the MHA, it is assumed that 10 percent of the airborne activity is released to the RCA due to the leakage characteristics of the IU cell penetrations during the assumed 10 minute worker exposure time. This is the dominant dose to the workers. Radiation alarms are assumed to be operating and facility personnel are assumed to evacuate the area if an area radiation alarm is activated. Evacuation occurs after 25 percent of the activity leaves the system.

There are 5 parameters used by the applicant that are used to calculate the airborne and respirable source terms and they affect the total effective dose equivalent (TEDE). The material at risk (MAR) is the total radionuclide source for the accident. The source term for the analysis is the TSV inventory after [redacted] irradiation cycles at a conservative power level and maximum fission product carryover. The damage ratio (DR) is the fraction of the MAR impacted by the accident scenario. The DR for the MHA is 1.0. The leak path factor (LPF) is the fraction of the radionuclide that is made airborne. The airborne release fraction (ARF) is the fraction of the material that can be suspended in the atmosphere as an aerosol and is subject to airborne transport. The respirable fraction (RF) is the fraction of airborne particles and aerosols that can be transported through the air and inhaled into the human respiratory system and is assumed to include all particles 10 microns and smaller. NRC staff requested, and SHINE provided the technical basis for these parameters in RAIs 13a2.2-1, 13a2.2-5, and 13a2.2-6 (References 14, and 16, respectively), and their associated responses (References 21, 27 and 24, respectively). This information is necessary to satisfy the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2, "Aqueous Homogeneous Reactor Accident Analyses," which states that the applicant should include a systematic analysis and discussion of credible accidents for determining the limiting event in each category. The mathematical models and analytical methods employed, including assumptions, approximations, validation, and uncertainties, should be clearly stated in this analysis. The staff finds that the technical basis provided by SHINE satisfies the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2 and demonstrates an adequate design basis in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The elevation of the exhaust stack is 66 feet above the site grade. The site boundary is approximately 300-350 yards from the exhaust stack and the nearest residence is 0.5 miles from the facility.

In the course of review of SHINE's description of the radiological dose consequence analysis, the staff determined that additional information was needed to determine the adequacy of SHINE's radiological dose consequence analysis. Therefore, in RAIs 13a2.2-4 and 13a2.2-7 (References 14 and 17), the staff requested that SHINE provide information on dose calculations, including a description of the methods and codes used, important input parameter values, and calculated values of dose components. This information was necessary to satisfy the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2, related to the demonstration of a systematic analysis of accidents, as described above. In response to these RAIs, (Reference 21 and XX),SHINE provided information related to important assumptions for radiological dose calculations, dose calculation methodology, internal dose, external dose equivalent, organ dose, off-site dose, input parameter values, and dose calculation results. The staff finds that descriptions of methods and codes used, input parameter values, and calculated values of dose components provided by SHINE in response to these RAIs satisfies the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2 and demonstrates an adequate design basis in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

The dose consequences of the MHA are calculated to be within the regulatory limits of 10 CFR Part 20. A TEDE of 3.06 rem was calculated for the workers at the facility. This on-site dose is less than the 5 rem regulatory limit specified in 10 CFR 20.1201. A TEDE of 0.0165 rem is calculated for a member of the public at the site boundary, and a TEDE of 0.0023 rem is calculated at the nearest residence. The off-site doses are less than the 0.1 rem regulatory limit specified in 10 CFR 20.1301.

Because the assumptions of the scenario are bounding, the doses calculated will likely not be exceeded by any accident considered credible. The applicant has also examined more realistic assumptions about operating time and release fractions that decreased the source term significantly, compared to the one calculated for the MHA, lowering the maximum doses by a factor of 2 for workers and a factor of 7.5 for members of the public. The staff finds that for the IF MHA, the health and safety of the facility staff and the public are protected.

On the basis of its review, the staff finds that the level of detail provided on SHINE's MHA demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant findings:

(1) The facility power and power density are sufficiently low such that insufficient energy is available to drive a large energetic release of radioactive material, as could occur in a nuclear power reactor. The analysis of the MHA is sufficiently conservative in that it does not take credit for certain mechanisms that would limit the release of fission products in a credible release. Any credible release from the irradiation units will go into the light water pool, which should provide scrubbing and control the release rates of iodine and bromine. The predominant form of iodine in the light water pool and its volatility will depend on the pH of the pool, which will be evaluated during the final design of the LWPS. The pH of an aqueous solution generally determines whether iodine is in a non-volatile (I-) or volatile (I2) form. In acidic conditions I2 is preferred resulting in

transfer of iodine to the gaseous phase. If organics are present they can react with iodine to form organic iodides some of which can also transfer to the gaseous phase. Judging from the behavior of organic iodine Radioiodine Test Facility (RTF) tests described in the Behaviour of Iodine Project Final Summary Report, NEA/CSNI/R(2011)11 (https://www.oecd-nea.org/nsd/docs/2011/csni-r2011-11.pdf), the organic iodide concentration seems to follow the same trends as I2. The organic iodide concentration decreases along with the reduction in the molecular iodine (I2) concentration with increasing pH. This reduction of the organic iodide concentration suggests that controlling pH would similarly control the organic iodide production and potential release to the gas phase. The radiolytic degradation of certain organics was also observed to influence pH. The RTF experiments were intended to represent containment sump water. It is therefore possible that additional reactions occurring in a homogeneous reactor may alter the organic iodide behavior observed in the RTF tests. The potential for change in releases should examined in more detail considering composition of and the organic contaminants expected in the AHR solution when final design information becomes available in the operating license review. While the applicant has not provided the anticipated pH of the light water pool in the IU following the postulated accident in which the entire contents of the TSV are released, the volume of the pool would increase the pH of the mixture, limiting potential releases by this pathway. Iodine releases would also be controlled by adsorption on the walls of the light water pool, as well as the mixing in the pool and transport of iodine to the gas space.

(2) The exposure time of workers is assumed to be 10 minutes which should be conservative for workers trained to evacuate in the event of a radiological release.

(3) For the preliminary design, the air handling and filtering systems are assumed to function as designed and described in the SHINE PSAR. Realistic methods were used to compute external radiation doses and dose commitments resulting from inhalation by the facility staff. As described in SHINE PSAR Chapter 11, "Radiation Protection Program and Waste Management," and supplemented by responses to RAIs, realistic but conservative methods are used to compute potential doses and dose commitments to the public in the unrestricted area. The methods of calculating doses from inhalation or ingestion (or both) and direct shine of gamma rays from dispersing plumes of airborne radioactive material are appropriate in support of a preliminary facility design.

(4) An MHA, which is an accident that would release fission products from target solution and would have consequences greater than any credible accident, has been analyzed. The MHA scenario is credible, but the combination of bounding conditions analyzed are beyond what is assumed for design basis accidents. The IF MHA serves as a bounding accident analysis for the IF.

(5) Because the assumptions of the scenario are bounding, the doses calculated will likely not be exceeded by any accident considered credible. The applicant has also examined more realistic assumptions about operating time and release fractions that decreased the source term significantly compared to the one calculated for the MHA, lowering the maximum doses by a factor of 2 for workers and a factor of 7.5 for members of the public. Thus, even for the IF MHA, the health and safety of the facility staff and the public are protected.

Therefore, the staff finds that the preliminary analysis of the MHA, as described in SHINE PSAR Sections 13a2.1.1 and 13a2.2.1, and supplemented by the applicant's responses to RAIs, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.2 Insertion of Excess Reactivity/Inadvertent Criticality

In SHINE PSAR Sections 13a2.1.2, "Insertion of Excess Reactivity/Inadvertent Criticality," and 13a2.2.2, "Excess Reactivity Insertion Accident," the applicant examined modes of operation including the fill process, the cold target solution prior to starting the neutron driver, and irradiation operations after the neutron driver is activated. The TSV is expected to operate in a subcritical condition during all modes of operation through a combination of automatic safety systems and administrative controls, including a passive standpipe overflow system and fill rate limits. The k_{eff} is expected to be at a maximum at the end of the filling mode. The k_{eff} will be reduced during irradiation operations due to void and temperature feedback in the target solution.

SHINE selected and analyzed three potential events, which could result in the insertion of excess reactivity:

A. Increase in the target solution density during operations due to void collapse.
B. Reduction in the target solution temperature due to excessive cooling.
C. Injection of additional target solution beyond the targeted fill volume during startup and irradiation operations.

SHINE PSAR, Section 13a2.1.2.1, "Identification of Causes, Initial Conditions, and Assumptions," discusses the insertion of excess reactivity. Since the system is over-moderated, decreasing the density of the coolant or introducing voids in the primary closed loop cooling system (PCLS) would result in a positive reactivity insertion. In its review of SHINE's analysis of potential events which could result in an insertion of excess reactivity, the staff determined that additional information was necessary to determine whether certain events had been considered, which could result in an insertion of reactivity and/or inadvertent criticality event. Therefore, in RAIs 13a2.1-3 through 5 and 13a2.2-2 (Reference 14), the staff requested that SHINE provide additional information on: (1) whether a decrease in coolant density or introduction of voids in the PCLS has been analyzed as a possible accident scenario, (2) whether a TOGS condenser heat exchanger (HX) failure or recombiner HX failure and water ingress had been considered as a possible accident scenario, (3) the expected reactivity insertion, following the maximum credible deflagration, and (4) what features limit a temperature drop in the subcritical assembly to 5 degrees C to prevent a criticality event. This information is necessary to satisfy the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2, "Aqueous Homogeneous Reactor Accident Analyses," which states that the applicant should include a systematic analysis and discussion of credible accidents for determining the limiting event in each category. The mathematical models and analytical methods employed, including assumptions, approximations, validation, and uncertainties, should be clearly stated in this analysis.

In response to RAI 13a2.1-3 (Reference 21), SHINE performed a calculation of the expected reactivity changes due to voiding out the PCLS from nominal coolant temperature and density to a fully voided cooling system and found that there is a negative insertion of reactivity as the percent of voids increased. The highest k_{eff} for both Mode 1 and Mode 2 conditions occurred when there were no voids present in the PCLS.

In response to RAI 13a2.1-4 (Reference 21), SHINE stated that the TOGS condenser heat exchanger failure and recombiner heat exchanger failure and water ingress had been considered as possible accident scenarios. SHINE performed calculations showing that these events would result in a dilution of the TSV solution and rise in TSV solution level, resulting in a reactivity decrease.

In response to RAI 13a2.1-5 (Reference 21), SHINE calculated the expected reactivity insertion from the maximum credible deflagration and found that the increase in solution concentration due to water loss combined with the maximum deflagration event did not result in a k_{eff} greater than that occurring during cold startup. The calculation was performed using MCNP5, version 1.60, and the SHINE best-estimate neutronics model.

In response to RAI 13a2.2.-2 (Reference 20), SHINE described two features that limit the temperature drop in the subcritical assembly during startup: temperature detection of the PCLS and neutron flux monitoring of the subcritical assembly. Furthermore, SHINE stated that "[a]ssuming the least negative initial reactivity and the limiting TSV temperature reactivity coefficient, the TSV temperature would have to drop approximately 6°C before reaching criticality."

The staff finds these responses satisfy the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2 and demonstrate an adequate design basis to protect the irradiation units from an insertion of reactivity event and inadvertent criticality event in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on SHINE's insertion of reactivity and inadvertent criticality events demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant findings:

(1) Reactivity insertion events have been identified and analyzed. None of these events would lead to challenges to the integrity of the primary system boundary or increase the release of radiation from the irradiation units. The SHINE irradiation units are designed to operate with a significant margin to criticality in all modes of operation. The physical design features, safety system trips, technical specifications and administrative controls will ensure that the system remains subcritical in all modes of operation. There is no scenario that allows a large and rapid reactivity insertion similar to a control rod ejection event in a reactor. While SHINE did not analyze an event that would cause a criticality, in the unlikely event that all safety trips and administrative controls failed and resulted in a SHINE IU criticality, the response of critical aqueous homogenous reactors to reactivity insertions is well understood and should not lead to any challenges to the integrity of the primary system boundary.

(2) There are no dose consequences identified for either on-site workers or the public. The consequences of excess reactivity insertion accidents have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of the insertion of reactivity and inadvertent criticality events, as described in SHINE PSAR Sections 13a2.1.2 and 13a2.2.2, and supplemented by the applicant's responses to RAIs, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.3 Reduction in Cooling

In SHINE PSAR Sections 13a2.1.3 and 13a2.2.3, "Reduction in Cooling," the applicant evaluated a reduction in cooling to the neutron driver, the neutron multiplier, and to the TSV, which contains the target solution. The IU and TSV are cooled by the PCLS and the LWPS. The PCLS removes heat from the TSV by circulation coolant. The LWPS cools the pool surrounding the TSV.

Several scenarios were identified that would lead to a reduction in cooling event including a loss-of-offsite-power (LOOP) event, flow blockages, equipment malfunctions or damage, or operator errors. The applicant postulated reduction in cooling events with both operating and de-energized neutron drivers. The applicant performed a detailed analysis of three potential scenarios that could result in a reduction in cooling:

A. A LOOP resulting in a loss of the PCLS, LWPS and the neutron driver.
B. Loss of PCLS due to a blockage, malfunction, damage, or operator error with the LWPS and PCLS still operating.
C. Loss of PCLS and LWPS due to an electrical failure or operator error with the neutron driver still operating.

The staff determined that these scenarios cover a representative sample of possible reduction in cooling scenarios and should provide representative results for the range of safety margins and consequences seen in actual reduction of cooling events during facility operations. For all of these scenarios the TRPS system trips on a loss of cooling and target solution is transferred to the TSV dump tank. However, the staff determined that additional information was needed to understand the basis for SHINE PSAR Section 13a2.1.3.1, "Identification of Causes, Initial Conditions, and Assumptions," stating that Scenario C was a low probability event not expected to occur during the facility lifetime. Therefore, SHINE was asked to provide a technical basis for this claim in RAI 13a2.1-6 (Reference 14). This information is necessary to satisfy the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2, which states that the applicant should include a systematic analysis and discussion of credible accidents for determining the limiting event in each category. The mathematical models and analytical methods employed, including assumptions, approximations, validation, and uncertainties, should be clearly stated in this analysis.

In response to RAI 13a2.1-6 (Reference 21), SHINE stated that multiple unlikely simultaneous failures would be required to result in continued operation of the neutron driver during the loss or reduced PCLS and LWPS flow. The neutron driver would be de-energized during both a LOOP and during a loss or reduction of PCLS flow below the trip setpoint.

The staff finds that this response satisfies the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2 and demonstrates an adequate design basis to protect the irradiation units from a reduction in cooling event in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on SHINE's reduction of cooling scenarios demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant findings:

(1) Reduction in cooling events have been identified and analyzed. The level of decay heat produced by the target solution is relatively low compared to the heat removal capabilities of the cooling systems. The relatively large volume of water in the light water pool provides an adequate heat sink and heat removal capacity whether or not the LWPS system is operable.

(2) There are no dose consequences for either on site workers or the public. The consequences of reduction in cooling events have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of the reduction in cooling scenarios, as described in SHINE PSAR Sections 13a2.1.3 and 13a2.2.3, and supplemented by the applicant's response to an RAI, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.4 Mishandling or Malfunction of Target Solution

SHINE PSAR Sections 13a2.1.4 and 13a2.2.4, "Mishandling or Malfunction of Target Solution," describe the IF as containing a liquid uranyl sulfate target solution that may include radioactive fission products. This accident category includes events that involve the mishandling of the target solution and the failure of the primary system boundary within the IF. The solution may be contained within the target solution hold tank, the TSV, TSV dump tank, or any of associated piping in the system. The applicant considered four general scenarios that qualitatively differ by where the target solution goes. In the TSV overfill scenario, the excess target solution goes into the dump tank and there is no leakage outside of the primary pressure boundary. A TSV or dump tank leak into the light water pool was considered where the solution enters the pool and pool cooling system. Fission products in the pool could also enter the IU atmosphere above the pool and be released into RVZ1 and the RCA as in the MHA for the IF. The release rate is much slower than the MHA and credit is given for fission product scrubbing in the pool. A TSV leak into the primary cooling system would allow radioactive water to exit the IU cell, but still remain in the closed PCLS. The PCLS is normally operating at a higher pressure than the TSV, so the expected direction of leakage is from the PCLS to the TSV.

A dump tank pipe leak in the IU cell atmosphere was considered to be the limiting event in this category. In this event, there would not be fission product scrubbing by the pool. This event is similar but less severe than the MHA since the leak rate is slower than the instantaneous loss of all target solution in the MHA. Assumptions used in the accident analysis are:

- The scenario analyzed by the applicant starts with a pipe break in the TSV dump tank outlet piping and 25 percent of the inventory is released into the IU cell gas space.
- The facility is evacuated after 25 percent of the radioactivity enters the IU.
- A high radiation signal activates the isolation dampers after 1 percent of the total activity is released into RVZ1.
- The airborne activity is filtered before being released to the environment.
- Ten percent of the activity in the shielded cell is released into the RCA through penetration leakage.
- Radiation alarms in the facility are operating to notify personnel in the area of the release.
- Facility personnel evacuate the area when the radiation alarm activates.

The airborne activity is released to an IU cell gas space. One percent of the activity is released to RVZ1 before the IU cell isolation dampers are closed. The airborne activity in RVZ1 is released to the environment through HEPA and carbon adsorber beds with assumed removal efficiencies of 99 percent or particulates and 95 percent of halogens. Ten percent of the IU cell activity is released to the RCA through IU cell penetrations.

The dose consequences of the TSV dump tank exit piping rupture are calculated to be within the regulatory limits of 10 CFR Part 20. A TEDE of 1.50 rem is calculated for the workers at the facility. This on-site dose is less than the 5 rem regulatory limit specified in 10 CFR 20.1201. A TEDE of 0.0022 rem is calculated for a member of the public at the site boundary, and a TEDE of 0.0003 rem is calculated at the nearest residence. The off-site doses are less than the 0.1 rem regulatory limit specified in 10 CFR 20.1301.

On the basis of its review, the staff finds that the level of detail provided on SHINE's mishandling or malfunction of target solution event demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant findings:

(1) Mishandling and malfunction of the target solution scenarios have been identified and analyzed. The facility power and power density are sufficiently low such that insufficient energy is available to drive a large energetic release of radioactive material, as could occur in a nuclear power reactor. Any release in this scenario will enter into the gas space of the IU. Iodine releases would be controlled by adsorption on the walls of the light water pool, as well as the mixing in the pool and transport of iodine to the gas space.

(2) The exposure time of workers is assumed to be 10 minutes, which should be conservative for workers trained to evacuate in the event of a radiological release.

(3) The applicant adequately considered the consequences of target solution mishandling and malfunction events. Because the assumptions of this scenario are bounding, the

> doses calculated for this event are conservative. More realistic assumptions about the release fractions would decrease the source term significantly compared to the source term assumed for this scenario. The consequences of the IF mishandling or malfunction of target solution event have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of the IF mishandling or malfunction of target solution event, as described in SHINE PSAR Sections 13a2.1.4 and 13a2.2.4, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.5 Loss of Electrical Power

In SHINE PSAR Sections 13a2.1.5 and 13a2.2.5, "Loss of Off-Site Power," the applicant examined a total loss-of-offsite power (LOOP) to the facility for an extended period of time with conservative operating conditions as an event that bounds all other loss of power events in the facility. An uninterruptable power supply system (UPSS) is available to supply battery power for essential loads for at least 2 hours. The neutron driver shuts down on LOOP. The UPSS powers the TOGS to remove hydrogen generated by radiolysis. The UPSS does not provide power for the heat removal systems connected to the TOGS. The decay heat is low and can be transferred to the light water pool through natural convection. The heat capacity of the pool is large enough that the pool temperature will increase by only 11.8 °F from 90 days of decay heat load.

On the basis of its review, the staff finds that the level of detail provided in SHINE's LOOP analysis demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

> There are no dose consequences for either on site workers or the public. While the applicant has not provided an analysis of the impact of the loss of the heat removal systems on the integrity of the TOGS pressure boundary, in the event that an analysis can not show that the heat produced by recombination during the LOOP will not cause a breach of the pressure boundary and release of radioactive gases to the TOGS shielded cell, the event would still be bounded by the MHA. The consequences of reduction in cooling events from loss of offsite power have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of the IF LOOP, as described in SHINE PSAR Sections 13a2.1.5 and 13a2.2.5, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.6 External Events

In SHINE PSAR Sections 13a2.1.6 and 13a2.2.6, “External Events,” the applicant has identified seismic events, tornados or high winds, and a small aircraft crash as external events that can affect the IF. These are treated as design basis accidents for the facility. Flooding has been ruled out due to the site location. The SHINE facility has been designed to survive design basis earthquake, tornado and wind loads including missiles, and aircraft impacts and keep the facility safety functions intact.

On the basis of its review, the staff finds that the level of detail provided on SHINE’s external events demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

> Chapters 2, “Site Characteristics,” and 3, “Design of Structures, Systems, and Components,” of the PSAR adequately discuss the preliminary design of the SHINE facility and its ability to withstand external events and the potential associated accidents. The SHINE facility is adequately designed to accommodate these events. For events that cause facility damage, the damage is within the bounds discussed for other accidents in this chapter and does not result in dose consequences. The consequences of all DBA external events have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of external events, as described in SHINE PSAR Sections 13a2.1.6 and 13a2.2.6, 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 the design basis during the evaluation of SHINE’s FSAR.

13a.4.7 Mishandling or Malfunction of Equipment

In SHINE PSAR Sections 13a2.1.7 and 13a2.2.7, “Mishandling or Malfunction of Equipment Affecting the PSB,” the applicant examined scenarios where mishandling of malfunction of equipment could lead to an accident where workers or the public are exposed to radiation. This includes scenarios where the PSB is not maintained. Some of those that could lead to a release of the target solution have already been examined in Section 13a2.1.4 of the PSAR. This section examines scenarios that could lead to radiation exposure including the release of radioactive gases.

The malfunctions of three systems were identified for further analysis. Events involving the Neutron Driver Assembly System (NDAS) and the tritium purification system (TPS) were identified as possible scenarios. Those scenarios include inadvertent actuation of the neutron driver, misalignment of the accelerator, and loss of tritium. There are specific design and safety system features that minimize the potential for events involving those systems. They are not the limiting events but they are analyzed further in facility specific events category which is described in PSAR Section 13a2.1.12.

A scenario where there is an inadvertent purge of the radioactive gases from the TOGS has been determined to be the limiting event in this category. The TOGS contains an inventory of radioactive fission product gases that build up over the irradiation cycle. Part of the iodine is removed by the zeolite beds that are part of the TOGS system. Gas is purged from the TOGS to the Noble Gas Removal System after an irradiation cycle. This scenario assumes that a malfunction or human error releases radioactive gas in one IU from the TOGS into the shielded cell that encloses the TOGS. Assumptions used in the accident analysis are:

- The scenario analyzed by the applicant starts with a pipe rupture in the TOGS and the complete release of the off gas into the TOGS shielded cell.
- The facility is evacuated after 25 percent of the TOGS radioactivity enters the shielded cell.
- A high radiation signal activates the isolation dampers after 1 percent of the total activity is released into RVZ1.
- The airborne activity is filtered before being released to the environment.
- Ten percent of the activity in the shielded cell is released into the RCA through penetration leakage.
- Radiation alarms in the facility are operating to notify personnel in the area of the release.
- Facility personnel evacuate the area when the radiation alarm activates.

The radioactive gas is released to a TOGS cell gas space. One percent of the activity is released to RVZ1 before the IU cell isolation dampers are closed. The airborne activity in RVZ1 is released to the environment through HEPA and carbon adsorber beds with assumed removal efficiencies of 99 percent or particulates and 95 percent of halogens. Ten percent of the IU cell activity is released to the RCA through IU cell penetrations.

The dose consequences of the TOGS piping rupture are calculated to be within the regulatory limits of 10 CFR Part 20. A TEDE of 1.87 rem is calculated for the workers at the facility. This on-site dose is less than the 5 rem regulatory limit specified in 10 CFR 20.1201. A TEDE of 0.0159 rem is calculated for a member of the public at the site boundary, and a TEDE of 0.0022 rem is calculated at the nearest residence. The off-site doses are less than the 0.1 rem regulatory limit specified in 10 CFR 20.1301.

On the basis of its review, the staff finds that the level of detail provided on mishandling or malfunction of equipment demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant findings:

(1) Mishandling and malfunction of equipment scenarios have been identified and analyzed. The facility power and power density are sufficiently low such that insufficient energy is available to drive a large energetic release of radioactive material, as could occur in a nuclear power reactor. Any release in this scenario will enter into the gas space of the IU. Iodine releases would be controlled by adsorption on the walls of the light water pool, as well as the mixing in the pool and transport of iodine to the gas space.

(2) The exposure time of workers is assumed to be 10 minutes, which should be conservative for workers trained to evacuate in the event of a radiological release.

(3) The applicant adequately considered the consequences of target solution mishandling and malfunction events. Because the assumptions of the scenario are bounding, the doses calculated for this event will be conservative. More realistic assumptions about the release fractions would decrease the source term significantly compared to the source term assumed for this scenario. The consequences of the IF mishandling or malfunction of equipment affecting the PSB event have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of mishandling or malfunction of equipment events, as described in SHINE PSAR Sections 13a2.1.7 and 13a2.2.7, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.8 Large Undamped Power Oscillations

SHINE PSAR Sections 13a2.1.8 and 13a2.2.8, "Large Undamped Power Oscillations," describe power oscillations will occur in the TSV in response to natural fluctuations in the target solution that result in fluctuations in reactivity. The size of the power oscillations will be determined by the physical characteristics of the system and any control inputs or changes to the TSV boundary conditions including the neutron driver, the primary heat exchanger, the autocatalytic recombiner, and the condenser. However, the operating conditions of the TSV and TOGS should not lead to large undamped power oscillations.

The applicant identified radiolytic bubble formation and transport, target solution spatial variations and circulation, neutron driver variation, and excessive reactivity insertions as possible causes of oscillations. The SHINE TSV operates at power densities significantly below the 1.8 kWt/L threshold observed to cause significant power oscillations in aqueous homogeneous reactors. The low operating power density and the subcritical driven operation should prevent large power oscillations. However, the NRC staff determined that additional information was necessary to verify that the TSV would not become critical during operation. Therefore, in RAI 13a2.1-7 (Reference 14), the NRC staff requested that SHINE provide the expected magnitude of potential power oscillations, and a description of the mechanisms that are in place to ensure that they are "self-limiting." This information is necessary to satisfy the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13a2, which states that the applicant should include a systematic analysis and discussion of credible accidents for determining the limiting event in each category. In response to this RAI (Reference 21), SHINE provided a stability analysis of the accelerator driven system that was performed by Los Alamos National Laboratory (LANL) and documented in the report LA-UR-14-28684, "STABILITY OF FISSILE SOLUTION SYSTEMS". The LANL stability analysis showed that the system is stable across the expected range of operation any oscillations should be damped. Driven bounded reactivity or source strength oscillations will also result in a bounded response. The system is expected to be stable to bounded perturbations. However, feedback effects from the recombiner and condenser were not included in the stability analysis and will need to be evaluated during the evaluation of the final design of the SHINE facility. The staff finds that this response satisfies the requirements discussed in the ISG Augmenting NUREG-

1537, Part 2, Section 13a2 and demonstrates an adequate design basis to protect the irradiation units from a large undamped power oscillation in support of a preliminary design.

On the basis of its review, the staff finds that the level of detail provided on large undamped power oscillations demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

> The applicant has evaluated potential unstable (growing), large undamped power oscillations and demonstrated that these oscillations are either not possible, or, if they develop, can be readily detected and suppressed so that the reactor reaches a stable state. There are no dose consequences for either on site workers or the public for these events. The consequences of large undamped power oscillations have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of large undamped power oscillations, as described in SHINE PSAR Sections 13a2.1.8 and 13a2.2.8, 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 (e.g., feedback effects from the recombiner and condenser) may reasonably be left for later consideration. The staff will confirm that the final design conforms to the design basis during the evaluation of SHINE's FSAR.

13a.4.9 Detonation and Deflagration

In SHINE PSAR Sections 13a2.1.9 and 13a2.2.9, "Detonation and Deflagration in Primary System Boundary," the applicant analyzed the effects of a possible hydrogen detonation or deflagration within the primary system boundary on the IF. Irradiating the target solution produces significant quantities of hydrogen and oxygen through radiolysis and small amounts of fission product gases. The TOGS is designed to control the level of hydrogen and oxygen so that a deflagration or detonation does not occur. The hydrogen and oxygen is recombined, condensed, and returned as water to the TSV by the TOGS. The applicant has identified failure or degradation of the TOGS as an initiating event that could lead to a deflagration or detonation.

The primary system boundary is designed to be capable of withstanding all credible deflagrations and detonations. However, if the primary system did fail, there could be a radioactive release into the IU and the evolution of the event would be similar to the Mishandling or Malfunction of Target Solution scenario.

On the basis of its review, the staff finds that the level of detail provided on detonation and deflagration events demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

> The applicant has evaluated the consequences of potential deflagration or detonation of combustible gases within the primary boundary. The assumptions regarding the impact of potential explosions on primary boundary integrity are valid. There are no dose consequences for either on site workers or the public for these events. The consequences of reduction in cooling events have been analyzed and shown to be bounded by the MHA.

> Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of detonation and deflagration events, as described in SHINE PSAR Sections 13a2.1.9 and 13a2.2.9, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.10 Unintended Exothermic Chemical Reactions Other Than Explosion

As described in SHINE PSAR Sections 13a2.1.10 and 13a2.2.10, "Unintended Exothermic Chemical Reactions Other than Detonation," there is no potential for the target solution to undergo any significant exothermic chemical reactions. While the zirconium TSV could react with oxygen or steam at high temperature, operating conditions should preclude conditions where there would be a significant reaction rate.

On the basis of its review, the staff finds that the level of detail provided on unintended exothermic chemical reactions other than explosions demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

> Since there is no potential for the target solution to undergo any significant exothermic chemical reactions, there are no dose consequences for either on site workers or the public for these events. The consequences of these events have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of unintended exothermic chemical reactions other than explosions, as described in SHINE PSAR Sections 13a2.1.10 and 13a2.2.10, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.11 Primary System Boundary System Interaction Events

As described in SHINE PSAR Sections 13a2.1.11 and 13a2.2.11, "Primary System Boundary System Interaction Events," the applicant considered events that could result from system interactions within the IF and interactions between the IF and RPF. The PSB is located within the IF and consists of the TSV, the TSV dump tank, and the TOGS. An event affecting the IF would have to cause a breach of the PSB to have dose consequences to workers or the public.

The applicant considered three categories of system interactions in the PSAR:

1) functional interactions
2) spatial interactions

3) human-intervention interactions

Functional interactions are interactions between systems that have a common interface. An example in this category is the RPCS, which provides the cooling for the water for many safety system heat exchangers including the PLCS, LWPS, and TOGS heat removal systems. A failure in the RPCS could affect all of the systems that rely on it. Spatial interactions are interactions that can occur between systems that do not have a common interface but they are located within close proximity of each other. An example of this is that the failure of one system can damage another system that is nearby. Human-intervention interactions are human errors made in one system that can cause an adverse effect in another system. An example is that a failure in the fuel mixing system can cause an excess reactivity event in the TSV.

The events considered in this category have been considered and bounded by events in other categories and will not be discussed further.

On the basis of its review, the staff finds that the level of detail provided on primary system boundary system interaction events demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

> There are no dose consequences for either on site workers or the public for these events. The consequences of PSB interaction events have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of primary system boundary system interaction events, as described in SHINE PSAR Sections 13a2.1.11 and 13a2.2.11, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.12 Inadvertent Exposure to Neutrons from the Neutron Driver

As described in SHINE PSAR Sections 13a2.1.12.1 and 13a2.2.12.1, "Inadvertent Exposure to Neutrons from the Neutron Driver," each irradiation unit contains a neutron driver, a neutron multiplier, and the subcritical uranyl sulphate contained in the TSV. These are all sources of neutrons during operations. The unexpected presence of personnel in the IU cell during operation of the neutron driver could expose those personnel to significant doses of neutron radiation. The applicant considered possible ways that this could occur and concluded that the event could be caused by either failure to control access to the IU cell during operation or failure to control neutron driver operation during maintenance.

The IU is shielded during normal operations by 6-foot thick concrete walls. Access is available to the unit through the IU cell concrete shield plug or the personnel access door. Personnel are only expected to be in the IU during maintenance activities when the driver is not operating. The possible scenarios that may occur under the failure to control access initiating event include inadvertently removing the concrete shield plug or inadvertently opening the personnel access door. The scenario for the failure to control neutron driver operation involves personnel in the opened IU cell during maintenance activities while the neutron driver is inadvertently activated.

On the basis of its review, the staff finds that the level of detail provided on inadvertent exposure to neutrons from the neutron driver demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant findings:

(1) The applicant has prevented the possible exposure of workers to neutron radiation from the neutron driver through safety controls including an interlock system for the neutron driver personnel access door and administrative controls on access to the IU and operation of the neutron driver.

(2) There are no dose consequences for either on site workers or the public for these events. The consequences of these events have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of inadvertent exposure to neutrons from the neutron driver, as described in SHINE PSAR Sections 13a2.1.12.1 and 13a2.2.12.1,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 the design basis during the evaluation of SHINE's FSAR.

13a.4.13 Irradiation Facility Fires

As described in SHINE PSAR Sections 13a2.1.12.2 and 13a2.2.12.2, "Irradiation Facility Fires," the IF contains the IUs, the TOGS cells, the cooling system, and other related electrical and mechanical systems. In addition to combustibles related to the equipment, there is also the potential for hydrogen to be in the area.

The applicant identified potential fire events in the IF that could occur during operations and maintenance activities and lead to radioactive releases. Fires that started inside the IF and external fires that propagate into the IF were considered. Both in-situ and transient sources of combustible material were considered as fuel sources for the fire.

On the basis of its review, the staff finds that the level of detail provided on Irradiation Facility Fires demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

> Fires are expected to be contained within the IF with no releases to the public. There are no dose consequences for either on site workers or the public for these events. The consequences of these events have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of irradiation facility fires, as described in SHINE PSAR Sections 13a2.1.12.2 and 13a2.2.12.2, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.14 Tritium Purification System (TPS) Design Basis Accident

As described in SHINE PSAR Sections 13a2.1.12.3 and 13a2.2.12.3, "Tritium Purification System (TPS) Design Basis Accident," the TPS contains and processes the tritium that is used in the neutron drivers. Tritium is delivered to the SHINE facility in Department of Transportation (DOT) approved containers. Those containers are loaded into the TPS glove boxes, which are located in the IF. The system purifies and delivers the gas containing the tritium to the accelerator target chamber. The TPS has two independent isotope separation subsystems that share a common supply and return piping system that supplies tritium to the neutron driver. The release of tritium from the TPS can result in radiation doses to workers and the public.

The applicant identified piping failure, equipment malfunctions, and human errors as possible initiating events that cause a release of tritium. Important conditions and assumptions that are important to the safety of the system are:

- The TPS process equipment is operated through a programmable logic controller/process automation controller (PLC/PAC). The process will be performed in semi-batch process steps of treating the contaminated flush gas and purifying the contaminated tritium gas. The process steps and local operator interfaces will be controlled and monitored by the PLC system.
- Two independent TPS glove boxes form a confinement boundary around the two isotope separation systems. Double-walled pipe forms a confinement boundary around the TPS supply and return tritium piping to and from the neutron drivers.
- The glove box atmosphere is inerted with nitrogen and oxygen levels are monitored.
- The piping to and from the neutron driver accelerator system (NDAS) is double-walled and designed to maintain its integrity during normal and accident conditions.
- Leakage of tritium from the system will be into either the double-wall piping or glovebox confinement.
- Leakage of tritium from the glove box enclosure or the external piping is detected by the RAMS or other leakage detection systems to ensure facility personnel are protected.
- The TPS glove boxes and piping are seismically designed and protected from external events by building design.
- Automatic isolation valves are installed in the system to isolate sections of the system to minimize system release.
- Tritium is delivered in robust DOT approved containers and transported in engineered transport containers, and is only handled inside the TPS glove boxes or a transfer confinement.
- TPS piping to and from the NDAS units is normally operated at sub-atmospheric pressures.

The applicant considered several possible scenarios including a loss of TSP system integrity inside the glove box or double-wall piping, loss of confinement integrity, mishandling or dropping of a TPS ambient molecular sieve bed (AMSB) during maintenance, release of tritium during a transfer operation, and fire.

A loss of TPS system integrity because of a pipe break in a neutron driver was determined to be the limiting event since the only significant tritium inventory that is not in double walled piping or an engineered confinement is in the neutron drivers. The TPS has isolation features to mitigate large releases of tritium and no active single failure can cause a large release. A pipe break on a neutron driver would be expected to release less than 15percent of the driver tritium inventory for all IUs because of automatic isolation valves, but a loss of the entire inventory is assumed for this accident. Isolation dampers on the RCA ventilation system will automatically close on high radiation signals. The sequence of events for the postulated scenario is as follows:

- A release of the tritium in the neutron driver system directly to the irradiation unit cell.
- A high radiation signal (e.g., loss of vacuum in TPS piping) or other actuation signal activates the bubble-tight isolation dampers after approximately one percent of the material is released to the RVZ1, and actuates isolation of tritium supply and return piping.
- The airborne activity is filtered prior to being released to the environment through the RVZ1 system until the bubble-tight dampers are closed.
- Alarms are available locally or in the control room to notify facility personnel of radiation leakage due to loss of TPS integrity.
- Facility personnel evacuate the immediate area upon actuation of the radiation area monitor alarms.

No credit is given for the confinement of the IU cell and all of the activity is assumed to be released to RVZ1. The airborne activity in RVZ1 is released to the environment without credit for any decontamination.

The dose consequences of the loss of TPS integrity are calculated to be within the regulatory limits of 10 CFR Part 20. A TEDE of 2.4 rem is calculated for the workers at the facility. This on-site dose is less than the 5 rem regulatory limit specified in 10 CFR 20.1201. A TEDE of 5.6e-4 rem is calculated for a member of the public at the site boundary, and a TEDE of 8.0e-5 rem is calculated at the nearest residence. The off-site doses are less than the 0.1 rem regulatory limit specified in 10 CFR 20.1301.

On the basis of its review, the staff finds that the level of detail provided on TPS design basis accident demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant findings:

(1) The tritium release in this scenario will enter into the gas space of the IU. The tritium release rate should be controlled by the mixing of the tritium in the gas space.

(2) The exposure time of workers is assumed to be 10 minutes, which should be conservative for workers trained to evacuate in the event of a radiological release.

(3) The applicant adequately considered the consequences of a tritium purification system accident. Because the assumptions of the scenario are bounding, the doses calculated

for this event will be conservative. More realistic assumptions for the release fractions would decrease the source term significantly compared to the source term assumed for this scenario. The consequences of the IF tritium purification system accident have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of the IF tritium purification system accident, as described in SHINE PSAR Sections 13a2.1.12.3 and 13a2.2.12.3, 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 the design basis during the evaluation of SHINE's FSAR.

13a.4.15 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 supporting the SHINE accident analysis, with special attention given to those items which may significantly influence the final design.

SHINE PSAR Section 13a2.2.2.7, "Safety Controls," identifies uranium enrichment and concentration as probable subjects of technical specifications to address excess reactivity insertion accidents. Section 13a2.2.2.7 also includes procedural controls of start-up as an administrative control.

SHINE PSAR Section 13a2.2.8, "Large Undamped Power Oscillation," lists negative temperature and void coefficients, as well as TSV thermal power limits as probable subjects of technical specifications required to address large undamped power oscillations.

SHINE PSAR Section 13a2.2.10, "Unintended Exothermic Chemical Reactions Other than Detonation," identifies uranium enrichment and concentration as probable subjects of technical specifications to prevent the effects of PSB interaction events.

SHINE PSAR Section 13a2.2.12.1, "Inadvertent Exposure to Neutrons from the Neutron Driver," identifies the use of accelerator audible/visual warnings as a probable administrative technical specification to prevent an inadvertent exposure to neutrons from the accelerator.

SHINE PSAR Section 13a2.2.12.2, "Irradiation Facility Fire Event," identifies limited tritium inventory based on TPS fixed glovebox volume and deuterium source vessel integrity program as probable administrative technical specifications to prevent irradiation facility fire events.

SHINE PSAR Section 13a2.2.12.3, "Tritium Purification System Design Basis Accident," lists engineered transport enclosures or containers and TPS system sampling, inspection, testing and operating procedures as probable administrative technical specifications to prevent a TPS design basis accident.

Based on the information provided in Section 13a2.2 of the SHINE PSAR, the staff finds that identification and justification of the proposed technical specifications is sufficient and meets the applicable regulatory requirements to support the issuance of a construction permit in accordance with 10 CFR 50.35. A complete evaluation of technical specifications, LCOs, and surveillance requirements will be performed during the review of SHINE's operating license application.

13a.5 Summary and Conclusions

The staff evaluated descriptions and discussions of SHINE's IF accident analysis, including probable subjects of technical specifications, as described in SHINE PSAR Section 13a2 and supplemented by the applicant's responses to RAIs, and finds that the preliminary accident analysis, including the principal design criteria; design bases; information relative to materials of construction, general arrangement, and approximate dimensions; and preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility: (1) provides reasonable assurance that the final design will conform to the design basis, (2) includes an adequate margin of safety, (3) structures, systems, and components adequately provide for the prevention of accidents and the mitigation of consequences of accidents, and (4) meets all applicable regulatory requirements and acceptance criteria in or referenced in ISG Augmenting NUREG-1537.

The staff further notes that the applicant has proposed and analyzed a set of accidents that should be representative of the possible range of events that may happen in an operating facility. The proposed set was the result of a detailed analysis of the facility design and identification of potential initiating events that can test possible vulnerabilities in the facility design. The analyzed set of accidents provides insights into the challenges to the safety systems and defense in depth features of the facility and consider how the potential accidents might be prevented or mitigated by administrative controls, engineered safety systems, and trained personnel actions.

One event that has not been analyzed in detail is an opening of the pressure safety valve on the PSB. The pressure safety valve is connected to the TOGS piping to passively prevent an over pressurization within the PSB, which may cause structural damage. The setpoint of the pressure safety valve will not exceed the design pressure of the PSB components. While the details of the system, including the setpoint value are not available in the PSAR, they will be provided in the FSAR. Since the TOGS system contains radioactive fission products, an event which causes the safety valve to open would allow fission products to exit the PSB and discharged to the Noble Gas Removal System (NGRS). SHINE intends to design the NGRS so that it has enough volume to receive the gas from the TOGS in an overpressure event and stay within pressure design limits. Although this event may not be as limiting as the events analyzed in the accident analysis, it may be more credible and occur with a higher probability. Therefore, an overpressure event that opens the pressure relief valve and discharges radioactive gas should be identified and analyzed in the FSAR to demonstrate the capability of the system to mitigate an overpressure event.

SHINE used International Commission on Radiation Protection (ICRP) Publication 30, "Limits for Intakes of Radionuclides by Workers," (ICRP 30) to calculate dose to members of the public in the preliminary accident analysis because ICRP 30 forms part of the basis for 10 CFR 20, and there is no regulatory requirement to use any guidance other than ICRP 30. However, SHINE acknowledges that ICRP Publication 72, "Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 5 Compilation of Ingestion and Inhalation Dose Coefficients," (ICRP 72) provides dose coefficients based on newer bio-kinetic models and data than ICRP 30. Therefore, during the detailed design process, SHINE will update the accident analysis calculations to use dose conversion factors (DCFs) from ICRP 72 and will calculate dose effects to ensure that the dose limits in 10 CFR 20.1301 are met.

The proposed features of the design, including the engineered safety features keep the radiation doses below acceptable limits and adequately protect the workers and the public for all proposed accidents. The safety systems are single failure proof and follow the defense in depth philosophy. The applicant has also proposed an MHA that uses conservative assumptions. The calculated dose release consequences of the MHA bound all other accidents. The proposed preliminary features of the design including administrative controls, engineered safety systems, and trained personnel actions keep the radiation doses below acceptable limits and adequately protect the workers and the public for the MHA. Therefore, the proposed preliminary accident analysis of the IU and the calculated consequences show that the design, including the engineered safety features adequately protect workers and the public.

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 systems supporting the accident analysis, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(2) Further technical or design information required to complete the safety analysis of the cooling systems may reasonably be left for later consideration the FSAR;

(3) There is reasonable assurance that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

13b Radioisotope Production Facility Accident Analysis

Section 13b, “Radioisotope Production Facility Accident Analysis,” provides an evaluation of the preliminary accident analysis of SHINE’s RPF as presented in PSAR Section 13b, “Radioisotope Production Facility Accident Analysis,” within which, SHINE describes accident-initiating events and scenarios, as well as the accident analysis and determination of consequences.

13b.1 Areas of Review

The staff reviewed SHINE PSAR Section 13b against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary accident analysis. As part of this review, the staff evaluated descriptions and discussions of SHINE’s accident analysis, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary accident analysis 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 that are determined to be probable subjects of technical specifications for the facility, with special attention given to those items that may significantly influence the final design. Structures, systems, and components were also evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents. The staff considered the preliminary analysis and evaluation of the design and performance of SSCs of the SHINE facility, including those SSCs shared by both the IF and RPF, with the objective of assessing the risk to public health and safety resulting from operation of the facility.

Areas of review for this section included accident analysis methodology, accidents with radiological consequences, and accidents with hazardous chemicals. Within these areas of review, the staff assessed processes conducted outside the IF; accident initiating events; the maximum hypothetical accident; loss of containment; external events; critical equipment malfunction; inadvertent nuclear criticalities; RPF fire; and chemical accident descriptions, consequences, controls, and surveillance requirements.

13b.2 Summary of Application

The accident analysis for the Radioisotope Production Facility (RPF) establishes safety limits and designates safety controls for facility operations in the RPF. A technical basis for control of those limits is provided in the PSAR and through inclusion in technical specifications. The accidents analyzed in this chapter also support the establishment of the design basis limits for the SSCs in the RPF processes. The RPF design has design features and analysis assumptions that are important for understanding the bases of the accident analysis as it applies to the design of the facility. The applicant has identified, through a systematic process, a variety of event types that are expected to be prevented or mitigated to acceptable limits for the credible accidents related to the RPF. All accident scenarios and analyses for the construction permit are based on the preliminary design of the facility and are considered preliminary from an operating licensing standpoint.

SHINE PSAR Section 13b describes accident analysis methodology, accidents with radiological consequences, and accidents with hazardous chemicals for the SHINE RPF. The application provides details on processes conducted outside the IF; accident initiating events; the maximum hypothetical accident; loss of containment; external events; critical equipment malfunction; inadvertent nuclear criticalities; RPF fire; and chemical accident descriptions, consequences, controls, and surveillance requirements. SHINE PSAR Section 13b.2.1 and Table 13b.1-1-4, "Potential Accident Sequences," which was provided in response to RAI 13b.1-1 (Reference 21), discuss initiating events that could accidentally release fission products from irradiated fuel while in process, in storage, or while being transferred within the facility.

Section 13b.2.5 of the PSAR discusses the potential for a criticality incident with un-irradiated SNM. An accidental criticality is shown to be highly unlikely, as the facility has been designed with passive engineering design features and other safety related controls to prevent criticality and assure that are processes remain subcritical. Additionally, administrative controls and safety-related (SR) SSCs provide control on enrichments and target solution uranium concentration to further prevent inadvertent criticality. Section 13b.2.5 identifies areas within the RPF where an inadvertent criticality is possible and discusses controls that are used to reduce the likelihood of an inadvertent criticality. Additional criticality safety analysis discussion and review is in Section 6b of this SER.

The RPF design basis is supported by information provided in SHINE PSAR Section 13b through discussions related to the use of Integrated Safety Analysis (ISA) methodology, determination of anticipated events, demonstration of acceptable risk, and the determination and designation of the safety controls needed to support the risk demonstration. The analysis performed by the applicant considers the radiological consequences, chemical consequences, fire analysis, and criticality status of credible accidents in the radioisotope production facility.

The applicant provided the following basis for the identification and evaluation of accident scenarios in the RPF:

- Hazard and operability studies (HAZOPS) and preliminary design hazard analyses (PHA) performed using guidance in accordance with NUREG-1520 (Reference 60).
- The list of accidents identified in the Final Interim Staff Guidance (ISG) Augmenting NUREG-1537.
- Experience of the hazard analysis team.
- Current preliminary design and design basis evaluations in the preliminary safety analysis report (PSAR) for the processes in the radioisotope production facility.
- The determination of safety controls needed to prevent or mitigate accidents.

13b.3 Regulatory Basis and Acceptance Criteria

The staff reviewed SHINE PSAR Section 13b against applicable regulatory requirements, regulatory guidance, and standards, to assess the sufficiency of the preliminary accident analysis in support of the issuance of a construction permit. In accordance with paragraph (a) of 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 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) taking into consideration the site criteria contained in Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

The staff’s evaluation of the preliminary accident analysis does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE facility as described in the FSAR as part of SHINE’s operating license application.

13b.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's preliminary accident analysis are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 20.1201, "Occupational dose limits for adults."
- 10 CFR 20.1301, "Dose limits for individual members of the public."

13b.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated SHINE's RPF accident analysis against the applicable regulatory requirements listed above, primarily using the guidance and acceptance criteria contained in Chapter 13b, "Radioisotope Production Facility Accident Analyses," of 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 RPF accident analysis. The use of additional guidance is based on the technical judgement of the reviewer, as well as references in the ISG Augmenting NUREG-1537, Parts 1 and 2; and the SHINE PSAR.

NRC staff has determined that the use of Integrated Safety Analysis (ISA) methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 60), application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, and establishment of management measures are an acceptable way of demonstrating adequate safety for the radioisotopes production facility. Applicants are free to propose alternate accident analysis methodologies, to propose alternate radiological and chemical consequence and likelihood criteria, to propose alternate safety features, and to propose alternate methods of assuring the availability and reliability of the safety features.

As used in Section 13b and elsewhere in this SER, the term "performance requirements" is not intended to suggest that Part 50 licensees are required to comply with the performance requirements found in 10 CFR 70.61, only that their use as accident consequence and likelihood criteria for the SHINE RPF would be found acceptable by NRC staff. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property.

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 13ab4, “Review Procedures, Technical Evaluation, and Evaluation Findings,” of this safety evaluation report (SER). Additional guidance documents used to evaluate SHINE’s preliminary accident analysis are provided as references in Appendix B.

13b.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 13b, as supplemented by the applicant’s responses to RAIs, to assess the sufficiency of the preliminary design and performance of SHINE’s accident analysis in the RPF in support of the issuance of a CP, in accordance with 10 CFR 50.35(a). The sufficiency of the SHINE preliminary accident analysis is demonstrated by compliance with applicable regulatory requirements, consistency with applicable guidance and acceptance criteria, as discussed in Section 13b.3, “Regulatory Basis and Acceptance Criteria,” of this SER. While the technical evaluation of preliminary accident analysis provided in this section is specific to the SHINE RPF, the staff’s review considers the interface of accident scenarios between the IF and RPF as part of a comprehensive technical evaluation. The results of this section-by-section technical evaluation are described in SER Section 13b.5, “Summary and Conclusion.”

For the purposes of issuing a CP, the preliminary accident analysis may be adequately described at a conceptual level. The staff evaluated the sufficiency of the preliminary accident analysis 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 accident analysis does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE facility, as described in the FSAR, as part of SHINE’s operating license application.

For SER Sections 13b.4.1 through 13b.4.9, the staff evaluated the sufficiency of the preliminary identification, analysis, and determination of consequences of accident-initiating events and scenarios, as described in SHINE PSAR Sections 13b.1, “Radioisotope Production Facility Accident Analysis,” and 13b.2, “Analyses of Accidents with Radiological Consequences,” in part, by reviewing the processes conducted outside of the irradiation facility, accident initiating events, maximum hypothetical accident, loss of containment, external events, loss of normal electric power, mishandling or malfunction of equipment, inadvertent nuclear criticality in the RPF, and RPF fire, using the guidance and acceptance criteria from Section 13b.1, “Radioisotope Production Facility Accident Analysis Methodology,” of the ISG Augmenting NUREG-1537, Parts 1 and 2.

For SER Sections 13b.4.1 through 13b.4.9, in accordance with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, the staff reviewed SHINE’s accident methodology and analysis and followed the sequence of events in each accident scenario from initiation to stabilization. The staff evaluated the maximum hypothetical accident; credible accidents; instruments, controls and automatic protective systems assumed to be operating normally before an initiating event; the identification of single malfunctions; the discussion of sequence of events and components and systems damaged during the accident scenario; mathematical models and analytical methods employed; radiation source term; and that potential radiation consequences to the facility staff and public were presented and compared with acceptable limits.

13b.4.1 Processes Conducted Outside of the Irradiation Facility

The processes that occur within the radioisotope production facility were evaluated by the applicant through the performance of an Integrated Safety Analysis (ISA) and expected generation of an ISA Summary. As part of the ISA analysis, the applicant evaluated the hazards associated with the processes in the radioisotope production facility. Section 13b.1.1 of the PSAR (Reference 13) contains information that provides assurance that all potential accidents at the RPF that could reach unmitigated and uncontrolled consequences of concern have been considered and their consequences adequately evaluated. SHINE considered postulated accidents in the categories identified below.

A summary of the evaluations for the radioisotope production facility falls into the following categories:

- Operations with Special Nuclear Material (SNM)
    - Irradiated target solution processing for radioisotope extraction
    - Irradiated target solution processing for reuse or for waste disposal
    - Processing with unirradiated SNM
- Radiochemical operations
- Operations with hazardous chemicals

In the course of reviewing SHINE's accident methodology, the staff determined that additional information was necessary to evaluate the adequacy of SHINE's methodology for determining the sequence of events in an accident scenario, including the qualifications of the ISA team. Therefore, RAI 13b.1-3 (Reference 16) was issued, in part, to satisfy the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13b.1.2, "Accident Initiating Events," which states that information in the PSAR should allow the reviewer to follow the sequence of events in the accident scenario from initiation to a stabilized condition. In response to this RAI (Reference 25), the applicant provided information that describes the ISA team that performed the preliminary ISA analysis of the adioisotope production facility. The staff reviewed the makeup of the ISA team provided and the applicable experience and expertise of the ISA team members. Team members were qualified in the areas of chemical safety, criticality safety, fire safety, and radiological safety, and multiple members were qualified, trained ISA team leaders, as required. The composition of the ISA team makeup and qualifications was consistent with the guidance of NUREG-1520 (Reference 60) and followed the requirements of 10 CFR 70.62(c)(2). The staff review finds that the team performing the preliminary ISA analysis, as described in response to RAI 13b.1-3 (Reference 25), to be acceptable as it contained members with technical expertise, ISA methodology knowledgeability, and operationally experienced personnel.

The applicant used two types of hazard assessment methods to evaluate the hazards of the RPF processes in the facility. These methods are a Hazards and Operability Study (HAZOPS), and a preliminary hazard analysis (PHA). A HAZOPS focuses on the evaluation of potential process upsets or deviations, which leads to identification of potential accidents and scenarios of concern which serve as input to the PHA and the identification of process safety controls. The PHA focuses on evaluating facility and external events that are common to the radioisotope production facility.

For the ISA methodology, the applicant provided likelihood and initiating event data for its preliminary ISA evaluations of the radioisotope production facility design. Acceptance criteria for radiological events and chemical hazards were provided by the applicant, similar to the requirements of 10 CFR 70.61. For the radiological events, the applicant uses 10 CFR Part 20 dose criteria rather than the 10 CFR 70.61 performance criteria. Given that the 10 CFR Part 20 criteria are more conservative than the 70.61 requirements, the staff finds that alternate approach acceptable. For chemical performance criteria, the applicant followed Part 70.61 limits. SHINE performed a PHA and HAZOPS on processes conducted outside the irradiation facility, and will provide the results of these evaluations in an ISA Summary for the RPF to be submitted as part of their application for an operating license.

However, in the course of reviewing SHINE's ISA process, the NRC staff determined that additional information was needed to asses the adequacy of SHINE's ISA process to its accident analysis. Therefore, in RAIs 13b.1-1 and 13b.1-2 (Reference 14), the staff requested that SHINE provide additional information on its accident sequences to understand how an ISA was performed for each process or process segment in the RPF. (See ISG Augmenting NUREG-1537, Part 2, Section 13b.1, "Radioisotope Production Facility Accident Analysis Methodology," which states that "an integrated safety analysis should be performed for each process or process segment" in the RPF). In response to these RAIs (Reference 21), and in a revision to PSAR Chapter 13, (Reference 61), SHINE provided a preliminary ISA Summary based on the current design of the facility that identified accident sequences with high or intermediate consequences, and designated safety-related structures systems and components (SR-SSCs) to prevent or mitigate the credible hazards to acceptable consequences. The majority of these SR-SSCs are passive and active engineered controls that will be constructed or installed during the CP phase of the SHINE project. SHINE PSAR Chapter 3, as supplemented by responses to RAIs, provided standards and reliability criteria for the passive and active engineered controls. While, administrative controls requiring the performance of operator actions were briefly described in the responses to RAIs 13b.1-1 and 13b.1-2, the management measures needed to justify their availability and reliability for performing their safety functions, as needed, were not described in detail. The staff finds that the preliminary ISA Summary provided by SHINE satisfies the requirements of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, and demonstrates an adequate design basis in support of a preliminary design. The staff will confirm that additional analyses and details on the ISA process and specific technical topics, such as on administrative controls and supporting management measures, conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on processes conducted outside the irradiation facility demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following relevant findings:

(1) The use of ISA methodologies as described in 10 CFR 70 and ISG Augmenting NUREG-1537, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61 and Part 20, and establishment of management measures demonstrate adequate safety for the radioisotopes production facility.

(2) The use of the performance criteria for demonstrating acceptable risk to the workers and public due to the credible hazards associated with the Radioisotope Production Facility are acceptable, including the use of Part 20 criteria for radiological related events.

(3) The staff also finds that the definitions of highly unlikely, unlikely and credible are consistent with the guidance in NUREG-1520 and are acceptable for use in the ISA analysis.

(4) The preliminary ISA performed by the applicant provides the basis to establish that the design of the facility including the associated structures, systems, and components can adequately assure that acceptable risk to the workers, public and the environment can be established and maintained. The evaluations performed by the applicant have resulted in the conditions needed to designate passive and active engineered safety controls needed for the safe operation of this section of the facility and for the processes performed in this section of the facility.

(5) Evaluations performed by the applicant will ensure that all nuclear processes will be subcritical during normal and credible abnormal operating conditions and that high consequence accidents are controlled to be highly unlikely, and that intermediate consequence accidents are controlled to be unlikely.

Therefore, the staff finds that the preliminary analysis of processes conducted outside the irradiation facility, as described in SHINE PSAR Sections 13b.1.1, and supplemented by the applicant's responses to RAIs, 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 the design basis during the evaluation of SHINE's FSAR.

13b.4.2 Accident Initiating Events

The staff reviewed the two types of hazard assessment methods the applicant selected to evaluate the hazards of the facility by evaluating specific accidents scenarios of various technical types. These methods are a HAZOPS and a (PHA). The HAZOPS focused on the evaluation of potential process upsets or deviations, which leads to identification of potential initiating events (IEs) and scenarios of concern and served as input to the PHA and the identification of process controls. The PHA focused on evaluating facility and external events that are common to the IF and RPF. These methods are typical methods used for the evaluation of hazards in fuel cycle facilities. The staff review included evaluation of the completeness of the hazards evaluated for the radioisotope production facility, as well as the determination of the preliminary likelihoods and consequences for each accident sequence event.

For the RPF, SHINE also analyzed an accident scenario with consequences exceeding all credible accidents, called the Maximum Hypothetical Accident (MHA). In the RPF, the MHA was identified as a release of inventory stored in the Noble Gas Removal System (NGRS) tanks, resulting in a maximum release of radiological material to the workers and individual members of the public.

The RPF accident analyses included all processes involving greater than critical mass (as defined in 10 CFR 70.4) quantities of SNM. The performance criteria in 10 CFR 70.61, "Performance Requirements," categorize accidents according to severity of consequences. These performance criteria require that high-consequence accidents to be rendered highly unlikely to occur through the application of in-depth preventive and mitigative measures. Other accidents with less than high consequences, as defined in 10 CFR 70.61, require fewer or lessstrict protective measures.

SHINE's RPF accident analyses identified structures, systems, components that SHINE has designated as SR-SSCs. SHINE intends to include the SR-SSCs in operating license technical specifications and apply the management measures needed to assure that the SSC's availability and reliability is well established and maintained.

The preliminary accident analyses for the operations with special nuclear material (SNM) in the radioisotope production facility included the following types of events:

- MHA
- External events
- Critical equipment malfunction
- RPF fire
- Chemical accidents.

In the course of reviewing SHINE's RPF accident analysis, the staff determined that additional information was necessary to evaluate the adequacy of SHINE's identification and analysis of accident sequences, from the initiating events through the sequence's mitigated consequences. Therefore, RAI 13b.1-3 (Reference 16) was issued, in part, to request that SHINE provide detailed accident sequence descriptions for at least four of the sequences listed in PSAR Table 13b.1-1-4, from the initiating events through the sequence's mitigating consequences. This information was necessary to understand how the PSAR allows the staff to follow the sequence of events in the accident scenario from initiation to a stabilized condition. (See NUREG-1537, Part 2, Section 13b.1.2, "Accident Initiating Events"). In response to this RAI (Reference 25), the applicant systematically analyzed and evaluated events in each category and identified the limiting event for each type for detailed quantitative analysis of the possible consequences. The limiting event in each category had consequences that exceed all others in that category. The applicant addressed the likelihood of occurrence for both the initiating events and the safety control failures in a qualitative manner consistent with the proposed methodology provided in the response to RAI 13b.1-3. Quantitative analysis of probability is not required and was not provided other than frequency of occurrence for certain external events. NRC staff reviewed SHINE's systematic analysis and discussion of credible accidents for determining the general types of accident sequences in each category, and finds that the response to RAI 13b.1-3 satisfies the requirements discussed in the ISG Augmenting NUREG-1537, Part 2, Section 13b.1.1 and demonstrates an adequate design basis in support of a preliminary design. Demonstration of meeting the risk-informed performance criteria was supported by the use of tables from NUREG-1510 that provided initiating event and failure likelihood scoring data, as well as a matrix for evaluating acceptability of the overall accident sequence risk. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on processes conducted outside the irradiation facility demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following relevant findings:

(1) SHINE has implemented an adequate preliminary safety program similar to the safety program in 10 CFR 70.62, including accident analysis and the future application of

management measures as described in Chapter 12 of the PSAR, "Conduct of Operations" (Reference 13).

(2) There is reasonable assurance that SHINE has addressed all significant credible accidents involving internal facility and processes, abnormal events and process deviations and credible external events that could result in serious adverse consequences to workers, the facility, the public, and the environment.

(3) SHINE has identified designated engineered and administrative SR-SSCs necessary to provide preventive or mitigative measures that give reasonable assurance that the facility will operate in compliance with the performance requirements proposed by the applicant.

(4) For the RPF, the results of the accident analysis demonstrate adequate safety by meeting the performance requirements proposed by the applicant for demonstrating acceptable risk.

(5) Information in the PSAR and in responses to staff RAIs allowed NRC staff to review the sequence of events in the accident scenario from initiation to a stabilized condition.

(6) NRC staff has reasonable assurance that all credible accidents at the RPF were considered and evaluated during the preliminary design stage. The demonstrations of the risk associated with credible accidents were shown to be adequate to prevent the release of radioactive materials, in amounts exceeding regulatory limits, to uncontrolled areas as a result of credible accidents.

(7) The applicant has considered the consequences to the public and the workers for all credible chemical accidents at the radioisotope production facility that reach the intermediate or high consequence thresholds as defined by the applicant.

Therefore, the staff finds that the preliminary analysis of accident initiating events, as described in SHINE PSAR Sections 13b.1.2, and supplemented by the applicant's responses to RAIs, 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 the design basis during the evaluation of SHINE's FSAR.

13b.4.3 *Maximum Hypothetical Accident*

As described in SHINE PSAR Sections 13a2.1.1, "Maximum Hypothetical Accident," and 13a2.2.1, "Target Solution Release into the IU Cell," SHINE considered an MHA for the IF as well as the RPF. While an evaluation of the MHA for the IF is provided in SER Section 13a.4.1, the RPF postulated MHA, as described in SHINE PSAR 13b.2.1, "Maximum Hypothetical Accident in the RPF," provides the bounding consequences to the public and is therefore considered the MHA for the SHINE facility. An evaluation of the RPF postulated MHA is provided below.

For the RPF, SHINE analyzed an accident scenario with consequences exceeding all credible accidents, called the Maximum Hypothetical Accident (MHA). In the RPF, the MHA was identified as a release of inventory stored in the Noble Gas Removal System (NGRS) tanks, resulting in a maximum release of radiological material to the workers and individual members of the public.

The dose consequences of the MHA are calculated to be within the regulatory limits of 10 CFR Part 20. A TEDE of 3.59 rem calculated for the workers at the facility. This on-site dose is less than the 5 rem regulatory limit specified in 10 CFR 20.1201. A TEDE of 0.0820 rem is calculated for a member of the public at the site boundary, and a TEDE of 0.0115 rem is calculated at the nearest residence. The off-site doses are less than the 0.1 rem regulatory limit specified in 10 CFR 20.1301.

Because the assumptions of the scenario are bounding, the doses calculated will likely not be exceeded by any accident considered credible. The applicant has also examined more realistic assumptions about operating time and release fractions that decreased the source term significantly compared to the one calculated for the MHA. The staff finds that for the MHA, the health and safety of the facility staff and the public are protected.

On the basis of its review, the staff finds that the level of detail provided on SHINE's MHA demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following relevant findings:

(1) The exposure time of workers is assumed to be 10 minutes, which should be conservative for workers trained to evacuate in the event of a radiological release.

(2) For the preliminary design, the confinement and engineered safety features are assumed to function as designed and radioactive material is held up temporarily in the facility and then released under controlled conditions. Realistic but conservative methods are used to compute potential doses and dose commitments to the public in uncontrolled areas and to compute external radiation doses and dose commitments resulting from inhalation by the facility staff. Methods of calculating doses from inhalation or ingestion (or both) and direct exposure to gamma rays from dispersing plumes of airborne radioactive material are applicable and no less conservative than those developed in Chapter 11 of the SAR.

(3) The applicant has considered the consequences to the public and the facility staff of all credible accidents at the radioisotope production facility. An (MHA, which, for this facility, is a release of inventory stored in the NGRS tanks with consequences greater than any credible accident, has been analyzed. The MHA, however, is not considered to be a credible event for this facility. The RPF MHA serves as a bounding accident analysis for the SHINE facility.

(4) Because the assumptions of the scenario are bounding, the doses calculated will likely not be exceeded by any accident considered credible. The applicant has also examined more realistic assumptions about operating time and release fractions that decreased the source term significantly compared to the one calculated for the MHA. Thus, even for the RPF MHA, whose consequences bound all credible accidents possible at the facility, the health and safety of the facility staff and the public are protected.

Therefore, the staff finds that the preliminary analysis of the MHA, as described in SHINE PSAR Section 13b.2.1, 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 the design basis during the evaluation of SHINE's FSAR.

13b.4.4 *Loss of Containment*

SHINE PSAR Sections 6a2.2.2, and 6b.2.2, "Containment," state, in part, that "[t]he SHINE facility does not employ a containment feature. Due to the low temperature and power level of facility operations, the safety analysis demonstrates that confinement features are adequate to mitigate potential accidents." In PSAR Section 13b.2.2, "Loss of Containment," SHINE further states that "[t]he use of confinements as an ESF [engineered safety feature] in the RPF is described in [PSAR] Section 6b.2.1. Control of the target solution is performed by piping systems and tanks. A loss of the integrity of piping systems or tanks containing target solution within the RPF is addressed in [PSAR] Subsection 13b.2.4."

On the basis of its review, the staff finds that the SHINE confinement features are adequate to mitigate potential accidents and a containment feature is not necessary. SHINE demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1.

Therefore, the staff finds that the loss of containment event, as described in SHINE PSAR Section 13b.2.2, 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 the design basis during the evaluation of SHINE's FSAR.

13b.4.5 *Loss of Normal Electric Power*

SHINE PSAR Sections 13b.2.1 and 13b.2.4 discuss the events that could result from the sudden loss of normal electrical power. As stated, in part, in SHINE PSAR Section 13b.2.4, "[t]he isolation dampers are of a fail-safe design, and close on…a loss of power. The total release to RVZ1 through the bubble-tight isolation dampers during the accident is assumed to be no more than 10 percent of the airborne activity in the noble gas storage cell based on design characteristics of the dampers and the response of the RAMs."

On the basis of its review, the staff finds that the level of detail provided on SHINE's loss of normal electrical power demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following relevant findings:

(1) All SR-SSCs are returned to a safe condition in a de-energized state. Any requirement for emergency cooling or ventilation functions is provided as intended in the facility design.

(2) The loss of normal electrical power will not result in an unsafe condition for either the facility staff or members of the public in uncontrolled areas. Chapter 8 of the PSAR describes emergency power to the facility. The emergency supply will power the safety-related equipment and systems required to operate after the loss of normal power.

Therefore, the staff finds that the loss of normal electrical power event, as described in SHINE PSAR Sections 13b.2.1 and 13b.2.4, 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 the design basis during the evaluation of SHINE's FSAR.

13b.4.6 *External Events*

In SHINE PSAR Section 13b.2.3, the applicant has identified seismic events, tornados or high winds, and a small aircraft crash as external events that can affect the RPF. These are treated as design basis accidents for the facility. Flooding has been ruled out due to the site location. The SHINE facility has been designed to survive design basis earthquake, tornado and wind loads including missiles, and aircraft impacts and keep the facility safety functions intact.

On the basis of its review, the staff finds that the level of detail provided on SHINE's external events demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

(1) Chapters 2 and 3 of the PSAR discuss the design of the RPF structures, systems, and components to withstand external events and the potential associated accidents. The radioisotope production facility is designed to withstand the effects of these events. Process operations could continue, provided that there would not be undue risk to the health and safety of the staff, the public, and the environment. Consequences of natural external events that cause facility damage (e.g., seismic events that damage the confinement or containment) are within the bounds discussed for other accidents in this chapter. Therefore, exposure to the staff and the public is within acceptable limits, and external events do not pose an unacceptable risk to the health and safety of the public.

Therefore, the staff finds that the preliminary analysis of external events, as described in SHINE PSAR Section 13b.2.3 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 the design basis during the evaluation of SHINE's FSAR.

13b.4.7 *Mishandling or Malfunction of Equipment*

SHINE PSAR Section 13b.2.4 presents the evaluation of a malfunction or mishandling of equipment (including vessel/line/valve failures, valve misalignments, and other process equipment failures) that leads to a loss of control of radiological material within the RPF.

Processes conducted within the RPF include the target solution preparation, molybdenum extraction, molybdenum purification, molybdenum packaging, uranyl nitrate conversion, target solution cleanup (UREX), thermal denitration, waste processing, noble gas decay storage, and process vessel vent gas treatment. Most of the associated process piping, vessels, and components are located within hot cells or other enclosures. However, transfer between the major processes is via transfer piping located along pipe trenches in the RPF. The liquid/aqueous radiological process streams that traverse the RPF are the target solution, uranyl nitrate solution, and UREX raffinate. Gaseous transfer lines are also present to transfer off gases from the IF to the NGRS for decay storage. Other process streams exist; however, the above processes represent the greatest radiological risk. Equipment malfunctions, including a loss of integrity of these solution and gas lines, presents the possibility of a radiological release at various locations in the RPF.

The molybdenum extraction, purification, and packaging takes place within the three separate sections of a hot cell referred to as a supercell. There are three supercells within the RPF that are operated in parallel, but independently, to process separate batches of irradiated target solution to extract, purify, and package the molybdenum product. The liquid and solid waste processing, pumping equipment, and storage tanks are located in hot cells and vaults located within the RPF. The NGRS equipment is located within a separate shielded cell within the RPF. Section 13b.2.4 addresses the potential for an inadvertent release of radiological material along the transfer lines throughout the RPF and within process hot cells and shielded cells due to a malfunction of critical equipment. The discussion includes initial conditions and assumptions, identification of causes, sequences of events, damage to equipment, quantitative evaluation of accident evolution, radiation source term analysis, radiological consequence analysis, and safety controls. NRC staff reviewed this discussion and the ISA Summary information in Tables 13b.1-1-4, “Potential Accident Sequences,” and 13b.1-2-1, “Accident Sequences and Associated IROFS,” and determined that the designated SR-SSCs will be available and reliable to control accident consequences and likelihoods to the standards proposed in PSAR Section 1.2.4 Design Features and Design Bases.

The dose consequences of a loss of control of radiological material within the RPF is calculated to be within the regulatory limits of 10 CFR Part 20. A TEDE of 3.58 rem is calculated for the workers at the facility. This on-site dose is less than the 5 rem regulatory limit specified in 10 CFR 20.1201. A TEDE of 0.0817 rem is calculated for a member of the public at the site boundary, and a TEDE of 0.014 rem is calculated at the nearest residence. The off-site doses are less than the 0.1 rem regulatory limit specified in 10 CFR 20.1301.

On the basis of its review, the staff finds that the level of detail provided on SHINE’s loss of control of radiological material within the RPF event demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following relevant findings:

(1) The exposure time of workers is assumed to be 10 minutes, which should be conservative for workers trained to evacuate in the event of a radiological release.

(2) The applicant adequately considered the consequences of loss of control of radiological material within the RPF events. The consequences of the RPF mishandling or malfunction events have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of the RPF mishandling or malfunction events, as described in SHINE PSAR Section 13b.2.4 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 the design basis during the evaluation of SHINE’s FSAR.

13b.4.8 Inadvertent Nuclear Criticality in the Radioisotope Production Facility

In SHINE PSAR Section 13b.2.5.2, "Identification of Causes," SHINE discussed four distinct types of postulated criticality scenarios for which engineered controls an design features have been designed to prevent:

(1) Accumulation of metal or oxide fissile material outside of a radiation shielded area of the facility, resulting in an inadvertent criticality.
(2) Accumulation of irradiated solution within a radiation shielded area of the facility, resulting in an inadvertent criticality.
(3) Accumulation of un-irradiated solution outside of a radiation shielded area of the facility, resulting in an inadvertent criticality.
(4) Accumulation of metal or oxide fissile material within a radiation shielded area of the facility, resulting in an inadvertent criticality.

Since SHINE considers an inadvertent criticality event in the RPF as highly unlikely, as it would be prevented by multiple passive safety-related SSCs and administrative controls under an approved margin of subcriticality, no radiological consequence analysis was performed for a radiological consequence analysis.

On the basis of its review, the staff finds that the level of detail provided on SHINE's inadvertent criticality events demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13a2, allowing the staff to make the following relevant finding:

> Since inadvertent criticality events in the RPF are highly unlikely, it is not necessary to perform a radiological consequence analysis. The safety and health of the staff and public will be adequately protected as a result of multiple passive safety-related SSCs and administrative controls designed to prevent a criticality event under an approved margin of subcriticality.

Therefore, the staff finds that the preliminary analysis of inadvertent criticality events, as described in SHINE PSAR Sections 13b.2.5, 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 the design basis during the evaluation of SHINE's FSAR.

13b.4.9 Radioisotope Production Facility Fire

As described in SHINE PSAR Section 13b.2.6, the IF contains processes associated with extraction and purification of the Mo-99 product from irradiated target solution, preparation and recycling of the target solution, and the waste processing. Individual chemical processes are located in hot cells and glove boxes which are connected via piping located in pipe trenches throughout the RPF. The equipment and processes in the RPF present a potential for fire. Ignition and fuel sources in this area are primarily small in nature, with the greatest hazards located within process enclosures. In addition to combustibles related to the equipment, there is also the potential for the accumulation of hydrogen in a noble gas storage tank.

The applicant identified potential fire events in the RPF that could occur during operations and maintenance activities and lead to radioactive releases. Fires that started inside the RPF and external fires that propagate into the RPF were considered. Both in-situ and transient sources of combustible material were considered as fuel sources for the fire.

The dose consequences of a fire within the RPF is calculated to be within the regulatory limits of 10 CFR Part 20. A TEDE of 0.578 rem is calculated for the workers at the facility. This on-site dose is less than the 5 rem regulatory limit specified in 10 CFR 20.1201. A TEDE of 0.000877 rem is calculated for a member of the public at the site boundary, and a TEDE of 0.000123 rem is calculated at the nearest residence. The off-site doses are less than the 0.1 rem regulatory limit specified in 10 CFR 20.1301.

On the basis of its review, the staff finds that the level of detail provided on RPF fires demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.1, allowing the staff to make the following relevant findings:

(1) The exposure time of workers is assumed to be 10 minutes, which should be conservative for workers trained to evacuate in the event of a radiological release.

(2) The applicant adequately considered the consequences of fires within the RPF. The consequences of the RPF fire event have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

Therefore, the staff finds that the preliminary analysis of RPF fires, as described in SHINE PSAR Sections 13b.2.6, 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 the design basis during the evaluation of SHINE's FSAR.

13b.4.10 Analyses of Accidents with Hazardous Chemicals Produced from Licensed Material

The staff evaluated the sufficiency of the analysis of accidents with hazardous chemicals produced from licensed material, as described in SHINE PSAR Section 13b.3, "Analyses of Accidents with Hazardous Chemicals Produced from Licensed Material," in part, by reviewing the chemical accidents description, chemical accident consequences, chemical process controls, and chemical process surveillance requirements using the guidance and acceptance criteria from Section 13b.2, "Chemical Process Safety for the Radioisotope Processing Facility," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 13b.2, the staff determined whether the application comprehensively described the chemical safety of the licensed activity.

NRC staff's chemical process safety review focused on chemical safety-related accidents, chemical safety controls, and the corresponding surveillance requirements to ensure that SHINE's proposed equipment and facilities are adequate to protect against releases and chemical exposures of licensed material, hazardous chemicals produced from licensed material, and chemical risks of plant conditions that affect the safety of licensed material.

The 1988 memorandum of understanding between the NRC and the Occupational Safety and Health Administration directs the NRC to oversee chemical safety issues related to (1) radiation risks of licensed materials, (2) chemical risks of licensed materials, and (3) plant conditions that affect or may affect the safety of licensed materials and thus increase radiation risk to workers, the public, and the environment. The NRC does not oversee plant conditions that do not affect or involve the safety of licensed materials.

The chemical process descriptions and chemical accidents determined by the applicant are the bases for the chemical process safety evaluation. NRC staff established that SHINE’s facility design, operations, and safety controls for chemical safety provide reasonable assurance that they will function as intended and ensure the safe handling of licensed material at the facility. NRC staff verified that SHINE’s description of proposed equipment and facilities provide reasonable assurance that they will be adequate to protect public health and safety and the environment. NRC staff examined the mechanisms, described in PSAR Section 13b.2, that will allow the applicant to identify and correct potential problems.

PSAR Section 13b described the potential accidents caused by process deviations or other events internal to the facility and credible external events, including natural phenomena. NRC staff assessed the chemical risks to ensure that the design for the facility reflects the level of safety.

NRC staff verified that the proposed quantitative standards used to assess the consequences to an individual and the public from acute chemical exposure are appropriate. Events with high potential consequences are identified in the accident analysis, and controls are proposed to reduce the likelihood or the consequences of the event. NRC staff ensured that the select standards are correctly applied to the workers and to the member of the public.

NRC staff reviewed the chemical process ESFs described in PSAR Section 6b, to ensure their adequacy in protecting against all unmitigated accidents identified by the applicant. NRC staff established that the applicant’s controls for chemical safety provide reasonable assurance that they will function as intended and ensure the safe handling of licensed material at the facility.

SHINE has proposed a graded approach to safety, described in PSAR Chapter 12, Appendix 12C. NRC staff established that the grading of controls or management measures is appropriate and sufficient to protect against chemical process risks.

NRC staff found SHINE’s chemical process safety information acceptable because it includes a description of each process in the facility. Process descriptions are sufficiently detailed to allow an understanding of the chemical process hazards (including radiological hazards caused by or involving chemical accidents) and to allow the development of potential accidents, and process descriptions are sufficiently detailed to allow an understanding of the theory of operation.

NRC staff determined that the PSAR comprehensively describes the chemical safety of the proposed activity.

On the basis of its review, the staff finds that the level of detail provided on the analysis of accidents with hazardous chemicals produce from licensed material demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 13b.2, allowing the staff to make the following relevant findings:

(1) The NRC staff has evaluated the application using the criteria in the Interim Staff Guidance to NUREG-1537. Based on the review of the PSAR, the NRC staff has concluded that SHINE has adequately described and assessed accident consequences that could result from the handling, storage, or processing of licensed materials and that could have potentially significant chemical consequences and effects. SHINE has constructed a hazard analysis that identified and evaluated those chemical process hazards and potential accidents and established safety controls to provide reasonable assurance of safe facility operation. To ensure that the requirements for acceptability are met, the applicant has provided reasonable assurance that ESFs are likely to be available and reliable when required to perform their safety functions. The staff has reviewed these safety controls and the applicant's plan for managing chemical process safety and finds them acceptable.

(2) The NRC staff concludes that both the applicant's plan for managing chemical process safety and the chemical process safety controls meet the requirements of the regulations and provide reasonable assurance that the health and safety of the public will be protected and that construction of the facility in accordance with Part 50 requirements can be permitted.

Therefore, the staff finds that the preliminary analysis of accidents with hazardous chemicals produced from licensed material, as described in SHINE PSAR Sections 13b.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 the design basis during the evaluation of SHINE's FSAR.

13b.4.11 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 supporting the SHINE accident analysis, with special attention given to those items which may significantly influence the final design.

SHINE PSAR Table 13b.2.5-1, "Safety-Related SSCs and Technical Specification Administrative Controls to Prevent Criticality Accidents," lists probable administrative technical specification controls to prevent criticality events, including controls placed on solution sampling, filters, differential pressure monitors, and solvent control program.

SHINE PSAR Section 13b.2.6.8, "Safety Controls," lists installed combustible loading in the RPF and process enclosures is low; administrative control of the admission and storage of transient combustible materials and the performance of hot work is maintained in the RPF; and use of and storage of flammable and combustible liquids and gases is in accordance with the facility fire protection program as probable administrative technical specification controls to ensure 10 CFR Part 20 dose limits are not exceeded during an RPF fire event.

SHINE PSAR Section 13b.3.4, "Chemical Process Surveillance Requirements," states that "[p]otential variables, conditions, or other items that will be probable subjects of a technical specification associated with chemical processes controls are provided in Chapter 14." PSAR Sections 14b.2, "Safety Limits and Limiting Safety System Settings," and 14b.2, "Limiting Conditions for Operation," provide the methodology to be employed for selecting safety limits (SLs), limiting safety system settings (LSSSs), and Limiting Conditions for Operation (LCOs) for radiochemical and chemical processing in the SHINE RPF.

Based on the information provided in PSAR Table 13b.2.5-1, as well as Sections 13b.2.6.8, 13b.3.4, 14b.2, an 14b.3 of the SHINE PSAR, the staff finds that identification and justification of the proposed technical specifications, SLs, LSSSs, and LCOs is sufficient and meets the applicable regulatory requirements to support the issuance of a construction permit in accordance with 10 CFR 50.35. A complete evaluation of technical specifications, LCOs, and surveillance requirements will be performed during the review of SHINE's operating license application.

13b.5 Summary and Conclusions

The staff evaluated descriptions and discussions of SHINE's RPF accident analysis, including probable subjects of technical specifications, as described in SHINE PSAR Section 13b and supplemented by the applicant's responses to RAIs, and finds that the preliminary accident analysis, including the principal design criteria; design bases; information relative to materials of construction, general arrangement, and approximate dimensions; and preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility: (1) provides reasonable assurance that the final design will conform to the design basis, (2) includes an adequate margin of safety, (3) structures, systems, and components adequately provide for the prevention of accidents and the mitigation of consequences of accidents, and (4) meets all applicable regulatory requirements and acceptance criteria in or referenced in ISG Augmenting NUREG-1537.

The staff further notes that SHINE PSAR Section 13b contains sufficient information to conclude that the engineered safety features would be expected to function as designed to perform their safety functions, and radioactive and chemical hazards associated with SNM can be prevented or mitigated to levels that are acceptable. Realistic, but conservative methods, were used to compute or estimate potential doses and dose commitments to the public in uncontrolled areas and to compute external radiation doses and dose commitments resulting from inhalation by the facility workers. Methods of calculating doses from inhalation or ingestion (or both) and direct exposure to gamma rays from dispersing plumes of airborne radioactive material are applicable and no less conservative than those developed in Chapter 11 of the PSAR.

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 systems supporting the accident analysis, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(2) Further technical or design information required to complete the safety analysis of the cooling systems may reasonably be left for later consideration the FSAR; and

(3) Taking into consideration the site criteria contained in Part 100, there is reasonable assurance that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.