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6.0 ENGINEERED SAFETY FEATURES

Engineered safety features (ESFs) are active or passive features designed to mitigate the consequences of accidents and to keep radiological exposures to the public, the facility staff, and the environment within acceptable values at the SHINE Medical Technologies, Inc. (SHINE) irradiation facility (IF) and radioisotope production facility (RPF). The concept of ESFs evolved from the defense-in-depth philosophy of multiple layers of design features to prevent or mitigate the release of radioactive materials to the environment during accident conditions. The need for ESFs is determined by SHINE's accident analysis.

This chapter of the SHINE construction permit (CP) safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) of the preliminary design of the SHINE IF and RPF ESFs as presented in Chapter 6, "Engineered Safety Features," of the SHINE Preliminary Safety Analysis Report (PSAR), as supplemented by the applicant's responses to requests for additional information (RAIs).

6a Irradiation Facility Engineered Safety Features

SER Section 6a, "Irradiation Facility Engineered Safety Features," provides an evaluation of the preliminary design of SHINE's IF ESFs, as presented in SHINE PSAR Section 6a2, "Irradiation Facility Engineered Safety Features," within which, features designed to mitigate consequences of accidents and events in order to keep radiological exposures within acceptable values are described.

6a.1 Areas of Review

The staff reviewed PSAR Section 6a2 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of the SHINE IF ESFs. As part of this review, the staff evaluated descriptions and discussions of the SHINE IF ESFs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the SHINE IF ESFs was evaluated to ensure the sufficiency of principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items, which are determined to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design.

Areas of review for this section included a summary description of the IF ESFs, as well as a detailed description of the IF confinement. Within these review areas, the staff assessed, in part, the design bases and functional descriptions of the required mitigative features of the confinement ESFs; drawings, schematic drawings and tables of important design and operating parameters, and specifications for confinement ESFs; necessary ESF equipment included as part of the confinement fabrication specifications; description of control and safety instrumentation, including locations and functions of sensors, readout devices, monitors and isolation components, as applicable; and the required limitations on the release of confined effluents to the environment.

6a.2 Summary of Application

PSAR Section 6a2.2.1.2, "Confinement Systems and Components," provides additional details on the specific SSCs making up the confinement system for the IF. This includes information on the mitigation of uncontrolled releases occurring within an irradiation unit (IU) cell, target solution vessel off gas system (TOGS) shielded cell, and the tritium purification system (TPS) glovebox by the confinement system. PSAR Section 6a2.2.1.3, "Functional Components," provides a brief description on the failure state of active components of the confinement system during upset conditions or in adverse conditions. This section also discusses single failure events, redundancy and independencies of design of systems, and components required to perform a safety function. PSAR Section 6a2.2.1.4, "Confinement Component," identifies and provides details on the components associated with the secondary confinement barrier of the IU cells, TOGS shielded cell, or TPS glovebox. This section also provides references to design, fabrication, and testing codes that will be used for the development of components. PSAR Section 6a2.2.1.5, "Engineered Safety Feature Test Requirements," describes general approaches to testing requirements and features for ESF components and systems. PSAR Section 6a2.2.1.6, "Design Basis," provides a general discussion of codes and standards to be used for the SHINE facility and supporting ESFs with cross references to PSAR Chapter 3, "Design of Structures, Systems, and Components;" Chapter 4, "Irradiation Unit and Radioisotope Production Facility Description;" Chapter 7, "Instrument and Control Systems;" Chapter 9, "Auxiliary Systems;" and Chapter 14, "Technical Specifications." As discussed in SHINE PSAR Sections 6a2.2.2, "Containment," and 6a2.3, "Emergency Cooling System," the SHINE facility does not have a containment nor does it have an emergency core cooling system.

Additionally, PSAR Table 6a2.1-1, "Summary of IF Design Basis Accidents and ESF Provided for Mitigation," summarizes the three design-basis accidents (DBAs) mitigated by the confinement ESF, including a list of structures, systems, and components (SSCs) that provide an ESF.

6a.3 Regulatory Basis and Acceptance Criteria

The staff reviewed SHINE PSAR Section 6a2 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the SHINE IF ESFs in support of the issuance of a construction permit. In accordance with paragraph (a) of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.35, "Issuance of Construction Permits," a construction permit authorizing SHINE to proceed with construction may be issued once the following findings have been made:

(1) SHINE has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.
(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).
(3) Safety features or components, if any, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

The staff's evaluation of the preliminary design of the SHINE IF ESFs 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 IF ESFs as described in the FSAR as part of SHINE's operating license application.

6a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's IF ESFs 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."

6a.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated SHINE's IF ESFs against the applicable regulatory requirements listed above primarily using the guidance and acceptance criteria contained in Chapter 6, "Engineered Safety Features" of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 4), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 5), as well as the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 6, and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 7).

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers [IEEE] standards, American National Standards Institute/American Nuclear Society [ANSI/ANS] standards) has been utilized in the review of SHINE's ESFs. The use of additional guidance is based on the technical judgement of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG Augmenting NUREG-1537, Parts 1 and 2; and the SHINE PSAR.

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 6a.4 of this SER. Additional guidance documents used to review SHINE's ESFs are provided as references in Appendix B.

6a.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in SHINE PSAR Section 6a2, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of the SHINE IF ESFs in support of the issuance of a construction permit, in accordance with 10 CFR 50.35(a). Sufficiency of the preliminary design and performance of the SHINE IF ESFs is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 6a.3, "Regulatory Basis and Acceptance Criteria," of this SER. While the technical evaluation of these systems provided in this section is specific to the SHINE IF, the staff's review considers the interface of these systems 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 6a.5, "Evaluation Findings and Conclusion."

For the purposes of issuing a CP, the preliminary design of the SHINE IF ESFs may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the SHINE IF ESFs based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of the SHINE IF ESFs 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 IF ESFs, as described in the FSAR, as part of SHINE's operating license application.

6a.4.1 Summary Description

The staff evaluated the sufficiency of SHINE's summary description of its IF ESFs, as described in SHINE PSAR Section 6a2.1, "Summary Description," and supplemented by the applicant's responses to RAIs, using the guidance from Section 6.1, "Summary Description," of NUREG-1537, Parts 1 and 2.

NUREG-1537, Part 1, Section 6.1, "Summary Description," states:

> In this section of the SAR, the applicant should briefly describe all of the ESFs in the facility design and summarize the postulated accidents they are designed to mitigate. These summaries should include the design bases and performance criteria and contain enough information for an overall understanding of the functions of the ESFs and the reactor conditions under which the equipment or systems must function.
>
> Simple block diagrams and drawings may be used to show the location, basic function, and relationship of each ESF to the facility. Detailed drawings, schematic diagrams, data, and analyses should be presented in subsequent sections of this chapter for specific ESFs.

NUREG-1537, Part 2, Section 6.1, "Summary Description," states:

> In this section of the SAR, the applicant should briefly describe all the ESFs in the facility design and summarize the postulated accidents whose consequences could be unacceptable without mitigation. A specific postulated accident scenario should indicate the need for each ESF. The details of the accident analyses should be given in Chapter 13 of the SAR and the detailed discussions

> of the ESFs in Section 6.2 of the SAR. These summaries should include the design bases, the performance criteria, and the full range of reactor conditions, including accident conditions, under which the equipment or systems must maintain function.
>
> The applicant may submit simple block diagrams and drawings that show the location, basic function, and relationship of each ESF to the facility. The summary description should contain enough information for an overall understanding of the functions and relationships of the ESFs to the operation of the facility. Detailed drawings, schematic diagrams, data, and analyses should be presented in Section 6.2 of the SAR for each specific ESF.

The ISG Augmenting NUREG-1537, Part 1, Section 6a2, "Aqueous Homogeneous Reactor Engineered Safety Features," states, in part: "… the guidance in this section is general enough to apply to any type of reactor facility, as long as the unique features of each are addressed and appropriate ESFs are provided to ensure that operations are conducted within safe limits."

The information in SHINE PSAR Section 6a2 forms the basis for evaluations performed in PSAR Chapter 13, "Accident Analysis." PSAR Section 6a2.1 provides PSAR Table 6a2.1-1, which describes the ESFs required to maintain the confinement function during three DBAs analyzed in SHINE PSAR Chapter 13. However, the staff determined that while Section 6a2.1 of the SHINE PSAR contains a description of the ESFs for the IF, it did not contain enough information for an overall understanding of the functions of the ESFs.

Therefore, in RAI 6a2.1-1 (Reference 14), the staff requested that the applicant provide a description of the conditions under which ESFs must function; block diagrams and drawings to clarify the location, basic function, and the relationship of each ESF to the facility; whether the target solution preparation systems (TSPSs) are part of the IF or the RPF; and whether any valves or piping located in the target solution preparation system room are considered part of the confinement boundary for either or both the IF or the RPF.

In response to RAI 6a2.1-1 (Reference 21), the applicant stated the conditions under which the ESFs were required to operate included: Mishandling or malfunction of target solution; Mishandling or malfunction of equipment affecting the PSB; and Tritium Purification System (TPS) DBA. The postulated accidents could potentially result in releases of radioactive materials with high radiation fields in the IU cells, primary cooling (PCLS and LWPS) rooms, TOGS shielded cells, and TPS gloveboxes. Additionally, the applicant stated that structures and components will be designed to perform their confinement function under adverse conditions for the duration of the accident, including: expected radiation exposure levels, acidic chemical environment, and capable of performing in environments determined from the fire hazards analysis. Additionally, the applicant provided a new block diagram, PSAR Figure 6a2.1-1-1, showing the basic function and relationship of the SSCs providing the confinement ESF in the IF to the facility, as well as the relationship between each ESF SSC in the confinement. The SSCs providing in the confinement ESF are: IU cells, including penetration seals, RVZ1 ductwork up to bubble-tight isolation dampers, Bubble-tight isolation dampers, Isolation valves on piping systems penetration the IU cells, TOGS shielded cells, including penetration seals, Engineered Safety Features Actuation System (ESFAS), Double-walled pipe used for the TPS, TPS gloveboxes, and TPS confinement system. Further, the applicant stated the TSPS is part of the RPF and valves and piping located inside the TSPS room are not expected to be part of the confinement boundary for either the IF or the RPF.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.1 and demonstrates adequate design criteria 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 in the summary description of the SHINE IF ESFs demonstrates an adequate design basis in support of a preliminary design.

Therefore, the staff finds that the summary description of the SHINE IF ESFs, as described in SHINE PSAR Section 6a2.1, 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 this design basis during the evaluation of SHINE's FSAR.

6a.4.2 Confinement

The staff evaluated the sufficiency of the preliminary design of the SHINE confinement and related systems as described in SHINE PSAR 6a.2.2.1, "Confinement," in part, by reviewing confinement mitigation requirements, the defined confinement envelope, and detailed descriptions of the ESFs associated with confinement. Additionally, the staff evaluated the passive and active ESF components, under normal and upset operational conditions. The functional requirements, design bases, probable subjects of technical specifications, and testing requirements were also evaluated for sufficiency.

In accordance with the review procedures of NUREG-1537, Part 2, Section 6.2.1, "Confinement," the staff: (1) reviewed the accident scenarios analyzed in PSAR Chapter 13 and evaluated whether the confinement will sufficiently mitigate consequences; (2) reviewed design and functional bases against analyzed accidents; and, (3) compared diffusion and dispersion of released airborne radionuclides.

SHINE PSAR, Section 6a2.2.1.2, "Confinement System and Components," states, in part, that "[t]his ESF effectively reduces the amount of ductwork in the confinement volume that needs to remain intact to achieve IU cell, TOGS shielded cell, or TPS glovebox confinement."

In RAI 6a2.2-2 (Reference 14), the staff asked the applicant to provide clarification regarding the meaning of this sentence.

In response to RAI 6a2.2-2 (Reference 20), the applicant stated, in part, that:

> PSAR Section 6a2.2.1.2 provides a discussion of the IF confinement systems and components that help to mitigate the consequences of a potential accident. These confinement systems and components include bubble-tight isolation dampers that isolate the ductwork into and out of a confinement area following a confinement isolation signal resulting from high radiation. PSAR Figure 9a2.1-1 shows typical cell isolation dampers adjacent to their respective cells.

The applicant also stated, in part, that:

> …[its] design locates the isolation dampers as close as practical to the confinement area. When the isolation dampers for a cell or glovebox close on the receipt of a confinement isolation signal, the spread of contamination is limited to that cell or glovebox plus the small amount of ductwork between the cell or glovebox and its isolation dampers. Ductwork downstream of an isolation damper therefore does not need to remain intact to achieve confinement of the IU cell, TOGS shielded cell, or TPS glovebox. Since contamination is prevented from spreading through the ventilation system, the total potential for leakage is reduced by minimizing the amount of ductwork in contact with contaminated material following a design basis accident.

The staff finds this response provides sufficient clarification of the aforementioned statement found in PSAR Section 6a2.2.1.2. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

SHINE PSAR, Section 6a2.2.1.2, "Confinement System and Components," states, in part, that "[a] failure of the TPS outside the glovebox is mitigated by the TPS confinement system. The TPS confinement system uses isolation valves to stop a tritium leak outside the glovebox when a leak is detected." Additional information was needed for the NRC staff to determine the adequacy of the design of the TPS confinement system.

Therefore, in RAI 6a2.2-3 (Reference 14), the staff asked the applicant to provide additional information on the design and function of the TPS confinement system, including the ability of the system to stop tritium leaks outside of the glovebox.

In response to RAI 6a2.2-3 (Reference 21), the applicant stated, in part, that:

> …the TPS confinement system boundaries consist of:
>
> - the TPS gloveboxes, including the pressure protection bubbler and glovebox airlock;
> - the outer jacket of double-walled piping that transfers tritium outside of gloveboxes; and
> - the TPS confinement isolation valves that isolate portions of the tritium system upon loss of integrity to limit tritium releases.

The applicant further stated, in part, that:

> …tritium outside the glovebox is contained in piping normally under vacuum, which assists in reducing the potential for releases. Pressure detection is expected be used to monitor for a leak in these lines, since an unexpected increase in pressure indicates a potential leak. Once the pressure rises past the allowable set points, isolation valves will close in order to reduce the potential amount of tritium released. The confinement isolation valve closure time will be accounted for in the accident analysis and the assumed value will be bounding. The only significant portion of the tritium inventory that is not in a confinement area or double-walled piping is the tritium in the neutron drivers. The evaluation of the release of tritium from the neutron drivers is described in Subsection 13a2.2.12.3. Isolation valves will isolate the NDAS from the TPS should a leak in NDAS be detected.

Isolation valve locations will be determined during detailed design and provided in the FSAR. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds this response provides sufficient detail regarding the TPS confinement system and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

SHINE PSAR, Section 6a2.2.1.3, "Functional Requirements," states, in part, "[a]ctive confinement components are designed to fail into a safe state if conditions such as loss of signal, loss of power, or adverse environments are experienced." Additional information is needed for the NRC staff to determine the adequacy of the SHINE design to withstand and mitigate adverse environments.

Therefore, in RAI 6a2.2-4 (Reference 14), the staff asked the applicant to provide information on the assumed "adverse environments" and how components are designed to accommodate for them.

In response to RAI 6a2.2-4 (Reference 21), the applicant stated, in part, that:

> …the assumed adverse environments for the active confinement components in the IF are due to the release of radioactive materials. These assumed adverse environments are high radiation fields in the IU cells, primary cooling (PCLS and LWPS) rooms, TOGS shielded cells, and TPS gloveboxes, and acidic environments in the PCLS and LWPS. The active confinement components (e.g., isolation dampers, isolation valves) will be designed to perform their functions under the expected radiation conditions for the duration of the accident. The active confinement components that may be exposed to acidic environments (e.g., isolation valves on PCLS and LWPS) due to target solution release will be chemically compatible with the target solution. Except for dampers credited for isolation during postulated fires, ESF components in the IF are not expected to experience adverse temperature or pressure environments due to the low temperature and low pressure nature of the SHINE IF processes. Dampers that are credited to perform isolation functions during postulated fires will be capable of performing the required level of isolation in the potential environments (e.g., elevated temperature) determined from the FHA.

The staff finds this response provides sufficient detail regarding "adverse environments" and the method used to determine design of components. The staff finds this response demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

SHINE PSAR, Section 6a2.2.1.3, "Functional Requirements," states:

> Mechanical, instrumentation, and electrical systems and components are designed to ensure that a single failure, in conjunction with an initiating event, does not result in the loss of the system's ability to perform its intended safety function. The single failure considered is a random failure and any consequential failures in addition to the initiating event for which the system is required and any failures that are a direct or consequential result of the initiating event.

Additional information is needed for the NRC staff to understand the meaning of the second sentence of this section.

Therefore, in RAI 6a2.2-5 (Reference 14), the staff asked the applicant to: (1) provide clarification regarding the meaning of the second sentence; and, (2) provide the basis for how the system design meets the single-failure criterion stated, or provide the reference to the section of the PSAR, which describes that basis.

In response to RAI 6a2.2-5 (Reference 20), the applicant stated that PSAR Subsection 6a2.2.1.3 contains an administrative error. SHINE will revise the statement in the FSAR as follows:

> Safety-related mechanical, instrumentation, and electrical systems and components are designed to ensure that a single failure of an active component, in conjunction with an initiating event, does not result in the loss of the system's ability to perform its intended safety functions. The single failure considered is a random failure."

Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved. The staff finds this response is sufficient in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

SHINE PSAR, Section 6a2.2.1.4, "Confinement Components," discusses the "secondary confinement barrier of the IU cells," but does not define or fully describe this term.

Therefore, in RAI 6a2.2-6 (Reference 14), the staff asked the applicant to explain precisely what comprises the "secondary confinement barrier of the IU cells."

In response to RAI 6a2.2-6 (Reference 20), the applicant stated PSAR Section 6a2.2.1.4 contains an administrative error. The applicant further provided that the facility has a primary and a secondary fission product barrier. The primary fission product barrier is the primary system boundary, while the secondary fission product barrier is designated the confinement boundary or barrier, or just confinement. The facility does not have a "secondary confinement barrier." The use of the phrase "secondary confinement barrier" was an administrative error.

Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved. The staff finds this response is sufficient in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

SHINE PSAR, Section 6a2.2.1.4, "Confinement Components," indicates that the details of the TPS confinement system will be left to the FSAR. Additional information is needed for the staff to determine the adequacy of waiting to provide details of the TPS confinement system in the FSAR.

Therefore, in RAI 6a2.2-7 (Reference 14), the staff asked the applicant to provide the rationale for leaving the details of TPS confinement to the FSAR.

In response to RAI 6a2.2-7 (Reference 21), the applicant noted that the TPS confinement system is described in the response to RAI 6a2.2-1. The applicant further provided that the details of the components that comprise the TPS are described in Subsection 9a2.7.1 of the

PSAR. Isolation valve locations will be determined during detailed design and provided in the FSAR. The specific valve locations will be dependent on the final design and layout of the system. However, the applicant also states that valve locations and number will be sufficient to limit consequences from accidents to less than 10 CFR 20 limits.

Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved. The staff finds this response is sufficient in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

SHINE PSAR, Section 6a2.2.1.4, "Confinement Components," mentions systems that are "open to the IU cell, TOGS shielded cell atmosphere, or TPS glovebox," but does not identify them.

Therefore, in RAI 6a2.2-8 (Reference 14), the staff asked the applicant to identify the systems that are open to the IU cell, TOGS shielded cell atmosphere, or TPS glovebox.

In response to RAI 6a2.2-8 (Reference 20), the applicant provided that PSAR Subsection 6a2.2.1.4 states, "For systems open to the IU cell, TOGS shielded cell atmosphere, or TPS glovebox, redundant isolation valves are provided." The applicant indicated that this statement:

> …describes the design requirement of the confinement system to ensure that no system creates a direct path from the atmosphere inside of the IU cell, TOGS shielded cell, or TPS glovebox to outside the cell or glovebox. A direct path would represent an unacceptable source of leakage from the respective confinement area during an accident, and proper isolation capability is required to ensure a complete confinement barrier. The sentence refers to systems that are normally open to the atmosphere, or may be open for maintenance or other operations when confinement capabilities are required (e.g., when an irradiated target solution batch is present in the IU cell, IU cell confinement capability is required).

The applicant further stated, in part, that "based on preliminary design, the Light Water Pool System (LWPS) and RVZ1 are normally open systems to the IU cell atmosphere; RVZ1 is normally open to the TOGS shielded cell atmosphere; and RVZ1 and the nitrogen supply from the Inert Gas Control System (IGS) are connected to the TPS glovebox atmosphere."

The staff finds this response provides sufficient detail regarding the open systems in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

SHINE PSAR, Table 6a2.2-1, "Irradiation Facility Confinement Safety Functions" (page 6a2-9), references isolation valves on piping systems, but the applicant does not identify the valves, provide a list of the valves or reference a schematic which details the isolation valves.

Therefore, in RAI 6a2.2-9 (Reference 14), the staff asked the applicant to provide a list, schematic or reference to a list of the isolation valves.

In response to RAI 6a2.2-9 (Reference 21), the applicant stated that PSAR Subsection 6a2.2.1.4:

> …describes confinement components of systems normally open to the IU cells, TOGS shielded cells, and TPS glovebox. The IU cells and TOGS shielded cells

> will have RVZ1 inlet and outlet bubble-tight isolation dampers to achieve the confinement boundary. A schematic of RVZ1 is shown in PSAR Figure 9a2.1-1. As shown in PSAR Figure 4a2.1-1, the IU cell has penetrations for the PCLS and LWPS. These systems provide cooling to the TSV, and both systems will be provided with isolation valves for confinement. TPS confinement is achieved by the TPS Confinement System. The TPS will also contain isolation valves. As described in the response to RAI 6a2.2-1, the necessary locations of isolations valves will be determined from the accident analysis during detailed design, and will include valves that isolate the NDAS from the TPS should a leak in NDAS be detected. Additional detail regarding the TPS isolation valves is also provided in the response to RAI 6a2.2-3. Additional isolation valve details will be developed during detailed design, and the FSAR will be updated with a list, details, or locations of these isolation valves.

Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved. The staff finds this response is sufficient in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part, "[f]or the confinement to function as an ESF, the design bases for the consequence-mitigation functions should be derived from the accident analyses in SAR Chapter 13." NUREG-1537, Part 2, Section 6.2.1, "Confinement," Acceptance Criteria, states, in part, "[t]o be considered an ESF, design features must exist to mitigate the consequences of specific accident scenarios."

SHINE PSAR, Section 6a2.2, "Irradiation Facility Engineered Safety Features Detailed Description," contains a list of initiating events (IEs) that were included for the DBA review. A subsequent list gives IEs, which do not have radiological consequences that require mitigation by ESFs. However, Section 6a2.2 did not explain the basis for the determination of which IEs do not have radiological consequences.

Therefore, in RAI 6a2.2-10 (Reference 14), the staff asked the applicant to provide the basis for this determination and a reference to the basis or analysis, which supports this determination or to the section(s) of SHINE PSAR that contain(s) such an analysis.

In response to RAI 6a2.2-10 (Reference 20), the applicant stated that the bases for the determination of which initiating events have radiological consequences are provided in Section 13a2.2 of the PSAR. SHINE will include a table in FSAR Section 6a2.2 that provides a reference to the FSAR Chapter 13 subsection where the specific radiological consequence analysis can be found for each initiating event. Following the receipt of SHINE's FSAR, staff will confirm that this issue has been resolved.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part: "[t]he discussion of mitigative effects should contain a comparison of potential radiological exposures to the facility staff and the public with and without the ESF"

NUREG-1537, Part 2, Section 6.2.1, "Confinement," Evaluation Findings, states, in part, that:

> [t]his section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the safety evaluation report:
>
> - The scenarios for all potential accidents at the reactor facility have been analyzed by the applicant and reviewed by the staff. Mitigation of consequences by a confinement system has been proposed in the SAR analyses for any accident that could lead to potential unacceptable radiological exposures to the public, the facility staff, or the environment.
> - The staff has reviewed the designs and functional descriptions of the confinement ESF; they reasonably ensure that the consequences will be limited to the levels found acceptable in the accident analyses of Chapter 13 of the SAR.
> - The designs and functional descriptions of the confinement ESF reasonably ensure that control of radiological exposures or releases during normal operation will not be degraded by the ESF.

SHINE PSAR, Section 6a2.2.1, "Confinement," does not contain a comparison of potential radiological exposures to the facility staff and the public with and without the ESF.

Therefore, in RAI 6a2.2-11 (Reference 14), the staff asked the applicant to provide the comparative study or reference the section of SHINE PSAR, which provides this information.

In response to RAI 6a2.2-11 (Reference 21), the applicant states that PSAR Table 6a2.1-1 "provides the IF DBAs that are mitigated by the IF confinement ESF. The IF maximum hypothetical accident (MHA) is also mitigated by the same confinement ESFs, as it is an extension of the mishandling or malfunction of target solution." The applicant provided PSAR Table 6a2.2-11-1, which contained a comparative study of the ESFs for mitigating these IF DBAs. For the unmitigated consequences, the applicant stated in part, that they "assumed none of the active ESFs functioned. The only active ESF components in the confinement credited for mitigating these accidents are the bubble-tight isolation dampers. The remaining assumptions and input values used to calculate the doses are the same between the unmitigated and mitigated cases. The unmitigated and mitigated radiation doses to workers at the SHINE facility are the same, as no active ESF components are credited in the accident analysis for the workers."

Table 6a2.2-11-1: Comparison of Unmitigated and Mitigated Radiological Doses for IF DBAs

Event	Unmitigated Public Dose (rem)				Mitigated Public Dose (rem)			
	Site Boundary		Nearest Resident		Site Boundary		Nearest Resident	
	TEDE	Thyroid	TEDE	Thyroid	TEDE	Thyroid	TEDE	Thyroid
Target Solution Release into the IU Cell (IF Postulated MHA)	1.65E+00	1.58E+00	2.30E-01	2.21E-01	1.65E-02	1.58E-02	2.30E-03	2.21E-03
Mishandling or Malfunction of Target Solution	2.19E-01	1.58E+00	3.06E-02	2.21E-01	2.19E-03	1.58E-02	3.06E-04	2.21E-03
Mishandling or Malfunction of Equipment Affecting the PSB	1.59E+00	7.03E-02	2.23E-01	9.84E-03	1.59E-02	7.03E-04	2.23E-03	9.84E-05
TPS Design Basis	5.6E-02	---	8E-03	---	5.6E-04	---	8E-05	---

The applicant also indicated that the leak path factors in PSAR Chapter 13 for the DBA of the TPS were incorrect in relation to the provided doses. The applicant has revised the TPS DBA described in PSAR Chapter 13 to correct the discrepancy and provide the reduced public doses.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 1, Section 6.2.1,"Confinement," states, in part, that "[a] schematic diagram of the system should be presented showing the blowers, dampers, filters, other components necessary for operation of the system and flow paths."

SHINE PSAR, Section 6a2.2.1, "Confinement," does not contain or reference the confinement ESF HVAC system schematic diagram.

Therefore, in RAI 6a2.2-12 (Reference 14), the staff asked the applicant to provide the schematic diagram(s) for this system.

In response to RAI 6a2.2-12 (Reference 20), the applicant provided that PSAR Figures 9a2.1-1 and 9a2.1-2 provide schematic diagrams showing the ESF heating, ventilation, and air conditioning (HVAC) systems, including blowers, dampers, filters, other components necessary for operation of the system, and flow paths.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part, that "[a]utomatic and manual trip circuits, bypasses, interlocks, and special I&C [instrumentation and control] systems for the

ESF system should be described briefly in this section and in detail in Chapter 7." NUREG-1537, Part 2, Section 6.2.1, "Confinement," Areas of Review, states, in part, that "[t]he reviewer should evaluate… [Thus, this section should contain a]…description of control and safety instrumentation, including the locations and functions of sensors, readout devices, monitors, and isolation components, as applicable."

SHINE PSAR, Section 6a2.2.1, "Confinement," discusses the confinement ESF system, but did not contain a description of the automatic and manual trip circuits, bypasses, interlocks, and special I&C systems.

Therefore, in RAI 6a2.2-13 (Reference 14), the staff asked the applicant to provide a brief description of automatic and manual trip circuits, bypasses, interlocks, and special I&C systems, including relevant schematics or functional block diagrams, or reference(s) to their location in PSAR Chapter 7.

In response to RAI 6a2.2-13 (Reference 20), the applicant stated, in part, that:

> …the confinement boundaries include passive barriers (e.g., walls) and active components (e.g., isolation dampers, isolation valves). The active components required to function to maintain the confinement barrier in an accident are Engineered Safety Features (ESFs) and they are actuated by the Engineered Safety Features Actuation System (ESFAS). A description of the ESFAS is provided in PSAR Section 7a2.5. No special I&C systems are employed in ESF actuation. A discussion of the automatic and manual trip circuits of the ESFAS is provided in PSAR Subsection 7a2.5.4. A typical ESF circuit is provided in PSAR Figure 7a2.5-1, an example ESFAS panel is provided in PSAR Figure 7a2.5-2, and the ESFAS operator control panel is provided in PSAR Figure 7a2.5-3. These figures represent the current schematics for the ESFAS. A description of the ESFAS interlocks and bypasses, if any, will be determined as a part of detailed design and provided in the FSAR. An IMR has been initiated to track the inclusion of a description of the ESFAS interlocks and bypasses, if any, in the FSAR.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1 and demonstrates adequate design criteria in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part, that "[p]eriodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints should be required and specified. See Chapter 14, "Technical Specifications," of this format and content guide, for details on what technical specification requirements should be identified and justified in this section."

NUREG-1537, Part 2, Section 6.2.1, "Confinement," Areas of Review, states, in part, that "[t]he reviewer should evaluate…[Thus, this section should describe]… [s]urveillance methods and intervals included in the technical specifications that ensure operability and availability of the confinement ESFs, when required."

SHINE PSAR, Section 6a2.2.1.5, "Engineered Safety Feature Test Requirements," states, in part, that "[e]ngineered safety features are periodically tested to ensure that ESF components maintain operability….” However, plans for testing ESF functionality as well as operability were not fully described.

Therefore, in RAI 6a2.2-14a (Reference 14), the staff asked the applicant to describe planned tests of ESFs for “functionality” as well as “operability” (an example would be leak tightness), including preoperational, as well as post-commissioning testing.

In response to RAI 6a2.2-14a (Reference 20), the applicant stated:

> Of the two terms “operable” and “functional,” “operable” is the more restrictive condition, applying only to SSCs described in the TS. A component or system is operable when it is capable of performing its intended function. To be operable, an SSC must be able to perform its design basis function, and be in compliance and in-frequency for the TS surveillances. “Functionality” is generally only applied to non-TS SSCs, and is therefore not specifically defined in the same manner as “operability,” but usually refers to the ability of non-TS SSCs to perform their design functions. ESF SSCs will be tested pre-operationally and following receipt of an OL via TS surveillances, to ensure that the assumptions made in PSAR Chapter 13 are valid. SHINE’s current planned tests for ESF components, both pre-operational and post-commissioning, are as follows:
>
> - Penetration seals, isolation valves, bubble-tight isolation dampers, gloveboxes, and other components that are relied upon to maintain the confinement boundary will be leak tested;
> - Isolation valves, bubble-tight dampers, and other equipment relied upon to change position in response to an ESFAS signal will be tested for freedom of movement and correct position indication in response to manual and automatic ESFAS signals;
> - Additional testing will be conducted based on applicable vendor recommendations; and
> - Intervals of testing will be included in the TS and may be based on factors such as manufacturer recommendations, industry operating experience, equipment reliability, or plant risk.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1 and demonstrates adequate design criteria 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 confinement is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 6.2.1, allowing the staff to make the following relevant findings:

1. The scenarios for potential accidents at the facility have been analyzed by the applicant and reviewed by the staff. Mitigation of consequences by a confinement system has been proposed in the SAR analyses for any accident that could lead to potential unacceptable radiological exposures to the public, the facility staff or the environment. The staff has reviewed the preliminary designs and functional descriptions of the confinement ESF; they reasonably ensure that the consequences will be limited to the levels found acceptable in the accident analyses of PSAR Chapter 13.

2. The radiological consequences from accidents to the public, the environment, and the facility staff will be reduced by the proposed confinement ESF to values that do not exceed the applicable limits of 10 CFR Part 20 and are as far below the regulatory limits as can be reasonably achieved.

Therefore, the staff finds that the preliminary design of the SHINE confinement ESFs, as described in PSAR Section 6a2.2 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 in the FSAR. The staff will confirm that the final design conforms to this design basis during evaluation of SHINE's FSAR.

6a.4.3 Containment

The staff evaluated the sufficiency of SHINE's treatment of confinement, as described in SHINE PSAR Section 6a2.2.2, "Containment," using the guidance and acceptance criteria of Section 6.2.2, "Confinement," of NUREG-1537, Parts 1 and 2. As stated in SHINE PSAR Section 6a2.2, "The 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."

Based on the information provided on the preliminary design of the SHINE facility, the staff finds that the SHINE confinement features are adequate to mitigate potential accidents and a containment feature is not necessary.

6a.4.4 Emergency Cooling System

The staff evaluated the sufficiency of SHINE's treatment emergency cooling systems, as described in SHINE PSAR Section 6a2.3, "Emergency Cooling System," using the guidance and acceptance criteria of Section 6.2.3, "Emergency Core Cooling System." SHINE PSAR Section 6a2.3, with reference to PSAR Chapter 13, states, "[d]ecay heat removal during accident scenarios is provided by the safety-related light water pool. No emergency core cooling system is required for the SHINE facility to mitigate the consequences of an accident."

Based on the information provided on the preliminary design of the SHINE facility, including the information provided in Sections 6a2.3 and 13a of the SHINE PSAR, the staff finds that an emergency cooling system is not required to mitigate the consequences of an accident at the SHINE facility.

6a.4.5 Probable Subjects of Technical Specifications

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications for the SHINE IF ESFs, with special attention given to those items which may significantly influence the final design. NUREG-1537, Part 1, Section 6.2.1, "Confinement," states, in part, that "[p]eriodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints should be required and specified. See Chapter 14, "Technical Specifications," of this format and content guide, for details on what technical specification requirements should be identified and justified in this section."

NUREG-1537, Part 2, Section 6.2.1, "Confinement," Areas of Review, states, in part, that "[t]he reviewer should evaluate… [Thus, this section should describe]… [s]urveillance methods and intervals included in the technical specifications that ensure operability and availability of the confinement ESFs, when required."

SHINE PSAR, Section 6a2.2.1.6, "Design Bases," states, in part, that "[p]otential variables, conditions, or other items that will be probable subjects of a technical specification associated with the IF confinement systems and components are provided in Chapter 14." Additional information is needed on the probable subjects of technical specifications to determine the adequacy of the IF confinement systems and components.

Therefore, in RAI 6a2.2-14b (Reference 14), the staff asked the applicant to provide the information on the probable subjects of technical specification requirements, including periodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints, in the appropriate location(s) in Section 6a2 that is specified in NUREG-1537, Part 1, Chapter 14.

In response to RAI 6a2.2-14b (Reference 20), the applicant stated, in part, that the ESF function for both the IF and RPF

> . . . consists of confinement systems, ventilation systems, and control systems. Post-accident mitigation is accomplished by confinement of radioactive or hazardous material to controlled areas to mitigate the consequences of design basis accidents (DBAs). This confinement occurs by shutting isolation dampers in the ventilation systems or isolation valves in lines penetrating the confinement area when parameters are determined to be outside predefined limits. This function is known as the ESF function. The control systems that perform this function are known as the ESFAS in the IF, and the Radiological Integrated Control System (RICS) in the RPF.
>
> Probable subjects of proposed TS for the IF and RPF ESF confinement systems are provided in PSAR Table 14a2-1, Section 3.4, and are also referenced for the RPF specifically in Subsection PSAR 14b.3.2. Per PSAR Table 14a2-1, the following Confinement Limiting Conditions of Operation (LCOs) will be developed:
>
> - TPS glove box system or confinement (IF)
> - IU and TOGS shielded cell confinement isolation valves (IF)
> - Confinement isolation valves (RPF)
>
> Probable subjects of proposed TS for the IF and RPF ESF ventilation systems are provided in PSAR Table 14a2-1, Section 3.5, and are also referenced for the RPF specifically in PSAR Subsection 14b.3.3. Per PSAR Table 14a2-1, the following LCOs will be developed:
>
> - RVZ1 and RVZ2 isolation dampers (IF and RPF)

> Probable subjects of proposed TS for ESF control and actuation are provided in PSAR Table 14a2-1 Sections 3.2 and 3.9 of, and are also referenced for the RPF specifically in PSAR Subsections 14b.3.1 and 14b.3.5. Per PSAR Table 14a2-1, the following LCOs will be developed:
>
> - ESFAS input to the TRPS, including the required operable channels per future TS Table 3.2.1 (i.e., TS Table 3.2.1 will include channel(s) monitored, number of channels required, allowable value, nominal setpoint, permissible bypass, or other conditions) (IF)
> - RICS (initiates the isolation functions necessary to achieve confinement in the RPF)
>
> The probable subjects of TS for ESF equipment are described above. Specific details related to these probable subjects, such as periodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints will be provided in the SHINE TS, which will be provided as part of the SHINE OL Application.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1 and demonstrates adequate design criteria 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.

Additionally, SHINE PSAR Section 6a2.4, "Irradiation Facility Engineered Safety Features Technical Specifications," states that "potential variables, conditions, or other items that will be probable subjects of technical specifications associated with the IF ESFs are provided in Chapter 14."

Based on the information provided in PSAR Chapters 6a and 14, as well as PSAR Table 14a2-1 and supplemented by the response to RAI 6a2.2-14(b), the staff finds that the identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications for the SHINE IF ESFs are sufficient and meet the applicable regulatory requirements and acceptance criteria of NUREG-1537 in support of the issuance of a construction permit in accordance with 10 CFR 50.35. A complete evaluation of technical specifications, LCOs, and surveillance requirements will be performed during the review of the SHINE operating license application.

6a.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of SHINE's IF ESFs, including probable subjects of technical specifications, as described in SHINE PSAR Section 6a2 and supplemented by the applicant's responses to RAIs, and finds that the preliminary design of SHINE's IF ESFs, including the principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in NUREG-1537.

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 IF ESF systems, 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 IF ESFs may reasonably be left for later consideration the FSAR.
(3) There is reasonable assurance that the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

6b Radioisotope Production Facility Engineered Safety Features

SER Section 6b, "Radioisotope Production Facility Engineered Safety Features," provides an evaluation of the preliminary design of SHINE's RPF ESFs, as presented in SHINE PSAR Section 6b, "Radioisotope Production Facility Engineered Safety Features," within which, SHINE describes RPF ESFs and nuclear criticality control.

6b.1 Areas of Review

The staff reviewed SHINE PSAR Section 6b against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of SHINE's RPF ESFs. As part of this review, the staff evaluated descriptions and discussions of SHINE's RPF ESFs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of SHINE's RPF ESF systems was evaluated to ensure the sufficiency of principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design.

Areas of review for this section included a summary description of the RPF ESFs, as well as a description of the RPF confinement and nuclear criticality safety analysis. Within these review areas, the staff assessed, in part, confinement system and components, functional requirements of confinement, management of the nuclear criticality safety program, planned responses to criticality accidents, criticality-safety controls, nuclear criticality safety evaluations, and the criticality accident alarm system (CAAS).

6b.2 Summary of Application

In PSAR Section 6b.1, SHINE briefly describes the SSCs that constitute the confinement ESFs in the RPF design and summarizes the postulated accidents whose consequences could be unacceptable without mitigation. As described in greater detail in PSAR Chapter 13b, specific postulated accident scenarios indicate the need for the confinement ESFs.

In PSAR Section 6b.2, SHINE described, in detail, the confinement ESF SSCs that will be incorporated into the RPF design. The HVAC and air exhaust systems RVZ1 and RVZ2 are associated with the confinement and are designed to change configuration or operating mode in response to several potential accidents analyzed in Chapter 13b and thereby mitigate its consequences. They are considered part of the confinement ESF and are discussed in PSAR Section 6b.2. The confinement ESF SSCs are passive and active features designed to mitigate the consequences of accidents and to keep the radiological and chemical exposures to the public, the facility staff, and the environment within acceptable values. PSAR Sections 6b.2 and 9a2.1 provides the details of design, initiation, and operation of confinement ESF SSCs that are provided to mitigate the DBAs discussed in PSAR Section 6b.1. This includes chemical storage areas outside the RCA.

In PSAR Section 6b.3, the applicant states that its nuclear criticality safety program (NCSP) for the design, construction, and operation of the RPF will be in accordance with applicable American National Standards Institute/American Nuclear Society (ANSI/ANS) standards as endorsed by Regulatory Guide 3.71 (Reference 75). The standards committed to include ANSI/ANS-8.1-1998, ANS-8.3-1997, ANS-8.7-1998, ANS-8.10-1983, ANS-8.20-1991, ANS-8.21-1995, ANS-8.23-2007, ANS-8.24-2007, and ANS-8.26-2007 (References 62-70).

Commitments related to the design of the facility and its SSCs are described in PSAR Section 6b.3, to ensure that subcriticality will be maintained with an acceptable margin under normal and credible abnormal conditions. These commitments include preference for passive over active engineered controls and engineered over administrative controls; adherence to the double contingency principle (DCP); and performance of documented and independently reviewed NCS evaluations (NCSEs) to identify significant parameters that will be controlled within each process. The dominant controlled parameters are geometry and mass, although interaction and neutron absorption are also mentioned. The NCSEs will be the basis for SSCs and administrative controls relied on to ensure subcriticality. The appropriate margin of subcriticality depends, in part, on using a calculational methodology that is validated for use within a demonstrated area of applicability (AOA). The staff reviewed the licensee's programmatic commitments for the NCSP against the acceptance criteria in ISG Section 6b.3, and determined that it met the guidance applicable to construction. The staff's review of the applicant's computer code validation report is in Section 6b.4.5 of this SER.

6b.3 Regulatory Basis and Acceptance Criteria

The staff reviewed SHINE PSAR Section 6b against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of SHINE's I&C systems 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) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

The staff's evaluation of the preliminary design of SHINE's RPF ESFs does not constitute approval of the safety of any design feature or specification unless such approval is specifically requested by SHINE. Otherwise, such approval will be made following the evaluation of the final design of SHINE's RPF ESFs as described in the FSAR as part of SHINE's operating license application.

6b.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's RPF ESFs 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."

In addition to any radiological hazards associated with operations in a production facility, 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," specifies limits regarding exposure to hazardous chemicals. Although not required of Part 50 licensees, these limits were considered when reviewing this section of the SHINE PSAR.

6b.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated SHINE's RPF ESFs against the applicable regulatory requirements listed above primarily using the guidance and acceptance criteria contained in Chapter 6 of NUREG-1537, Parts 1 and 2, as well as the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

As appropriate, additional guidance (e.g., NRC regulatory guides, IEEE standards, ANSI/ANS standards) has been utilized in the review of SHINE's I&C systems. The use of additional guidance is based on the technical judgement of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG Augmenting NUREG-1537, Parts 1 and 2; and the SHINE PSAR.

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 6b.4, "Review Procedures, Technical Evaluation, and Evaluation Findings," of the SER. Guidance documents used to review SHINE's ESFs are provided as references in Appendix B.

6b.4 Review Procedures , Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in SHINE PSAR Section 6b, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of the SHINE RPF ESFs in support of the issuance of a construction permit, in accordance with 10 CFR 50.35(a). Sufficiency of the preliminary design and performance of the SHINE RPF ESFs is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 6b.3, "Regulatory Basis and Acceptance Criteria," of this SER. While the technical evaluation of these systems provided in this section is specific to the SHINE RPF, the staff's review considers the interface of these systems between the IF and RPF as part of a comprehensive technical evaluation. The results of this section-by-section technical evaluation are described in Section 6b.5, "Summary and Conclusion."

For the purposes of issuing a CP, the preliminary design of the SHINE RPF ESFs may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the SHINE RPF ESFs based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of the SHINE RPF ESFs 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 RPF ESFs, as described in the FSAR, as part of SHINE's operating license application.

6b.4.1 Summary Description

The staff evaluated the sufficiency of SHINE's summary description of its RPF ESFs, as described in SHINE PSAR Section 6b.1, "Summary Description," using the guidance from Section 6.1, "Summary Description," of NUREG-1537, Parts 1 and 2.

In PSAR Section 6b.1, SHINE briefly describes the SSCs that constitute the confinement ESFs in the RPF design and summarizes the postulated accidents whose consequences could be unacceptable without mitigation. As described in greater detail in PSAR Chapter 13b, specific postulated accident scenarios indicate the need for the confinement ESFs. The details of the accident analyses are given in PSAR Chapter 13b, and the detailed discussions of the confinement ESFs in PSAR Section 6b.2. The confinement ESF summary includes the design bases, the performance criteria, and the full range of RPF conditions, including accident conditions, under which the confinement ESF SSCs must maintain function.

According to Chapter 13 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'" (Reference 6), the following DBAs are to be addressed for the RPF:

a. Critical equipment malfunction.
b. Inadvertent nuclear criticality in the RPF.
c. RPF fire.
d. Accidents with hazardous chemicals.
e. External events.

These DBAs encompass loss-of-offsite power (LOOP) and operator errors (See SER Section 13b).

SHINE states that three of the DBAs – b., c., and e. above – do not have consequences that require mitigation by the confinement ESFs. The remaining two DBAs – a. and d. above – require the confinement ESF SSCs to mitigate consequences.

The confinement ESF SSCs provide active and passive protection against the potential release of radioactive materials or chemicals to the environment following a design basis accident. The confinement ESF SSCs provide for active isolation of piping and HVAC systems penetrating confinement boundaries in certain post-accident conditions.

PSAR Section 6b.2 and its subsections describe the confinement ESF and its modes of initiation and operation, and describe the SSCs in detail. The confinement ESF consists of the following SSCs:

- Hot cells, including penetration seals
- RCA ventilation system Zone 1 (RVZ1) (including ductwork up to filters and filters) and Zone 2 (RVZ2)
- Bubble-tight isolation dampers
- Tank vaults
- Radiological integrated controls system (RICS)
- Isolation valves on piping systems penetrating hot cells

Table 6b.2-1, "Radioisotope Production Facility Confinement Safety Functions," shows the location, basic function, and relationship of the confinement ESF to the facility. The summary description contained enough information for an overall understanding of the function and relationship of the ESF to the operation of the facility.

On the basis of its review, the staff finds that the level of detail provided in the summary description of the SHINE RPF ESFs demonstrates an adequate design basis in support of a preliminary design.

Therefore, the staff finds that the summary description of the SHINE RPF ESFs, as described in SHINE PSAR Section 6b.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 this design basis during the evaluation of SHINE's FSAR.

6b.4.2 Confinement

The staff evaluated the sufficiency of the preliminary design of the SHINE confinement and related systems as described in SHINE PSAR 6b.2.1, "Confinement," in part, by reviewing confinement mitigation requirements, the defined confinement envelope, and detailed descriptions of the ESFs associated with confinement. Additionally, the staff evaluated the passive and active ESF components, under normal and upset operational conditions. The functional requirements, design bases, probable subjects of technical specifications, and testing requirements were also evaluated for sufficiency.

In accordance with the review procedures of NUREG-1537, Part 2, Section 6.2.1, "Confinement," the staff: (1) reviewed the accident scenarios analyzed in PSAR Chapter 13 and evaluated whether the confinement will sufficiently mitigate consequences; (2) reviewed design and functional bases against analyzed accidents; and, (3) compared diffusion and dispersion of released airborne radionuclides. More specifically, the staff evaluated the following elements of SHINE's confinement:

- Design bases and functional description of the required mitigative features of the confinement ESF SSCs, derived from the accident scenarios.
- Drawings, schematic diagrams, and tables of important design and operating parameters and specifications for the confinement ESF SSCs, including the following:
  - seals, gaskets, filters, and penetrations (e.g., electrical, experimental, air, and water)
  - necessary ESF equipment included as part of the confinement
  - fabrication specifications for essential and safety-related components
- Discussion and analyses, keyed to drawings, of how the structure provides the necessary confinement analyzed in PSAR Chapter 13, with cross reference to other PSAR sections for discussion of normal operations including Section 4b, "Radioisotope Production Facility Description," and Chapter 11, "Radiation Protection and Waste Management."
- Discussion of the required limitations on release of confined effluents to the environment.
- Surveillance methods and intervals will be included in the FSAR technical specifications that ensure operability and availability of the confinement ESF SSCs.

In PSAR Section 6b.2, SHINE described in detail the confinement ESF SSCs that will be incorporated into the RPF design. The HVAC and air exhaust systems RVZ1 and RVZ2 are associated with the confinement and are designed to change configuration or operating mode in response to several potential accidents analyzed in Chapter 13b and thereby mitigate its consequences. They are considered part of the confinement ESF and are discussed in PSAR Section 6b.2. The confinement ESF SSCs are passive and active features designed to mitigate the consequences of accidents and to keep the radiological and chemical exposures to the public, the facility staff, and the environment within acceptable values. PSAR Section 6b.2 provides the details of design, initiation, and operation of confinement ESF SSCs that are provided to mitigate the DBAs discussed in PSAR Section 6b.1. This includes chemical storage areas outside the RCA.

Confinement in the radioisotope production facility includes the low-leakage boundary surrounding radioactive or hazardous chemical materials released during an accident, and parts of RVZ1 and RVZ2. The boundary and parts of RVZ1 and RVZ2 localize releases of radioactive or hazardous materials to controlled areas and mitigate the consequences of DBAs. Adequate shielding and RCA ventilation (RV) minimize the hazards normally associated with radioactive or chemical materials. A design objective of confinement is to minimize reliance on administrative or complex active engineering controls and provide a confinement system that is as simple and fail-safe as reasonably possible.

The RPF confinement areas include hot cell enclosures for process operations and trench and vault enclosures for process tanks and piping. Confinement is achieved through RV, RICS, and biological shielding provided by the steel and concrete structures comprising the walls, roofs, and penetrations of the hot cells. Shielding of the hot cells is discussed in detail in PSAR Section 4b.2.

The RV serving the RCA, outside of the IF, includes components whose functions are designated as nonsafety-related and safety-related. The ductwork, the isolation dampers, and the filter trains of RVZ1 are designated as safety-related.

The hot cells employ a combination passive-active confinement methodology. During normal operation, passive confinement is achieved through the contiguous boundary between the hazardous materials and the surrounding environment and is credited with confining the hazards generated as a result of DBAs.

This boundary includes the biological shield (created by the physical construction of the cell itself) and the extension of that boundary through the RVZ1. The intent of the passive boundary is to confine hazardous materials while also preventing the introduction of external energy sources that could disturb the hazardous materials from their steady-state condition. The extent of this passive confinement boundary extends from the upstream side of the intake high efficiency particulate air (HEPA) filter to the final downstream HEPA filter prior to exiting the building.

In the event of a DBA that results in a release inside the hot cells, radioactive material would be confined by the biological shield and physical walls of the cell itself. Each line that connects directly to the hot cell atmosphere and penetrates the hot cell is provided with redundant isolation valves to prevent releases of gaseous or other airborne radioactive material. Confinement isolation valves on piping penetrating the hot cell are located as close as practical to the confinement boundary and active isolation valves are designed to take the position that provides greater safety upon loss of actuating power.

To mitigate the consequences of an uncontrolled release occurring within a hot cell, as well as the off-site consequences of releasing fission products through the ventilation system, the confinement barrier utilizes an active component in the form of bubble-tight isolation dampers (safety-related) on the inlet and outlet ventilation ports of each hot cell. This ESF effectively reduces the amount of ductwork in the confinement volume that needs to remain intact to achieve hot cell confinement. These dampers close automatically (fail-closed) upon loss of power or receipt of a confinement isolation signal generated by the RICS. Following an initiating event, the RICS isolates the hot cells. Additional detail on the RICS is provided in PSAR Section 7b.

However, in the discussion of SHINE's mitigative effects, the staff noted the absence of a confinement ESF effectiveness comparison. Therefore, the staff issued RAI 6b.2-6 (Reference 14) requesting that SHINE provide a mitigative study of the confinement ESF effectiveness. This information was necessary in order to meet the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1, which states, that "[t]he discussion of mitigative effects should contain a comparison of potential radiological exposures to the facility staff and the public with and without the ESF."

In response to RAI 6b.2-6 (Reference 21), SHINE provided a comparative study of the ESFs for mitigating RPF DBAs, as presented in Table 6b.2-6-1, "Comparison of Unmitigated and Mitigated Radiological Doses for RPF DBAs." For unmitigated consequences, SHINE only credited the bubble-tight isolation dampers, assuming none of the active ESFs are functioning.

Table 6b.2-6-1: Comparison of Unmitigated and Mitigated Radiological Doses for RPF DBAs

Event	Unmitigated Public Dose (rem)				Mitigated Public Dose (rem)			
	Site Boundary		Nearest Resident		Site Boundary		Nearest Resident	
	TEDE	Thyroid	TEDE	Thyroid	TEDE	Thyroid	TEDE	Thyroid
Release of Inventory Stored in NGRS Storage Tanks (RPF MHA)	8.20E-01	---	1.15E-01	---	8.20E-02	---	1.15E-02	---
Critical Equipment Malfunction: Loss of Piping or Tank Integrity	2.19E-01	1.58E+00	3.06E-02	2.21E-01	2.19E-03	1.58E-02	3.06E-04	2.21E-03
Critical Equipment Malfunction: Inadvertent Release from NGRS	8.17E-01	---	1.14E-01	---	8.17E-02	---	1.14E-02	---
RPF Fire	8.77E-03	1.60E-01	1.23E-03	2.24E-02	8.77E-04	1.60E-02	1.23E-04	2.24E-03

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1 and demonstrates adequate design criteria 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.

Overall performance assurance of the active confinement components is achieved through factory testing and in-place testing. Duct and housing leak tests will be performed in accordance with ASME N511, "Standard for In-Service Testing of Nuclear Air Treatment, Heating, Ventilating, and Air Conditioning Systems" (Reference 73), with minimum acceptance criteria as specified in ASME AG-1-2009, "Code on Nuclear Air and Gas Treatment" (ASME 2009).

Active confinement components are designed to fail into a safe state if conditions such as loss of signal, loss of power, or adverse environments are experienced. Mechanical, instrumentation, and electrical systems and components required to perform their intended safety function in the event of a single failure, are designed to include sufficient redundancy and independence such that a single failure of any active component does not result in a loss of the capability of the system to perform its safety functions.

Mechanical, instrumentation, and electrical systems and components are designed to ensure that a single failure, in conjunction with an initiating event, does not result in the loss of the system's ability to perform its intended safety function. The single failure considered is a random failure and any consequential failures in addition to the initiating event for which the system is required and any failures that are a direct or consequential result of the initiating event.

The design of safety-related systems (including protection systems) is consistent with IEEE Standard 379-2000, "IEEE Standard Application of the Single-Failure Criterion to Nuclear Power Generating Station Safety Systems" (Reference 71), and NRC Regulatory Guide 1.53, Revision 2, "Application of the Single-Failure Criterion to Nuclear Power Plant Protection Systems" (Reference 72), in the application of the single-failure criterion.

The following components are associated with the confinement barriers of the hot cells, tank vaults and pipe trenches, as described in PSAR Section 6b. Their specific materials, construction, and installation and operating requirements are evaluated based on the safety analysis.

Bubble-tight isolation dampers, designed, constructed and tested in accordance with ASME AG-1-2009, Section DA, "Dampers and Louvers" (ASME 2009):

- Maintain their functional integrity.
- Maintain their rated leak-tightness following a seismic event.
- Maintain their structural integrity under fan shut-off pressure.
- Provide bubble-tight isolation upon receipt of a control signal or, in the event of loss of actuator power, by closure of actuator.
- Provide bubble-tight isolation when using manual actuator or when locked closed with power actuator removed.
- Relay damper full-open and full-closed position for control and indication by the use of limit switches.

Dampers will be butterfly type, blade and frame fabricated of heavy-gage stainless steel. Total leakage based on bubble solution test as outlined in ASME AG-1-2009, Section DA-5141 (ASME 2009).

Ventilation ductwork and ductwork support materials will meet the requirements of ASME AG-1-2009, Article SA-3000, "Materials." Supports are designed and fabricated in accordance with the requirements of ASME AG-1-2009, Section SA, "Ductwork" (ASME 2009).

Low leakage seals will be provided on each penetration through the hot cells. For systems open to the hot cell atmosphere, redundant isolation valves will be provided.

The ESFs will be tested to ensure that ESF components will maintain operability and can provide adequate confidence that the system will perform satisfactorily in service during postulated events. In reviewing SHINE's ESF testing, the staff determined that additional information was needed in order to satisfy the criteria of NUREG-1537, Part 1, Section 6.2.1, which states, in part, that "[p]eriodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints should be required and specified." Therefore, in RAI 6b.2-11 (Reference 14), the staff requested, in part, that SHINE describe preoperational and post-commissioning testing for ESF components.

In response to this RAI (Reference 20), SHINE provided the following list of planned preoperational and post-commissioning tests for ESF components:

- Penetration seals, isolation valves, bubble-tight isolation dampers, gloveboxes, and other components that are relied upon to maintain the confinement boundary will be leak tested;
- Isolation valves, bubble-tight dampers, and other equipment relied upon to change position in response to an ESFAS signal will be tested for freedom of movement and correct position indication in response to manual and automatic ESFAS signals;

- Additional testing will be conducted based on applicable vendor recommendations; and
- Intervals of testing will be included in the TS and may be based on factors such as manufacturer recommendations, industry operating experience, equipment reliability, or plant risk.

The staff finds this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 6.2.1 and demonstrates 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.

To the extent possible, the RICS and the confinement ESF whose operation it initiates, will be designed to permit testing during plant operation. Testing actuation devices and actuated equipment may be done individually or in groups to avoid negative impact to plant operations.

The design basis of the RVZ1 and RVZ2 are discussed in PSAR Section 9a2.1.1. The design basis of the hot cells is discussed in PSAR Section 4b.2. The ESF-related design basis of the RICS is discussed in PSAR Section 7b.4.1.

NRC staff determined that the need for the specified confinement ESF has been properly identified. The confinement ESF will not interfere with normal operations or safe RPF shutdown. The confinement ESF design features ensure that the system is available and operable when it is required for mitigating accident consequences. The minimum design goal of the confinement ESFs is to reduce below regulatory limits the potential radiological and chemical exposures to the facility staff and members of the public for the accidents discussed at the beginning of this chapter for the radioisotope production facility. The design of the confinement does not transfer radiological risk to the health and safety of the public in order to reduce potential exposures to the facility staff.

PSAR Section 6b shows that the confinement ESF reduces predicted radiological exposures and releases from applicable potential accidents to acceptable levels. The staff examined all accident scenarios analyzed in PSAR Section 13b that could lead to significant radiological or chemical exposures or releases and verified that consequences can be sufficiently mitigated by the confinement ESF. The staff confirmed that the design and functional bases of the confinement ESF are derived from the accidents analyzed. The staff compared the dispersion and diffusion of released airborne radionuclides discussed in PSAR Chapters 6 and 13, with methods described in PSAR Chapter 11, as applicable.

The staff determined that PSAR Section 13b contains sufficient information to conclude that scenarios for all potential accidents at the radioisotope production facility, with consequences greater than the design bases, have been analyzed by the applicant. Mitigation of consequences by a confinement system has been proposed in the PSAR analyses for any accident that could lead to potential unacceptable radiological or chemical exposures to the public, the facility staff, or the environment. The staff reviewed the designs and functional descriptions of the confinement ESF; the designs and functional descriptions reasonably ensure that accident consequences will be limited to the levels found acceptable in the accident analyses of PSAR Section 13b. The staff concluded that the designs and functional descriptions of the confinement ESF reasonably ensure that control of radiological and chemical exposures or releases during normal operation will not be degraded by the ESF. The staff determined that the radiological consequences from accidents to the public, the environment, and the facility staff will be reduced by the confinement ESF to values that do not exceed the applicable limits of 10 CFR Part 20 and the chemical exposure criteria specified in PSAR Section 3.5b.

On the basis of its review, the staff finds that the level of detail provided on confinement is adequate and supports the preliminary design and satisfied the applicable acceptance criteria of NUREG-1537, Part 2, Section 6.2.1, allowing the staff to make the following relevant findings:

1. The scenarios for potential accidents at the facility have been analyzed by the applicant and reviewed by the staff. Mitigation of consequences by a confinement system has been proposed in the SAR analyses for any accident that could lead to potential unacceptable radiological exposures to the public, the facility staff, or the environment. The staff has reviewed the preliminary designs and functional descriptions of the confinement ESF; they reasonably ensure that the consequences will be limited to the levels found acceptable in the accident analyses of PSAR Chapter 13.

2. The radiological consequences from accidents to the public, the environment, and the facility staff will be reduced by the proposed confinement ESF to values that do not exceed the applicable limits of 10 CFR Part 20 and are as far below the regulatory limits as can be reasonably achieved.

Therefore, the staff finds that the preliminary design of the SHINE confinement ESFs, as described in PSAR Section 6b.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 in the FSAR. The staff will confirm that the final design conforms to this design basis during evaluation of SHINE's FSAR.

6b.4.3 Containment

The staff evaluated the sufficiency of SHINE's treatment of containment, as described in SHINE PSAR Section 6b.2.2, "Containment," using the guidance and acceptance criteria of Section 6.2.2, "Confinement," of NUREG-1537, Parts 1 and 2. SHINE PSAR Section 6b.2.2 states that the SHINE RPF 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. PSAR Section 6b.2.1 is provided to describe the use of confinements as an ESF for the RPF.

On the basis of its review, the staff determined that, because SHINE provides a confinement ESF to keep the potential risk to the public from accidents at the RPF low, containment is not required for normal operation or accident mitigation. The safety analyses in PSAR Section 13b show that confinement provides sufficient mitigation and containment is not necessary.

6b.4.4 Emergency Cooling System

The staff evaluated the sufficiency of SHINE's treatment emergency cooling systems, as described in SHINE PSAR Section 6b.2.3, "Emergency Cooling System," using the guidance and acceptance criteria of Section 6.2.3, "Emergency Core Cooling System." As stated in SHINE PSAR Section 6b.2.3, "[t]here is no emergency cooling system associated with the RPF side of the SHINE facility[.]"

Based on a review of the accident analysis provided in SHINE PSAR Section 13b, the staff finds that an emergency cooling is not required to mitigate the consequences of an accident in the RPF.

6b.4.5 Nuclear Criticality Safety

The staff evaluated the sufficiency of SHINE's nuclear criticality safety design criteria and methods, as described in SHINE PSAR Section 6b.3, "Nuclear Criticality Safety," and supplemented by the applicant's responses to RAIs, and the applicant's Nuclear Criticality Safety (NCS) Manual, computer code validation report, and a sampling of preliminary NCS calculations and evaluations using the guidance and acceptance criteria from Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2, which is based on Chapter 5, "Nuclear Criticality Safety," of NUREG-1520 (Reference 60). More specifically, the pertinent sections of Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2, are drawn from Section 5.4.3, "Regulatory Acceptance Criteria," of NUREG-1520, Rev. 1.

In accordance with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety," the staff reviewed the applicant's NCS program, including organization and administration, management measures, organization, and technical practices, as well as the preliminary criticality safety evaluations. For the purposes of issuing a construction permit, the staff determined that it was not necessary for SHINE's Nuclear Criticality Safety Program (NCSP) to meet all of the acceptance criteria provided in Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2. The staff's review of SHINE PSAR Section 6b.3 evaluated adequacy of pertinent commitments to the design of processes within the SHINE facility.

Since the design and analyses of the SHINE facility are in preliminary stages, the scope of the staff's evaluation focused on the NCS design criteria and methods that will be utilized to perform NCS analyses and design the facility in a manner to maintain subcriticality of fissile material processes outside of the irradiation facility. As such, this section of the SER pertains to the analysis and design methodologies used to ensure the RPF will remain subcritical under normal and credible abnormal conditions by an acceptable margin. While the staff's review concluded that the applicant may proceed with construction, additional research and development will be required to confirm the adequacy of the design. As such, the staff imposes conditions, also described below, in the SHINE construction permit to establish the necessary research and development programs to confirm the adequacy of the identified safety features and components of the SHINE facility. The staff will consider the conditions of the construction permit to be met following the review and approval of any supporting documentation submitted by the applicant, and subsequently confirmed by the NRC's construction inspection program. All conditions of the construction permit must be satisfied prior to the completion of construction and issuance of an operating license. Any such further technical or design information outside of the scope of these construction permit conditions and as may be required to complete the safety analysis of the SHINE facility can reasonably left for later consideration during the evaluation of SHINE's FSAR, as part of the review of an operating license application.

During the course of reviewing SHINE's nuclear criticality safety-program, the staff found it necessary to request additional information to evaluate the adequacy of SHINE's principal design criteria and design bases, in accordance with the requirements of 10 CFR 50.34(a)(4). Therefore, in RAIs 6b.3-1 through 34 (References 14, 16 and XX), the staff requested information of the applicant to satisfy the acceptance criteria of the ISG Augmenting NUREG-

1537, Part 2, Section 6b.3. As discussed below, these RAIs covered topics such as SHINE's treatment of controlled parameters, application of the double-contingency principle, and ability to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical.

The applicant commits to a Criticality Accident Alarm System (CAAS) beginning on page 6b-19 of the PSAR. The applicant stated that the CAAS will be consistent with (ANSI/ANS)-8.3-1997 as modified by Regulatory Guide 3.71 (Reference 75). The applicant stated the CAAS will be appropriate for the facility for the type of radiation detected, the intervening shielding, and the magnitude of the minimum accident of concern, and that the CAAS will be designed to remain operational during design basis accidents. The applicant has further stated that emergency power will be provided to the CAAS via an uninterruptible power supply. While the staff determined that these commitments met the necessary acceptance criteria to allow SHINE to proceed with construction, additional research and development is necessary to confirm the adequacy of the design of the CAAS, including the methods for determining detector placement, in accordance with the requirements of 10 CFR 70.24, prior to the completion of construction. Specifically, the design must provide reasonable assurance that the CAAS will have the capability of detecting the minimum accident of concern given the shielding designed into the facility. Therefore, the staff imposes the inclusion of the following condition in the SHINE construction permit:

> **Prior to the installation of the criticality accident alarm system (CAAS), SHINE shall provide the technical basis for the design of the CAAS, including a description of the methodology for determining detector placement.**

The applicant committed to establishing an NCSP meeting the requirements of ANSI/ANS-8.1-1998 (Reference 62), and ANSI/ANS-8.19-2005 (Reference 76), as well as the other standards listed in Section 6.b.3-1. To ensure subcriticality, the applicant committed to perform a validation of its calculational method consistent with the acceptance criteria listed in the ISG, as discussed in detail below. Using those methods, the applicant stated that it would establish Safety Limits (SLs) for processes in the RPF to meet the DCP with a conservative margin. Limiting Safety System Settings (LSSSs) will be calculated to provide conservative margin below the SL to account for measurement uncertainty, operating characteristics of control systems, and accuracy of control instruments, for each parameter for which an SL is specified and for which monitoring instruments are used. In addition to LSSSs, the applicant will also establish Limiting Conditions for Operations (LCOs) to ensure operations are maintained within safe limits. Further evaluation of SHINE's probable subjects of technical specifications is provided in Section 6b.4.6, "Probable Subjects of Technical Specifications."

On PSAR page 1-4, the applicant states that the RPF is maintained with $k_{eff} \leq 0.95$. Beginning on page 6b-17, the applicant discusses proposed equipment and how they will maintain the process equipment in a subcritical state, based on MCNP analyses. In response to RAI 6b.3-1 (Reference 21), the applicant stated, in part, that it used MCNP to determine preliminary criticality safety limits and does not currently plan to use other methods for determination of criticality safety limits. Staff finds that the commitments to using either ANSI/ANS standards endorsed in RG-3.71 or performing specific analyses using the widely accepted MCNP code to be consistent with NRC guidance and industry practice and therefore acceptable.

In addition to the SLs, LSSSs, and LCOs discussed on pages 14b-2 and 14b-3 of the PSAR, in its response to RAI 6b.3-2 (Reference 21), the applicant stated that administrative controls will be established to ensure that engineered controls and control systems will be designed, implemented, and maintained to ensure they are available and reliable to perform their function when needed. Management measures identified through the accident analysis process, including safety and operating limits, will be included in the Administrative Controls section of the SHINE Technical Specifications (TS) or described in the FSAR and implemented through SHINE procedures. These administrative controls will ensure that safety-related SSCs are available and reliable to perform their functions when needed. Management measures are administrative in nature and may be finalized subsequent to the completion of construction.

The SHINE quality assurance program is described in the SHINE QAPD. This program is intended to ensure the long-term reliability and availability of engineered controls through robust design control, verification, change control, and procurement. The SHINE configuration management program is intended to ensure the design and licensing basis requirements of plant SSCs are properly reflected in plant documents such as drawings, calculations, equipment specifications, procedures, and software, and that these documents properly reflect the physical plant SSC configuration. SSCs identified as engineered NCS safety controls (geometry, absorbers, etc.) will be designated as safety-related. In response to RAI 6b.3-7 (Reference 21), the applicant stated that the SHINE configuration management program is intended to ensure that criticality safety controls defined in the NCSEs will not be changed without appropriate review by a qualified criticality safety engineer. Procedures will be developed and put in place prior to operation so that personnel will not change NCS controls without proper NCS review.

The change management program will include incorporating NCS controls into operating procedures and equipment drawings and identifying them as such to ensure they are not changed or removed without proper NCS review. Prior to implementing a change, an evaluation must conclude that the entire process will remain subcritical, with an approved margin for safety, under normal and credible accident conditions. Changes to NCS controls will be documented in the appropriate NCSE. In response to RAI 6b.3-2 (Reference 21), the applicant stated that procedures will be developed and put in place prior to operation so that personnel will not change NCS controls without proper NCS review by a qualified person. The applicant stated that changes that involve or could affect SNM will be evaluated under 10 CFR 50.59. This program will permit changes to the facility or procedures as described in the FSAR and the conduct of tests or experiments not described in the FSAR if prior NRC approval pursuant to 10 CFR 50.90 is not required. Such changes include new or modified SSCs, computer programs, processes, operating procedures, and administrative controls. In Table 6b.3-2, the applicant identifies configuration control and change management as required NCS program elements. The above process for NCS change management is in accordance with the endorsed standard ANSI/ANS-8.19-1996 (Reference76), and is therefore acceptable to the staff.

Staff finds the applicant's commitments for using the NCS program to establish and maintain NCS safety and operating limits, including verification and configuration management to be adequate. The applicant committed to administrative controls (management measures) to ensure that NCS controls are designed, implemented and maintained to ensure they are available and reliable. These commitments meet the guidance in the ISG, and the staff therefore finds them acceptable.

Because the SHINE facility will be licensed under 10 CFR Part 50, the performance requirements in 10 CFR 70.61 do not explicitly apply. However, as described in Section 6b of the ISG Augmenting NUREG-1537, the NRC staff has determined that the performance requirements of 10 CFR 70.61 are an acceptable way of demonstrating adequate safety for the SHINE RPF. These requirements ensure subcriticality under normal and credible abnormal conditions and are drawn from ANSI/ANS-8.1-1998 (R2007). Therefore, there is a need to define what is considered a credible criticality scenario and, in accordance with risk-informed regulation, define acceptable risk to the public for credible scenarios. Page 1-4 of the PSAR states, in part, that safety-related SSCs "will assure…that the potential for an inadvertent criticality is not credible." This was clarified in the applicant's response to RAI 6b.3-25 (Reference 25) to mean that SSC's will be utilized to ensure credible criticality sequences will be "highly unlikely." In the response to RAI 13b.1-1, the applicant established, in Table 13b.1-1-2, "Likelihood Index Limit Guidelines", an event frequency associated with highly unlikely consistent with the values found in NUREG-1520 (Reference 60). In response to RAIs 6b.3-3 and 6b.3-25, the applicant provided the basis for considering a criticality sequence to be "not credible" consistent with the three criteria from NUREG-1520 (page 3-27 of NUREG-1520, Revision 1). Therefore, the staff finds the applicant's definition of the terms "not credible, unlikely, and highly unlikely" to be acceptable.

While the staff finds SHINE's method of determination of "not credible" criticality sequences is sufficient to proceed with construction, additional research and development is necessary to confirm the adequacy of SHINE's analysis of criticality sequences prior to the completion of construction. Specifically, SHINE's analysis shall provide the technical justification for its designations of "not credible" criticality sequences (e.g., accumulations of uranium in the process ventilation system and intermixing of neutron driver deuterium in SNM processes), such that all relevant process hazards have been adequately considered. Therefore, the staff imposes the inclusion of the following condition in the SHINE construction permit:

> **Prior to the installation of equipment supporting processes for which a criticality event has been determined to not be credible even though fissile materials may be present, SHINE shall provide the basis for such determinations.**

The ISG for NUREG-1537, Part 2, includes acceptance criteria for technical practices to ensure that sufficient NCS controls developed in NCSEs are identified for each process. The staff considers the technical practices for each controlled parameter and associated design criteria, including the preferred hierarchy of controls, to be part of the design basis of the proposed facility.

On page 1-4 of the PSAR, the applicant commits that, for operations in the RPF, the facility is designed to meet the requirements of ANSI/ANS-8.1-1998 (R2007), including adherence to the double contingency principle. The double contingency principle states "process design should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible." The applicant stated that each process that has criticality accident sequences meets the double contingency principle. In response to RAI 6b.3-13 (Reference 21), the applicant stated that there are currently no planned exceptions to compliance with the double contingency principle. In its response to RAI 6.3-14 (Reference 21), the applicant stated that when a single NCS control is capable of controlling two or more criticality controlled parameters, another control will be identified to provide double contingency protection.

In response to RAI 6b.3-10 (Reference 21), the applicant revised its discussion that tank 1-TSPS-01T met double contingency through geometry and concentration (staff had determined that concentration was not an independent control for the tank). The applicant then stated that double contingency is met by geometry and the configuration management program. However, configuration management is not an independent control as it simply ensures the availability of the geometry control. In response to RAIs 6b.3-24 and 6b.3-30 (Reference XX and Reference 29), the applicant clarified that double contingency will be satisfied by the tank geometry and the criticality safe sump/drain system should the tank sustain a leak. Acceptable logic for double contingency was also noted in the other accident sequences in the NCSE provided in response to RAI 6b.3-30.

The staff finds that the applicant has adequate commitments to the double contingency principle, but that verification of its proper implementation should be addressed as the design is finalized in accordance with the imposed conditions of the construction permit..

The applicant has committed to ANSI/ANS-8.1-1998 (Reference 62), which requires that processes be shown to be subcritical under normal and credible abnormal conditions. Obtaining reasonable assurance that processes will be subcritical requires that calculational methods be validated against experimental data and an acceptable margin of subcriticality provided. Ensuring subcriticality with an acceptable margin is part of the design basis for the RPF. Determining the bias, uncertainty in the bias, and an administrative margin are all necessary tasks in setting a USL that ensures an adequate margin of subcriticality. For the purpose of demonstrating subcriticality, the calculated k_{eff} must satisfy $k_{eff} + 2\sigma \leq$ USL, where σ is the calculated standard deviation. On page 6b-11 of the PSAR, the applicant stated that the facility will be designed to meet ANSI/ANS-8.24-2007 (Reference 69). The applicant proposed use of an administrative margin of subcriticality (MoS) for the RPF of 0.05. The stated basis for this choice of MoS was the ISG for NUREG-1537, Part 2.

Staff reviewed the validation report submitted in response to RAIs 6b.3-23 (Reference 25 and 28) to confirm that the USL determination will adequately address the materials and enrichments that are of concern for criticality safety as well as any bias and uncertainty present in the modeling. The applicant modeled 140 criticality benchmark experiments using MCNP 6.1 and the ENDF/B-VII.1 continuous energy group cross section library. The modeling was performed on the Atkins' Linux computer cluster. The software and hardware are managed with the Atkins NS System's configuration control. The results of the modeled experiments were compiled and analyzed consistent with methods outlined in NUREG/CR-6698, "Guide for Validation of Nuclear Criticality Safety Calculational Methodology" (Reference 77). Staff verified the applicant's correct application of the statistical methodology in NUREG/CR-6698.

The staff noted that the experiments selected for the validation had limited data for the specific enrichment used in the calculations (21wt% ^{235}U) and for one particular material type (uranyl sulfate). With regard to sulfur, staff used the TSUNAMI sensitivity/uncertainty module in the SCALE-6.1 code package to determine the sensitivity of k_{eff} to sulfur cross section uncertainties as a function of enrichment in various benchmarks included in the validation report. Staff determined that sulfur has, at most, a minor effect on system reactivity and has a very low integral sensitivity coefficient as compared to other nuclides in the benchmarks. A similar evaluation was done for boron, which was included in the area of applicability (AOA) definition table but appeared to be underrepresented in the benchmark experiments, with similar results. In both cases, staff determined that uranium sulfate and boron were adequately represented in the experiments chosen for benchmarks.

The applicant evaluated its selected 140 benchmarked experiments in three separate data sets: intermediate enriched uranium (14.7 to 36 wt% ^{235}U), low to intermediate enriched uranium (10 to 36 wt% ^{235}U), and low to high enriched uranium (10 to 94 wt% ^{235}U). The applicant noted that only 4 of 54 experiments in the intermediate enriched uranium data set were less than 30 wt% ^{235}U and, as such, the combined 84 low and intermediate enriched experiments were considered to more accurately bound the SHINE enrichment and materials. The combined data set evaluated all 140 benchmark experiments together. When evaluating the data, the applicant set positive biases to zero in calculating the USL, consistent with the guidance in NUREG/CR-6698.

The applicant initially included four experiments from the IEU-SOL-THERM-001 data set in its validation benchmark suite. Whereas most of the benchmarks analyzed had either a small positive bias (overestimating the experimental k_{eff}) or at worst a very slight negative bias (underestimating the experimental k_{eff}), the 4 benchmarks from the IEU-SOL-THERM-001 benchmark set had a negative bias of up 2.9 percent in k_{eff}. The applicant subsequently considered the benchmark set to be unreliable and dropped the 4 benchmarks from its validation as being outliers. Staff noted that the applicant committed to the validation methodology in ANSI/ANS-8.24-2007 (Reference 69), to which the NRC took two exceptions in Regulatory Guide 3.71 (Reference 75). With regard to dismissal of outliers, Regulatory Guide 3.71 states, in part, that “rejection of outliers should be based only on the inconsistency of the data with known physical behavior, rather than on statistical methods... The rejection of outliers, without a physical basis for doing so, may lead to a failure to consider all available information on possible contributions to the bias.” Although questions had been raised concerning the benchmark evaluation for this data set (International Handbook of Evaluated Criticality Safety Benchmark Experiments (IHECSBE)), the reason for the observed negative bias was not confirmed. In response to RAI 6b.3-34 (Reference XX), the applicant had initially indicated there was a likely discrepancy in the specification of the critical volume in the benchmark evaluation that could explain the calculated negative bias. The applicant stated that it had been in contact with the International Criticality Safety Benchmark Evaluation Project (ICSBEP) staff and stated that they were not currently recommending IEU-SOL-THERM-001 for use in validation pending more detailed investigation of the apparent error. However, the applicant subsequently revised its response to RAI 6b.3-34, and clarified that the discrepancy appeared to be in the benchmark model used, and not in the experiment. Therefore, consistent with the above criteria in Regulatory Guide 3.71, the four IEU-SOL-THERM-001 experiments are no longer considered outliers and will be included in a future revision to the validation because they reflect materials most similar to those utilized at the SHINE facility. Pending revision of the validation report to include the four experiments, SHINE has committed to increase its minimum margin of subcriticality to 0.06 to bound any possible reduction in the USL resulting from the inclusion of these experiments. The staff’s independent analysis using the USLSTATS module from the SCALE computer code indicated the inclusion of the four benchmarks, as originally modeled, reduced the overall USL by approximately 0.8 percent. Therefore, the additional 1 percent subcritical margin would be sufficient to bound the effect once the four benchmarks are reevaluated.

The USL determination for each data set is shown in Table 5 of the current validation report (Atkins-NS-DAC-SHN-15-03, Rev 1) without the four IEU-SOL-THERM-001 benchmarks included, and is repeated below:

Table 6b-1. Summary of USL Determination

Enrichment	Bias	Bias Uncertainty	USL
Intermediate	0.0025	0.0109	0.9391
Low to Intermediate	0.0020	0.0078	0.9422
Low, Intermediate, High	0.0011	0.0091	0.9409

The applicant established the USL for RPF operations as the USL for the intermediate enrichment data set. The applicant considered this to be a conservative choice, since that was the lowest USL for all the data sets considered. The staff considers this the most appropriate choice because it is the intermediate enrichment range that most closely corresponds to the proposed SHINE activities. The applicant then established the area of applicability (AOA) of the benchmarks in Table 9 of the validation report (recreated below in Table 6b-2) using the full data set of 140 benchmark experiments, with the exception that it limited the enrichment range to that of the intermediate enrichment cases. The staff performed additional analysis using the TSUNAMI code to determine the sensitivity of the benchmark correlation to variations in the enrichment. Based on this, the staff determined that benchmarks across the entire combined enrichment range would be applicable for validation. In addition, the staff compared the AOAs determined using each of the three data sets and determined that there were no significant differences when only the intermediate enrichment data was included. Therefore, the staff finds the methods for determination of the USL and AOA acceptable.

Table 6b-2. Area of Applicability Summary

Parameter	**Area of Applicability**
Fissile Material	UO_2, UH_3, Metal, $UO_2(NO_3)_2$, UF_4, U-ZrH, UO_2F_2, U_xO_y, UO_2SO_4
Fissile Material Form	Solid and Solution
$H/^{235}U$ ratio	$0 \le H/^{235}U \le 1400$
Average Nuetron Energy Causing Fission (MeV)	0.0027 < ANECF < 1.46
Enrichment	10 to 36 wt% ^{235}U
Moderating Materials	None, Water, Nitric Acid, Sulfuric Acid, Hydrocarbon, CF_2
Reflecting Materials	None, Water, Concrete, BeO, Hydrocarbon Material, Iron, Graphite
Absorber Materials	Boron, Aluminum, Steel, Stainless Steel, Hydrocarbon Material
Geometry	Homogenous and Heterogeneous Spheres, Hemispheres, Cylinders, Cuboids, Single Unit and Arrays

Staff noted that Section 6b.3 of the PSAR did not include the technical practices for each controlled parameter as described on pages 72 – 74 of the ISG for NUREG-1537, Part 2. The technical practices, which describe requirements for the use of each controlled parameter (both in establishing controls for the parameter and for modeling it in criticality analysis), are part of the principal design criteria for the RFP. The margin provided by conservatively modeling controlled parameters is part of the overall margin of subcriticality that gives reasonable assurance that all processes will be subcritical under normal and credible abnormal conditions. Initially, the details of how NCSEs will handle the controlled parameters was absent from the PSAR, and was not included in the NCS Manual submitted in response to RAI 6b.3-30 (Reference 29) The applicant did submit some representative analysis (discussed below) that illustrated how the parameters were dealt with in specific cases, but these were not reviewed in detail. In response to RAI 6b.3-31 (Reference XX), the applicant subsequently committed to meet the acceptance criteria for the use of each parameter in the ISG.

On page 6b-12 of the PSAR, the applicant stated that heterogeneous effects are not considered applicable because the uranium enrichment is less than 20 wt%. In the response to RAI 6b.3-6

(Reference 21), the applicant elaborates by quoting LA-12808, "Nuclear Criticality Safety Guide," such that heterogeneous effects can be ignored for uranium above 6 percent enrichment. Staff found that this response was insufficient as some guidance, specifically, Figures 22 through 25 of LA-10860-MS, "Critical Dimensions of Systems Containing U-235, Pu-239, and U-233," showed heterogeneity can have effects at greater than 6 percent enrichment. In response to RAI 6.3-27 (Reference 25), the applicant stated it will consider heterogeneity effects when establishing NCS controls and limits, where such are credible and relevant. Staff finds this acceptable.

In response to RAI 6b.3-16 (Reference 21), the applicant stated that specifics of mass control have not yet been defined and will be determined as part of the detailed design. However, it stated that if mass is used as a controlled parameter, determinations of mass will be based on either weighing the material and assuming the entire mass is SNM or conducting physical measurements to establish the actual weight percent of SNM in the material. The staff finds these are consistent with the commitments for mass control in the ISG, and are therefore acceptable.

The applicant's response to RAI 6b.3-17 (Reference 21) stated that preliminary criticality scoping safety assessments assume theoretical densities of dry and moderated fissile solids and that SHINE does not anticipate utilizing density as a control for criticality safety purposes. As such, staff finds the applicant's commitments regarding density controls to be acceptable.

The applicant's response to RAI 6b.3-18 (Reference 21) stated that SHINE plans to assume an enrichment of 21 percent to conservatively address uranium enrichment. In response to RAI 6b.3-29 (Reference 25), the applicant stated that enrichment will be independently verified upon receipt. The details of how enrichment is verified will be worked out prior to operation. Because the material should be, generally, slightly less than 20 percent enriched, the enrichment will not be further controlled throughout the facility design. Staff finds this acceptable.

The applicant's response to RAI 6b.3-19 (Reference 21) stated that preliminary criticality safety assessments have been performed using worst-case credible reflection conditions and that reflection will not be a controlled parameter. As such, staff finds the applicant's commitments regarding reflection to be acceptable.

In response to RAI 6b.3-8 (Reference 21), the applicant stated that preliminary criticality scoping safety assessments include optimum moderation conditions. In response to RAI 6b.3-28 (Reference 25), the applicant states that if using moderation as a controlled parameter, it will meet the acceptance criteria outlined in NUREG-1520. Staff therefore finds this acceptable.

In response to RAI 6b.3-9 (Reference 21), the applicant stated that preliminary criticality scoping safety assessments have been performed at optimum concentration, with the exception of the evaluation for the liquid waste processing tanks. The liquid waste processing tanks are the only tanks or vessels at the SHINE facility that are not criticality-safe by geometry where fissionable material exists outside the TSV. This will be acceptable because these tanks are not expected to ever contain an appreciable amount of fissionable material. Limits on uranium concentration will be applied to these tanks to ensure that uranium-bearing solution which exceeds the NCS limit is prevented from entering non-favorable geometry vessels.

On page 6b-16 of the PSAR, the applicant states that interaction may be used as a controlled parameter if engineered controls are used to maintain minimum separation. Enhanced administrative controls are used where engineered controls are not feasible. In response to RAI 6b.3-10 (Reference 21), the applicant stated that preliminary criticality scoping safety assessments use interaction control in conjunction with geometry control related to arrays of cylindrical tanks and storage rack arrays. These geometric designs control the spacing between storage locations in racks and the spacing of tanks containing fissile material. The structural integrity of the features will be designed such that proper spacing between fissile material units is maintained during normal and credible abnormal conditions. These commitments are consistent with guidance in the ISG and the staff therefore finds them acceptable.

On page 6b-16, the applicant states that use of neutron absorption as a controlled parameter is acceptable by following ANSI/ANS-8.21-1995 (Reference 67). Neutron spectra will be considered in the evaluation of absorber effectiveness. The applicant does not commit to ANSI/ANS-8.5-1986 as it does not anticipate using raschig rings. As such, staff finds the applicant's commitments regarding neutron absorption as a control to be acceptable.

In response to RAI 6b.3-21 (Reference 21), the applicant stated that the preliminary criticality scoping safety assessments use volume control as a controlled parameter. Volume control entails assuming an optimum concentration in a spherical geometry of fissile material, as well as full water reflection and allows for criticality safety to be demonstrated without regard to geometric shape. These commitments are consistent with guidance in the ISG and the staff therefore finds them acceptable.

The applicant did make several additional commitments in its PSAR regarding implementation of the various controlled parameters. Page 1-4 of the PSAR describes the preferred hierarchy of controls as follows:

a) The facility and equipment is designed so that significant quantities of fissionable material cannot be placed in a favorable configuration for criticality
b) Engineered controls
c) Administrative controls (e.g., limitations on allowed movements and processes involving special nuclear material [SNM])

Page 6b-1 contains an essentially equivalent list:

a) Passive engineered
b) Active engineered
c) Enhanced administrative
d) Simple administrative

The two lists are equivalent, as geometry is almost always controlled passively, and therefore incorporates both the preference for passive control and preferred reliance on geometry. The lists are consistent with the guidance in the ISG to NUREG-1537, Part 2, and therefore the staff finds these commitments acceptable.

The applicant submitted the following NCS analyses and calculations. They are in the form of preliminary criticality scoping safety assessments and do not necessarily contain all elements that would be required to support construction and operation of the facility. It is anticipated that additional hazards and controls will be identified as the facility and process design develops. The analyses submitted were:

- ATKINS-NS-DAC-SHN-15-04, Rev. 0, "Single Parameter Subcritical Limits for Homogeneous 21 wt% ^{235}U Uranyl Sulfate, Uranium Oxide, and Uranium Metal"
- ATKINS-NS-DAC-SHN-150-2, Rev. 0, "Criticality Safety Calculations for the Preliminary Design of Annular Tanks for the SHINE Medical Isotope Facility"
- ATKINS-NS-TR-SHN-15-06, Rev. 1, "Criticality Safety Evaluation for the SHINE Target Solution Preparation System"

The staff determined that a detailed review of these preliminary analyses was not necessary to support the issuance of a construction permit. The staff did verify that the NCS calculations fell within the AOA established in the validation report. Due to SHINE's preferential reliance on passive engineered NCS features, additional research and development is necessary to confirm the adequacy of the implementation of SHINE's NCS design criteria prior to the completion of construction. Specifically, SHINE's RPF design must provide reasonable assurance that all RPF processes will remain subcritical under all normal and credible abnormal conditions. Therefore, the staff imposes the inclusion of the following condition in the SHINE construction permit:

> **Prior to the installation of process equipment that may contain special nuclear material, or other such structures, systems, or components that may affect criticality safety, SHINE shall submit summaries of the criticality safety analysis for the affected processes. The criticality safety analysis summaries shall include the following: (1) a list of identified criticality hazards, (2) a list of controlled parameters, (3) a description of evaluated normal and abnormal conditions, (4) a description of the licensee's approach to meeting the double contingency principle, and (5) a list of anticipated passive and active engineered controls, including any assumptions, to ensure the process(es) will remain subcritical under normal and credible abnormal conditions.**

Following the review of the SHINE's preliminary NCS Manual and a preliminary review of the NCSEs, the staff noted inconsistencies in the applicant's treatment of fissile isotopes other than U-235. Notably, on pages 4b-4 and -5 of the PSAR, the applicant states that small quantities of Pu-239 and U-233 may be present in recycled target solution. These nuclides are generally accepted as being more reactive than U-235 at thermal neutron energies. However, in the preliminary NCSEs and NCS manual provided in response to RAI 6b.3-30 (Reference 25 and 29), staff noted that there was no mention of these nuclides. The staff's modeling of the SHINE systems using the SCALE code determined that inclusion of these nuclides in SHINE's NCS analysis may result in a statistically significant increase in k_{eff}. While the staff finds that SHINE's preliminary NCS analyses and calculations are sufficient to allow SHINE to proceed with construction, due to SHINE's inconsistent treatment of fissile isotopes, additional research and development is necessary to confirm the adequacy of the implementation of SHINE's NCS design criteria prior to the completion of construction. Specifically, SHINE's RPF design must provide reasonable assurance that all RPF processes will remain subcritical under all normal and credible abnormal conditions. Therefore, the staff imposes the inclusion of the following condition in the SHINE construction permit:

> **Prior to the installation of process equipment that may contain fissile nuclides other than U-235, or other such structures, systems, or components that may affect criticality safety for these processes, SHINE shall specifically address in the relevant NCSEs the reactivity contributions**

from all fissile isotopes, or apply an additional subcritical margin to account for neglecting these nuclides.

On the basis of its review, the staff finds that the level of detail provided on nuclear criticality safety for the RPF satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 6b.3, allowing the staff to make, with reasonable assurance, the following relevant findings, subject to the satisfaction of the permit conditions in this section of the SER:

1. The applicant will have in place an NCS program.

2. The applicant will have in place personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

3. The applicant’s conduct of operations will be based on NCS technical practices, which will ensure that the fissile material will be possessed, stored, and used safely.

4. The applicant will develop, implement, and maintain a criticality accident alarm system that meets applicable acceptance criteria.

Therefore, the staff finds that SHINE’s NCS program, as described in PSAR Section 6b.3 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, subject to the aforementioned conditions Those safety features and components requiring additional research and development to confirm adequacy of design have been identified and recommended for inclusion as conditions in the SHINE construction permit. The staff will consider the conditions of the construction permit to be met following the review and approval of any supporting documentation submitted by the applicant, and subsequently confirmed by the NRC’s construction inspection program. All conditions of the construction permit must be satisfied prior to the completion of construction and issuance of an operating license. Any such further technical or design information outside of the scope of these construction permit conditions and as may be required to complete the safety analysis of the SHINE facility can reasonably left for later consideration during the evaluation of SHINE’s FSAR, as part of the review of an operating license application.

6b.4.6 Probable Subjects of Technical Specifications

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

SHINE PSAR Sections 6b.2.1.6, “Design Bases,” 6b.2.4, “Radioisotope Production Facility Engineered Safety Features Technical Specifications,” and 6b.3.2, “Technical Specifications,” state that potential variables, conditions, or other items that will be probable subjects of a technical specification associated with the RPF confinement systems and components, ESFs, and nuclear criticality safety are provided in SHINE PSAR Chapter 14. However, in Tables 6b.1-1, “Summary of RPF Design Basis Accidents and ESF Provided for Mitigation,” 6b.2-1, “Radioisotope Production Facility Design Basis Accident Consequence Determination,” 6b.2-2, “Radioisotope Production Facility Confinement Safety Functions,” 6b.3-1, “Tanks Subject to

Criticality-Safety Controls," and 6b.3-2, "Nuclear Criticality Safety Program Elements and Requirement Bases," SHINE identifies structures systems and components, events, and programs likely to be addressed by technical specifications.

In Table 14a2-1, "SHINE Facility Proposed Parameters for Technical Specifications," SHINE identifies the criticality safety design, including the condition of criticality safe sumps, and RPF confinement isolation valves as likely to be the subject of LCOs.

In PSAR Section 14b.2.1, "Safety Limits for Processing Irradiated Special Nuclear Material Outside of the Reactor," SHINE states that "SLs are derived for criticality accident prevention based on the Nuclear Criticality Safety Program, and also from an Integrated Safety Analysis (ISA). Limits are specified, using the double-contingency principle, to avoid a criticality accident. Limits are set with a conservative margin."

In response to RAI 6b.2-9 (Reference 21), the applicant stated the ESF function for both the IF and RPF consists of confinement systems, ventilation systems, and control systems. Post-accident mitigation is accomplished by confinement of radioactive or hazardous material to controlled areas to mitigate the consequences of design basis accidents (DBAs). This confinement occurs by shutting isolation dampers in the ventilation systems or isolation valves in lines penetrating the confinement area when parameters are determined to be outside predefined limits. This function is known as the ESF function. The control systems that perform this function are known as the ESFAS in the IF, and the Radiological Integrated Control System (RICS) in the RPF.

Probable subjects of proposed TS for the IF and RPF ESF confinement systems are provided in PSAR Table 14a2-1, Section 3.4, and are also referenced for the RPF specifically in Subsection PSAR 14b.3.2. Per PSAR Table 14a2-1, the following Confinement LCOs will be developed:

- TPS glove box system or confinement (IF)
- IU and TOGS shielded cell confinement isolation valves (IF)
- Confinement isolation valves (RPF)

Probable subjects of proposed TS for the IF and RPF ESF ventilation systems are provided in PSAR Table 14a2-1, Section 3.5, and are also referenced for the RPF specifically in PSAR Subsection 14b.3.3. Per PSAR Table 14a2-1, the following LCOs will be developed:

- RVZ1 and RVZ2 isolation dampers (IF and RPF)

Probable subjects of proposed TS for ESF control and actuation are provided in PSAR Table 14a2-1 Sections 3.2 and 3.9 of, and are also referenced for the RPF specifically in PSAR Subsections 14b.3.1 and 14b.3.5. Per PSAR Table 14a2-1, the following LCOs will be developed:

- ESFAS input to the TRPS, including the required operable channels per future TS Table 3.2.1 (i.e., TS Table 3.2.1 will include channel(s) monitored, number of channels required, allowable value, nominal setpoint, permissible bypass, or other conditions) (IF)
- RICS (initiates the isolation functions necessary to achieve confinement in the RPF)

The probable subjects of TS for ESF equipment are described above. Specific details related to these probable subjects, such as periodic functional testing of damper closure, room isolation, minimum airflow rates, automatic system shutdown and startup, and activation setpoints will be provided in the SHINE TS, which will be provided as part of the SHINE OL Application.

Based on the information provided in PSAR Chapters 6b and 14, as well as PSAR Table 14a2-1 and supplemented by the response to RAI 6b.2-9, the staff finds that the identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications for the SHINE RPF ESFs are sufficient and meet the applicable regulatory requirements and acceptance criteria of NUREG-1537 in support of the issuance of a construction permit in accordance with 10 CFR 50.35. A complete evaluation of technical specifications, LCOs, and surveillance requirements will be performed during the review of the SHINE operating license application.

6b.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of SHINE's RPF ESFs, including probable subjects of technical specifications, as described in SHINE PSAR Section 6b and supplemented by the applicant's response to RAIs, and finds that the preliminary design of SHINE's RPF ESFs, including the principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in NUREG-1537.

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 RPF ESF systems, 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 will be supplied in the FSAR.

(3) Safety features or components, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

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