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, LLC (SHINE, the applicant) irradiation facility (IF) and radioisotope production facility (RPF) (together, the SHINE facility). 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 operating license application safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE IF and RPF ESFs as presented in chapter 6, "Engineered Safety Features," of the SHINE Final Safety Analysis Report (FSAR) and supplemented by the applicant's responses to staff requests for additional information (RAIs).

6a Irradiation Facility Engineered Safety Features

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

6a.1 <u>Areas of Review</u>

The NRC staff reviewed SHINE FSAR section 6a2 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE IF ESFs. The final design bases of the SHINE IF ESFs were evaluated to ensure that the design bases and functions of the structures, systems, and components (SSCs) are presented in sufficient detail to allow a clear understanding of the facility and to ensure that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the facility staff and the public. Drawings and diagrams were evaluated to determine if they present a clear and general understanding of the physical facility features and of the processes involved. In addition, the staff evaluated the sufficiency of SHINE's proposed technical specifications for the facility.

Areas of review for this section include a summary description of the SHINE IF ESFs, as well as a detailed description of IF confinement. Within these review areas, the NRC staff assessed, in part, the final 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.

The ESFs described in SHINE FSAR section 6a2 are achieved through a combination of passive and active features of many SSCs. Detailed descriptions of many of the SSCs are in their applicable portions of the FSAR and referenced in this SER.

6a.2 Summary of Application

SHINE FSAR section 6a2 includes a summary of the ESFs installed in the SHINE IF, including references to SHINE FSAR tables and sections that address accidents considered in the facility's design. Additionally, SHINE FSAR table 6a2.1-1, "Summary of Engineered Safety Features and Design Basis Accidents Mitigated," contains a summary of the ESFs and the IF design basis accidents (DBAs) that they are designed to mitigate.

6a.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR section 6a2 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE IF ESFs for the issuance of an operating license.

6a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE IF ESFs are as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report"
- 10 CFR 50.36, "Technical specifications"
- 10 CFR 50.40, "Common standards"
- 10 CR 50.57, "Issuance of operating license"
- 10 CFR Part 20, "Standards for Protection Against Radiation"

6a.3.2 Applicable Regulatory Guidance and Acceptance Criteria

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

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.

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

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

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

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

In addition, the following SHINE design criteria in SHINE FSAR chapter 3, “Design of Structures, Systems, and Components,” are applicable to the confinement part of the ESFs:

Criterion 29 - Confinement design

> Confinement boundaries are provided to establish a low-leakage barrier against the uncontrolled release of radioactivity to the environment and to assure that confinement design leakage rates are not exceeded for as long as postulated accident conditions require. Four classes of confinement boundaries are established:
>
> 1) the primary confinement boundary,
>
> 2) the process confinement boundary,
>
> 3) hot cells and gloveboxes, and
>
> 4) radiologically-controlled area ventilation isolations.

Criterion 32 - Provisions for confinement testing and inspection

> Each confinement boundary is designed to permit:
>
> 1) appropriate periodic inspection of important areas, such as penetrations;

2) an appropriate surveillance program; and

3) periodic testing of confinement leakage rates.

Criterion 33 - Piping systems penetrating confinement

Piping systems penetrating confinement boundaries that have the potential for excessive leakage are provided with isolation capabilities appropriate to the potential for excessive leakage.

Piping systems that pass between confinement boundaries are equipped with either:

1) a locked closed manual isolation valve, or

2) an automatic isolation valve that takes the position that provides greater safety upon loss of actuating power.

Manual isolation valves are maintained locked-shut for any conditions requiring confinement boundary integrity.

Criterion 34 - Confinement isolation

Lines from outside confinement that penetrate the primary confinement boundary and are connected directly to the primary system boundary are provided with redundant isolation capabilities.

Ventilation, monitoring, and other systems that penetrate the primary, process, glovebox or hot cell confinement boundaries, are connected directly to the confinement atmosphere and are not normally locked closed, have redundant isolation capabilities or are otherwise directed to structures, systems, and components capable of handling any leakage.

Isolation valves outside confinement boundaries are located as close to the confinement as practical and upon loss of actuating power, automatic isolation valves are designed to take the position that provides greater safety. Manual isolation valves are maintained locked-shut for any conditions requiring confinement boundary integrity.

All electrical connections from equipment external to the confinement boundaries are sealed to minimize air leakage.

Criterion 35 - Control of releases of radioactive materials to the environment

The facility is designed to include means to suitably control the release of radioactive materials in gaseous and liquid effluents and to handle radioactive solid wastes produced during normal operation, including anticipated transients. Sufficient holdup capacity is provided for retention of radioactive gases.

Criterion 39 - Hydrogen mitigation

> Systems to control the buildup of hydrogen that is released into the primary system boundary and tanks or other volumes that contain fission products and produce significant quantities of hydrogen are provided to ensure that the integrity of the system and confinement boundaries are maintained.

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

The NRC staff performed a review of the technical information presented in SHINE FSAR section 6a2, as supplemented, to assess the sufficiency of the final design and performance of the SHINE IF ESFs for the issuance of an operating license. The sufficiency of the final design and performance is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 6a.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the staff review are described in section 6a.5, "Review Findings," of this SER.

6a.4.1 Summary Description

The NRC staff evaluated the sufficiency of the summary description of the SHINE IF ESFs, as presented in SHINE FSAR section 6a2.1, "Summary Description," using the guidance and acceptance criteria from section 6.1, "Summary Description," of NUREG-1537, Part 2, and section 6a2.1, "Summary Description," of the ISG augmenting NUREG-1537, Part 2.

SHINE FSAR table 6a2.1-1 contains a summary of ESFs and the IF DBAs that they are designed to mitigate. The credited ESFs are primary confinement boundary, tritium confinement boundary, and combustible gas management.

SHINE FSAR figure 6a.2.1-1, "Irradiation Facility Engineered Safety Features Block Diagram," provides a block diagram for the SHINE IF ESFs that shows the location and basic function of the SSCs providing ESFs in the IF portion of the SHINE facility. The diagram indicates the passive components for which credit is taken for the three ESFs (i.e., primary confinement boundary, tritium confinement boundary, and combustible gas management). The diagram also indicates the active components in the three ESFs that respond to confinement isolation signals from the engineered safety features actuation system (ESFAS) and the target solution vessel (TSV) reactivity protection system (TRPS). The active components that respond to TRPS and ESFAS are listed in SHINE FSAR chapter 7, "Instrumentation and Control Systems," section 7.4, "Target Solution Vessel Reactivity Protection System," and section 7.5, "Engineered Safety Features Actuation System," respectively.

Based on its review, the NRC staff finds that the SHINE IF ESFs are adequately described in SHINE FSAR section 6a2.1; therefore, the staff finds that the summary description of the SHINE IF ESFs meets the acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, for the issuance of an operating license.

6a.4.2 Confinement

The NRC staff evaluated the sufficiency of the final design of the SHINE confinement and related systems, as presented in SHINE FSAR section 6a.2.2.1, "Confinement," using the guidance and acceptance criteria from section 6.2.1, “Confinement,” of NUREG-1537, Parts 1 and 2, and section 6a2.2.1, “Confinement,” of the ISG augmenting NUREG-1537, Part 2. The staff reviewed 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, proposed technical specifications, and testing requirements were also evaluated for sufficiency.

Primary Confinement Boundary

The primary confinement boundary contains the primary system boundary that contains the fission products. The primary confinement boundary is primarily passive and consists predominantly of the irradiation unit (IU) cell, the TSV off-gas system (TOGS) shielded cell, and a cell enclosing the two heating, ventilation, and air conditioning (HVAC) units serving the IU and TOGS cells. The boundary of each IU is independent from the other IUs. The IU cell portion of the primary confinement boundary contains the TSV, TSV dump tank, portions of the TOGS, portions of the primary closed loop cooling system (PCLS), associated primary system boundary (PSB) piping, the light water pool, and the neutron driver. The primary confinement boundary is operated within a normally-closed atmosphere except through the PCLS expansion tank. The PCLS expansion tank connection to the radiological ventilation zone 1 (RVZ1) exhaust subsystem (RVZ1e) provides a vent path for radiolysis gases produced in the PCLS and light water pool, to avoid the buildup of hydrogen gas. The connection to RVZ1e is equipped with redundant dampers or valves that close on a confinement actuation signal, isolating the cells from RVZ1. SHINE FSAR section 9a2, “Irradiation Facility Auxiliary Systems,” subsection 9a2.1.1.2, “System Description,” provides a detailed description of RVZ1 including the associated exhaust system RVZ1e.

Each piping system capable of excessive leakage that penetrates the primary confinement boundary, as indicated in SHINE FSAR figure 6a2.2-1, “Primary Confinement Boundary,” is equipped with one or more isolation valves that serve as active confinement components, except for the nitrogen purge system (N2PS) supply and process vessel vent system (PVVS) connections, which may remain open to provide combustible gas mitigation. Actuation of the isolation valves is controlled by the TRPS.

SHINE FSAR section 7.4.3.1, “Safety Functions,” provides a listing of TRPS monitored variables that can cause the initiation of an IU Cell Safety Actuation. Following an actuation, PSB and primary confinement boundary isolation valves transition to their deenergized states, closing valves to safely isolate the corresponding system.

Tritium Confinement Boundary

Portions of the tritium purification system (TPS) serve as the tritium confinement boundary as indicated in the functional block diagram in SHINE FSAR figure 6a2.2-2, “Tritium Confinement Boundary.”

Tritium in the SHINE IF is confined using active and passive features of the TPS. The TPS gloveboxes and secondary enclosure cleanup subsystems are credited as passive confinement barriers. The TPS gloveboxes enclose TPS process equipment, thus allowing credit as a passive confinement barrier. TPS gloveboxes are maintained at negative pressure relative to the TPS room and have a helium atmosphere. The TPS gloveboxes provide confinement in the event of a breach in the TPS process equipment that results in a release of tritium from the isotope separation process equipment.

The TPS gloveboxes include isolation valves on the helium supply, the glovebox pressure control exhaust, and the vacuum/impurity treatment subsystem process vents.

The TPS has isolation valves on the process connections to the neutron driver assembly system (NDAS) target chamber supply and exhaust lines. The TPS-NDAS interface lines themselves are part of the credited tritium confinement boundary up to the interface with the primary confinement boundary.

When the isolation valves for a process line or glovebox close, the spread of radioactive material is limited to the glovebox plus the small amount in the lines between the glovebox and its isolation valves. The liquid nitrogen supply and exhaust lines and the gaseous nitrogen pneumatic lines for the TPS equipment are credited to remain intact during a DBA and the internal interface between the gloveboxes and nitrogen lines serves as a passive section of the tritium confinement boundary.

Upon detection of TPS exhaust to facility stack high tritium concentration or TPS glovebox high tritium concentration, the ESFAS automatically initiates a TPS isolation. Upon TPS isolation initiation, required active components maintaining confinement are transitioned to their deenergized (safe) state. A description of the ESFAS and a complete listing of the active components that transition to a safe state upon a TPS isolation are provided in SHINE FSAR section 7.5. The evaluated DBAs for which the tritium confinement boundary is necessary are listed in SHINE FSAR table 6a2.1-1 and further discussed in SHINE FSAR chapter 13a2, “Irradiation Facility Accident Analysis.” SHINE FSAR section 9a2.7.1, “Tritium Purification System,” contains a detailed description of tritium purification and the interfaces that function for tritium confinement.

Combustible Gas Management

Hydrogen gas is produced by radiolysis in the target solution during and after irradiation. During normal operation, the concentration of hydrogen gas is monitored and maintained below the lower flammability limit (LFL) using the TOGS. If the TOGS becomes unavailable, the buildup of hydrogen gas is limited using the combustible gas management system, which uses the N2PS, PSB piping, and portions of the PVVS to establish an inert gas flow through the IUs. The objective of the combustible gas management system is to prevent conditions that could lead to a hydrogen deflagration within the PSB.

The N2PS provides back-up nitrogen sweep gas to each IU upon a loss of power or loss of normal sweep gas flow to maintain hydrogen concentrations in these systems below acceptable values. The combustible gas management system is depicted in SHINE FSAR figure 6a2.2-3, “Irradiation Facility Combustible Gas Management Functional Block Diagram.” Detailed descriptions of the PVVS and the N2PS are provided in SHINE FSAR section 9b.6.1, “Process Vessel Vent System,” and section 9b.6.2, “Nitrogen Purge System,” respectively.

On a loss of power or receipt of an appropriate TRPS or ESFAS actuation signal, solenoid-operated isolation valves on the nitrogen discharge manifold open and supply nitrogen to the IU cell supply header. The nitrogen is supplied to each TSV dump tank and flows through the TSV dump tank, the TSV, and the TOGS equipment and piping, and is then directed to the PVVS guard beds, delay beds, and high-efficiency particulate air (HEPA) filter before being discharged to the environment via a safety-related vent path.

The complete listing of variables within the TRPS that can cause the initiation of an IU Cell Nitrogen Purge is provided in SHINE FSAR section 7.4.3.1.” These variables indicate a loss of flow or ability to recombine hydrogen by the TOGS. Upon initiation of an IU Cell Nitrogen Purge, active components required to function to establish and maintain the N2PS flow path are transitioned to their deenergized state by the TRPS and the ESFAS. Descriptions of the TRPS and the ESFAS are provided in SHINE FSAR sections 7.4 and 7.5, respectively.

Failure of the TOGS to manage the combustible gases generated by the subcritical assembly can potentially result in a deflagration within the PSB. Hydrogen deflagration within the PSB is an initiating event and DBA analyzed in SHINE FSAR chapter 13a2. The evaluated DBAs for which the combustible gas management system is necessary are listed in SHINE FSAR table 6a2.1-1 and further discussed in SHINE FSAR chapter 13a2.

Dose Consequences

SHINE FSAR table 6a2.1-2, “Comparison of Unmitigated and Mitigated Radiological Doses for Select Irradiation Facility DBAs,” provides unmitigated and mitigated doses for select DBAs in the SHINE IF. The maximum mitigated doses in SHINE FSAR table 6a2.1-2 are 0.8 rem total effective dose equivalent (TEDE) to the public and 1.9 rem TEDE to the worker. In SHINE FSAR section 13a2.2, “Accident Analysis and Determination of Consequences,” the applicant proposed the following accident dose criteria:

Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 1 rem TEDE for the duration of the accident; and

Radiological consequences to workers do not exceed 5 rem TEDE during the accident.

The NRC staff finds these dose criteria to be acceptable in section 13a.4.1, “Radiological and Design Criterion,” of this SER. The dose consequences, in some cases, would be unacceptable with respect to these criteria without mitigation by ESFs. As described in SHINE FSAR chapter 13a2, specific postulated accident scenarios indicate the need for the confinement ESFs.

Based on its review, the NRC staff finds that there is reasonable assurance that the confinement ESFs are designed to ensure that the radiological consequences to a member of the public and a worker would remain below 1 rem and 5 rem, respectively, and, therefore, that the confinement ESFs are acceptable with respect to dose consequences.

Design Criteria

Section 6b.4.2, “Confinement,” of this SER describes the NRC staff’s evaluation of the design criteria as it applies to both the SHINE IF and RPF.

Conclusion

Based on the evaluation of the SHINE IF ESFs, the NRC staff concludes that the final design of the SHINE IF ESFs, including the principal design criteria, design bases, and information relative to confinement, satisfies the relevant acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds the final design of the SHINE IF ESFs acceptable.

6a.4.3 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed technical specifications (TSs) for the SHINE IF ESFs as described in SHINE FSAR section 6a2.

The proposed TS 3.4, "Confinement," Limiting Condition For Operation (LCO) 3.4.1 and surveillance requirement (SR) 3.4.1 state the following:

LCO 3.4.1	Each primary Confinement boundary or PSB isolation valve listed in Table 3.4.1-a shall be Operable. A valve is considered Operable if: 1. The valve is capable of opening or closing on demand from TRPS Note – A single isolation valve in a flow path may be inoperable for up to 2 hours during the performance of required surveillances. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3, or 4
Action	According to Table 3.4.1
SR 3.4.1	1. Valves and dampers listed in Table 3.4.1-a shall be verified to stroke upon demand from TRPS annually.

The proposed TS Table 3.4.1, "Confinement Boundary and Isolation Actions," states the following:

	Condition and Action (per IU)	Completion Time
1.	If one or more isolation valve(s) in one or more flow path(s) is inoperable,	
	Close at least one valve in the affected flow path	6 hours
	OR	
	Place the associated IU in Mode 3	6 hours
	AND	
	Place the associated IU in Mode 0.	[[PROP/ECI]]

2.	If one or more isolation valve(s) in one or more flow path(s) is inoperable, Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	 6 hours [[PROP/ECI]]

LCO 3.4.1 specifies that each confinement boundary and PSB isolation valve in TS table 3.4.1-a, “Isolation Valves,” shall be operable from TRPS in IU Modes 1, 2, 3, and 4 and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure that the TRPS automatically isolates the confinement system and PSB to prevent the inadvertent release of radioactive material. The staff also finds that if the valves listed in table 3.4.1-a are inoperable, then their flow path is isolated by closing at least one valve or the target solution would be transferred to the TSV dump tank and then to the RPF. The staff finds that for systems that do not have an option to close one valve in the flow path, the target solution would be transferred to the TSV dump tank and then to the RPF. The staff finds that the completion time allows for investigation and the performance of minor repairs and is based on the continued availability of the redundant isolation valve or redundant check valve in the flow path. Therefore, the staff finds LCO 3.4.1 acceptable.

SR 3.4.1 requires that the valves in TS table 3.4.1-a be verified to stroke upon demand from TRPS annually. Section 4.4.2, “Confinement,” of ANSI/ANS-15.1-2007, “The Development of Technical Specifications for Research Reactors,” states, in part, that a functional test should be performed. NUREG-1431, Revision 5.0, “Standard Technical Specifications: Westinghouse Plants,” Volume 1, “Specifications” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21259A155), SR 3.6.3.8 states, in part, that a test to verify that automatic containment isolation valves actuate to the isolation position on an actual or simulated signal be performed every 18 months. As described in chapter 14, “Technical Specifications,” of the SER, the NRC staff used guidance in NUREG-1431 to review SHINE’s proposed TSs. Based on the foregoing, the staff finds that the stroke test of SR 3.4.1 is an appropriate functional test and that its frequency is adequate to confirm the operability of the confinement boundary or PSB. Therefore, the staff finds SR 3.4.1 acceptable.

The proposed TS 3.4, LCO 3.4.2 and SR 3.4.2 state the following:

LCO 3.4.2	The Confinement check valves listed in Table 3.4.2-a shall be Operable. Note – This LCO is applied to each IU or TPS train independently; actions are only applicable to the IU(s) or TPS train(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3, or 4, according to Table 3.4.2-a
Action	According to Table 3.4.2
SR 3.4.2	1. The check valves listed in Table 3.4.2-a shall be inspected annually.

The proposed TS Table 3.4.2, “Confinement Check Valve Actions,” states the following:

	Condition and Action (per IU or per TPS train)	Completion Time
1.	If the check valve is inoperable, Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	6 hours [[PROP/ECI]]
2.	If the check valve is inoperable, Place the associated IU in Mode 3 AND Close the PCLS supply isolation valve.	 6 hours 6 hours
3.	If the check valve is inoperable, Close the TPS isolation valve in the affected flow path.	 6 hours

LCO 3.4.2 specifies that each confinement check valve in TS table 3.4.2-a, “Confinement Check Valves,” shall be operable in IU Modes 1, 2, 3, and 4, with tritium not in storage for the TPS, and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure redundant isolation of the confinement system to prevent the inadvertent release of radioactive material. The staff also finds that if the TOGS radioisotope process facility cooling system (RPCS), subcritical assembly system (SCAS) nitrogen purge, and PCLS supply check valves are inoperable, the target solution would be transferred to the TSV dump tank and to the RPF, if required. For the PCLS and TPS check valves, the staff finds that the flow path for the system is also isolated. For the PCLS and TPS check valves, the staff finds that the completion time allows for investigation and the performance of minor repairs and is based on the continued availability of the redundant isolation valve in the flow path. For the TOGS RPCS and SCAS nitrogen purge check valves, the staff finds that the completion time is based on the orderly shutdown of the IU and continued availability of redundant components. Therefore, the staff finds LCO 3.4.2 acceptable.

SR 3.4.2 requires that the valves in TS table 3.4.2-a be inspected annually. The NRC staff finds that this surveillance and frequency would ensure that the check valves maintain operability to isolate the system to prevent the inadvertent release of radioactive material from the system. Therefore, the staff finds SR 3.4.2 acceptable.

The proposed TS 3.4, LCO 3.4.5 and SR 3.4.5 state the following:

LCO 3.4.5	Primary Confinement boundary shield plugs shall be Operable. Primary Confinement boundary shield plugs are Operable if: 1. The shield plug sealing surfaces have a proven satisfactory leak rate. Note – This LCO is applied to each IU independently; actions are only applicable to the IU(s) that fail to meet the LCO.
Applicability	Associated IU in Mode 1, 2, 3, or 4
Action	According to Table 3.4.5
SR 3.4.5	1. IU cell primary Confinement boundary shall be verified to be Operable by measuring leak rate past shield plug sealing surfaces upon each reinstallation of the IU cell confinement boundary shield plug or inspection port. The IU cell shield plug leak rate must be less than 2.10E+06 standard cubic centimeters per minute (sccm) at ≥ 3.9 psi. 2. TOGS cell primary Confinement boundary shall be verified to be Operable by measuring leak rate past shield plug sealing surfaces upon each reinstallation of the TOGS cell confinement boundary shield plug or inspection port. TOGS cell shield plug leak rate must be less than 1.16E+05 sccm at ≥ 3.9 psi.

The proposed TS Table 3.4.5, "Primary Confinement Boundary Shield Plug Actions," states the following:

	Action (per IU)	Completion Time
1.	If a primary Confinement boundary shield plug is not Operable Place the associated IU in Mode 3 AND Place the associated IU in Mode 0.	Immediately [[PROP/ECI]]

LCO 3.4.5 specifies that each primary confinement boundary shield plug shall be operable by the sealing surfaces having a proven satisfactory leak rate for IU Modes 1, 2, 3, and 4 and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure that the primary confinement boundary is maintained after maintenance activities that result in the reinstallation of the shield plugs in the IU and TOGS primary confinement boundary. The staff also finds that if the shield plugs are inoperable, the target solution would be transferred to the TSV dump tank immediately and then to the RPF. The staff finds that the completion time to drain the TSV to the TSV dump tanks immediately secures operations to limit the generation of radioactive material available for potential release during a DBA. Therefore, the staff finds LCO 3.4.5 acceptable.

SR 3.4.5 requires that each IU and TOGS shield plug sealing surface leak rate be measured after reinstallation of the shield plug or inspection port. Section 4.4.1, "Containment," of ANSI/ANS-15.1-2007 states that a leak-tightness test should be performed following modifications or repair. The NRC staff finds that this frequency to perform a leak-tightness test of the shield plug or inspection port after reinstallation is in accordance with ANSI/ANS-15.1-2007. In response to RAI 13-16 (ML21243A269, SHINE stated that the analytical leak rate out of the IU cell is 6E+04 standard cubic centimeters per minute (sccm) at 0.5 kilopascal (kPa) (0.072 pounds per square inch (psi)) and out of the TOGS cell is 4E+04 sccm at 6 kPa (0.87 psi). Because the leak rates in SR 3.4.5 provide margin to the analytical leak rates, the staff finds these leak rates acceptable. Therefore, the staff finds SR 3.4.5 acceptable.

The proposed TS 5.5.5, "Maintenance of Safety-Related SSCs," states, in part, the following:

> The SHINE maintenance program, which includes inspection, testing, and maintenance, ensures that the safety-related SSCs are available and reliable when needed. The maintenance program includes corrective maintenance, preventative maintenance, surveillance and monitoring, and testing. The maintenance program includes the following activities to ensure that safety-related SSCs can perform their functions as required by the accident analysis:
>
> 1. Inspection and maintenance of Confinement boundaries;….

TS 5.5.5 specifies that SHINE's maintenance program ensures that safety-related SSCs, such as the confinement boundaries, are available and reliable to perform their safety function during a postulated accident. The NRC staff finds that this TS is an administrative control to implement a maintenance program that would help ensure that the confinement boundaries are reliable and available to perform their safety function. Therefore, the staff finds TS 5.5.5 acceptable.

6a.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE IF ESFs, as described in SHINE FSAR section 6a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the IF ESFs and identified the major features or components incorporated therein for the protection of the health and safety of the public.

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

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

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE IF ESFs are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

6b Radioisotope Production Facility Engineered Safety Features

SER section 6b, “Radioisotope Production Facility Engineered Safety Features,” provides an evaluation of the final design of SHINE’s RPF ESFs as presented in SHINE FSAR section 6b, “Radioisotope Production Facility Engineered Safety Features,” within which the applicant described the RPF ESFs and nuclear criticality control.

6b.1 Areas of Review

The NRC staff reviewed SHINE FSAR section 6b against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE RPF ESFs. The final design bases of the SHINE RPF ESFs were evaluated to ensure that the design bases and functions of the SSCs are presented in sufficient detail to allow a clear understanding of the facility and to ensure that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the facility staff and the public. In addition, the staff evaluated the sufficiency of SHINE’s proposed TSs for the facility.

Areas of review for this section include a summary description of the SHINE RPF ESFs, as well as a detailed description of RPF confinement and nuclear criticality safety analysis. Within these review areas, the NRC staff assessed, in part, the 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).

The ESFs described in SHINE FSAR section 6b are achieved through a combination of passive and active features of many SSCs. Detailed descriptions of many of the SSCs are in their applicable portions of the FSAR and referenced in this SER.

6b.2 Summary of Application

SHINE FSAR section 6b.1, “Summary Description,” describes the SSCs that constitute the confinement ESFs in the RPF final design and summarizes the postulated accidents whose consequences could be unacceptable without mitigation. As described in greater detail in SHINE FSAR chapter 13b, “Radioisotope Production Facility Accident Analyses,” specific postulated accident scenarios indicate the need for the RPF confinement ESFs.

6b.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR section 6b against the applicable regulatory requirements, using regulatory guidance and acceptance criteria, to assess the sufficiency of the final design and performance of the SHINE RPF ESFs for the issuance of an operating license.

6b.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the SHINE RPF ESFs are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (b), "Final safety analysis report"
- 10 CFR 50.36, "Technical specifications"
- 10 CFR 50.40, "Common standards"
- 10 CFR 50.57, "Issuance of operating license"
- 10 CFR Part 20, "Standards for Protection Against Radiation"

In addition to any radiological hazards associated with operations in a production facility, 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," 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 a requirement for 10 CFR Part 50 licenses, these limits were considered when reviewing this section of the SHINE FSAR consistent with the ISG augmenting NUREG-1537, Part 2, which states that "the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotope production facilities."

6b.3.2 Applicable Regulatory Guidance and Acceptance Criteria

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

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.
- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power

Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012.

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

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, IEEE standards, ANSI/ANS standards, etc.) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, "References," of this SER.

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

The NRC staff performed a review of the technical information presented in SHINE FSAR section 6b, as supplemented, to assess the sufficiency of the final design and performance of the SHINE RPF ESFs for the issuance of an operating license. The sufficiency of the final design and performance is determined by ensuring that they meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in section 6b.3, "Regulatory Requirements and Guidance 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 findings of the staff review are described in section 6b.5, "Review Findings," of this SER.

6b.4.1 Summary Description

The NRC staff evaluated the sufficiency of the summary description of the SHINE RPF ESFs, as presented in SHINE FSAR section 6b.1, using the guidance and acceptance criteria from section 6.1, "Summary Description," of NUREG-1537, Parts 1 and 2, and section 6b.1, "Summary Description," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR table 6b.1-1, "Summary of Engineered Safety Features and Design Basis Accidents Mitigated," contains a summary of ESFs and the RPF DBAs that they are designed to mitigate. The credited ESFs are supercell confinement, below grade confinement, process vessel ventilation isolation, and combustible gas management.

SHINE FSAR figure 6b.1-1, "Radioisotope Production Facility Engineered Safety Features Block Diagram," provides a block diagram for the SHINE RPF ESFs that shows the location and basic function of the SSCs providing ESFs in the RPF portion of the SHINE facility. The diagram indicates the passive components for which credit is taken for the ESFs. The diagram also indicates the active components in the ESFs that respond to confinement isolation signals from the ESFAS. The active components that respond to ESFAS are listed in SHINE FSAR section 7.5.

Based on its review, the NRC staff finds that the SHINE RPF ESFs are adequately described in SHINE FSAR section 6b.1; therefore, the staff finds that the summary description of the SHINE RPF ESFs meets the acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, for the issuance of an operating license.

6b.4.2 Confinement

The NRC staff evaluated the sufficiency of the final design of the SHINE confinement and related systems, as presented in SHINE FSAR section 6b.2.1, "Confinement," using the guidance and acceptance criteria from section 6.2.1, "Confinement," of NUREG-1537, Parts 1 and 2, and section 6b.2.1, "Confinement," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff reviewed 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, proposed technical specifications, and testing requirements were also evaluated for sufficiency.

<u>Supercell Confinement</u>

The supercell is a set of hot cells in which isotope extraction, purification, and packaging is performed, and gaseous waste is handled. The supercell provides shielding and confinement to protect the workers, members of the public, and the environment by confining the airborne radioactive materials during normal operation and in the event of a release. SHINE FSAR figure 6b.2-1, "Supercell Confinement Boundary," provides a block diagram of the supercell confinement boundary. The RVZ1e draws air through each individual confinement box to maintain negative pressure inside the confinement, minimizing the release of radiological material to the facility. Filters and carbon adsorbers are provided on the ventilation inlets and outlets. Radiation monitoring on the outlet side to detect off-normal releases will isolate the hot cells by closing both inlet and outlet dampers or valves. Additionally, the actuation signal closes isolation valves on the molybdenum extraction and purification system (MEPS) heating loops and conducts a vacuum transfer system (VTS) safety actuation. As part of VTS safety actuation, connections to the supercell from the facility chemical reagent system (FCRS) skid isolate, closing the MEPS and iodine and xenon purification and packaging (IXP) supply valves as described in SHINE FSAR subsection 7.5.3.1.17, "VTS Safety Actuation." The active components required to function to maintain the confinement barrier are actuated by the ESFAS, as described in SHINE FSAR section 7.5. If sufficient radioactive material reaches the radiation monitors in the RVZ1e exhaust duct, ESFAS will isolate the RVZ building supply and exhaust. The evaluated DBA for which the supercell confinement is necessary is listed in SHINE FSAR table 6b.1-1 and further discussed in SHINE FSAR section 13b.2, "Analyses of Accidents with Radiological Consequences."

<u>Below Grade Confinement</u>

RPF tank vaults, valve pits, pipe trench, and carbon delay bed vaults are part of the below grade confinement. SHINE FSAR figure 6b.2-2, "Below Grade Confinement Boundary," provides a block diagram of the below grade confinement. Radioactive material is confined primarily by the structural components, including gaskets, and other non-structural features are used, as necessary, to provide sealing. Each vault is equipped with a concrete cover plug fabricated in multiple sections with inspection ports to facilitate remote inspection of the confined areas. The pipe trench, vaults, and valve pits with equipment containing fissile material are equipped with drip pans and drains to the radioactive drain system (RDS). The below grade confinement is primarily passive. Process piping for auxiliary systems entering the boundary from outside confinement is provided with appropriate manual or automatic isolation capabilities. Contaminated air is confined to the vaults, valve pits, and pipe trench. The facility accident analysis considers the effect of air exchange from the confinement to the general areas in its evaluation of radiological consequences. Three mechanisms by which the confinement boundary exchanges air with the RPF are considered: pressure-driven flow, counter-current flow, and barometric breathing. The combined effect of these mechanisms is a minor outflow of radioactive material from the confined area to the RPF and the environment under accident conditions. If sufficient radioactive material reaches the radiation monitors in the RVZ1e duct, ESFAS will isolate the RVZ building supply and exhaust. The evaluated DBA for which the below grade confinement is necessary is listed in SHINE FSAR table 6b.1-1 and further discussed in SHINE FSAR section 13b.2.

Process Vessel Ventilation Isolation

The PVVS captures or provides holdup for radioactive particulates, iodine, and noble gases generated within the RPF and primary system boundary. The PVVS draws air from the process vessels through a series of processing components that remove the radioactive components by condensation, acid adsorption, mechanical filtration with HEPA filters, and adsorption in carbon beds. The PVVS guard and delay beds are equipped with isolation valves to isolate affected guard bed or group of delay beds from the system. The isolation valves serve a dual purpose: they prevent release of radioactive material to the environment and isolate fire-impacted beds from unimpacted beds. The delay beds are equipped with sensors to detect fires, which provide indication to ESFAS. The redundancy in the beds and the ability to isolate individual beds allow the PVVS to continue to operate following an isolation. The evaluated DBA for which PVVS isolation is necessary is listed in SHINE FSAR table 6b.1-1 and further discussed in SHINE FSAR section 13b.2.

Combustible Gas Management

Hydrogen gas is produced by radiolysis in the target solution during and after irradiation. During normal operation, the PVVS removes radiolytic hydrogen and radioactive gases generated within the RPF and primary system boundary. If the PVVS becomes unavailable, the buildup of hydrogen gas is limited using the combustible gas management system, which uses the N2PS, process system piping, and portions of the PVVS to establish an inert gas flow through the process vessels. The objective of the combustible gas management system is to prevent the conditions that could lead to a hydrogen deflagration in the gas spaces in the RPF process tanks.

The N2PS provides a back-up supply of sweep gas following a loss of electrical power or loss of sweep gas flow to the RPF tanks normally ventilated by the PVVS. SHINE FSAR figure 6b.2-3, “RPF Combustible Gas Management Functional Block Diagram,” provides a functional block diagram of the RPF combustible gas management system. The source of nitrogen is high pressure nitrogen gas stored in pressurized vessels. On a loss of power or receipt of an ESFAS actuation signal, isolation valves on the radiological ventilation zone 2 (RVZ2) air supply to the PVVS shut and isolation valves on the N2PS discharge manifold open, releasing nitrogen into the RPF N2PS distribution piping. The nitrogen gas flows through the RPF equipment and into the PVVS process piping and the PVVS passive filtration equipment before being discharged out through an alternate vent path in the PVVS. The variable within the ESFAS that can cause the initiation of an RPF Nitrogen Purge (low PVVS flow) is provided in SHINE FSAR subsection 7.5.3.1.23, “RPF Nitrogen Purge.” The active components required to function to initiate the RPF Nitrogen Purge are actuated by the ESFAS. A detailed description of the ESFAS is provided in SHINE FSAR section 7.5. Combustible gas management prevents deflagrations and detonations in RPF process tanks that could lead to a tank or pipe failure and cause a target solution spill inside the process confinement boundary. The evaluated DBAs for which combustible gas management is necessary are listed In SHINE FSAR table 6b.1-1 and further discussed in SHINE FSAR section 13b.2.

Dose Consequences

SHINE FSAR table 6b.1-2, “Comparison of Unmitigated and Mitigated Radiological Doses for Select Radioisotope Production Facility DBAs,” provides unmitigated and mitigated doses for select DBAs in the SHINE RPF. The maximum mitigated doses in SHINE FSAR table 6b.1-2 are 0.042 rem TEDE to the public and 0.076 rem TEDE to the worker. In SHINE FSAR section 13a2.2 and Determination of Consequences,” the applicant proposed the following accident dose criteria:

Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 1 rem TEDE for the duration of the accident; and

Radiological consequences to workers do not exceed 5 rem TEDE during the accident.

The NRC staff finds these dose criteria to be acceptable in section 13a.4.1 of this SER.

The dose consequences, in some cases, would be unacceptable with respect to these criteria without mitigation by ESFs. As described in SHINE FSAR chapter 13b, specific postulated accident scenarios indicate the need for the confinement ESFs.

Based on its review, the NRC staff finds that there is reasonable assurance that the confinement ESFs are designed to ensure that the radiological consequences to a member of the public and a worker would remain below 1 rem and 5 rem, respectively, and, therefore, that the confinement ESFs are acceptable with respect to dose consequences.

Design Criteria

As stated in SHINE FSAR section 3.1, “Design Criteria,” the nuclear safety classification of safety-related SSCs at SHINE entails those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public and to control or mitigate the consequences of such accidents. SHINE FSAR table 3.1-1, “Safety-Related Structures, Systems, and Components,” identifies the SSCs at SHINE that are classified as safety-related. The list includes the confinement features and all its supporting structures and systems. SHINE FSAR table 3.1-3, “SHINE Design Criteria,” provides the generally applicable design criteria to the SHINE facility. The NRC staff review focused on the design criteria applicable to confinement, namely criteria 29, 32, 33, 34, 35, and 39. These criteria are described in section 6a.3.2, “Applicable Regulatory Guidance and Acceptance Criteria,” of this SER.

For design criterion 29, the NRC staff finds that SHINE appropriately identified passive confinement boundaries and active components for the establishment of the four classes of confinement boundaries. Specifically, the primary confinement boundary, the process confinement boundary, the hot cells and gloveboxes, and the radiologically controlled area

(RCA) ventilation isolations are addressed in sufficient detail in SHINE FSAR sections 6a2.2.1, and 6b.2.1, and SHINE FSAR figures 6a2.2-1, 6a2.2-2, 6b.2-1, and 6b.2-2.
For design criterion 32, the NRC staff finds that periodic inspection, surveillance, and periodic testing are satisfied by the proposed technical specifications.

For design criterion 33, the NRC staff finds that the piping systems penetrating confinement boundaries have been provided with automatic isolation capabilities, manual valve positions, and isolation valves in close proximity of the outside of confinement based on descriptions in SHINE FSAR sections 6a2 and 6b and SHINE FSAR figures 6a2.2-1, 6a2.2-2, 6b.2-1, and 6b.2-2.

For design criterion 34, the NRC staff finds that based on the descriptions in SHINE FSAR sections 6a2 and 6b, along with SHINE FSAR figures 4a2.8-1, “Subcritical Assembly System and TSV Off-Gas System Flow Diagram,” 6a2.2-1, 6a2.2-2, 6b.2-1, 6b.2-2, 9a2.1-3, “Radiological Ventilation Zone 1 Exhaust Subsystem (RVZ1e) Flow Diagram,” and 9a2.7-1, “TPS Process Flow Diagram,” the confinement isolation of process piping and ventilation is sufficiently described and depicted in the FSAR.

For design criterion 35, the NRC staff finds that the SHINE facility is equipped with isolation provisions in the ventilation system at the RCA boundary and that the PVVS exhaust beds are designed for holdup capacity for retention of radioactive gases.

For design criterion 39, the NRC staff finds that the applicant has described systems to control the buildup of hydrogen to ensure that the integrity of the system and confinement boundaries are maintained.

Based on the foregoing, the NRC staff concludes that the applicant provided final analysis and evaluation of the design and performance of SSCs and satisfies 10 CFR 50.34(b)(4) as it relates to confinement.

Conclusion

Based on the evaluation of the SHINE RPF ESFs, the NRC staff concludes that the final design of the SHINE RPF ESFs, including the principal design criteria, design bases, and information relative to confinement, satisfies the relevant acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2. Therefore, the staff finds the final design of the SHINE RPF ESFs acceptable.

6b.4.3 Nuclear Criticality Safety

The NRC staff evaluated the sufficiency of SHINE’s nuclear criticality safety design criteria and methods, as presented in SHINE FSAR section 6b.3, “Nuclear Criticality Safety,” using the guidance and acceptance criteria from section 6b.3, “Nuclear Criticality Safety for the Processing Facility,” of the ISG augmenting NUREG-1537, Part 2. Where appropriate, the staff referenced the guidance in NUREG-1520, Revision 2, “Standard Review Plan for Fuel Cycle Facilities License Applications” (ML15176A258), and NUREG/CR-6698, “Guide for Validation of Nuclear Criticality Safety Calculational Methodology” (ML050250061), to support its evaluation of the acceptance criteria from the ISG augmenting NUREG-1537, Part 2.

6b.4.3.1 Nuclear Criticality Safety Program

General requirements to protect the public health and safety in 10 CFR 50.34(b) are implemented for the SHINE facility, in part, by establishing and maintaining a nuclear criticality safety program (CSP) that assures subcriticality under normal and all credible abnormal conditions, with a margin of subcriticality for safety. Assurance of subcriticality is typically implemented in conjunction with the double contingency principle as stated in ANSI/ANS-8.1-2014, “Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactor.”

SHINE FSAR section 6b.3.1, “Nuclear Criticality Safety Program,” describes the SHINE CSP and states that it applies to all nuclear processes within the RPF and the IF, excluding the TSVs. The NRC staff evaluates the insertion of reactivity within the TSVs in section 13a.4.3.4.2, “Insertion of Excess Reactivity,” of this SER.

<u>Organization and Administration</u>

SHINE FSAR section 6b.3.1 discusses the objectives of the SHINE CSP and states that its goal is to ensure that workers, the public, and the environment are protected from the consequences of a nuclear criticality event. The CSP is executed by qualified facility staff using written procedures, which are maintained by SHINE’s document control program.

SHINE FSAR section 6b.3.1.1, “Nuclear Criticality Safety Program Organization,” discusses the organization of the SHINE CSP. SHINE committed to, and described a program whose structure is consistent with, the requirements of ANSI/ANS-8.1-2014 and ANSI/ANS-8.19-2014, “Administrative Practices for Nuclear Criticality Safety,” both of which are endorsed by NRC Regulatory Guide (RG) 3.71, Revision 3, “Nuclear Criticality Safety Standards for Nuclear Materials Outside Reactor Cores” (ML18169A258). SHINE FSAR section 6b.3.1.1 also discusses the responsibilities and roles of key program personnel, including the Chief Executive Officer, Safety Analysis Manager, SHINE facility management, fissionable material operation (FMO) supervisors, and nuclear criticality safety (NCS) staff. The overall responsibility for the CSP lies with the SHINE Chief Executive Officer, and the Safety Analysis Manager is the facility manager responsible for the program’s implementation. NCS staff are kept administratively independent from operations to the extent practicable. The NRC staff finds that the information provided with respect to the SHINE CSP organization is consistent with ANSI/ANS-8.1-2014 and ANSI/ANS-8.19-2014 and the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

SHINE FSAR sections 6b.3.1.2, “Nuclear Criticality Safety Staff Qualifications,” and 6b.3.1.6, “Nuclear Criticality Safety Training,” discuss NCS staff training and qualifications. The NCS staff consists of three qualification levels: (1) NCS analyst; (2) NCS engineer; and (3) senior NCS engineer. The NCS training program consists of two tiers, with Tier 1 being directed toward personnel who manage, work in, or work near areas where a potential for a criticality accident exists and Tier 2 being specific to NCS staff. Tier 1 content is derived from ANSI/ANS-8.20-1991, “Nuclear Criticality Safety Training,” and Tier 2 content is derived from ANSI/ANS-8.26-2007, “Criticality Safety Engineer Training and Qualification Program.” Both tiers include content on procedural compliance, stop-work authority, response to CAAS alarms, including evacuation to designated areas using designated routes, and reporting of defective or anomalous conditions. SHINE committed to the requirements of ANSI/ANS-8.26-2007 for the training of NCS staff, and SHINE’s specific training requirements for NCS staff are taken from this standard. The NRC staff finds that the information provided with respect to NCS staff training and qualifications is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2, as well as ANSI/ANS-8.20-1991and ANSI/ANS-8.26-2007 (both endorsed by RG 3.71) and is, therefore, acceptable.

Management Measures

The management measures applied to the SHINE CSP consist of training, procedures (including NCS postings), and audits and assessments. These aspects of the CSP are discussed in SHINE FSAR section 6b.3.1.

SHINE FSAR section 6b.3.1.6 discusses NCS training, which the NRC staff finds acceptable, as discussed above.

SHINE FSAR section 6b.3.1.8, “Criticality Safety Nonconformances,” discusses NCS-related non-conformances. Personnel are trained to promptly report any deviations from procedures and/or unintended changes in process conditions to management. Non-conformances are entered into SHINE’s corrective action program, investigated promptly, corrected as appropriate, and documented. Corrective actions are performed in accordance with procedures and with guidance from the NCS staff.

SHINE FSAR section 6b.3.1.7, “Criticality Safety Program Oversight,” discusses NCS procedures (including NCS postings). As previously discussed, SHINE committed to the requirements of ANSI/ANS-8.19-2014 and ANSI/ANS-8.20-1991, which both discuss the use of procedures. SHINE FSAR section 6b.3.1.7 also states that “[a]ctivities involving fissile material are conducted using written and approved procedures.” Section 6b.3.1.7 further states that for situations in which approved procedures are inadequate or do not exist, personnel are required to take no action until the NCS staff has evaluated the situation and provided instructions. To supplement procedures, SHINE also uses postings and labeling.

SHINE FSAR section 6b.3.1.7 discusses audits and assessments related to the SHINE CSP. SHINE performs several different types of audits and assessments, which are consistent with the requirements of ANSI/ANS-8.19-2014 and have been incorporated into the SHINE facility technical specifications (TSs). The audits and assessments consist of: (1) annual audits of operations to evaluate procedural compliance and process conditions, including walkthroughs of facility processes and procedures by NCS staff; (2) periodic reviews of active procedures by supervisors; (3) periodic reviews of procedural non-compliance and other NCS-related deficiencies; (4) annual reviews of nuclear criticality safety evaluations (NCSEs) to ensure their continued validity, with each NCSE and its associated calculations being reviewed at least once every 3 years; and (5) a triennial audit of the overall effectiveness of the CSP, with active participation from SHINE management. The adequacy of NCS controls is routinely assessed by SHINE’s audits and assessments. Deficiencies that are identified during an audit or assessment are promptly reported to management via the SHINE corrective action program, investigated promptly, corrected as appropriate, and documented. Action to correct deviations or alterations is taken in accordance with procedural requirements and with guidance obtained from the NCS staff. Action is taken to prevent recurrence for significant conditions adverse to quality. Records of NCS deficiencies and associated corrective actions are maintained in the corrective action program. The ISG augmenting NUREG-1537, Part 2 contains an acceptance criterion that all aspects of the CSP will be audited at least every 2 years; however, SHINE stated that it will conduct such audits triennially. In its RAI response dated January 29, 2021 (ML21029A102), SHINE stated that this longer audit frequency is justified based on SHINE’s commitment to the requirements of ANSI/ANS-8.19-2014, which states in paragraph 4.7 that “Management shall participate in auditing the overall effectiveness of the nuclear criticality safety program at least once every 3 years." The NRC staff notes that RG 3.71 endorses the use of ANSI/ANS-8.19-2014 without exception. Therefore, based on SHINE's commitment to the requirements of ANSI/ANS-8.19-2014, the staff determined that a triennial program audit is acceptable.

In addition to the management measures applied to the SHINE CSP, SHINE FSAR section 6b.3.1.5, "Computational System Validation," states that any process or design change that could impact NCS limits or controls is evaluated against the requirements of 10 CFR 50.59, "Changes, tests, and experiments." Prior to implementing the change, the applicable NCSE is reviewed and revised, if necessary, to maintain the assurance of subcriticality under normal and all credible abnormal conditions with a margin of subcriticality for safety. The NRC staff's evaluation of SHINE's change control process is discussed in chapter 12, "Conduct of Operations," of this SER.

Based on the above, the NRC staff finds that the information provided with respect to management measures applied to the SHINE CSP is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and applicable NRC-endorsed guidance and is, therefore, acceptable.

Use of Industry Standards

In SHINE FSAR section 6b.3.1.3, "Use of National Consensus Standards," SHINE committed to the requirements of the following ANSI/ANS standards related to NCS, subject to any clarifications and exceptions provided in RG 3.71, with certain SHINE-specific limitations. The NRC staff notes that although in some instances the acceptance criteria in section 6b.3 of the ISG augmenting NUREG-1537, Part 2 reference different versions of the standards than those committed to by SHINE, SHINE's commitments are to the latest version of each standard, which is consistent with section 3.1, "Design Criteria," of NUREG-1537, Part 2, which states that design criteria should include references to applicable up-to-date standards, guides, and codes, and are, therefore, acceptable.

- ANSI/ANS-8.1-2014, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."

SHINE committed to the requirements of ANSI/ANS-8.1-2014, noting that the clarification applied to this standard by RG 3.71 is related to subcritical limits for plutonium isotopes and is, therefore, not applicable to the SHINE facility.

- ANSI/ANS-8.3-1997, "Criticality Accident Alarm System."

SHINE committed to the requirements of ANSI/ANS-8.3-1997, acknowledging that the clarifications and exceptions applied to this standard by RG 3.71 are applicable to the SHINE facility.

- ANSI/ANS-8.5-1996, "Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material."

Borosilicate-glass Raschig rings are not used in the SHINE facility; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.6-1983, "Safety in Conducting Subcritical Neutron-Multiplication Measurements In Situ."

SHINE committed to the requirements of ANSI/ANS-8.6-1983.

- ANSI/ANS-8.7-1998, "Nuclear Criticality Safety in the Storage of Fissile Materials."

SHINE committed to the requirements of ANSI/ANS-8.7-1998.

- ANSI/ANS-8.9-1987, "Nuclear Criticality Safety for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Material."

ANSI/ANS-8.9-1987 was withdrawn in May 1997 and is no longer maintained as an ANSI/ANS standard; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.10-2015, "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement."

SHINE does not rely on the criteria provided in ANSI/ANS-8.10-2015 for determining the adequacy of shielding and confinement; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.12-1987, "Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors."

Plutonium is not used as a target component at the SHINE facility; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.14-2004, "Use of Soluble Neutron Absorbers in Nuclear Facilities Outside Reactors."

The SHINE facility does not use soluble neutron absorbers for criticality control; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.15-2014, "Nuclear Criticality Safety Control of Selected Actinide Nuclides."

SHINE does not conduct operations with non-negligible quantities of selected actinides; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.17-2004, "Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR [Light-Water Reactor] Fuel Outside Reactors."

SHINE does not handle, store, or transport LWR fuel rods or units; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.19-2014, “Administrative Practices for Nuclear Criticality Safety.”

SHINE committed to the requirements of ANSI/ANS-8.19-2014.

- ANSI/ANS-8.20-1991, “Nuclear Criticality Safety Training.”

SHINE committed to the requirements of ANSI/ANS-8.20-1991.

- ANSI/ANS-8.21-1995, “Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors.”

SHINE does not rely on the use of fixed absorbers as a means of criticality control; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

- ANSI/ANS-8.22-1997, “Nuclear Criticality Safety Based on Limiting and Controlling Moderators.”

SHINE committed to the requirements of ANSI/ANS-8.22-1997.

- ANSI/ANS-8.23-2007, “Nuclear Criticality Accident Emergency Planning and Response.”

SHINE committed to the requirements of ANSI/ANS-8.23-2007, acknowledging that the clarification applied to this standard by RG 3.71 is applicable to the SHINE facility.

- ANSI/ANS-8.24-2017, “Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations.”

SHINE committed to the requirements of ANSI/ANS-8.24-2017, acknowledging that the clarifications applied to this standard by RG 3.71 are applicable to the SHINE facility.

- ANSI/ANS-8.26-2007, “Criticality Safety Engineer Training and Qualification Program.”

SHINE committed to the requirements of ANSI/ANS-8.26-2007.

- ANSI/ANS-8.27-2015, “Burnup Credit for LWR Fuel.”

SHINE does not possess irradiated LWR fuel assemblies; therefore, this standard is not applicable to the SHINE facility and SHINE did not commit to it.

The NRC staff determined that SHINE committed to the requirements of the applicable ANSI/ANS standards, and NRC clarifications and exceptions thereto, related to NCS. Therefore, the staff determined that the above commitments are consistent with the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and are, therefore, acceptable.

Subcriticality and Double Contingency Principle

In SHINE FSAR section 6b.3.1.3, SHINE committed to the requirements of ANSI/ANS-8.1-2014, as endorsed by RG 3.71, which includes adherence to the double contingency principle (DCP) where practicable as a method of ensuring subcriticality. Further, SHINE FSAR section 6b.3.1.5 provides that processes within the RPF generally comply with the DCP. This is expanded upon by SHINE FSAR section 6b.3.2, “Criticality Safety Controls,” which states that control on two independent criticality parameters is generally preferred over multiple controls on a single parameter, and if multiple controls on a single parameter are used, then a preference is given to diverse means of control on that parameter. SHINE FSAR section 6b.3.1.5 also states that the failure of a single NCS control that maintains two or more controlled parameters is considered a single process upset with respect to the DCP. By letter dated December 10, 2020 (ML20357A084), Enclosure 3 (ML20357A087), SHINE stated that “[p]rocess upsets are considered credible unless they are not physically possible or are caused by a sequence of events involving many unlikely human actions or errors for which there is no reason or motive.” SHINE further stated that the credibility of process upsets is based on the judgement of key professionals involved in the evaluation process from operations, design engineering, and safety analysis disciplines, considering factors such as the conditions of the system, its construction, and the applicable accident sequences. The NRC staff notes that the guidance provided in appendix A to chapter 5.0 of NUREG-1520 acknowledges that a qualitative approach to the DCP is acceptable. Therefore, the staff finds that SHINE’s qualitative approach to evaluating the credibility and likelihood of process upsets is consistent with the DCP and guidance provided by appendix A to chapter 5.0 of NUREG-1520 and is, therefore, acceptable.

Based on the above, the NRC staff finds that the information provided with respect to the DCP is consistent with ANSI/ANS-8.1-2014 (as endorsed by RG 3.71) and the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Technical Practices

SHINE FSAR sections 6b.3.1.4, “Nuclear Criticality Safety Evaluations,” 6b.3.1.5, “Computational System Validation,” and 6b.3.2, “Criticality Safety Controls,” describe the NCS technical practices at the SHINE facility. These include the performance and documentation of NCSEs, the treatment of NCS parameters and their methods of control, the derivation of NCS limits, computational system validation, and the establishment and use of a margin of subcriticality for safety.

SHINE FSAR section 6b.3.1.4 discusses SHINE’s performance and documentation of NCSEs. NCSEs are conducted for each FMO to ensure subcriticality under normal and all credible abnormal conditions with a margin of subcriticality for safety, with the exception of the IU cells and the material staging building (see section 6b.4.3.2 of this SER for further discussion of criticality hazards in the IU cells and the material staging building and SHINE’s request for exemption from the requirements of 10 CFR 70.24, “Criticality accident requirements,” for these areas). For analytical purposes, all fissionable isotopes are conservatively assumed to be fissile. NCSEs are conducted using hazard evaluation techniques, including “What-if,” “What-if Checklist,” and Event Tree Analysis, to identify potential accident sequences leading to inadvertent criticality. When the DCP is used, the NCSEs also describe how the DCP is implemented. SHINE performs NCSEs using the industry-accepted and peer-reviewed methods discussed in the requirements of ANSI/ANS-8.1-2014 and ANSI/ANS-8.19-2014, both endorsed by RG 3.71.

NCS limits identified in NCSEs are derived using one of three methods: (1) industry-accepted and peer-reviewed references including ANSI/ANS standards; (2) hand calculations using industry-accepted and peer-reviewed techniques consistent with their limitations; or (3) computational methods. Limits are derived by assuming optimum or most-reactive credible values unless otherwise controlled. For cases in which less than optimum values are used, the basis is documented in the appropriate NCSE. Operating limits are derived conservatively in consideration of any potential process variability and uncertainty to ensure that NCS limits are unlikely to be exceeded. When computational methods (i.e., "code") are used to derive NCS limits and/or to perform NCS analyses, they are used consistent with the limitations and penalties identified in the code's validation report. SHINE TS table 5.5.4, "Controls," states, in part, that engineered criticality "controls are identified in the criticality safety evaluations to prevent criticality in the SHINE Facility, excluding the TSVs."

SHINE FSAR section 6b.3.2 discusses the various NCS control methods, including preference for engineered controls over administrative controls, and passive engineered controls over active controls. Controls are established to restrict certain NCS parameters within subcritical limits. The NCS parameters that SHINE controls are mass, moderation, enrichment, geometry, volume, concentration, interaction, physiochemical form, reflection, heterogeneity, density, and process variables. SHINE does not use fixed or soluble neutron absorbers as a method of control and, therefore, did not provide any information on the treatment of absorption as an NCS parameter. The discussion associated with the treatment of each of these parameters is below.

The NRC staff notes that under one or more of the individual parameters, several of the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 are covered by the more general discussions in SHINE FSAR section 6b.3.2. For example, the expectation that instrumentation relied on to verify compliance with limits on mass, density, enrichment, etc., will be subjected to facility management measures is bound by a general statement in SHINE FSAR section 6b.3.2. The expectations that firefighting procedures will be evaluated for moderator intrusion, or that all precipitating agents will be identified and controlled against, are corollary to the general requirement that the licensee ensures that processes are subcritical under normal and all credible abnormal conditions, as well as SHINE's commitment to the requirements of ANSI/ANS-8.22-1997. Regarding the acceptance criteria stating that process variables that can affect the value of a particular parameter should be controlled by safety-related controls identified in NCSEs, the staff finds it sufficient for the applicant to follow its SHINE Safety Analysis (SSA) methodology as described in SHINE FSAR section 13a2, "Irradiation Facility Accident Analysis," in determining what controls should be designated as safety-related controls. The staff's evaluation of the SSA methodology is discussed in chapter 13, "Accident Analysis," of this SER.

The NRC staff noted that several subsections of SHINE FSAR section 6b.3.2, pertaining to NCS parameters, contain provisions that are simply definitions of the parameter or state that the parameter may be used on its own in combination with other parameters. In accordance with the guidance in appendix A to chapter 5.0 of NUREG-1520, this is acceptable in the context of the DCP and is, therefore, acceptable. The above discussion is applicable to each of the parameters discussed in the subsections of SHINE FSAR section 6b.3.2. Significant points regarding the specific parameters are discussed in the paragraphs below.

<u>Mass</u>: SHINE stated that whenever mass limits are based on assuming a certain weight percent of uranium, either the entire mass present will be ascribed to uranium or the actual weight percent determined by physical measurement. Thus, any material associated with a special nuclear material (SNM) process will be treated as having a high uranium content until

demonstrated otherwise. SHINE also assumed a conservative process density to calculate mass when the dimensions of equipment or containers with fixed geometry are used to limit mass, and to demonstrate that the largest mass resulting from a single failure remains subcritical wherever over-batching is credible. The use of instrumentation to measure mass is addressed by a general statement that when measurement of a parameter is needed, instrumentation subject to facility management measures is used. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Geometry and Volume: SHINE restricts SNM volume with geometry and to verify all dimensions relied on in demonstrating subcriticality before beginning operations, in response to changes in operations, and at periodic intervals. Relevant dimensions and material properties are maintained by the facility's configuration management program. Abnormal conditions involving the loss of geometry are evaluated in NCSEs, if credible. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG--1537, Part 2 and is, therefore, acceptable.

Density: SHINE's discussions regarding the treatment of density as a controlled parameter are provided by general statements that apply to all other controlled parameters. Limits on density are established with consideration given to any tolerances and uncertainty. If control is based on measuring density, independent means of measurement are used subject to facility management measures. If process variables can affect the normal or most reactive credible value of density, controls to maintain density within a certain range are used. For cases where a single parameter limit on density is used, all other parameters are evaluated at their optimum or most reactive credible value. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Enrichment: SHINE assumed a bounding enrichment for all fissile material based on a facility-wide maximum authorized enrichment controlled by receipt inspections of feed material. Measurements of the enrichment of feed material are performed using instrumentation subject to facility management measures. The SHINE facility does not have any processes capable of enriching SNM further. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Reflection: SHINE considers wall thickness and all adjacent reflecting material when determining subcritical limits for individually evaluated units of fissile material. Although SHINE did not explicitly state that individually evaluated units will be farther than 12 inches away from reflecting adjacent materials, SHINE will establish and document criteria for determining whether materials are sufficiently spaced to be considered neutronically isolated. When reflection is not controlled, full reflection is assumed and is represented by 12 inches of tight-fitting water or 24 inches of tight-fitting concrete, as appropriate. Unit arrays are evaluated using the most reactive combination of interstitial moderation and exterior array reflection. Minimum reflection conditions, equivalent to a 1-inch tight-fitting water reflector, are assumed to account for personnel and other transient reflectors not explicitly included in criticality calculations. When less than full reflection is assumed, controls to limit reflection around individual units are established, with rigid barriers preferred. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG--1537, Part 2 and is, therefore, acceptable.

Moderation: SHINE committed to the requirements of ANSI/ANS-8.22-1997. Physical structures are designed to prevent the ingress of moderators, and conspicuously marked moderation-controlled areas are used to exclude moderators from process areas. Firefighting procedures for use in moderation-controlled areas, as well as the effects of fire and the activation of fire suppression systems, are evaluated in NCSEs, and restrictions are applied to the use of moderating firefighting agents. The use of instrumentation to measure moderation is addressed by a general statement that when measurement of a parameter is needed, instrumentation subject to facility management measures is used. Process variables that can affect moderation are also addressed by a general statement to identify in accident analyses the process variables relied on to control or monitor controlled parameters, with sufficient management measures applied. The associated parameter (in this case moderation) is explicitly identified and the correlation of process variables to the associated parameter is established by experiment or plant-specific measurements. When moderation needs to be sampled, dual independent sampling methods are used. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG--1537, Part 2 and is, therefore, acceptable.

Concentration: SHINE implements controls to limit concentration unless the process has been demonstrated to be subcritical under the most reactive credible uranium concentrations. For solution tanks under concentration control, precautions are taken to preclude the introduction of precipitating agents, including keeping the tank closed and locked. When concentration needs to be sampled, such as prior to a transfer of solution to an unfavorable geometry tank, dual independent sampling methods and/or in-line monitoring are used such that no single error may result in the transfer of concentrated solution. Process variables that can affect the solubility of fissile solutions are controlled and monitored, and the need to ensure homogeneity of solution is assessed in NCSEs. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Interaction: SHINE maintains physical separation between fissile-bearing units with engineered controls. If engineered controls are not feasible, visual aids are used to support administrative controls. The structural integrity of spacers, storage racks, etc. is sufficient to ensure subcriticality under normal and all credible abnormal conditions, including seismic events. Movable engineered devices are periodically inspected to verify that no deformation has occurred. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

Physiochemical Form and Process Variables: Physiochemical form and process variables are not explicitly discussed in the acceptance criteria of the ISG augmenting NUREG-1537, Part 2, but rather are used to indirectly control one or more NCS parameter. For example, specifying the material form as uranyl nitrate solution may be necessary to use certain dimensional or mass limits, and implicitly takes credit for the neutron absorbing properties of nitrogen. As another example, specifying the form as uranium dioxide powder implicitly assumes a maximum enrichment and density. Reliance on this parameter is based on known scientific principles or known physical or chemical properties, in conjunction with experimental data supported by operating history. By letter dated December 10, 2020 (ML20357A088, not publicly available; proprietary information), SHINE stated that correlation of process variables to controlled parameters is accomplished by direct or indirect measurements. Direct correlations apply when monitored process variables are directly measured. Indirect correlations may be established when direct measurements of controls are not possible and may be developed using known empirical or theoretical relationships or developed through plant-specific data collection. Correlation inputs will be defined and documented for a specific controlled parameter, including process assumptions and characteristics. The NRC staff finds that this is sufficient to ensure that reliance is not placed on as-found conditions or on process assumptions and characteristics that are not appropriately controlled. SHINE will establish controls to limit material composition to a particular form. Process variables that can change fissile material composition to a more reactive physiochemical form are identified as controls, and both in situ changes in physiochemical form and the migration of material between process areas are considered in evaluating credible abnormal conditions. While the ISG augmenting NUREG-1537, Part 2 does not contain acceptance criteria specifically associated with these parameters, the staff finds that this information is consistent with the general principles that apply to all parameters as discussed above and is, therefore, acceptable.

Heterogeneity: The ISG augmenting NUREG-1537, Part 2 does not provide specific acceptance criteria regarding the treatment of heterogeneity. Rather, it simply states that heterogeneous effects should be considered as appropriate. Given the enrichment and material forms of SHINE's processes, it is necessary to consider heterogeneity effects. Therefore, the acceptance criteria from NUREG-1520 were used as guidance in determining whether the information provided regarding heterogeneity is acceptable. SHINE evaluates potential methods of causing fissile solution to become inhomogeneous and establishes controls as necessary. If heterogeneity is considered credible, its effect is evaluated in NCSEs. Assumptions that can affect the physical scale of homogeneity are based on observed physical characteristics, and process variables that can affect the scale of heterogeneity are controlled.

Given that SHINE's methods for determining the subcritical limits for uranyl sulfate systems are based on comparison with uranyl fluoride and uranyl nitrate systems, and that SHINE's computational method for performing NCS analyses was validated, in part, against uranyl fluoride and uranyl nitrate benchmark experiments, the NRC staff performed a literature search and an independent analysis to assess the potential impacts of heterogeneity as both uranyl fluoride and uranyl nitrate present special concerns due to the formation of water hydrates at low hydrogen-to-uranium (H/U) ratios. Oak Ridge National Laboratory (ORNL) report ORNL/TM-12292, "Estimated Critical Conditions for [Uranyl Fluoride – Water] Systems in Fully Water-Reflected Spherical Geometry," suggests that special considerations should be given to uranyl fluoride systems with an H/U ratio of less than 4.0 and to uranyl nitrate systems with an H/U ratio of less than 12. A review of Atlantic Richfield Hanford Company report ARH-600, "Criticality Handbook, Volume I," suggests that uranyl sulfate may be subject to the same phenomena and require special considerations for an H/U ratio of less than 7. Below these values, the formation of water hydrates complicates efforts to determine the bulk fissile material density as concentration values can be somewhat erroneous. Above these values, these effects are not of concern, and a general molar volume additive approach can be used. As stated in SHINE's validation report, CALC-2018-0012, the H/U ratios for uranium solutions in SHINE processes that are evaluated using SHINE's computational method are all well above these limits. Although SHINE does have processes in which low H/U ratios may occur (e.g., the dissolution of uranium oxides in sulfuric acid to form uranyl sulfate solution), SHINE assumes the most reactive material composition in analyses. In this particular example, the process of dissolving uranium oxide into uranyl sulfate solution would be evaluated assuming the most reactive composition (moderated uranium oxide) for the entire process. This generally negates the need to consider the potential effects of low H/U ratios involving uranyl sulfate because uranyl sulfate would not be the material composition evaluated. Additionally, the application of subcritical limits (SPLs) derived from ANSI/ANS standards for uranium metal and oxides generally negates the need to conduct an analysis to identify the optimum solution concentration as the SPLs already inherently assume optimum conditions. In cases where optimum solution concentration does need to be determined, such as in the design of a favorable geometry vessel or in accident sequences involving precipitation, the optimum concentration for a 20 weight percent U-235 uranyl sulfate system corresponds to an H/U ratio significantly greater than the H/U ratios listed above for the formation of water hydrates. This alleviates any concern of skewed results due to the formation of water hydrates. Based on its literature search and independent analysis, the NRC staff determined that SHINE's practices for controlling heterogeneity appropriately bound any potential concerns regarding the formation of water hydrates at low H/U ratios. While the ISG augmenting NUREG-1537, Part 2 does not contain acceptance criteria specifically associated with this parameter, the staff finds that this information is consistent with the general principles that apply to all parameters as discussed above and is, therefore, acceptable.

SHINE FSAR section 6b.3.1.5 discusses the validation and verification of computational methods. SHINE committed to the requirements of ANSI/ANS-8.24-2017 and stated that computational systems are verified and validated using the guidance contained in NUREG/CR-6698. SHINE validated its computational methods by comparing the results calculated with computer models to the results of 128 benchmark experiments from the Handbook of the International Criticality Safety Benchmark Evaluation Project (ICBEP). Benchmarks were selected for evaluation based on their similarity to SHINE solution systems, and a modified form of the Shapiro-Wilk test for normality from NUREG/CR-6698 was used to determine whether the resulting benchmark data was normally distributed. The single-sided tolerance limit approach from section 2.4.4, "Select Statistical Method of Treatment of Data," of NUREG/CR-6698 was used to calculate the upper subcritical limit (USL), which is defined in SHINE FSAR section 6b.3.1.5 as the difference between unity and the sum of the bias, the bias uncertainty, and the minimum margin of subcriticality (MMS). For cases involving positive bias, SHINE conservatively assumed the bias to be zero. SHINE FSAR section 6b.3.1.5 states that verification of the Monte Carlo N-Particle (MCNP) software installation was performed using developer-supplied verification tools, and that re-verification of the computational system is conducted following any changes to the hardware or operating system. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

SHINE's discussion regarding the use of an MMS is in SHINE FSAR section 6b.3.1.5. SHINE's computational method identified in SHINE document CALC-2018-0012, "MCNP5 Validation for Reactivity in Solution Systems for the SHINE Facility," is MCNP5 using the ENDF/B-VII.1 standard cross-section library and the ENDF/B.VII.0 thermal scattering cross-section library, which is validated to establish the areas of applicability in which the code can be used.

SHINE relied on the use of SPLs and other data from NRC-endorsed ANSI/ANS standards to establish safe limits for non-solution processes. For solution processes (i.e., the TSV dump tank and the TOGS), a margin of 0.05 is applied with an additional penalty of 0.01 to account for any differences between benchmark material composition and the material composition of the SHINE processes. This results in an MMS of 0.06, which corresponds to a USL of 0.94. Appendix B to chapter 5.0 of NUREG-1520 states that an MMS of 0.05 is generally acceptable for low-enriched uranium facilities provided that: (1) a criticality code validation study has been performed consistent with ANSI/ANS-8.24-2017 and/or NUREG/CR-6698; (2) there is an acceptable number of critical experiments with similar geometric forms, material compositions, and neutron energy spectra to the applicable processes; and (3) the processes evaluated include materials and process conditions similar to those that occur in low-enriched fuel cycle applications. As previously discussed, SHINE performed a validation study consistent with NUREG/CR-6698 and ANSI/ANS-8.24-2017 involving 128 benchmark experiments from the ICBEP selected for evaluation based on their similarity to SHINE solution systems. Although

SHINE's processes involve some operations that are not typical of a fuel cycle facility (e.g., irradiation of fissile solution), such processes are limited to the TSVs and the TSVs are not subject to the SHINE CSP. The majority of SHINE's processes are largely similar to that of a fuel cycle facility. Furthermore, SHINE applied a penalty to the USL to account for any differences between benchmark material composition and the material composition of SHINE's processes. Appendix B to chapter 5.0 of NUREG-1520 states that the justification of an MMS should be based on: (1) conservative practices in calculational models; (2) validation methodology and results; and (3) additional risk informed considerations. Given that SHINE uses conservative NCS practices (see section 6b.4.3.1 of this SER) and has performed a validation study consistent with NUREG/CR-6698 and ANSI/ANS-8.24-2017 using a sufficient quantity of data from a quality source (i.e., the ICBEP) with an acceptable statistical methodology and benchmarks similar to SHINE processes, the NRC staff determined that an MMS of 0.06 (corresponding to a USL of 0.94) is acceptable.

6b.4.3.2 Criticality Accident Alarm System

SHINE FSAR section 6b.3.3, "Criticality Accident Alarm System," discusses the use of a CAAS at the SHINE facility. SHINE FSAR section 6b.3.3 states that the SHINE facility maintains CAAS coverage in areas where quantities of fissile material greater than the limits identified in 10 CFR 70.24(a) are used, handled, or stored, except for those areas for which SHINE has requested an exemption from the requirements of 10 CFR 70.24, which the NRC staff discusses below (i.e., the IU cells and the material storage building). SHINE FSAR section 6b.3.3 further states that the CAAS is designed to meet the requirements of 10 CFR 70.24 and conforms to the requirements of ANSI/ANS-8.3-1997, as endorsed by RG 3.71.

SHINE FSAR section 6a2.3.2, "Criticality Accident Alarm System," states that coverage of SNM in the IU cells is provided by the neutron flux detection system (NFDS) and level instrumentation in the TSV dump tank, which provide indication of abnormal conditions in the IU cells.

<u>Criticality Accident Alarm System</u>

Consistent with the ISG augmenting NUREG-1537, SHINE FSAR section 6b.3.3 states that the SHINE facility is designed to meet the requirements of 10 CFR 70.24 and conforms to the requirements of ANSI/ANS-8.3-1997, as endorsed by RG 3.71, Revision 3. Despite this being a different version of RG 3.71 than the version referenced in the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 (i.e., Revision 1 (ML051940351)), the NRC staff finds this acceptable because both versions endorse ANSI/ANS-8.3-1997 with the following exceptions:

- At or above the mass thresholds established in ANSI/ANS-8.3-1997, section 4.2.1, the applicant should commit to CAAS coverage in each area where SNM is handled, stored, or used, as opposed to merely an evaluation for such areas.

- Two detectors are required for each area requiring CAAS coverage, as opposed to coverage by a single reliable detector.

- The CAAS is required to be capable of detecting a criticality condition that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within 1 minute, as opposed to requiring CAAS coverage in areas where personnel would be subject to "excessive radiation dose," defined as any dose corresponding to a neutron and gamma combined absorbed dose equal to or greater than 12 rads in free air.

The NRC staff finds that the applicant's commitments to the requirements of ANSI/ANS-8.3-1997, as endorsed by RG 3.71, Revision 3, and to maintain a CAAS that provides two detector coverage and is capable of detecting a criticality that produces a combined neutron and gamma radiation absorbed dose in soft tissue of 20 rads at an unshielded distance of 2 meters within 1 minute are sufficient to satisfy the requirements of 10 CFR 70.24(a)(1) and are, therefore, sufficient to satisfy the acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and are acceptable.

To accommodate maintenance and testing activities, SHINE FSAR section 6b.3.3.2, "Criticality Accident Alarm System Design," states that the CAAS detectors are arranged such that all areas within the SHINE main production facility requiring coverage generally receive coverage from at least three detectors, allowing a single detector for any given area to be taken out of service for a specified period of time. For maintenance or testing evolutions requiring multiple detectors or the logic unit to be taken out of service, SHINE implements administrative controls to secure the movement of fissile material and limit personnel access (i.e., quarantine) to affected areas until CAAS coverage is restored. Portable instruments may be used in rare circumstances. SHINE FSAR section 6b.3.3.2 states that the CAAS is designed to be resistant to credible events, such as fire, explosion, a corrosive atmosphere, seismic shock, and other adverse conditions that do not result in evacuation of the entire facility. SHINE FSAR section 6b.3.3.2 further states that the CAAS will energize clearly audible alarm signals if accidental criticality were to occur. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

SHINE FSAR section 6b.3.3.1 states that the minimum accident of concern (MAC) for the SHINE facility was developed based on a critical sphere of 20 weight percent U-235 uranyl sulfate solution. Transport analysis was used to convert the neutron and gamma spectrum of the MAC to a point source, which was then used to determine the appropriate detector placement based on the facility structure, shielding, and potential intervening equipment. The thresholds defined in 10 CFR 70.24 were used to establish detection thresholds. Neutron detectors were selected for use to reduce potential inappropriate interference from multiple gamma sources throughout the facility.

The NRC staff determined that although processes at the SHINE facility involve uranium compositions other than uranyl sulfate solution (such as uranium metal and oxides), uranyl sulfate is the uranium composition for the majority of the SHINE facility's processes. Additionally, the information contained in Los Alamos National Laboratory Report LA-13638, "A Review of Criticality Accidents" (ML003731912), demonstrates that 21 of the 22 historical process-related criticalities involved solutions and suggests that solutions (such as uranyl sulfate) represent the uranium compositions most likely to be involved in a process-related criticality accident. The NRC staff also determined that the use of neutron detectors is appropriate given the potential for interference from gamma sources throughout the SHINE facility. The NRC staff determined that SHINE's CAAS is appropriate for the facility and type of radiation detected, the intervening shielding, and the magnitude of the accident of concern; therefore, the staff finds this information acceptable.

Request for Exemption from 10 CFR 70.24(a)

SHINE FSAR section 6b.3.3 states that SHINE's CAAS is designed to meet the requirements of 10 CFR 70.24(a)(1), except for the IU cells and the material staging building (MATB). Accordingly, by letter dated January 29, 2021 (ML21029A038), SHINE requested an exemption from the requirements of 10 CFR 70.24(a) for the IU cells and the MATB. In accordance with 10 CFR 70.17(a), the Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of 10 CFR Part 70 as it determines: (1) are authorized by law; (2) will not endanger life or property or the common defense and security; and (3) are otherwise in the public interest. The NRC staff evaluation of SHINE's request for exemption from the requirements of 10 CFR 70.24(a) for the IU cells and the MATB follows.

Irradiation Unit Cells

For the IU cells during normal operation, SHINE stated that the cells are each a robust shielded enclosure that is designed to protect workers and the public from the irradiation operation. SHINE further stated that SNM handling within an IU cell occurs in a light-water pool, which provides radiation shielding during irradiation operations and would also provide protection from radiation due to an accidental criticality. The components within an IU cell are designed to be subcritical based on control of geometry with no credible means of deformation or loss of credited geometric properties. Furthermore, SHINE stated that the NFDS would detect the MAC if a criticality were to occur in the TSV dump tank in an IU cell, presenting as an increased count rate visible to operators through the process integrated control system. Inadvertent criticality in the TOGS associated with an IU cell would require a precursor condition to occur (i.e., target solution overflowing into the TOGS), which would be detected by safety-related high-level indicators in the TSV dump tank alerting operations personnel of the need to take appropriate response actions.

Based on the above, the NRC staff determined that although a credible criticality hazard exists in the TOGS associated with IU cells, appropriate measures are in place to limit the risk of criticality and to protect workers, the public, and the environment should criticality occur. The staff's evaluation of shielding is discussed in chapter 4, "Irradiation Units and Radioisotope Production Facility Description," of this SER. Therefore, the staff determined that an exemption from the requirements of 10 CFR 70.24(a) for the IU cells will not endanger life or property or the common defense and security.

The NRC staff also determined that the exemption will be otherwise in the public interest because, as discussed above, a CAAS is not necessary to protect life or property or the common defense and security and maintaining a CAAS anyway would require personnel to occasionally perform maintenance and testing on the system. Such maintenance and testing would require personnel to enter the IU cells and thus increase the frequency with which those personnel are exposed to sources of ionizing radiation, increasing their radiation doses. Therefore, granting this exemption will allow SHINE to safely produce medical isotopes while preventing maintenance workers from receiving unnecessary dose. Thus, because this exemption prevents unnecessary worker dose while not affecting safety, it is otherwise in the public interest.

Additionally, the NRC staff has the ability to grant exemptions under 10 CFR 70.17. The staff determined that the requested exemption is permissible under the Atomic Energy Act of 1954, as amended, and that no other prohibition of law exists to preclude the activities that would be authorized by the exemption. Accordingly, the staff finds that granting this exemption is in accordance with law.

Based on the above, the NRC staff grants the exemption with respect to the IU cells.

Material Staging Building

The MATB provides a location for packaged radioactive material, both as-generated solid waste and solidified liquid waste, to decay until it can be transported to an offsite final disposal location. In its exemption request, SHINE stated that the material in the MATB is as-generated solid waste packaged and staged for transport that meets the requirements of 10 CFR 71.15(a) and solidified liquid waste stored in packages that meet the requirements of 10 CFR 71.15(c). The NRC staff notes that these transportation exemptions do not apply to SNM being stored under 10 CFR Part 50 or 10 CFR Part 70, including 10 CFR 70.24(a). Nevertheless, the staff reviewed NUREG/CR-7239, "Review of Exemptions and General Licenses for Fissile Material in 10 CFR 71" (ML18052A520), and SHINE's submittal to determine if a technical basis exists to use these criteria as justification for an exemption from the requirements of 10 CFR 70.24(a) for the MATB. More specifically, the staff reviewed NUREG/CR-7239, sections 4.1.1, "10 CFR 71.15(a): Individual Package Containing 2 g or Less Fissile Material"; and 4.1.3, "10 CFR 71.15(c) Low Concentrations of Solid Fissile Material Comingled with Solid Nonfissile Material," which describe the basis for the criteria in 10 CFR 71.15(a) and (c), respectively, to consider transportation packages exempt from the criticality safety requirements of 10 CFR Part 71.

10 CFR 71.15(a)

The transportation exemption criterion in 10 CFR 71.15(a) is for individual packages containing 2 grams or less of fissile material. Section 4.1.1 of NUREG/CR-7239 states that criticality would not be credible based on practical and economic considerations for such packages. Specifically, section 4.1.1 of NUREG/CR-7239 states that a cubic array of 84,853 one-liter packages, each containing 2 grams of U-235 with no absorbers or packaging material at near-optimal moderation, is required for criticality to be possible. The NRC staff determined that this basis does not necessarily apply to the MATB because the purpose of the MATB is to store many such packages, and the MATB is not physically restricted to less than 84,853 liters. However, the staff determined that similar logic can be applied to the MATB.

Packages that meet 10 CFR 71.15(a) requirements stored in the MATB would contain as-generated solid waste absent of interstitial moderation. Packages containing, or potentially containing, interstitial moderation would not satisfy the conditions for treatment as solid waste and, therefore, would likely be treated as solidified liquid waste and packaged to meet 10 CFR 71.15(c) or further processed to remove the presence of interstitial moderation. The logic discussed in NUREG/CR-7239, which establishes that a minimum of 84,853 one-liter packages would be required for criticality, assumes near-optimal moderation with no absorbers or packaging material. Absent a significant amount of moderating material, criticality would not be possible. In order to introduce a significant amount of moderating material into the MATB, a number of significant, difficult, and unauthorized changes in process conditions would need to occur. The NRC staff considers such a condition to be not credible short of a willful, concerted effort. In addition to the required presence of significant amounts of moderating material, the packages would also need to be arranged in a specific geometrical configuration for criticality to occur. Each package is limited to 2 grams of fissile material and spacing between the fissile material in each package is provided by packaging material. The staff considers a geometrical arrangement that could support criticality to be contrived and not credible short of several unauthorized, willful changes in process conditions. Given the required presence of significant amounts of moderating material and the specific geometrical configuration required, the staff determined that the conditions required for inadvertent criticality to occur in the MATB involving packages that meet 10 CFR 71.15(a) are highly contrived and are extremely unlikely short of an unauthorized, concerted effort. The staff's review of SHINE's physical security plan is in section 12.4.8, "Security Planning," of this SER. Accordingly, the staff determined that packages meeting 10 CFR 71.15(a) do not present a credible criticality hazard, and an exemption from the requirements of 10 CFR 70.24(a) for such packages stored in the MATB will not endanger life or property or the common defense and security.

10 CFR 71.15(c)

The transportation exemption criterion in 10 CFR 71.15(c) is for packages of large volumes of low-concentration, solid fissile material commingled with solid non-fissile material. The quantity of fissile material is not limited, but it must be an essentially homogeneous mixture of fissile and non-fissile material such that no more than 180 grams of fissile material is distributed within 360,000 grams of solid non-fissile material. This 2000:1 ratio represents approximately 60 percent of the minimum critical fissile material concentration of 1.33 grams of U-235 per liter in a 1600-gram silicon dioxide per liter (SiO_2/L) matrix (NUREG/CR-7239 section 4.1.3). The NRC staff determined that the technical basis for this exemption criterion applies to material being stored at the MATB as it also involves large volumes of diluted dry materials packaged in accordance with 10 CFR 71.15(c). Accordingly, the staff determined that packages meeting 10 CFR 71.15(c) do not present a credible criticality hazard, and an exemption from the requirements of 10 CFR 70.24(a) for such packages stored in the MATB will not endanger life or property or the common defense and security.

The NRC staff also determined that the exemption will be otherwise in the public interest because, as discussed above, a CAAS is not necessary to protect life or property or the common defense and security and maintaining a CAAS anyway would require personnel to occasionally perform maintenance and testing on the system. Such maintenance and testing would require personnel to enter the MATB and thus increase the frequency with which those personnel are exposed to sources of ionizing radiation, increasing their radiation doses. Therefore, granting this exemption will allow SHINE to safely produce medical isotopes while preventing maintenance workers from receiving unnecessary dose. Thus, because this exemption prevents unnecessary worker dose while not affecting safety, it is otherwise in the public interest.

Additionally, the NRC staff has the ability to grant exemptions under 10 CFR 70.17. The staff determined that the requested exemption is permissible under the Atomic Energy Act of 1954, as amended, and that no other prohibition of law exists to preclude the activities that would be authorized by the exemption. Accordingly, the staff finds that granting this exemption is in accordance with law.

Based on the above, the NRC staff grants the exemption with respect to the MATB.

Environmental Considerations

NRC approval of the requested exemption from the requirements of 10 CFR 70.24(a) for the IU cells and the MATB is categorically excluded under 10 CFR 51.22(c)(25), and there are no extraordinary circumstances present that would preclude reliance on this exclusion.

Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the approval of the requested exemption.

For the IU cells, the NRC staff determined that although a credible criticality hazard exists in the TOGS associated with IU cells, appropriate measures, such as shielding, subcriticality design, and indications to operations personnel, are in place to limit the risk of criticality and to protect workers, the public, and the environment should criticality occur. For the MATB, the staff determined that the storage of packages containing radioactive materials that meet the requirements of 10 CFR 70.15(a) and (c) does not represent a credible criticality hazard. Accordingly, related to the requested exemption, there is no significant hazards consideration; there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; there is no significant increase in individual or cumulative public or occupational radiation exposure; and there is no significant increase in the potential for or consequences from radiological accidents. Additionally, because there are no construction activities associated with the requested exemption, there is no significant construction impact. Finally, the requirement from which the exemption is sought involve the types of activities enumerated in 10 CFR 51.22(c)(25)(vi). Specifically, in accordance with 10 CFR 51.22(c)(25)(vi)(A), (B), and (C); 10 CFR 70.24, which requires the installation of a CAAS that would provide continuous monitoring, surveillance; and recordkeeping for criticality events, pertains to inspection or surveillance requirements as well as related recordkeeping and reporting requirements. Accordingly, the requested exemption is an action within the category of actions categorically excluded from further environmental review by 10 CFR 51.22(c)(25).

Emergency Planning and Response

SHINE FSAR section 6b.3.1.3 states that SHINE commits to the requirements of ANSI/ANS-8.23-2007, as endorsed by RG 3.71. SHINE FSAR section 6b.3.1.8.1, “Planned Response to Criticality Accidents,” states that “SHINE maintains an emergency plan which includes the planned response to criticality accidents.” SHINE FSAR section 6b.3.1.8.1 further states that the emergency plan contains information on the provision of personnel accident dosimeters in areas that require CAAS coverage, arrangements for onsite decontamination of personnel, and the transport and medical treatment of exposed individuals. The SHINE Emergency Plan, section 8.6.2, “Assembly,” states, in part, that “SHINE has the capability of quickly identifying individuals who have received doses of 10 rads or more due to a criticality accident via reading of electronic dosimeters worn by personnel in the RCA.” The SHINE Emergency Plan, section 9.6, “Personnel Monitoring Equipment,” states that SHINE maintains emergency dosimetry that is readily available to emergency support personnel, and that equipment for prompt onsite readouts is maintained onsite. Fixed criticality accident dosimeters or instruments are located within the SHINE facility to provide spectrum information and assist in the reconstruction of a criticality accident. The SHINE Emergency Plan, section 11.7, “Emergency Plan and Procedure Use and Maintenance,” states that SHINE maintains implementing procedures for the emergency plan for each area in which SNM is handled, used, or stored to ensure that all personnel evacuate to designated areas in the event of a CAAS alarm. The SHINE Emergency Plan, sections 3.3.6, “Criticality Safety Engineer,” 3.5.2, “Criticality Safety Lead Engineer,” and 11.1.6, “Criticality Safety Engineer,” state that qualified NCS engineers are responsible for advising and assisting the emergency organization in response to a criticality event, and that they are trained on their responsibilities. The NRC staff finds that this information is consistent with the applicable acceptance criteria of the ISG augmenting NUREG-1537, Part 2 and is, therefore, acceptable.

SHINE FSAR section 6b.3.3.2, “Criticality Accident Alarm System Design,” states that the CAAS is equipped with a back-up connection to the uninterruptible electrical power supply system (UPSS) and batteries to keep the system in operation for at least two hours following a facility loss of offsite power, providing operators with sufficient time to secure the movement of fissile material before a loss of alarm system coverage occurs.

SHINE FSAR section 6b.3.3.2 states that for maintenance or other conditions that would disable multiple detectors or the logic unit, administrative controls are used to secure the movement of fissile material and limit personnel access to the affected areas until alarm system coverage is restored. The SHINE FSAR further provides that these administrative controls are specific to the various processes within the RPF and include short time allowances to restore the system to full operation in lieu of immediate process shutdown in areas where process shutdown creates additional risk to personnel.

Based on the above, the NRC staff determined that information provided for the CAAS and emergency planning and response provide reasonable assurance of adequate protection against the consequences of a criticality accident in accordance with the requirements of 10 CFR 70.24(b).

<u>Reporting Requirements</u>

SHINE FSAR section 6b.3.1.8 states that NCS events are reported to the NRC in accordance with the reporting requirements of 10 CFR 70.50, “Reporting requirements”; 10 CFR 70.52, “Reports of accidental criticality”; and Appendix A to 10 CFR Part 70, “Reportable Safety Events.” However, SHINE does not have an integrated safety analysis and associated controls designated as items relied on for safety (IROFS) pursuant to 10 CFR 70.61, “Performance requirements,” because SHINE does not meet the Subpart H applicability criteria specified in 10 CFR 70.60, “Applicability.” Consequently, SHINE will never experience events meeting some of the reporting requirements in Appendix A to 10 CFR Part 70. In these instances, the SHINE TSs commit to reporting events roughly equivalent to those specified in Appendix A to 10 CFR Part 70. TS 5.8.3, “Additional Event Reporting Requirements,” states, in part, that the following events shall be reported to “the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:”

- An inadvertent nuclear criticality.
- An acute intake by an individual of 30 mg [milligrams] or greater of uranium in a soluble form.
- An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could endanger the life of a worker or could lead to irreversible or other serious, long-lasting health effects to any individual located outside the owner controlled area.
- An event or condition such that no credited controls, as documented in the SHINE Safety Analysis, remain available and reliable, in an accident sequence evaluated in the SHINE Safety Analysis.

TS 5.8.3 further states, in part, that the following events shall be reported to “the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 60 days:”

- Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that described in the SHINE Safety Analysis, and which results in inadequate controls in place to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

- Loss or degradation of credited controls, as documented in the SHINE Safety Analysis, other than those items controlled by a limiting condition of operation established in section 3 of the technical specifications, that results in a failure to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.

- An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that could lead to irreversible or other serious, long-lasting health effects to a worker, or could cause mild transient health effects to any individual located outside the owner controlled area.

- Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more safety-related structures, systems, or components.

TS 5.8.2, “Special Reports,” describes the special reports that will be submitted to the NRC. Special reports will be reported no later than the following working day by telephone and confirmed in writing by facsimile or similar conveyance to the NRC Operations Center, to be followed by a written report to the NRC Document Control Desk describing the circumstances of the event within 14 days. This includes reports for observed inadequacies in the implementation of administrative or procedural controls such that the inadequacy causes or could have caused the existence or development of an unsafe condition with regard to operations, as well as reports for safety system component malfunctions that render or could render the safety system incapable of performing its intended safety function.

The NRC staff determined that the above information is consistent with, and meets the intent of, the reporting requirements of 10 CFR 70.50, 10 CFR 70.52, and Appendix A to 10 CFR Part 70. The staff determined that the above information is sufficient to provide reasonable assurance that events constituting a required report to the NRC will be reported appropriately.

6b.4.3.3 Conclusion

The NRC staff reviewed the SHINE CSP and various aspects of the SSA and Emergency Plan against the ISG augmenting NUREG-1537, Part 2 referencing NUREG-1520 and NUREG/CR-6698, as appropriate. Based on its review, the staff has reasonable assurance of the following:

(1) SHINE will have in place a CSP that will be developed, implemented, and maintained to ensure that all nuclear processes are subcritical under normal and all credible abnormal conditions, with an approved margin of subcriticality for safety. Double contingency protection will be provided, where practicable.

(2) SHINE will establish and maintain NCS controls that are subject to facility management measures to support limiting the risk of inadvertent criticality to acceptable limits, as defined in the SSA. Controls will be included in the TSs as required by 10 CFR 50.36.

(3) SHINE will have in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the CSP in accordance with the facility organization and administration and management measures.

(4) SHINE's conduct of operations will be based on NCS technical practices that ensure that fissile material will be possessed, stored, and used safely.

(5) SHINE will develop, implement, and maintain a CAAS in accordance with 10 CFR 70.24 and the facility emergency management program. An exemption from the requirements of 10 CFR 70.24 for the IU cells and for the MATB is warranted.

Based on the above determinations, the NRC staff finds SHINE's nuclear criticality safety design criteria and methods, as presented in SHINE FSAR section 6b.3, consistent with the guidance and acceptance criteria from section 6b.3 of the ISG augmenting NUREG-1537, Parts 1 and 2 for the issuance of an operating license.

6b.4.4 Proposed Technical Specifications

In accordance with 10 CFR 50.36(a)(1), the NRC staff evaluated the sufficiency of the applicant's proposed TSs for the SHINE RPF ESFs as described in SHINE FSAR section 6b.

The proposed TS 3.4, LCO 3.4.3 and SR 3.4.3 state the following:

LCO 3.4.3	Each tritium Confinement boundary valve for each TPS glovebox listed in Table 3.4.3-a shall be Operable. A valve is considered Operable if: 1. The valve is capable of closing on demand from ESFAS Note – A single valve in a flow path may be inoperable for up to 2 hours during the performance of required surveillances. Note – This LCO is applied to each TPS train independently; actions are only applicable to the TPS train(s) that fail to meet the LCO.
	Tritium present in associated TPS process equipment and not in storage
Action	According to Table 3.4.3

SR 3.4.3	1. Valves listed in Table 3.4.3-a shall be verified to close on demand from ESFAS annually.

The proposed TS Table 3.4.3, "TPS Glovebox Confinement Boundary Valve Actions," states the following:

	Condition and Action (per TPS Train)	Completion Time
1.	If one or more isolation valve(s) in one or more flow path(s) is inoperable, Place tritium in the associated train of TPS process equipment in its storage location OR Close at least one valve in the affected flow path.	 12 hours 12 hours

LCO 3.4.3 specifies that each confinement boundary valve in TS Table 3.4.3-a, "TPS Glovebox Confinement Valves," shall be operable by closing on demand from ESFAS and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure that ESFAS automatically isolates the TPS glovebox system to prevent the inadvertent release of tritium, a radioactive gas. The staff also finds that if the valves listed in TS table 3.4.1-a are inoperable, the tritium is placed in storage or at least one valve is closed to isolate the flow path. The staff finds that the completion time allows for investigation and the performance of minor repairs and adequate time to place the tritium in its storage location, and is based on the continued availability of the redundant actuation valve or redundant check valve in the flow path. Therefore, the staff finds LCO 3.4.3 acceptable.

SR 3.4.3 requires that the valves in TS table 3.4.3-a be verified to close on demand from ESFAS annually. section 4.4.2 of ANSI/ANS-15.1-2007 states that a functional test should be performed. NUREG-1431, Volume 1, SR 3.6.3.8 states, in part, that a test to verify that automatic containment isolation valves actuate to the isolation position on an actual or simulated signal be performed every 18 months. As described in chapter 14 of the SER, the NRC staff used guidance in NUREG-1431 to review SHINE's proposed TSs. Based on the foregoing, the staff finds that the stroke test of SR 3.4.3 is an appropriate functional test and that its frequency is adequate to confirm the operability of the TPS confinement boundary. Therefore, the staff finds SR 3.4.3 acceptable. Therefore, the staff finds SR 3.4.3 acceptable.

The proposed TS 3.4, LCO 3.4.4 and SR 3.4.4 state the following:

LCO 3.4.4	Each supercell Confinement damper listed in Table 3.4.4-a shall be Operable. A damper is considered Operable if: 1. The damper is capable of closing on demand from ESFAS
Applicability	Supercell process operations in-progress in the associated hot cell

Action	According to Table 3.4.4
SR 3.4.4	1. Dampers listed in Table 3.4.4-a shall be verified to close on demand from ESFAS annually.

The proposed TS Table 3.4.4, “Supercell Confinement Damper Actions,” states the following:

	Condition and Action	**Completion Time**
1.	If one isolation damper in one or more flow path(s) is inoperable,	
	Close at least one damper in the affected flow path	72 hours
	OR	
	Suspend hot cell operations involving the introduction of liquids into the associated hot cell	72 hours
	AND	
	Drain target solution and radioactive liquids in process lines from the associated hot cell.	72 hours
2.	If two redundant isolation dampers in one or more flow path(s) are inoperable,	
	Close at least one damper in the affected flow path	6 hours
	OR	
	Suspend hot cell operations involving the introduction of liquids into the associated hot cell	6 hours
	AND	
	Drain target solution and radioactive liquids in process lines from the associated hot cell.	6 hours

LCO 3.4.4 specifies that each supercell confinement damper in TS table 3.4.4-a, “Supercell Confinement Dampers,” shall be operable by being capable of closing on demand from ESFAS when supercell process operations are in-progress in the associated hot cell and provides actions to be taken if they are inoperable. The NRC staff finds that this LCO would ensure that ESFAS automatically isolates the supercell areas to prevent the inadvertent release of radioactive material. The staff also finds that if the dampers listed in TS table 3.4.4-a are inoperable, either the flow path is isolated by closing a damper or hot cell operations are suspended, which involves no further introduction of liquids into the hot cell and the draining of all solutions that are in the process lines. The staff finds that the completion time allows for investigation and the performance of minor repairs and is based on the continued availability of

the redundant isolation damper with the low likelihood of a release occurring during a 6-hour duration. Therefore, the staff finds LCO 3.4.4 acceptable.

SR 3.4.4 requires that each supercell confinement damper in TS table 3.4.4-a be verified to close on demand from ESFAS annually. Section 4.4.1, "Containment," of ANSI/ANS-15.1-2007 states that a functional test should be performed. NUREG-1431, Volume 1, SR 3.6.3.8 states, in part, that a test to verify that automatic containment isolation valves actuate to the isolation position on an actual or simulated signal be performed every 18 months. As described in chapter 14, "Technical Specifications," of the SER, the NRC staff used guidance in NUREG-1431 to review SHINE's proposed TSs. Based on the foregoing, the staff finds that the verification to close on demand from ESFAS of SR 3.4.4 is an appropriate functional test and that its frequency is adequate to confirm the operability of the supercell confinement boundary. Therefore, the staff finds SR 3.4.4 acceptable.

6b.5 Review Findings

The NRC staff reviewed the descriptions and discussions of the SHINE RPF ESFs, as described in SHINE FSAR section 6b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of the information in the SHINE FSAR and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE described the RPF ESFs and identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs provide reasonable assurance that the applicant will comply with the applicable regulations in 10 CFR Part 70, 10 CFR Part 50, and 10 CFR Part 20 and that the health and safety of the public will be protected.

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

Based on the above determinations, the NRC staff finds that the descriptions and discussions of the SHINE RPF ESFs are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.