CONTENTS

7.0 INSTRUMENT AND CONTROL SYSTEMS

Instrument and control (I&C) systems comprise the sensors, electronic circuitry, displays, and actuating devices that provide the information and means to safely control the SHINE Medical Technologies, Inc. (SHINE) irradiation facility (IF) and radioisotope production facility (RPF) and to avoid or mitigate accidents. Together the IF and RPF constitute the SHINE facility.

Instruments are provided to monitor, indicate, and record such operating parameters as neutron flux density, target solution temperature, coolant flow and temperature, and radiation intensities in selected areas around the SHINE facility. Certain l&C systems will automatically shut down the SHINE irradiation units (IUs) when a safety parameter reaches a predetermined set point. I&C subsystems may also be designed to actuate engineered safety features (ESFs) upon the detection of abnormal conditions.

This chapter of the SHINE construction permit safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) of the preliminary design of the SHINE IF and RPF I&C systems as presented in Chapter 7, "Instrument and Control Systems," of the SHINE Preliminary Safety Analysis Report (PSAR), as supplemented by the applicant's responses to requests for additional information (RAIs).

7a Irradiation Facility Instrument and Control Systems

SER Section 7a, "Irradiation Facility Instrumentation and Control Systems," provides an evaluation of the preliminary design of SHINE's IF I&C systems as presented in SHINE PSAR Section 7a2, "Irradiation Facility Instrument and Control Systems," within which, SHINE describes the design of I&C systems, target solution vessel (TSV) process control, TSV reactivity protection system, ESFs, ESF actuation system (ESFAS), control console and display information, and radiation monitoring systems.

7a.1 Areas of Review

The staff reviewed SHINE PSAR Section 7a2 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of SHINE's IF I&C systems. As part of this review, the staff evaluated descriptions and discussions of SHINE's IF I&C systems, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of SHINE's IF I&C systems was evaluated to ensure the sufficiency of principle design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items that are determined to be probable subjects of technical specifications for the facility, with special attention given to those items that may significantly influence the final design.

Areas of review for this section included IF I&C control systems, process control descriptions, reactivity protection system, ESFAS, control console and display information, and radiation monitoring systems. Within these review areas, the staff assessed the preliminary analysis of I&C systems needed to monitor key parameters and variables, maintain parameters and variables within prescribed operating ranges, alert operators when operating ranges are

exceeded, assure safety limits are not exceeded, and initiate mitigating systems and components important to safety.

7a.2 Summary of Application

SHINE utilizes independent I&C systems to protect and control the neutron driver and TSV associated with each irradiation unit in the IF. The I&C systems in the IF include reactivity protection systems, reactivity control systems, radiation detection systems, ESFAS, and control room and instrument displays.

SHINE PSAR Section 7a2 provides the preliminary design of the I&C systems, the TSV process control description, the TSV reactivity protection system, the ESFAS, the control console and display information, and the radiation monitoring systems.

7a.3 Regulatory Basis and Acceptance Criteria

The staff reviewed SHINE PSAR Section 7a2 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of SHINE's I&C systems in support of the issuance of a construction permit. In accordance with paragraph (a) of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.35, "Issuance of construction permits," a construction permit authorizing SHINE to proceed with construction may be issued once the following findings have been made:

(1) SHINE has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety evaluation, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).

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

(4) On the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in part 100 of Part 50, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

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

7a.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's IF I&C systems are as follows:

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

Note: As required by 10 CFR 50.34(a)(3)(i), SHINE must describe the principal design criteria for its facility in the PSAR; however, SHINE is not required to follow 10 CFR Part 50, Appendix A, "General Design Criteria [GDCs] for Nuclear Power Plants," as this appendix only applies to nuclear power reactors. Nonetheless, SHINE has applied several of the GDCs to the preliminary design of its I&C systems in the IF. As such, the staff based its review, in part, on SHINE's application of the following GDCs to its I&C systems:

- GDC 2, "Design Bases for Protection Against Natural Phenomena"
- GDC 4, "Environmental and Dynamic Effects Design Bases"
- GDC 5, "Sharing of Structures, Systems, and Components"
- GDC 10, "Reactor Design"
- GDC 12, "Suppression of Reactor Power Oscillations"
- GDC 13, "Instrumentation and Control"
- GDC 15, "Reactor Coolant System Design"
- GDC 16, "Containment Design"
- GDC 17, "Electric Power Systems"
- GDC 19, "Control Room"
- GDC 20, "Protection System Functions"
- GDC 21, "Protection System Reliability and Testability"
- GDC 22, "Protection System Independence"
- GDC 23, "Protection System Failure Modes"
- GDC 24, "Separation of Protection and Control Systems"
- GDC 25, "Protection System Requirements for Reactivity Control Malfunctions"
- GDC 26, "Reactivity Control System Redundancy and Capability"
- GDC 27, "Combined Reactivity Control Systems Capability"
- GDC 28, "Reactivity Limits"
- GDC 29, "Protection Against Anticipated Operational Occurrences"

7a.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated SHINE's IF I&C systems against the applicable regulatory requirements listed above primarily using the guidance and acceptance criteria contained in

Chapter 7, "Instrumentation and Controls" of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 4), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 5), as well as the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 6), and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 7).

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

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 7a.4, "Review Procedures, Technical Evaluation, and Evaluation Findings," of this SER. Additional guidance documents used to review SHINE's I&C systems are provided as references in Appendix B.

7a.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed a section-by-section evaluation of the technical information presented in SHINE PSAR Section 7a, as supplemented by responses to RAIs, to assess the sufficiency of the preliminary design and performance of SHINE's IF I&C systems in support of the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency as discussed in Section 7a.3, "Regulatory Basis and Acceptance Criteria," of this SER, the staff determined that the sufficiency of preliminary design and performance of SHINE's IF I&C systems is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria. While the technical evaluation of these systems provided in this section is specific to the SHINE IF, the staff's review considers the interface of these systems between the IF and RPF as part of a comprehensive technical evaluation. The results of this section-by-section technical evaluation are described in Section 7a.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the preliminary design of the SHINE I&C systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the SHINE I&C systems based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of SHINE's I&C systems does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of SHINE's I&C systems, as described in the FSAR, as part of SHINE's operating license application.

7a.4.1 Summary Description

The staff evaluated the sufficiency of SHINE's summary description of its IF I&C systems, as described in SHINE PSAR Section 7a2.1, "Summary Description," using the guidance and acceptance criteria from Section 7.1, "Summary Description," of NUREG-1537, Parts 1 and 2.

As stated in Section 7.1 of NUREG-1537, Part 1, the description of the I&C systems should, in part, summarize the "technical aspects, safety, philosophy, and objectives of the I&C system design," including discussions on types of instruments and classifications of systems.

Section 7a2.1 of the SHINE PSAR provides brief descriptions of the types of equipment, types of parameters monitored, and the types of reactivity control measures for the principal irradiation facility I&C systems, including the TSV reactivity protection systems (TRPS), the TSV reactivity control systems (TRCS), the ESFAS, and control room instruments and displays. The principal IF I&C systems are briefly described in SHINE PSAR Sections 7a2.1.1 through 7a2.1.5, as discussed below. Additionally, a description of the human-machine interface is provided in SHINE PSAR Section 7a2.6, "Control Console and Display Information."

The staff determined that descriptions of actuating logic for the TSVs are not necessary to support the issuance of a construction permit. Such logic will be evaluated in the SHINE FSAR.

SHINE PSAR Section 7a2.1.1, "Reactivity Protection Systems," introduces the TRPS, a digital control system covering the TSV and entire primary system boundary. The TRPS is responsible for monitoring various essential inputs and has the ability to mitigate abnormal or accident conditions through automated protective actions. The protective actions include opening the TSV dump valves, de-energizing the neutron driver, closing the TSV fill valves, and closing the TSV dump tank outlet valves. This system is classified as a safety-related system. Additional details of the TRPS design is provided in SHINE PSAR Section 7a2.4, "TSV Reactivity Protection System," and Figures 7a2.1-1, "Safety Approach for TSV Shutdown," and 7a2.2-1, "I&C System Block Diagram for Irradiation Facility."

SHINE PSAR Section 7a2.1.2, "Reactivity Control Systems," introduces the TRCS as the TSV process control system (TPCS) used for control of normal operations, startup, and shutdown of the neutron driver, and the TSV residing in the IU cell. This system is a separate digital control system and is independent from the TRPS. The TPCS is non-safety-related and is further described in SHINE PSAR Section 7a2.3, "TSV Process Control Description."

SHINE PSAR Section 7a2.1.3, "Reactivity Detection Systems," briefly describes the independent neutron flux detection system (NFDS), which is the primary means for monitoring the reactivity and power of the sub-critical assembly system (SCAS). The NFDS measures neutron flux outside of the TSV and provides input to the TPCS and TRPS. These are redundant and independent signal channels that represent the neutron flux in the SCAS. The NFDS has independent high flux trip settings that are input signals to the TRPS. Should the neutron flux measured at the detectors exceed the allowable operating conditions, the NFDS triggers the TRPS to perform its protective action. There is a separate independent NFDS for each IU cell in the SHINE facility. This system is further described in PSAR Section 7a2.4.3, "NFDS Description."

SHINE PSAR Section 7a2.1.4, "Engineered Safety Features Actuation System," briefly describes the ESFAS as consisting of two independent, safety-related, analog relay trains. Upon sensing essential parameters outside predefined limits, the ESFAS is designed to automatically activate the ESF mitigative actions for the affected IU cell and TSV off gas system (TOGS) shielded cell. During activation, the ESFAS isolates systems that penetrate the IU cell

and TOGS shielded cell boundaries, including the bubble-tight dampers in the radiologically controlled area (RCA) ventilation system Zone 1 (RVZ1) cells. In addition, the ESFAS signals the TRPS to actuate its trip mechanisms. The ESFAS can isolate any individual IU cell or all of the IU cells or any combination, depending on the need. This system is further described in PSAR Section 7a2.5, "Engineered Safety Features Actuation System."

SHINE PSAR Section 7a2.1.5, "Control Room and Instrument Displays," briefly describes the IF centralized control room, from which each IU within the IF is monitored and controlled. The SHINE PSAR states that the TRPS and the TPCS each have independent and electrically isolated, dedicated operator workstations, complete with annunciation, alarm, and operator interface displays. The work stations are housed in two consoles, which are redundant in nature and can be operated simultaneously and independently. This system is further described in PSAR Section 7a2.6.

Additionally, the control room houses the annunciation for the radiation monitoring that occurs throughout the IF and the RPF. The IF and RPF utilize a continuous air monitoring system (CAMS) and radiation area monitoring system (RAMS) for continuous radiological monitoring. The RAMS and CAMS are strategically placed throughout the facility to alert personnel of any potential radiation hazards. These systems are further described in PSAR Section 7a2.7, "Radiation Monitoring Systems."

On the basis of its review, the staff finds that the level of detail provided in the summary description of the SHINE IF I&C systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria discussed in NUREG-1537, Part 2, Section 7.1.

Therefore, the staff finds that the summary description of the SHINE IF I&C systems, as described in SHINE PSAR Section 7a2.1, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7a.4.2 Design of Instrumentation and Control Systems

The staff evaluated the sufficiency of the design of SHINE's IF I&C systems, as described in SHINE PSAR Section 7a2.2, "Design of Instrumentation and Control Systems," and supplemented by responses to RAIs, in part, by reviewing the design criteria, design basis requirements, system description, and system performance analysis of SHINE's I&C systems, as described below, using the guidance and acceptance criteria from Section 7.2, "Design of Instrumentation and Control Systems," NUREG-1537, Parts 1 and 2.

As stated in Section 7.2.1, "Design Criteria," of NUREG-1537 Part 1, the "applicant should [, in part,] discuss the criteria for developing the design bases for the I&C systems," including the "basis for evaluating the reliability and performance of the I&C systems[.]"

Section 7a2.2.1, "Design Criteria," of the SHINE PSAR indicates that the IF design criteria were adopted from analogous structures, systems, or components (SSCs) in nuclear power plants and adapted for applicability to the unique design of the SHINE facility. The specific design criteria and design bases used by the applicant are summarized in SHINE PSAR Table 7a2.2-1, "Design Criteria for the TSV Instrumentation and Control System."

The staff reviewed SHINE PSAR Section 7a2.2 in accordance with NUREG-1537, Part 1, Section 7.2.2, "Design-Basis Requirements," which states, in part, that the "design bases for the I&C system, subsystems, and components should include the following, as applicable:

- The range of values that monitored variables may exhibit for normal operation, shutdown conditions, and for postulated accidents.
- The specification of precision and accuracy requirements for the instruments, control subsystems, or components. . ."

Design basis requirements for the SHINE IF I&C systems are discussed in SHINE PSAR Table 7a2.2-1.

During its review, the staff noted that SHINE PSAR Table 7a2.2-2, "IF Verification Matrix Design Criteria, Bases, Description" (Sheet 9 of 10) states, in part, that "the amount and rate of reactivity increases during the fill and irradiation processes are limited through physical and control system design to ensure that the effects of postulated reactivity accidents can neither (1) result in damage to the primary system boundary greater than limited local yielding, nor, (2) sufficiently disturb the target solution vessel, its support structures or other target solution vessel internals to impair significantly the capability to drain the target solution vessel." However, the staff determined that additional information was needed to support these assertions to determine if the design provides reasonable assurance that the design criteria will be met. This information is necessary to satisfy the design-basis requirements discussed in NUREG-1537, Part 1, Section 7.2, "Design-Basis Requirements," and demonstrate the adequacy of the design basis of the SHINE I&C systems.

Therefore, in RAI 7a2.2-1 (Reference 14), the staff requested additional information to support the assertions in SHINE PSAR Table 7a2.2-2 (Sheet 9 of 10). In particular, the staff requested information to support details on the anticipated accuracy for the reactivity control and the criteria for determining that draining of the TSV is not impaired.

In its response to RAI 7a2.2-1 (Reference 21), the applicant stated the following:

> Part 1 of NUREG-1537 . . . states, in part, that the design bases for the instrument and control (I&C) system, subsystems, and components should include the range of values that monitored variables may exhibit for normal operation, shutdown conditions, and for postulated accidents. SHINE will monitor neutron flux and process variables during the entire fill (Mode 1) and irradiation (Mode 2) process. Neutron flux is plotted to obtain the 1/M versus the fill volume (height) during the fill process and continuously monitored during the irradiation process to ensure that measured parameters do not exceed acceptable limits. Reactivity in the TSV will only be directly controlled during the startup process and when the target solution is drained. The nominal margin to critical (e.g., five percent by volume) will be controlled through the 1/M process. The expected accuracies for the parameters used for reactivity monitoring are provided in Table 7a2.2-1-1. The expected ranges of variables for normal operation and postulated accidents are also provided in the table. The accuracy of the overall margin to critical during startup is described in the SHINE Response to RAI 7a2.3-1.
>
> During the irradiation (Mode 2) process, the control system does not directly control the reactivity. The physical design and characteristics of the subcritical assembly (e.g., natural convection cooling design, nuclear feedback coefficients)

determine the reactivity response. The target solution does not require reactivity monitoring after it is transferred into the TSV dump tank during Mode 3, because it is contained in a criticality-safe geometry and is passively cooled by the light water pool.

The draining of the TSV is monitored by valve position indication on the TSV dump valves and TSV level instrumentation. Only one of the two dump valves is required to function to meet the required drain rate for the TSV. Periodic surveillance testing will be performed to verify the draining of the TSV is not impaired by observing the rate of TSV level decrease following opening of the TSV dump valves, which will be compared to the required rate. Discrepancies identified during surveillance testing (e.g., significant decrease in flow rate) will be placed into the Corrective Action Program.

Additionally, in its response to RAI 7a2.2-1 (Reference 21), the applicant provided PSAR Table 7a2.2-1-1, "Reactivity Monitoring Variables, Ranges, and Accuracies (Design Basis for Reactivity Control and Protection Trips-Nominal)," which gives the range and accuracies of the monitored variables. The staff finds these figures to be acceptable. The applicant further stated that the nominal margin to critical volume in the TSV is, for example, 5 percent. With this margin, as shown in PSAR Reference 21 (Reference 32), the TSV would be substantially more subcritical than the applicant's target effective multiplication factor (k_{eff}).

Regarding the overall accuracy or uncertainty, the applicant's response to RAI 7a2.2-1 references the response to RAI 7a2.3-1, which then references the response to RAI 4a2.6-6,(all contained in Reference 21), which cites an example of overall uncertainty of 30 percent. The staff finds that this response satisfies the design-basis criteria discussed in NUREG-1537, Part 1, Section 7.2, and demonstrates an adequate design basis in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE FSAR.

As stated in Section 7.2.3, "System Description," of NUREG-1537, Part 1, the system description should, in part, "include equipment and major components as well as block, logic, and schematic diagrams."

SHINE PSAR Section 7a2.2.3, "System Description," further describes IF I&C systems, equipment, and major components. Block, logic, and schematic diagrams are provided in PSAR Figure 7a2.2-1, "I&C System Block Diagram for Irradiation Facility." The applicant also provides hardware and software descriptions, as well as software flow diagrams for digital computer systems.

Descriptions of system operational and support requirements, operator interface requirements, and methodology and acceptance criteria used to establish and calibrate the trip or actuation setpoints or interlock functions are not necessary to support the issuance of a construction permit. Evaluation of these requirements will occur during the review of SHINE's FSAR.

As stated in Section 7.2.4, "System Performance Analysis," of NUREG-1537, Part 1, the applicant should, in part, "conduct a performance analysis of the proposed I&C system to ensure the design criteria and design bases are met and license requirements for the performance of the system are specified."

SHINE PSAR Section 7a2.2.4, "System Performance Analysis," presents an analysis of how the system design meets the design criteria and design bases. The discussion touches on accuracy, reliability, adequacy, and timeliness of I&C system action, trip setpoint drift, redundancy, independence, and how the single-failure criterion is to be met to ensure safe operation and safe shutdown of the affected IU. The PSAR sections listed below provide information on various design aspects:

- 7a2.2.4.1, "IU Trip Design Basis"
- 7a2.2.4.1.1, "Safety Functions and Corresponding Protective/Mitigative Actions for Design Basis Events"
- 7a2.2.4.1.2, "Variables Monitored to Control Protective/Mitigative Action"
- 7a2.2.4.1.3, "Variable Monitored Having Spatial Dependence"
- 7a2.2.4.1.4, "Range of Transient and Steady-State Conditions During Normal, Abnormal, and Accident Conditions"
- 7a2.2.4.1.5, "Functional Degradation of Safety System Performance"
- 7a2.2.4.2, "Analysis"
- 7a2.2.4.2.1, "TSV Trip Function Conformance to Applicable Criteria"
- 7a2.2.4.2.1.1, "General Functional Requirement Conformance"
- 7a2.2.4.2.1.2, "Single Failure Criterion Conformance"
- 7a2.2.4.2.1.3, "Independence for Control and IU Trip Conformance"
- 7a2.2.4.2.1.4, "Derivation of System Inputs Conformance"
- 7a2.2.4.2.1.5, "Requirements on Bypassing Trip Functions Conformance"
- 7a2.2.4.2.1.6, "Requirements on Setpoint Determination and Multiple Setpoint Conformance"
- 7a2.2.4.2.1.7, "Requirements for Completion of Trip Conformance"
- 7a2.2.4.2.1.8, "Requirements for Manual Control of Trip Conformance"

The staff finds that the level of detail provided on systems performance analysis satisfies the criteria of NUREG-1537, Part 2, Section 7.2, and demonstrates an adequate design basis in support of a preliminary design. A more detailed evaluation of information (e.g., ranges of transient and steady-state conditions and requirements for multiple setpoints and trip criteria) will occur during the review of SHINE's FSAR, at which time the staff will confirm that the final design conforms to this design basis.

On the basis of its review, the staff finds that the level of detail provided in the design of the SHINE IF I&C systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.2.

Therefore, the staff finds that the design of the SHINE IF I&C systems, as described in SHINE PSAR Section 7a2.2, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis (e.g., information related to the design of instrument and control systems designed to prevent an

inadvertent criticality event) may reasonably be left for later consideration. The staff will confirm that the final design conforms to the design basis during the evaluation of SHINE's FSAR.

7a.4.3 Target Solution Vessel Process Control Description

The staff evaluated the sufficiency of the preliminary design of SHINE's TPCS, as described in SHINE PSAR Section 7a2.3, "TSV Process Control Description," and supplemented by the applicant's responses to RAIs, in part, by reviewing the description, process control systems, and sequence and interlock summary of SHINE's TPCS using the guidance and acceptance criteria from Section 7.3, "Reactor Control System," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 7.3, the staff confirmed that TPCS information for all normal functions and systems described in other chapters of the PRAR are addressed in this section and verified that all design bases are justified, as presented in SHINE PSAR Section 7a2.3 and other relevant chapters of the PSAR.

NUREG-1537, Part 2, Section 7.3 states, in part, that the "RCS [Reactor Control System] [should be] designed to provide for the reliable control of the reactor power level, rate of change of power levels . . . during reactor startup, the full range of normal operation, and shutdown."

Section 7a2.3 of the SHINE PSAR describes the preliminary design of the TPCS, including descriptions of the four operational modes.

In its review, the staff noted that PSAR Section 7a2.3.2.1, "Mode 1 - Startup Mode," states that the startup process calculates the subcritical multiplication factor M from the neutron flux level and plots 1/M versus the fill volume (height). This is then compared to a graph of predicted acceptance values for the same parameter. However, it was not clear how bias and uncertainties associated with the benchmarking of criticality calculations, together with the expected variability in process parameters and instrumentation readings were being considered.

Therefore, in RAI 7a2.3-1 (Reference 14), the staff requested additional information regarding the uncertainties in the computations described in SHINE PSAR Section 7a2.3.2.1, including a quantitative estimate of the expected overall uncertainty in their subcritical reactivity values during startup. This information is necessary to demonstrate the adequacy of the design basis of the SHINE TPCS and satisfy the acceptance criteria of NUREG-1537, Part 2, Section 7.3, which states, in part, that the "RCS should give continuous indication of the neutron flux from subcritical source multiplication level through the licensed maximum power range."

In its response to RAI 7a2.3-1 (Reference 21), the applicant stated:

> The SHINE Response to RAI 4a2.6-6 discusses the uncertainties in k_{eff} and subcritical reactivity during startup. As discussed in that response, SHINE plans to use a volume margin to critical approach, which will determine the target solution volume below critical during startup and calculate the subcritical reactivity by multiplying this volume margin to critical by the reactivity worth per volume. By using this approach, the bias of criticality calculations is eliminated from the calculation process.

Regarding the overall accuracy or uncertainty, the applicant's response to RAI 7a2.2-1 references the response to RAI 7a2.3-1, which then references the response to RAI 4a2.6-6, which cites an example of overall uncertainty of 30 percent. The staff finds this value to be

acceptable, considering the values in PSAR Table 7a2.2-1-1, and satisfies the acceptance criteria of NUREG-1537, Part 2, Section 7.3, and demonstrates an adequate design basis in support for a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on the TPCS demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.3, allowing the staff to make the relevant finding that the applicant has described the normal operating modes of the facility.

Therefore, the staff finds that the preliminary design of the SHINE TPCS, as described in SHINE PSAR Section 7a2.3 and supplemented by the applicant's response to an RAI, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7a.4.4 Target Solution Vessel Reactivity Protection System

The staff evaluated the sufficiency of the preliminary design of SHINE's TRPS, as described in SHINE PSAR Section 7a2.4 and supplemented by the applicant's responses to RAIs, in part, by reviewing the description and performance analysis of SHINE's TRPS using the guidance and acceptance criteria from Section 7.4, "Reactor Protection System," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 7.4, the staff compared the design bases for the RPS with the PSAR description of possible hazards to the facility or personnel that could be prevented or mitigated by timely protective action, as presented in SHINE PSAR Section 7a2.3 and other relevant chapters of the PSAR.

During its review, the staff noted that SHINE PSAR Section 7a2.4.1, "TRPS Description," states that the only nuclear trips are on high neutron flux, source range, and high range. However, there are no apparent anticipatory trip(s) provided for high startup rates or short periods, which are usually needed to adequately limit the fission reaction during high-reactivity transients.

Therefore, in RAI 7a2.4-1 (Reference 14), the staff requested analyses supporting the adequacy of the trips described in SHINE PSAR, Section 7a2.4.1, to avoid a possibly unacceptable high reactivity transient, considering uncertainties and possible reactivity insertion events. Additionally, the applicant was requested to explain why a period trip in the source range would not be necessary, noting that the source range period is already provided. This information is necessary to demonstrate the adequacy of the design basis of the SHINE TRPS and satisfy the acceptance criteria of NUREG-1537, Part 2, Section 7.4, which states, in part, that "the reactor should have operable protection capability in all operating modes and conditions, as analyzed in the SAR."

In response to RAI 7a2.4-1 (Reference 20), the applicant stated, in part, that "[t]ransient behavior will be analyzed using a transient system model currently being completed. Transient systems modeling will be used to support the adequacy of the current nuclear trips to prevent unacceptably high reactivity transients as well as to verify protection capability in all operating

modes, including determining if there is a need for a period trip during filling operations. The results of this analysis will be used as part of the detailed design and provided in the FSAR."

The staff finds that this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 7.4, and demonstrates an adequate design basis in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail the applicant provided on the RPCS demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.4, allowing the staff to make the following relevant findings: (1) the preliminary design reasonably ensures that the design bases can be achieved, (2) the RPCS is designed to maintain function or to achieve safe shutdown, and (3) the RPS is designed to prevent or mitigate hazards to the facility or escape of radiation.

Therefore, the staff finds that the preliminary design of the SHINE RPCS, as described in SHINE PSAR Section 7a2.4 and supplemented by the applicant's response to an RAI, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7a.4.5 Engineered Safety Features Actuation System

The staff evaluated the sufficiency of the preliminary design of SHINE's IF ESFAS, as described in SHINE PSAR Section 7a2.5, in part, by reviewing the description and performance analysis of SHINE's ESFAS using the guidance and acceptance criteria from Section 7.5, "Engineered Safety Features Actuation Systems," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 7.5, the staff compared the design criteria and bases of the ESFAS with the ESFs and accident scenarios, as well as comparing the design and functional descriptions of the ESFAS with the applicable criteria and functions in NUREG-1537, Part 2, Chapters 6, "Engineered Safety Features," and 13, "Accident Analysis."

On the basis of its review, the staff finds that the level of detail provided on the ESFAS demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.5, allowing the staff to make the following relevant findings: (1) the applicant has analyzed postulated accident scenarios at the facility, including accidents for which consequence mitigation by the ESFAS is required or planned, (2) the applicant has considered the environments in which the ESFs are expected to operate, and (3) the design considerations of the ESFAS give reasonable assurance that the final design of the system will detect changes in measured parameters as designed and will initiate timely actuation of the applicable ESF.

Therefore, the staff finds that the preliminary design of the SHINE ESFAS, as described in SHINE PSAR Section 7a2.5, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably

be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7a.4.6 Control Console and Display Information

The staff evaluated the sufficiency of the preliminary design of SHINE's control console and display information, as described in SHINE PSAR Section 7a2.6, in part, by reviewing the operator interface description; control room and display access; operator interface data entry; display interface hardware and software; human factors engineering; static annunciator and fixed status display; alarm and event display; human machine interface; and display independence using the guidance and acceptance criteria from Section 7.6, "Control Console and Display Instruments," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 7.6, the staff compared the design bases and functional requirements of the control console and display information with other facility systems.

On the basis of its review, the staff finds that the level of detail provided on the control console and display information demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.6, allowing the staff to make the following relevant finding: the applicant has indicated that systems important to the safe and effective operation of the facility (i.e., TRPS and TPCS) will be displayed at the control console.

Therefore, the staff finds that the preliminary design of the SHINE control console and display information, as described in SHINE PSAR Section 7a2.6 is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7a.4.7 Radiation Monitoring Systems

The staff evaluated the sufficiency of the preliminary design of SHINE's radiation monitoring systems, as described in SHINE PSAR Section 7a2.7, in part, by reviewing the descriptions and locations of SHINE's radiation monitoring equipment using the guidance and acceptance criteria from Section 7.7, "Radiation Monitoring Systems," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 7.7, the staff confirmed that the design bases for the radiation monitoring systems and equipment I&Cs are consistent with giving reliable indication of the presence of radiation or release of radioactive material in the various areas monitored and in the monitored effluent streams from the facility.

On the basis of its review, the staff finds that the level of detail provided on the radiation monitoring systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.7, allowing the staff to make the following relevant findings: (1) the preliminary design of the radiation monitoring system has been described and is applicable to the anticipated sources of radiation, (2) the PSAR discusses all likely radiation and radioactive sources anticipated at the SHINE facility and describes equipment, systems, and devices that will give reasonable assurance that all such sources will be identified and accurately evaluated, and (3) the radiation monitoring

systems described in the PSAR give reasonable assurance that dose rates and effluents at the facility will be acceptably detected, and that the health and safety of the facility staff, environment, and public will be acceptably protected.

Therefore, the staff finds that the preliminary design of the SHINE radiation monitoring systems, as described in SHINE PSAR Section 7a2.7 is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7a.4.8 Probable Subjects of Technical Specifications

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

Section 7a2.2.4, "System Performance Analysis," of the SHINE PSAR states that "potential variables, conditions, or other items that will be probable subjects of technical specifications associated with the IF instrumentation and control systems are provided in Chapter 14." Similarly, PSAR Sections 7a2.6.9, "TRPS/TPCS and Display Independence," and 7a2.7.4.3, "Audible and Visual Alarm Devices," indicate that probable subjects of technical specifications associated with the TRPS, TPCS, and display instrumentation and radiation monitoring instrumentation are provided in PSAR Chapter 14, "Technical Specifications." SHINE PSAR Section 14a2.6, "Administrative Controls," lists hot cell audible and visual warnings as part of the facility's as low as is reasonably achievable (ALARA) program, which will be covered by administrative controls in the technical specifications.

Based on the information provided in Sections 7a2.2.4, 7a2.6.9, 7a2.7.3, "Radiation Monitor Locations," and 14a2.6 of the SHINE PSAR, the staff finds that the identification and justification of hot cell audible and visual warnings as part of the facility's ALARA program as a probable subject of technical specifications for the SHINE IF I&C systems is sufficient and meets the applicable regulatory requirements to support the issuance of a construction permit in accordance with 10 CFR 50.35. A complete evaluation of technical specifications, limiting conditions for operation (LCOs), and surveillance requirements will be performed during the review of SHINE's operating license application.

7a.5 Summary and Conclusions

The staff evaluated descriptions and discussions of SHINE's IF I&C systems, including probable subjects of technical specifications, as described in Section 7a2 of the SHINE PSAR and supplemented by the applicant's responses to RAIs, and finds that the preliminary design of SHINE's IF I&C systems, including the principle design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in NUREG-1537. The staff further notes that any modifications to the preliminary design of the SHINE I&C systems

and operating procedures can be readily implemented in the final design and after facility construction activities have been completed.

On the basis of these findings, the staff has made the following conclusions to support the issuance of a construction permit in accordance with 10 CFR 50.35:

(1) SHINE has described the proposed design of IF I&C systems, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Further technical or design information required to complete the safety analysis of the IF I&C systems may reasonably be left for later consideration in the FSAR.

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

7b Radioisotope Production Facility Instrument and Control Systems

Section 7b, "Radioisotope Production Facility Instrumentation and Control Systems," provides an evaluation the preliminary design of SHINE's RPF I&C systems as presented in SHINE PSAR Section 7b, "Radioisotope Production Facility Instrument and Control Systems," within which, SHINE describes the design of instrumentation and control systems, production facility process control systems, ESFs and alarming, control console and display instrumentation, and radiation monitoring systems.

7b.1 Areas of Review

The staff reviewed Section 7b, "Radioisotope Production Facility Instrument and Control System," of the SHINE PSAR against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of SHINE's RPF I&C systems. As part of this review, the staff evaluated descriptions and discussions of SHINE's RPF I&C systems, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of SHINE's RPF I&C systems was evaluated to ensure the sufficiency of principle design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design.

Areas of review for this section included RPF I&C process control descriptions, ESFs and alarming, control console and display information, and radiation monitoring systems. Within these review areas, the staff assessed the preliminary analysis of I&C systems needed to monitor key parameters and variables, maintain parameters and variables within prescribed operating ranges, alert operators when operating ranges are exceeded, assure safety limits are not exceeded, and initiate mitigating systems and components important to safety.

7b.2 Summary of Application

The SHINE RCA integrated control system (RICS) monitors and controls both safety-related and non-safety-related components within the RPF.

Section 7b of the SHINE PSAR provides the preliminary design of the RPF I&C systems, including the RPF process control systems, ESFs and alarming, control console and display information, and radiation monitoring systems.

7b.3 Regulatory Basis and Acceptance Criteria

The staff reviewed SHINE PSAR Section 7b against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of SHINE's I&C systems in support of the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, a construction permit authorizing SHINE to proceed with construction may be issued once the following findings have been made:

(1) SHINE has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR.

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

(4) On the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

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

7b.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's RPF I&C systems are as follows:

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

Note: As required by 10 CFR 50.34(a)(3)(i), SHINE must describe the principal design criteria for its facility in the PSAR; however, SHINE is not required to follow 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants," as this appendix only applies to nuclear power reactors. Nonetheless, SHINE has applied several of the GDCs to the preliminary design of its I&C systems in the RPF. As such, the staff based its review, in part, on SHINE's application of the following GDCs to its I&C systems:

- GDC 2, "Design Bases for Protection Against Natural Phenomena"
- GDC 4, "Environmental and Dynamic Effects Design Bases"
- GDC 5, "Sharing of Structures, Systems, and Components"
- GDC 10, "Reactor Design"
- GDC 12, "Suppression of Reactor Power Oscillations"
- GDC 13, "Instrumentation and Control"
- GDC 15, "Reactor Coolant System Design"
- GDC 16, "Containment Design"
- GDC 17, "Electric Power Systems"
- GDC 19, "Control Room"
- GDC 20, "Protection System Functions"
- GDC 21, "Protection System Reliability and Testability"
- GDC 22, "Protection System Independence"
- GDC 23, "Protection System Failure Modes"
- GDC 24, "Separation of Protection and Control Systems"
- GDC 25, "Protection System Requirements for Reactivity Control Malfunctions"
- GDC 26, "Reactivity Control System Redundancy and Capability"
- GDC 27, "Combined Reactivity Control Systems Capability"
- GDC 28, "Reactivity Limits"
- GDC 29, "Protection Against Anticipated Operational Occurrences"

7b.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated SHINE's RPF I&C systems against the regulatory requirements listed above primarily using the guidance and acceptance criteria contained in Chapter 7 of NUREG-1537, Parts 1 and 2, as well as the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

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

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 7b.4, "Review Procedures, Technical Evaluation, and Evaluation Findings," of the SER. Guidance documents used to review SHINE's I&C systems are provided as references at the end of this chapter.

7b.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed a section-by-section evaluation of the technical information presented in Section 7b of SHINE's PSAR, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of SHINE's RPF I&C systems in support of the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency as discussed in Section 7b.3, "Regulatory Basis and Acceptance Criteria," of this SER, the staff has determined that the sufficiency of preliminary design and performance of SHINE's RPF I&C systems is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria. While the technical evaluation of these systems provided in this section is specific to the SHINE RPF, the staff's review considers the interface of these systems between the IF and RPF as part of a comprehensive technical evaluation. The results of this section-by-section technical evaluation are described in Section 7b.5, "Summary and Conclusions."

For the purposes of issuing a construction permit, the preliminary design of the SHINE I&C systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the SHINE I&C systems based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of the preliminary design of SHINE's I&C systems does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of SHINE's I&C systems, as described in the FSAR, as part of SHINE's operating license application.

7b.4.1 Summary Description

The staff evaluated the sufficiency of SHINE's summary description of its RPF I&C systems, as described in SHINE PSAR Section 7b.1, "Summary Description," using the guidance and acceptance criteria from Section 7b.1, "Summary Description," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

As stated in Section 7b.1 of the ISG Augmenting NUREG-1537, Part 1, the description of the I&C systems should, in part, summarize the "description of the I&C systems, including the design bases; the safety, considerations, and objectives; the operational characteristics of the production facility that determine or limit the I&C design; and the ways in which the various subsystems constitute the whole and interact to contribute to its essential functions. This summary should also include schematic, logic, and flow diagrams illustrating the various subsystems."

Section 7b.1 of the SHINE PSAR provides a summary description of the RPF I&C systems that includes the design bases; the safety, considerations, and objectives; the operational characteristics of the RPF that determine or limit the I&C design; and the ways in which the various subsystems constitute the whole and interact to contribute to its essential functions.

The summary description references schematic, logic, and flow diagrams illustrating the various subsystems. The staff finds that each RPF I&C system was designed to perform functions commensurate with the complexity of the processes therein. The principal RPF I&C systems are briefly described in SHINE PSAR Sections 7b.1.1 through 7b.1.4, and include the RICS (Safety-Related/ESF), RICS Description (Process Control), Radiation Monitoring, and Control Room and Instrument Displays.

On the basis of its review, the staff finds that the level of detail provided in the summary description of the SHINE RPF I&C systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 7b.1.

Therefore, the staff finds that the summary description of the SHINE RPF I&C systems, as described in SHINE PSAR Section 7b.1, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7b.4.2 Design of Instrumentation and Control Systems

The staff evaluated the sufficiency of the design of SHINE's RPF I&C systems, as described in SHINE PSAR Section 7b.2, "Design of Instrumentation and Control Systems," in part, by evaluating the design criteria, design basis requirements, system description, and system performance analysis of SHINE's RPF I&C systems using the guidance and acceptance criteria from Section 7b.2, "Design of Instrumentation and Control Systems," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

On the basis of its review, the staff finds that the level of detail provided in design of the SHINE RPF I&C systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 7b.2.

Therefore, the staff finds that the design of the SHINE RPF I&C systems, as described in SHINE PSAR Section 7b.2, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7b.4.3 Production Facility Process Control Systems

The staff evaluated the sufficiency of the preliminary design of SHINE's RPF process control system, as described in SHINE PSAR Section 7b.3, "Production Facility Process Control Systems," and supplemented by the applicant's responses to RAIs, in part, by reviewing the valve position mimic tables, pump controls, IU cell transfers, fresh target solution loading, and recycled target solution loading of SHINE's RPF process control system using the guidance and acceptance criteria from Section 7b.3, "Process Control Systems," of the ISG Augmenting NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 7b.3, the staff confirmed that RPF process control system information for all normal functions and systems described in other chapters of the PSAR is addressed in this section and verified that all design bases are justified, as presented in SHINE PSAR Section 7b.3 and other relevant chapters of the PSAR.

During its review, the staff noted that SHINE PSAR, Section 7b.3 states, in part, that the RICS "[m]onitors and controls inter-equipment process fluid transfers in the RPF. For transport requiring a pump, the RICS controls the ability of the pump to be energized, and for specific transfers, provides controlled fluid flow transfers. . .."

The staff determined that the application provided insufficient information for the staff to conclude that the RPF instrumentation was adequate to detect excessive deviations from critical process variables. Therefore, the staff issued RAI 7b.3-1 (Reference 14), in which the staff requested that the applicant provide additional information regarding the adequacy of the facility's instrumentation to detect deviations from nominal concentrations and quantities of fissile materials, should they occur. This information is necessary to demonstrate the adequacy of the design basis of the SHINE RPF instrumentation and satisfy the acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 7b.3, which states, in part, that "[t]he system should be designed with sufficient control of reactivity for all required production and SNM fuel reconditioning process operations…."

In its response to RAI 7b.3-1 (Reference 20), the applicant stated the following:

> Except for the liquid waste processing tanks downstream of the raffinate hold tank (1-UNCS-05T), the RPF tanks that contain fissile materials are designed to be criticality-safe for the most reactive uranium concentration, as described in Subsection 6b.3.1 of the PSAR. If these RPF tanks are over-filled, the excess liquid is contained in criticality-safe geometry configurations. Liquid that overfills these tanks is controlled through the use of sumps and drains to the criticality-safe sump catch tank.
>
> Before liquid is transferred downstream of the raffinate hold tank (to the liquid waste storage tank), the absence of appreciable quantities of fissile material is verified, as described in Subsection 9b.7.3.2.2 of the PSAR. This verification will include appropriate interlocks or other means to prevent the transfer until the verification is completed.
>
> Therefore, the RICS does need to control deviations from nominal concentrations and quantities for the purpose of criticality safety. However, the SHINE facility will contain appropriate instrumentation to adequately monitor the transfer of liquids in the IF and RPF, including tank level indication, flow indication, and leak detection, to prevent tank overfills and identify leaks.

The staff finds that this response satisfies the acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 7b.3, and demonstrates an adequate design basis in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

Based on the information provided in Section 7b.3 of the SHINE PSAR, as supplemented by the applicant's responses to RAIs, the staff finds that the preliminary design of the SHINE RPF process controls is sufficient and meets the applicable regulatory requirements and acceptance

criteria of NUREG-1537 in support of the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration in the FSAR.

7b.4.4 Engineered Safety Feature and Alarming

The staff evaluated the sufficiency of the preliminary design of SHINE's RPF ESF and alarming, as described in SHINE PSAR Section 7b.4, "Engineered Safety Feature and Alarming," as supplemented by the applicant's responses to RAIs, in part, by reviewing the system description, annunciation and display, and system performance and analysis of SHINE's ESF and alarming using the guidance and acceptance criteria from Section 7.5, of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 7.5, the staff compared the design criteria and bases of the ESFAS with the ESFs and accident scenarios, as well as compared the design and functional descriptions of the ESFAS with the applicable criteria and functions in Chapters 6, "Engineered Safety Features," and 13, "Accident Analysis."

Section 7.5 of NUREG-1537, Part 2, states, in part, that "[t]he range and sensitivity of ESF actuation system sensors should be sufficient to ensure timely and accurate signals to the actuation devices."

During its review, the staff noted that SHINE PSAR, Section 7b.4.1.2.3, "Uranyl Nitrate Conversion System Over Temperature Alarm," states, in part, that "[t]he RICS monitors the temperature of each UNCS [uranyl nitrate conversion system] in the RPF with independent redundant sensors. These sensors measure the temperature at the outlet of the UNCS." However, the staff noted that there was insufficient information to confirm the applicant's assertion. Therefore, the staff issued RAI 7b.4-1 (Reference 14), in which the staff requested that the applicant provide additional information to justify how the location of temperature sensors at the outlet of the UNCS is representative of the process. This information is necessary to demonstrate the adequacy of the design basis of the SHINE RPF ESF and alarming and satisfy the acceptance criterial of NUREG-1537, Part 2, Section 7.5, which states, in part, that "[t]he range and sensitivity of ESF actuation system sensors should be sufficient to ensure timely and accurate signals to the actuation devices."

In its response to RAI 7b.4-1 (Reference 20), the applicant explained that temperature sensors will be located at appropriate points representative of the UNCS process, sufficient to ensure safe and reliable operation of the system. Specific temperature sensor locations will be determined during the detailed design and will be provided in the FSAR. Examples of temperature sensor locations, which will be verified as appropriate during detailed design, include the following:

(1) Upstream of the uranyl nitrate conversion tank (1-UNCS-01T-A/B) to monitor the feed from the molybdenum extraction and purification system (MEPS)

(2) Downstream of the uranyl nitrate conversion tank (1-UNCS-01T-A/B) to measure average temperature and prevent bulk boiling and extra vapor input to the vent stack

(3) Downstream of the heat exchanger for the uranyl nitrate conversion tank (1-UNCS-01T-A/B)

(4) Upstream of the extraction contactors (1-UNCS-01Z)

(5) Downstream of the recycle uranyl nitrate hold tank (1-UNCS-06T)

(6) At the uranyl nitrate evaporator vessel (1-UNCS-07T)

(7) At the thermal denitrator (1-UNCS-08T)

The staff finds that this response satisfies the acceptance criteria of NUREG-1537, Part 2, Section 7.5, and demonstrates an adequate design basis in support of a preliminary design. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

On the basis of its review, the staff finds that the level of detail provided on the RPF ESF and alarming demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.5, allowing the staff to make the following relevant findings: (1) the applicant has analyzed postulated accident scenarios at the facility, including accidents for which consequence mitigation by the RPF ESF and alarming is required or planned, (2) the applicant has considered the environments in which the ESFs are expected to operate, and (3) the design considerations of the RPF ESF and alarming give reasonable assurance that the final design of the system will detect changes in measured parameters as designed and will initiate timely actuation of the applicable ESF.

Therefore, the staff finds that the preliminary design of the SHINE RPF ESF and alarming, as described in SHINE PSAR Section 7b.4 is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7b.4.5 Control Console and Display Instrumentation

The staff evaluated the sufficiency of the preliminary design of SHINE's RPF control console and display information, as described in SHINE PSAR Section 7b.5, "Control Console and Display Instrumentation," using the guidance and acceptance criteria from Section 7.6, "Control Console and Display Instruments," of NUREG-1537, Parts 1 and 2, and Section 7b.5, "Control Console and Display Instruments," of the ISG Augmenting NUREG-1537.

In accordance with the review procedures of NUREG-1537, Part 2, Section 7.6, the staff compared the design bases and functional requirements of the control console and display information with other facility systems.

SHINE PSAR Section 7b.5 describes the control console or human machine interface (HMI) for the RPF, located in the SHINE Medical Isotope Production Facility (MIPF) control room, as an extension of the RICS, discussed in more detail in SHINE PSAR Sections 7b.2.1, "Design Criteria;" 7b.2.2, "Design Bases;" 7b.2.3, "System Description;" 7b.2.4, "System Performance Analysis;" 7b.2.5, "Conclusion;" 7b.3, "Production Facility Process Control Systems;" and 7b.4, "Engineered Safety Feature and Alarming. The RICS is used for RPF monitoring and process control. In addition, this PSAR section discusses alarms and annunciators for the RPF CAMS, RAMS, and criticality accident alarm system (CAAS), discussed in more detail in SHINE PSAR Section 7b.6, "Radiation Monitoring Systems."

On the basis of its review, the staff finds that the level of detail provided on the control console and display information demonstrates an adequate design basis in support of a preliminary

design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.6, allowing the staff to make the following relevant finding: the applicant has indicated that systems important to the safe and effective operation of the facility (i.e., RICS, CAMS, RAMS, and CAAS) will be displayed at the control console.

Therefore, the staff finds that the preliminary design of the SHINE control console and display information, as described in SHINE PSAR Section 7b.5, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7b.4.6 Radiation Monitoring Systems

The staff evaluated the sufficiency of the preliminary design of SHINE's radiation monitoring systems, as described in SHINE PSAR Section 7b.6, in part, by reviewing the descriptions and locations of SHINE's radiation monitoring equipment described in SHINE PSAR Section 7a2.7, as well as the description of the CAAS using the guidance and acceptance criteria from Section 7.7, "Radiation Monitoring Systems," of NUREG-1537, Parts 1 and 2.

In accordance with the review procedures of NUREG-1537, Part 2, Section 7.7, the staff confirmed that the design bases for the radiation monitoring systems and equipment I&Cs are consistent with giving reliable indication of the presence of radiation or release of radioactive material in the various areas monitored and in the monitored effluent streams from the facility.

On the basis of its review, the staff finds that the level of detail provided on the radiation monitoring systems demonstrates an adequate design basis in support of a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 7.7, allowing the staff to make the following relevant findings: (1) the preliminary design of the radiation monitoring system has been described and is applicable to the anticipated sources of radiation, (2) the PSAR discusses all likely radiation and radioactive sources anticipated at the SHINE facility and describes equipment, systems, and devices that will give reasonable assurance that all such sources will be identified and accurately evaluated, and (3) the radiation monitoring systems described in the PSAR give reasonable assurance that dose rates and effluents the facility will be acceptably detected, and that the health and safety of the facility staff, environment, and public will be acceptable protected.

Therefore, the staff finds that the preliminary design of the SHINE radiation monitoring systems, as described in SHINE PSAR Section 7b.6 is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

7b.4.7 Probable Subjects of Technical Specifications

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

SHINE PSAR Section 7b.2.4, "System Performance Analysis," states, in part, that "potential variables, conditions, or other items that will be probable subjects of technical specifications associated with the RPF instrumentation and control systems are provided in Chapter 14." Similarly, Sections 7b.3, "Production Facility Process Control Systems," 7b.4.3, "System Performance Analysis," and 7b.5.1, "System Description," indicate that probable subjects of technical specifications associated with the production facility process control systems, RICS, and control console and displays are provided in Chapter 14. Table 14a2-1, "SHINE Facility Proposed Parameters for Technical Specifications," lists the RICS as an LCO for critical equipment malfunctions as described in Section 13b.2.4, "Critical Equipment Malfunction," of the PSAR.

Based on the information provided in Sections 7b.2.4, 7b.3, 7b.4.3, 7b.5.1, and Table 14a2-1 of the SHINE PSAR, the staff finds that the identification and justification of the RICS as an LCO for the SHINE RPF is sufficient and meets the applicable regulatory requirements and acceptance criteria of NUREG-1537 in support of the issuance of a construction permit in accordance with 10 CFR 50.35. A complete evaluation of technical specifications, LCOs, and surveillance requirements will be performed during the review of SHINE's operating license application.

7b.5 Summary and Conclusions

The staff evaluated descriptions and discussions of SHINE's RPF I&C systems, including probable subjects of technical specifications, as described in Section 7b of the SHINE PSAR and supplemented by the applicant's responses to RAIs, and finds that preliminary design of SHINE's RPF I&C systems, including the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in NUREG-1537. The staff further notes that any modifications to the preliminary design of the SHINE I&C systems and operating procedures can be readily implemented in the final design and after facility construction activities have been completed.

On the basis of these findings, the staff has made the following conclusions to support the issuance of a construction permit in accordance with 10 CFR 50.35:

(1) SHINE has described the proposed design of RPF I&C systems, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Further technical or design information required to complete the safety analysis of the RPF I&C systems may reasonably be left for later consideration in the FSAR.

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

CONSTRUCTION PERMITS