

14.0 TECHNICAL SPECIFICATIONS

The principal purpose of technical specifications (TSs) is to maintain system performance and safe operation. This is accomplished by addressing limiting or enveloping conditions of design and operation ensuring that emphasis is placed on the safety of the public, the facility staff, and the environment. TSs are typically derived from the analyses and evaluation included in a facility's final safety analysis report (FSAR).

This chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) 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 proposed TSs for the SHINE irradiation facility (IF) and radioisotope production facility (RPF) (together, the SHINE facility), as presented in chapter 14, "Technical Specifications," of the SHINE FSAR and in SHINE's proposed TSs and supplemented by the applicant's response to the staff's requests for additional information (RAIs).

14.1 Areas of Review

The NRC staff reviewed SHINE FSAR chapter 14 and SHINE's proposed TSs against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the proposed TSs. The staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items included in the proposed TSs for the SHINE facility, with special attention given to those items that may significantly influence the final design.

The specific areas of review for this chapter of the SER are those TSs proposed for the SHINE IF and RPF. Within these areas of review, the NRC staff assessed whether SHINE's proposed TSs, including relevant safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation, surveillance requirements, design features that affect the function, availability, or reliability of structures, systems, or components (SSCs), and administrative controls would ensure the availability of SSCs.

14.2 Summary of Application

The principal purpose of TSs is to maintain system performance and safe operation emphasizing the safety of the public, the facility staff, and the environment. The summary provided below applies to both the SHINE IF and RPF.

SHINE FSAR chapter 14 states that the proposed TSs for the SHINE IF and RPF were developed following the format and content guidance of American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.1-2007, "The Development of Technical Specifications for Research Reactors," and using the applicable guidance of NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," and Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria," and the interim staff guidance (ISG) augmenting NUREG-1537, Parts 1 and 2. It further states that normal operation of the SHINE facility within the limits of the proposed TSs will not result in offsite radiation exposure in excess of the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation," and that the observance of the proposed TSs limits the likelihood and consequences of malfunctions.

The NRC staff reviewed SHINE's proposed TSs submitted by letter dated January 26, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22034A612; Enclosure 6 (ML22034A633)). Based upon audit discussions, SHINE submitted revised proposed TSs to the NRC on August 31, 2022 (ML22249A148), Enclosure 8 (ML22249A129). The discussion in this chapter of the SER uses the most recent revision of the proposed TSs. The proposed TS 1.2, "Format," states that the usage rules in TS 3.0, "Limiting Conditions for Operation and Surveillance Requirements," and the descriptions of logical connectors and completion times in TS 1.4, "Logical Connectors and Completion Times," are based on the guidance provided in NUREG-1431, "Standard Technical Specifications: Westinghouse Plants," Volume 1, "Specifications" (ML21259A155).

14.3 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 14 and SHINE's proposed TSs against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the proposed TSs for the issuance of an operating license.

14.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of SHINE's proposed TSs 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"

14.3.2 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.
- ANSI/ANS 15.1-2007, “The Development of Technical Specifications for Research Reactors.”

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, Institute of Electrical and Electronics Engineers (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; NUREG-1431, Volume 1; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

14.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the content of SHINE’s proposed TSs, as supplemented, to determine whether the requirements in 10 CFR 50.36, “Technical specifications,” are met with respect to the TSs being derived from the analyses and evaluation included in the SHINE FSAR and that they include items in the categories of: (1) safety limits (SLs), limiting safety system settings (LSSSs), and limiting control settings; (2) limiting conditions for operation (LCOs); (3) surveillance requirements (SRs); (4) design features (DFs); and (5) administrative controls. Additionally, the staff reviewed the proposed TSs to ensure their general consistency with the format and guidance in chapter 14, “Technical Specifications,” of NUREG-1537, Parts 1 and 2, chapter 14, “Technical Specifications,” of the ISG augmenting NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.1-2007. For general TS applicability and usage in LCO 3.0.1 and SR 3.0.1, SHINE proposed similar content as used in NUREG-1431, Volume 1, which is the standard technical specifications for Westinghouse nuclear power reactor plants. The staff also noted that SHINE submitted TS bases that provide the reasons for the proposed TSs.

The NRC staff audited SHINE’s proposed TSs to gain a complete understanding of the information provided in the operating license application with respect to TSs and to focus on TS format, clarity, and consistency with regulatory guidance. During the audit, the staff reviewed SHINE’s proposed TSs in their entirety to ensure that the applicable guidance and acceptance criteria were met. The information that the staff audited is documented in an audit report dated September 12, 2022 (ML22220A261). The staff’s approach to the audit was to group the staff’s

comments and information into four categories based on significance. The four categories, from least to most significant, were for the staff to: (1) gain an understanding of the proposed TSs; (2) provide observations and recommend format changes to promote consistency; (3) provide regulatory or guidance directed changes; and (4) identify a TS deviation or exception that is not adequately explained or justified.

For the majority of SHINE's proposed TSs, the NRC staff's review of the TSs is documented in the chapter of this SER that is most relevant to those TSs. For those reviews, the staff focused on TS parameters and values from a technical perspective to ensure safety. In this chapter of the SER the staff specifically reviews TS 1.3, "Definitions"; TS 1.4, LCO and SR 3.0.1; LCO and SR 3.8.4 since they were not addressed in chapter 6, "Engineered Safety Features," of this SER; and TS 3.9, "Startup Testing." The staff also reviews the SHINE proposed DFs in TS 4.0, "Design Features," that were not evaluated in other chapters of this SER. With respect to the SHINE proposed administrative controls TSs in TS 5.0, "Administrative Controls," the staff's review focused mainly on the more safety significant of those TSs. Although this chapter of the SER concentrates on these proposed TSs, the staff has reviewed all of SHINE's proposed TSs and, between this chapter and the other chapters of this SER, all of the proposed TSs are discussed as appropriate.

SHINE included definitions in proposed TS 1.3 to provide for the uniform interpretation of the terms and phrases used in the TSs and to be generally consistent with the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. SHINE's proposed TS definitions include minor modifications to some definitions in the guidance and some additional facility-specific definitions. The NRC staff reviewed the TS definitions and finds that they are either appropriate facility-specific definitions or are consistent with applicable guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff concludes that TS 1.3 is acceptable.

SHINE proposed the use of the logical connectors "AND" and "OR" in TS 1.4. These logical connectors are used throughout the SHINE LCOs and SRs to discriminate between required actions and completion times under the conditions when an LCO or SR is not met. TS 1.4 explains the meaning of these logical connectors and the rationale for identifying the order to complete the required action(s) in a specific LCO. The "AND" connector is used to indicate that all associated actions must be completed while the "OR" connector is used to indicate that only one of the associated actions must be completed. Required actions are also sometimes nested where the physical arrangement (indentation) indicates the successive nature and order of required actions.

Based on the information provided by SHINE TS 1.4, the NRC staff finds that SHINE's proposed implementation of logical connectors is consistent with the guidance in NUREG-1431, Volume 1. Because SHINE appropriately uses logical connectors to state a condition, completion time, surveillance, or frequency, the staff concludes that TS 1.4 is acceptable.

Proposed LCO 3.0.1 provides general requirements and specific allowances for LCO application, completion of required actions, and test exceptions. Additionally, LCO 3.0.1.2 requires the associated conditions and actions for a TS to be addressed individually and independently of other LCOs, conditions, and actions unless otherwise stated. ANSI/ANS 15.1-2007 provides that deviations from LCOs may be allowed under specified conditions, such as the use of actions statements. SHINE's proposed TSs contain action statements that are immediately initiated upon the discovery that an LCO is not met. The NRC staff also reviewed the general LCO usage and applicability requirements in NUREG-1431, Volume 1 to determine whether the usage and applicability requirements in LCO 3.0.1 are

consistent with them. The staff finds that LCO 3.0.1 ensures that LCOs will be met during the Modes of applicability for the LCOs and that when an LCO and corresponding actions are not met or provided, immediate action is initiated to place the facility in a Mode or condition in which the LCO is not applicable. Additionally, the staff finds that LCO 3.0.1.4 identifies channels that may be rendered inoperable using administrative controls for the purpose of completing recovery actions. The staff determined that LCO 3.0.1 provides appropriate LCO practices and is consistent with the guidance in NUREG-1537, ANSI/ANS 15.1-2007, and NUREG-1431, Volume 1. Because LCO 3.0.1 clearly identifies the LCO application and usage, describes actions when an LCO is not met, and identifies specific channels that may be rendered inoperable to complete recovery actions, the staff concludes that it is acceptable.

The proposed SR 3.0.1 provides general requirements for surveillance application, performance frequency, identification of surveillances that require entry into the Mode of applicability or condition to perform the surveillance, and surveillance testing. The NRC staff finds that SR 3.0.1 helps to maintain the quality of SSCs within specifications. Further, the staff finds that SR 3.0.1 specifies the conduct of SRs required to allow operational flexibility that does not impact the safe operation of the facility. NUREG-1537 and ANSI/ANS 15.1-2007 provide guidance that SRs define the frequency and scope of the surveillance activities required to ensure that LCOs are acceptably maintained. The staff determined that SR 3.0.1 provides appropriate surveillance practices and is consistent with the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff concludes that SR 3.0.1 is acceptable.

The proposed TS 3.8, "Facility-Specific," LCO 3.8.4 and SR 3.8.4 state the following:

LCO 3.8.4	The concentration of uranium present in the second uranium liquid waste tank and the liquid waste blending tank shall be less than 25 gU/L.
Applicability	At all times
Action	According to Table 3.8.4
SR 3.8.4	<ol style="list-style-type: none"> 1. Uranium concentration in the first uranium liquid waste tank shall be measured and verified to be below the limit in accordance with the requirements of the criticality safety program and prior to transfer of liquid to the second uranium liquid waste tank. 2. Uranium concentration in the second uranium liquid waste tank shall be measured and verified to be below the limit in accordance with the requirements of the criticality safety program and prior to transfer of liquid to the liquid waste blending tank. 3. Uranium concentration in the liquid waste blending tank shall be measured and verified to be below the limit in accordance with the requirements of the criticality safety program.

The proposed TS Table 3.8.4, “Waste Tank Uranium Concentration Actions,” states the following:

	Condition and Action	Completion Time
1.	<p>If uranium concentration is above the limit in either the second uranium liquid waste tank or the liquid waste blending tank,</p> <p style="padding-left: 40px;">Stop transfers of solution to the liquid waste blending tank</p> <p style="text-align: center;">AND</p> <p>Dilute solution in the liquid waste blending tank until the uranium concentration is verified to be below the limit.</p>	<p>Immediately</p> <p>6 hours</p>

LCO 3.8.4 specifies that the concentration of uranium present in the second uranium liquid waste tank and the liquid waste blending tank shall be less than 25 grams of uranium per liter at all times. The NRC staff finds that this LCO and associated actions would ensure that the uranium concentration in the second uranium liquid waste tank, which is designed with a favorable geometry, is below the uranium concentration limit specified in SHINE's nuclear criticality safety program to prevent a potential criticality event in the non-geometrically favorable liquid waste blending tank. Therefore, the staff finds LCO 3.8.4 acceptable.

SR 3.8.4.1 and SR 3.8.4.2 require uranium concentration measurements in both the first and second uranium liquid waste tanks prior to transfer of the liquid to the liquid waste blending tank. Further, SR 3.8.4.3 requires sampling the liquid in the liquid waste blending tank to verify that the uranium concentration is below the limit specified in SHINE's nuclear criticality safety program. The NRC staff finds that measuring and verifying the uranium concentration in both the first and second uranium liquid waste tanks, as well as the liquid waste blending tank, ensures that the liquid can be safely transferred and stored in the liquid waste blending tank. Therefore, the staff finds SR 3.8.4 acceptable.

The proposed TS 3.9, LCOs 3.9.1 through 3.9.3 and SRs 3.9.1 through 3.9.3, and the proposed TS table 3.9.1, "Actions for Mode 1 Startup Testing Exceptions," TS table 3.9.2, "Actions for Mode 2 Startup Testing Exceptions," and TS table 3.9.3, "Actions for Mode 2 Initial NFDS [Neutron Flux Detection System] Calibration," describe activities and testing to support startup testing in Mode 1 and Mode 2. The NRC staff finds that these LCOs, SRs, and tables specify exceptions to other LSSSs and LCOs provided that sufficient actions are taken to ensure that testing activities can be safely accomplished during startup testing in Mode 1 and Mode 2. Therefore, the staff finds LCOs 3.9.1 through 3.9.3 and SRs 3.9.1 through 3.9.3 acceptable.

The NRC staff reviewed the following SHINE proposed DFs in TS 4.0 that were not evaluated in other chapters of this SER:

DF 4.1.1	<ol style="list-style-type: none"> 1. The SHINE Facility is owned and operated by SHINE Technologies, LLC and is located at 4021 S. U.S. Highway 51, Janesville, WI, 53546. The SHINE Facility includes the Main Production Facility, N2PS structure, resource building, material staging building, and the storage building. 2. The nearest distance from a potential release point from the Main Production Facility to the site boundary is 756 ft. 3. The site boundary corresponds to the property line around the perimeter of the SHINE site and encompasses approximately 91 acres of land. The owner controlled area is the area within the site boundary. 4. The operations boundary is the area within the site boundary where the Shift Supervisor or the designee has direct authority over all activities. The controlled access area fence and the perimeter walls of the Main Production Facility, the material staging building, the storage building, and the resource building constitute the SHINE operations boundary. The operations boundary is the emergency planning zone.
DF 4.1.2	<ol style="list-style-type: none"> 1. The building free volume of the irradiation facility is approximately 13,400 m³. 2. The building free volume of the radioisotope production facility is approximately 18,000 m³. 3. The accident dose effluent release height is 0 feet above grade. 4. The normal effluent release height is 67 feet above grade.
DF 4.1.4	<p>Supercell ventilation is designed with a maximum flowrate of 40 air exchanges per hour (ACH) for extraction and purification cells.</p>
DF 4.1.6	<p>Irradiation cell biological shield (ICBS) and production facility biological shield (PFBS) features are provided to maintain radiation exposure to workers and the public within acceptable limits as required by 10 CFR 20.</p>

The NRC staff finds that these DFs provide a general description of the SHINE site and facility including building volumes and features of the supercell ventilation. The staff finds that DF 4.1.1, DF 4.1.2, DF 4.1.4, and DF 4.1.6 appropriately implement the guidance in ANSI/ANS 15.1-2007 to provide a general description of the site, building volumes, ventilation flow rates, and effluent release heights that are important to safety. Therefore, the staff finds DFs 4.1.1, 4.1.2, 4.1.4, and 4.1.6 acceptable.

With respect to the proposed TS 5.0, the NRC staff focused its review on the following administrative controls TSs.

The proposed TS 5.1.1, "Structure," and TS figure 5.1.1, "SHINE Operational Organization Chart," describe the SHINE organizational structure, functional responsibilities, and levels of authority. The NRC staff finds that TS 5.1.1 and TS figure 5.1.1 help ensure that the SHINE organizational structure, including the communication and reporting lines, is appropriately defined and properly delineated in the TSs. The staff also finds that by delineating the SHINE organizational structure, TS 5.1.1 and TS figure 5.1.1 appropriately implement the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.1.1 and TS figure 5.1.1 acceptable.

The proposed TS 5.1.2, "Responsibility," describes the authority and responsibility of the SHINE organizational members identified in TS figure 5.1.1. The NRC staff finds that by clearly defining the responsibilities of personnel as they relate to the facility, TS 5.1.2 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.1.2 acceptable.

The proposed TS 5.1.3, "Facility Staffing Required," states the following:

1. The minimum staffing when the facility is not Secured shall be:
 - a. A Senior Licensed Operator present in the facility,
 - b. A Licensed Operator or second Senior Licensed Operator present in the control room, and
 - c. An additional designated person present at the facility able to carry out prescribed written instructions.

Unexpected absence of the position described in 5.1.3.1.a for as long as 30 minutes to accommodate a personal emergency may be acceptable provided immediate action is taken to designate a replacement.

Unexpected absence of the position described in 5.1.3.1.c for as long as two hours to accommodate a personal emergency may be acceptable provided immediate action is taken to obtain a replacement.

The proposed TS 5.1.3 describes the minimum staffing required when the SHINE facility is not secured as defined in TS 1.3. Specifically, TS 5.1.3 requires, when the SHINE facility is not secured the minimum shall be: an NRC-licensed senior operator in the facility, either an NRC-licensed operator or second NRC-licensed senior operator in the control room, and an additional designated person at the facility able to carry out prescribed written instructions. TS 5.1.3 also provides exceptions to the minimum staffing requirements to accommodate personal emergencies. The NRC staff finds that TS 5.1.3.1.a helps ensure that a senior licensed operator is present at the facility to provide supervision. Excepting this requirement for an unexpected absence of the senior licensed operator for a personal emergency for up to 30 minutes meets the intent of the guidance in ANSI/ANS 15.1-2007. The staff also finds that by requiring a senior licensed operator to be present at the facility when the facility is not secured, TS 5.1.3.1.a appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. The staff finds that TS 5.1.3.1.b helps ensure appropriate staffing at the facility and is consistent with the

regulation at 10 CFR 50.54(k), which states that “[a]n operator or senior operator licensed pursuant to [10 CFR Part 55] shall be present at the controls at all times during the operation of the facility.” The staff finds that the designation of an additional person at the facility able to carry out prescribed written instructions helps ensure the prompt implementation of the emergency plan. Excepting this requirement for an unexpected absence of the additional person for a personal emergency for up to 2 hours is consistent with the guidance in ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.1.3 acceptable.

The introductory text to the proposed TS 5.2, “Review and Audit,” requires SHINE to have a review and audit committee (RAC) to ensure that there is appropriate technical expertise for review and audit activities, which ensure that facility deficiencies that affect nuclear safety are immediately reported to Level 1 management. The proposed TS 5.2.1, “Composition and Qualifications,” requires that the Diagnostics General Manager (Level 1 Alternate) or designee be the chair of the RAC and appoint additional members to the RAC. TS 5.2.1 also requires a minimum number of RAC members with qualifications over a broad spectrum of technical, operational, and managerial expertise, where the facility operations personnel do not constitute a majority. TS 5.2.1 allows the RAC chair to appoint non-SHINE employees in certain circumstances if expertise is not available from SHINE employees. The NRC staff finds that by establishing a method for the independent assessment of operations and establishing requirements for the committee responsible for review and audit activities, the introductory text to TS 5.2 and TS 5.2.1 appropriately implement the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds the introductory text to TS 5.2 and TS 5.2.1 acceptable.

The proposed TS 5.2.2, “Charter and Rules,” requires that the charter for the RAC require at least one meeting per year; require at least one-half its committee membership be present (where the facility operations personnel, including the Director of Plant Operations (Level 2), do not constitute a majority of those present) to achieve a quorum; and require distribution of meeting minutes to its members within 3 months. TS 5.2.2 requires a majority vote of members for approval. The NRC staff finds that TS 5.2.2 helps ensure that RAC functions are appropriately conducted in accordance with an established charter, and that the RAC follows appropriate rules related to meeting frequency, quorum, and timely distribution of meeting minutes. The staff also finds that the requirement that facility operations personnel not be a majority in order to achieve an RAC quorum helps ensure independence of the RAC. Additionally, the staff finds that by establishing rules for the RAC and requiring the RAC to operate in accordance with its charter, TS 5.2.2 appropriately implements the guidance of NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.2.2 acceptable.

The proposed TS 5.2.3, “Review Function,” identifies items that require review by the RAC, and also requires that written reports of RAC reviews be submitted to the Level 1 management within 3 months following the completion of a review. The NRC staff finds that TS 5.2.3 helps ensure that the scope of RAC reviews is appropriate and includes items that relate to facility safety, and that RAC review findings are reported in a timely manner. The staff also finds that by defining the RAC’s review function, TS 5.2.3 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.2.3 acceptable.

The proposed TS 5.2.4, “Audit Function,” imposes requirements for audits, including that audits be performed by an individual without immediate responsibility for the area being audited; that audits be performed (annually or biennially, as specified) of facility operations for conformance with the TSs and license, of the retraining and requalification program, of corrective actions, of the emergency plan and its implementing procedures, of the radiation protection plan, of the

quality assurance program description, of the physical security plan, and a triennial review of the nuclear criticality safety program and the SHINE Safety Analysis Summary report. Further, TS 5.2.4 requires that deficiencies identified by audits be entered into SHINE's corrective action program and that any deficiencies uncovered that affect nuclear safety be immediately reported to the Level 1 management; and that follow-up written reports of audit findings be submitted to the Level 1 management and the RAC members within 3 months after the completion of an audit. The NRC staff finds that TS 5.2.4 helps ensure that audits are conducted with appropriate independence, that the scope of audits is appropriate and includes important items relating to facility safety, and that audit findings are reported in a timely manner. The staff also finds that by establishing requirements related to audits, TS 5.2.4 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007. Additionally, the audit intervals specified in TS 5.2.4 are consistent with the recommended intervals provided in ANSI/ANS 15.1-2007, section 6.2.4, as applicable. Therefore, the staff finds TS 5.2.4 acceptable.

The proposed TS 5.7.1, "Safety Limit Violation," requires specific actions to be taken if one of the SLs in TS 2.1 is exceeded. TS 5.7.1.1 requires that the SHINE facility operations related to medical isotope production be shut down immediately and that operations not be resumed until authorized by the NRC. TS 5.7.1.2 requires prompt reporting of the violation to Level 2 management or designated alternates. TS 5.7.1.3 requires reporting of the violation to the NRC. TSs 5.7.1.4 and 5.7.1.5 require the preparation and RAC review of a safety limit violation report, and that any follow-up report be submitted to the NRC when authorization is sought to resume operation of the SHINE facility. The NRC staff finds that TS 5.7.1 helps ensure that SHINE will take appropriate actions in the event of an SL violation, including reporting, analysis, corrective actions, and documentation of the violation, and also helps ensure that the facility will not be restarted until it is safe to do so, and it has been determined that recurrence of the violation is unlikely. The staff notes that the SL violation report is required to be prepared and submitted within 14 days in accordance with TS 5.8.2.1.a. The staff finds that TS 5.7.1 helps ensure that SHINE meets the requirements in 10 CFR 50.36(c)(1)(i)(A) related to follow-up actions for a SL violation. The staff also finds that by listing specific actions that must be taken if an SL is exceeded, TS 5.7.1 appropriately implements the guidance in NUREG-1-537 and ANSI/ANS 15.1-2007. Therefore, the staff finds TS 5.7.1 acceptable.

The proposed TS 5.8.1, "Operating Reports," requires SHINE to submit, within 30 days of the end of the calendar year (30 days from December 31), a report to the NRC providing information related to facility operations during the previous 1-year period. TS 5.8.1 also specifies the minimum information that is required to be included in each such report. The NRC staff finds that TS 5.8.1 helps ensure that important information regarding facility operations is provided to the NRC at intervals that are appropriate to allow timely NRC review. The staff also finds that by specifying requirements related to annual operating reports, TS 5.8.1 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007, including guidance related to the content of annual reports. Therefore, the staff finds TS 5.8.1 acceptable.

The proposed TSs 5.9.1, "Lifetime Records"; 5.9.2, "Five Year Records"; and 5.9.3, "Records to be retained for at least one certification cycle," provide requirements for record retention at the SHINE facility. TS 5.9.1 specifies records that must be maintained until the facility license is terminated. TS 5.9.2 specifies records that must be maintained for 5 years (or for the life of the component involved if less than 5 years). TS 5.9.3 specifies records related to licensed operators that must be maintained for the term of each operators' license. The NRC staff finds that TSs 5.9.1, 5.9.2, and 5.9.3 help ensure that SHINE maintains important records and retains them for appropriate time periods. The staff finds that TSs 5.9.1, 5.9.2, and 5.9.3 appropriately implement the guidance in NUREG-1537 and ANSI/ANS 15.1-2007 related to recordkeeping

requirement TSs, and that TS 5.9.2.7 helps ensure SHINE's compliance with the 10 CFR 50.59(d) requirement to retain records of changes in procedures for 5 years. Therefore, the staff finds TSs 5.9.1, 5.9.2, and 5.9.3 acceptable.

Although its review of the proposed TS 5.0 did not focus on the following TSs, the NRC staff did review these TSs that were not evaluated in other chapters of this SER:

5.1.4 Selection and Training of Personnel

SHINE establishes and maintains training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. ANSI/ANS 15.4-2016 is used in the selection and training of personnel and compliance is maintained with 10 CFR Part 55, as it pertains to non-power facilities. This includes initial and requalification training programs for Licensed Operators. The Training Manager (TM) reports to the Director of Corporate Support (DCS) and is responsible for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety. Records of personnel training and qualification are maintained.

In general, personnel have the combination of academic training, job-related experience, health, and skills commensurate with their level of responsibility that provides reasonable assurance that decisions and actions during normal and abnormal conditions are such that the facility is operated in a safe manner.

Additional information is detailed in FSAR Subsection 12.1.4 for the minimum qualification level of personnel.

5.4 Procedures

1. Procedures for the operation and use of the SHINE Facility provide appropriate direction to ensure that the facility is operated normally within its design basis, and in compliance with technical specifications. Procedures also provide guidance for addressing abnormal and emergency situations. These procedures are controlled and monitored to ensure that the content is technically correct, and the wording and format are clear and concise.
2. Revisions to the procedures for the operation and use of the SHINE Facility are initiated and tracked through the document control processes. The process required to make changes to procedures, including substantive and minor permanent changes, and temporary deviations to accommodate special or unusual circumstances during operation shall be documented and shall include a screening for 10 CFR 50.59 applicability.
3. SHINE shall prepare, review, and approve written procedures for the following topics:
 - a. startup, operation, and shutdown of the IU;

- b. target solution fill, draining, and movement within the SHINE Facility;
 - c. maintenance of major components of systems that may have an effect on nuclear safety;
 - d. surveillance checks, calibrations and inspections required by the technical specifications;
 - e. personnel radiation protection, consistent with applicable regulatory guidance. The procedures shall include management commitment and programs to maintain exposures and releases as low as reasonably achievable in accordance with ANSI/ANS 15.11-2016, Radiation Protection at Research Reactor Facilities;
 - f. administrative controls for operations and maintenance and for the conduct of irradiations that could affect nuclear safety;
 - g. implementation of required plans (e.g., emergency, security); and
 - h. use, receipt, and transfer of byproduct material.
4. The specific procedures within these topic areas are developed in accordance with the SHINE QAPD.
 5. SHINE shall review and approve written procedures prior to initiating any of the activities listed above. The procedures shall be reviewed by the SHINE review and audit committee and approved by Level 2 management or designated alternates, and such reviews and approvals shall be documented in a timely manner.
 6. Substantive changes to procedures related to the activities listed above shall be made effective only after documented review by the SHINE review and audit committee and approval by Level 2 management or designated alternates.
 7. Prior to a new or revised procedure being issued for use, the procedure is verified and validated to ensure it will accomplish its intended purpose.
 8. The extent of detail in a procedure is dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error. A controlled copy of all operations procedures is maintained in the control room.

5.5.1 Nuclear Safety Program

The SHINE nuclear safety program documents and describes the methods used to minimize the probability and consequences of accidents resulting in radiological or chemical release. The program applies a graded approach to the design and management of processes to assure plant safety through risk reduction and satisfaction of SHINE's performance goals. The safety program

accomplishes these goals through development and maintenance of the accident analysis, identification of safety-related controls credited for the prevention or mitigation of accidents, and establishment of programmatic administrative controls to ensure reliability of the credited controls.

5.5.2 Training and Qualification

The SHINE training and qualification programs are established as described in Section 5.1.4.

5.5.4 Configuration Management

The SHINE configuration management program provides oversight and control of design information, safety information, and records of modifications that might impact the ability of safety-related SSCs to perform their functions. The configuration management program is applied to all safety-related SSCs and is used to evaluate each change to the SHINE Facility for the potential to affect safety-related SSCs. The configuration management program is used to maintain consistency among the design requirements, the physical configuration and the facility documentation, and ensures changes are made in accordance with 10 CFR 50.59 and the administrative controls and reviews specified by this program.

Table 5.5.4 lists controls derived from the accident analysis not otherwise included in Sections 3, 4, or 5 of the technical specifications. SHINE maintains these controls under the configuration management program.

5.5.5 Maintenance of Safety-Related SSCs

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;
2. Corrective maintenance or inspections following safety-related system or component actuations or adverse conditions;
3. Overhead crane maintenance and requirements for usage;
4. Safety-related electrical equipment preventive maintenance; and
5. Other inspections and surveillances deemed necessary to ensure the continued functionality of safety-related SSCs.

5.5.6 Fire Protection

The SHINE fire protection program documents and describes the methods used to minimize the probability of and the consequences of fire. The fire protection program ensures, through defense-in-depth, that a fire will not prevent the performance of necessary safety-related functions and that radioactive releases to the environment, in the event of fire, will be minimized. The fire protection program implements the following activities to prevent and mitigate potential fire events in the SHINE Facility:

1. Periodic surveillances;
2. Control of hot work;
3. Control of transient combustibles;
4. Control of physical design characteristics of the facility relied on to prevent or mitigate the effects of fires; and
5. Maintenance of the fire hazards analysis and safe shutdown analysis for the facility.

5.5.7 Nuclear Criticality Safety

The SHINE nuclear criticality safety program ensures that workers, the public, and the environment are protected from the consequences of a nuclear criticality event. The nuclear criticality safety program complies with applicable national consensus standards, as clarified by Regulatory Guide 3.71, Revision 3, Nuclear Criticality Safety Standards for Fuels and Material Facilities, and is described in FSAR Subsection 6b.3.1.

The nuclear criticality safety program evaluates the fissionable material operations in the SHINE Facility and establishes appropriate criticality safety controls which are described in the criticality safety evaluations and the accident analysis. The criticality safety controls are preventative in nature and comply with the preferred hierarchy of controls: passive controls over active controls and engineered controls over administrative controls.

A criticality accident alarm system (CAAS) is provided for the SHINE Facility. The CAAS meets the requirements of 10 CFR 70.24(a) and follows the guidance of ANSI/ANS 8.3-1997. Maintenance and testing of the CAAS is performed in accordance with ANSI/ANS 8.3-1997. The CAAS is further described in FSAR Subsection 6b.3.3.

5.7.2 Occurrence of Events Requiring a Special Report.

In the event of an occurrence requiring a special report as specified in Section 5.8.2.1, other than a violation of a safety limit:

1. The affected processes or areas of the facility shall be returned to normal conditions or shut down. If it is necessary to shut down processes to

correct the occurrence, operation of those affected processes shall not be resumed unless authorized by Level 2 management or designated alternates.

2. The occurrence shall be reported to Level 2 management or designated alternates and to the NRC.
3. The occurrence shall be reviewed by the RAC at its next scheduled meeting.

5.8.2 Special Reports

Special reports are used to report unplanned events as well as planned major facility and administrative changes. Special reports will follow the schedule below:

1. There will be a report not later than the following working day by telephone and confirmed in writing by electronic mail or similar conveyance to the NRC Operations Center, to be followed by a written report to the NRC Document Control Desk that describes the circumstances of the event within 14 days of any of the following:
 - a. Violation of a safety limit;
 - b. Release of radioactivity from the site above allowed limits;
 - c. Operations with actual Safety System settings for required systems less conservative than the limiting safety system settings specified in Section 2.2;
 - d. Operation in violation of limiting conditions for operation established in Section 3, unless prompt remedial action is taken as permitted in Section 3;
 - e. A Safety System component malfunction that renders or could render the Safety System incapable of performing its intended safety function.

If the malfunction or condition occurs during Modes or conditions in which the LCO is not applicable, then no report is required.

Where components or systems are provided in addition to those required by the technical specifications, the failure of the extra components or systems is not considered reportable provided that the minimum numbers of components or systems specified or required perform their intended safety function;

- f. Abnormal and significant degradation of the PSB (including minor leaks);

- g. Abnormal and significant degradation in the PCLS and the light water pool (excluding minor leaks); and
 - h. An observed inadequacy 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.
2. There shall be a written report within 30 days to the NRC Document Control Desk of the following:
 - a. Permanent changes in the facility organization involving Level 1 or Level 2 management, and
 - b. Significant changes in the transient or accident analysis as described in the FSAR.

5.8.3 Additional Event Reporting Requirements

1. Events which meet the reporting requirements of 10 CFR 70.50 or 10 CFR 70.52 shall be reported to the NRC as prescribed in the applicable regulation.
2. SHINE shall report 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:
 - a. An inadvertent nuclear criticality.
 - b. An acute intake by an individual of 30 mg or greater of uranium in a soluble form.
 - c. 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.
 - d. 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.
3. SHINE shall report 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:
 - a. 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.

- b. 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 failure to limit the risk of chemical, radiological, or criticality hazards to an acceptable risk level, as required by the SHINE Safety Analysis.
 - c. 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.
 - d. 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.
4. SHINE shall concurrently report to the NRC Operations Center any event or situation, related to the health and safety of the public or on-site personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made.

5.8.4 Startup Report

SHINE shall conduct startup testing in accordance with the Startup Testing Program, as described in FSAR Section 12.11. Following completion of startup testing, SHINE will submit a Startup Report to the NRC Document Control Desk that identifies the startup tests performed.

The Startup Report shall be submitted within 6 months of the completion of all startup testing activities.

Based on its review, the NRC staff finds that the SHINE proposed administrative controls TSs provide a description of the organizational structure, program and procedure requirements, reporting requirements, and facility-specific controls. The staff finds that TS 5.0 appropriately implements the guidance in NUREG-1537 and ANSI/ANS 15.1-2007 to help ensure that the SHINE facility is operated safely. Therefore, the staff finds TS 5.0 acceptable.

The regulation at 10 CFR 50.36(a)(1) states, in part, that a summary statement of the bases or reasons for TSs, other than those covering administrative controls, shall also be included in the application for an operating license, but shall not become part of the TSs. Consistent with 10 CFR 50.36(a)(1), the applicant submitted TS bases that provide the reasons for the proposed TSs. The NRC staff determined that the TS bases are consistent with the proposed TSs and provide the purpose for each proposed TS. Therefore, the staff concludes that 10 CFR 50.36(a)(1) is met with respect to TS bases.

14.5 Review Findings

The NRC staff reviewed SHINE's proposed TSs. The proposed TSs define certain features, characteristics, organizational and reporting requirements, and conditions governing the operation of the SHINE facility. The staff reviewed the format and content of the proposed TSs for consistency with the guidance in ANSI/ANS 15.1-2007, NUREG-1431, Volume 1, and NUREG-1537 and finds that they are appropriately consistent with this guidance. The staff also specifically evaluated the content of the proposed TSs to determine if they meet the requirements in 10 CFR 50.36. Based on its review, the staff determined that:

- As required by 10 CFR 50.36(a)(1), the SHINE operating license application includes a summary statement of the bases or reasons for the proposed TSs, other than those covering administrative controls.
- As required by 10 CFR 50.36(b), the SHINE operating license application includes proposed TSs derived from the analyses and evaluation included in the SHINE FSAR, as supplemented.
- SHINE's proposed TSs include (1) SLs on the wall temperature and differential pressure across the primary system boundary and the pressure within process tanks containing irradiated uranyl sulfate and connected piping, which are the important process variables necessary to reasonably protect against the uncontrolled release of radioactivity and (2) LSSSs, which are settings for the automatic protection systems related to those variables having significant safety functions, so chosen to prevent exceeding the SLs, that satisfy 10 CFR 50.36(c)(1)(i)(A) and (ii)(A).
- SHINE's proposed TSs include LCOs, which are the lowest functional capability or performance levels of equipment required for safe operation of the facility, for each item that meets one or more of the criteria specified in 10 CFR 50.36(c)(2)(ii).
- SHINE's proposed TSs include SRs, which are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within SLs, and that the LCOs will be met, that satisfy 10 CFR 50.36(c)(3).
- SHINE's proposed TSs include design features, which are those features of the facility such as materials of construction and geometric arrangements, which, if altered or modified, would have a significant effect on safety, that satisfy 10 CFR 50.36(c)(4).
- SHINE's proposed TSs include administrative controls, which are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the facility in a safe manner, that satisfy 10 CFR 50.36(c)(5).
- SHINE's proposed TSs include requirements for initial notification, written reports, and records that satisfy 10 CFR 50.36(c)(1), (2), and (7) and

requirements for special reports that the staff deemed necessary in accordance with 10 CFR 50.36(c)(8).

- 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 SHINE's proposed TSs meet the requirements of 10 CFR 50.36 and concludes that normal operation of the SHINE facility within the limits of the TSs will not result in radiation exposures in excess of the limits in 10 CFR Part 20 for members of the public or for workers. The staff also concludes that the proposed TSs provide reasonable assurance that the facility will be operated as analyzed in the SHINE FSAR, as supplemented; that adherence to the TSs will limit the likelihood of malfunctions and the potential accident scenarios analyzed in SHINE FSAR chapter 13, "Accident Analysis," and discussed in chapter 13, "Accident Analysis," of this SER; that facility operation will be in accordance with the applicable regulations and meet regulatory requirements for the issuance of an operating license; and that the conduct of activities by the applicant will not endanger the public or workers.