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12.0 CONDUCT OF OPERATIONS

The conduct of operations involves the administrative aspects of facility operation, the organizational structure, the functional responsibilities, levels of authority, and interface for establishing, executing, and verifying the organizational structure, staffing, and selection and training of personnel.

This chapter of the SHINE construction permit (CP) safety evaluation report (SER) describes the review and evaluation of the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) of the preliminary design of the SHINE conduct of operations as presented in Chapter 12, "Conduct of Operations," of the SHINE PSAR, as supplemented by the applicant's response to requests for additional information (RAIs).

12.1 Areas of Review

SHINE PSAR Chapter 12 describes the conduct of operations for the IUs and RPF; therefore, the areas of review related to conduct of operations presented in this section are applicable to both the IUs and RPF.

The staff reviewed SHINE PSAR Chapter 12 against applicable regulatory requirements using regulatory guidance and standards to assess the sufficiency of the preliminary design of the SHINE conduct of operations program. The following sections of the SER describe the areas reviewed as specified in NUREG-1537, Part 2.

Section 12.4.1, "Organization," provides an evaluation of the SHINE organizational structure. Within this review area, the staff assessed the organizational structure, responsibilities of individuals and groups, staffing for reactor operations, selection and training of personnel, organizational aspects of radiation protection, and radioisotope production facility safety program.

Section 12.4.2, "Review and Audit Activities," provides an evaluation of the SHINE composition and qualification of the SHINE committee members, charter and rules of the committees, conduct of the review functions, and conduct of the audit functions.

Section 12.4.3, "Procedures", provides an evaluation of the SHINE procedures, and procedural controls, to include the minimum topics for which procedures are required, the process for the review and approval of procedures, and the process for making substantive, minor, and temporary changes to procedures.

Section 12.4.4, "Required Actions," usually provides an evaluation on actions to be taken after a reportable event or a violation of the facility safety limits; however, the applicant has deferred submittal of this section.

Section 12.4.5, "Reports," usually provides an evaluation on the submission of timely information to the NRC in the form of annual reports and special reports (e.g. reportable events, violations of safety limits, changes in key personnel, changes in transient or accident analysis); however, the applicant has deferred submittal of this section.

Section 12.4.6, "Records," usually provides an evaluation on facility records, including review and retention guidelines; however, the applicant has deferred submittal of this section.

Section 12.4.7, "Emergency Planning," provides an evaluation of the SHINE Preliminary Emergency Plan. The Preliminary Emergency Plan discusses those necessary provisions for coping with radiological emergencies and minimizing the consequences of accidents at facilities. The staff evaluation included the review of plans, design features, facilities, functions, and equipment necessary to address the provisions for coping with radiological emergencies at the facility.

Section 12.4.8, "Security Planning," usually provides an evaluation of the SHINE Physical Security Plan; however, the applicant has deferred submittal of this section.

Section 12.4.9, "Quality Assurance," provides an evaluation of the SHINE quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.

Section 12.4.10, "Operator Training and Requalification," usually provides an evaluation of the operator training and requalification plan; however, the applicant has deferred submittal of this section.

Section 12.4.11, "Startup Plan," usually provides an evaluation of the proposed tests to determine operability and the timing of a report that summarizes the results of the startup tests; however, the applicant has deferred submittal of this section.

Section 12.4.12, "Environmental Reports," has been superseded by Chapter 19, "Environmental Review," and is therefore permanently vacated.

Section 12.4.13, "Material Control and Accounting Plan," usually provides an evaluation of the proposed material control and accounting (MC&A) plan; however, the applicant has deferred submittal of this section.

12.2 Summary of Application

SHINE PSAR Section 12.1, "Organization," describes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure. The organizational structure includes internal and external functions for SHINE, including interface responsibilities for multiple organizations.

SHINE PSAR Section 12.2, "Review and Audit Activities," discusses review and audit activities. The Plant Manager is responsible to establish review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. These activities are summarized and reported to Executive Management. Independent audits of the SHINE facility are conducted periodically.

SHINE PSAR Section 12.3, "Procedures," provides a description of the operating procedures. Operating procedures provide appropriate direction to ensure that the facility is operated normally within its design basis, and in compliance with technical specifications. Operating procedures are written, reviewed, and approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct and the wording and format are clear and concise. The SHINE policy on use of procedures is documented. 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. The process for making changes and revisions to procedures is documented. A controlled copy of all operations procedures is maintained in the control room or equivalent area. Activities and tasks are performed in accordance with approved implementing procedures.

SHINE PSAR Section 12.4, “Required Actions,” will be provided by the applicant in the FSAR after issuance of CP.

SHINE PSAR Section 12.5, “Reports,” will be provided by the applicant in the FSAR after issuance of the CP.

SHINE PSAR Section 12.6, “Records,” will be provided by the applicant in the FSAR after issuance of the CP.

SHINE PSAR Section 12.7, “Emergency Planning,” consists of the SHINE Preliminary Emergency Plan, Revision 0, which describes the necessary provisions are established for coping with radiological emergencies and minimizing the consequences of accidents at facilities. The SHINE Emergency Response Organization (ERO) is defined, including the roles, responsibilities and interfaces with other organizations. The emergency classification system describes the classifications based on a range of events described in SHINE PSAR Chapter 13. The emergency action levels provide specific parameters that are intended to activate appropriate portions of the SHINE ERO and initiate protective actions for an event. The plan also discusses whether any radiological emergencies would necessitate establishing an Emergency Planning Zone (EPZ). A general discussion is provided on the organizational response to emergencies. An overview is provided on emergency facilities and equipment necessary to respond to emergencies. Additionally, actions needed to restore the facility to a safe condition following emergency conditions is discussed.

SHINE PSAR Section 12.8, “Security Planning,” will be provided by the applicant in the FSAR after issuance of the CP.

SHINE PSAR Section 12.9, “Quality Assurance,” provides a description of the quality assurance (QA) program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. The applicant provided the SHINE Quality Assurance Program Description (QAPD) in **Appendix C** of Chapter 12.

SHINE PSAR Section 12.4.10, “Operator Training and Requalification,” will be provided by the applicant in the FSAR after issuance of the CP.

SHINE PSAR Section 12.4.11, “Startup Plan,” will be provided by the applicant in the FSAR after issuance of the CP.

SHINE PSAR Section 12.4.12, “Environmental Reports,” has been superseded by Chapter 19, “Environmental Review,” and is therefore vacated.

SHINE PSAR Section 12.4.13, “Material Control and Accountability Program,” will be provided by the applicant in the FSAR after issuance of the CP.

12.3 Regulatory Basis and Acceptance Criteria

As previously stated, SHINE PSAR Chapter 12 describes the conduct of operations for the IUs and RPF; therefore, the regulatory basis and acceptance criteria provided below apply to both the IUs and RPF.

The staff reviewed SHINE PSAR Chapter 12 against applicable regulatory requirements, using regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the SHINE organization in support of the issuance of a construction permit. In accordance with paragraph (a) of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.35, "Issuance of Construction Permits," a construction permit authorizing SHINE to proceed with construction may be issued once the following findings have been made:

- (1) SHINE has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.
- (2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR).
- (3) Safety features or components, if any, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.
- (4) On the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

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

12.3.1 Applicable Regulatory Requirements

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

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

10 CFR Part 50, Appendix E, Part II, "Preliminary Safety Analysis Report."

12.3.2 Regulatory Guidance and Acceptance Criteria

The NRC staff evaluated the SHINE organization against the applicable regulatory requirements listed above primarily using the guidance and acceptance criteria contained in Chapter 12, “Conduct of Operations,” 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), “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 (ADAMS Accession No. Reference 7), and NUREG-0849, “Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors,” issued October 1983 (Reference 52).

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 the SHINE engineered safety feature (ESFs). 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. This includes Regulatory Guide 2.6, “Emergency Planning for Research and Test Reactors” (Reference 53), and, ANSI/ANS-15.16-2008, “Emergency Planning for Research Reactors” (Reference 54).

Specific acceptance criteria are provided in the section-by-section technical evaluation in Section 12.1.4, “Review Procedures and Technical Evaluation,” of this SER. Additional guidance documents used to review the SHINE organization are provided as references at the end of this chapter.

12.4 Review Procedures and Technical Evaluation

As previously stated, SHINE PSAR Chapter 12 describes the conduct of operations for the IUs and RPF; therefore, the technical evaluation of the SHINE conduct of operations, described in SHINE PSAR Chapter 12, applies to both the IUs and RPF.

The staff performed a section-by-section evaluation of the technical information presented in SHINE PSAR Chapter 12, as supplemented by the applicant’s response to RAIs, to assess the sufficiency of the preliminary design and performance of the SHINE conduct of operations in support of the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance of the SHINE conduct of operations is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in SER Section 12.3, “Regulatory Basis and Acceptance Criteria.” The results of this section-by-section technical evaluation are described in SER Section 12.5, “Summary and Conclusions.”

12.4.1 Organization

The staff evaluated the sufficiency of the preliminary design of the SHINE organization, as described in SHINE PSAR Section 12.1, in part by reviewing the organizational structure, the responsibilities of individuals and groups, the staffing for operations, the selection and training of personnel, the organizational aspects of radiation protection, and the production facility safety program, using the guidance and acceptance criteria from Section 12.1, "Organization," of ISG Augmenting NUREG-1537, Parts 1 and 2, and of NUREG-1537, Parts 1 and 2. The staff also used the guidance and acceptance criteria of Chapter 14, "Technical Specifications," of NUREG-1537, Part 2, to ensure that the applicant sufficiently described the basis of the organizational technical specifications.

The review procedures of NUREG-1537, Part 1, Section 12.1.1, "Structure," state that the description of the organizational structure should include the radiation safety function and indicate how the staff implementing that function interacts with the staff responsible for reactor operations and the top administrative officials. The multilevel chart should show the relationship of the review and audit function to the organizational structure. The persons implementing the review and audit function should communicate with the management of the reactor facility, but should report to an organizational level above this management to ensure independence of the review and audit function."

The SHINE PSAR provides the functional organization in Figure 12.1-1, and PSAR, Section 12.1, "Structure," states, in part, that "[t]he staff implementing the radiation safety function supports on-shift plant operations and interacts with Executive Management through the chain of command." However, the organization chart does not include the review and audit function or the radiation safety function.

Therefore, in RAI 12.1-1 (Reference 14), the staff requested that the applicant:

- a) Include the review and audit committee and the radiation safety function in the organization chart.
- b) Describe the responsibilities of the review and audit committee and the radiation safety function under PSAR Section 12.1.2, "Responsibility."

Additionally, the applicant was requested to ensure that the responsibility for the safe operation of the facility and for the protection of the health and for safety of the staff and the public is clearly shown in Section 12.1.2 of the PSAR.

In its response to RAI 12.1-1 (Reference 20), the applicant stated that the SHINE Review and Audit Committee will report to the Plant Manager (PM) and the SHINE radiation safety function (Radiation Protection Supervisor) will report to the Environmental Safety and Health Manager. The applicant also provided an updated Operational Organization Chart showing the reporting and communication lines of the Review and Audit Committee and the Radiation Protection Supervisor. The applicant stated that an Issues Management Report (IMR) has been initiated to track the update to Section 12.1.2 and Figure 12.1-1.

The staff reviewed Figure 12.1-1 and the information to be included in Section 12.1.2 of the SHINE FSAR to determine whether it is acceptable by evaluating the new figure and reviewing the information against the requirements of NUREG-1537.

The staff finds the new Figure 12.1-1 and the information to be included in Section 12.1.2 of the FSAR to be acceptable to support the issuance of a construction permit because the new figure and information describe and show the review and audit committee and the radiation safety function and describe their responsibilities. Following receipt of the SHINE FSAR, the staff will confirm that this issue has been resolved.

NUREG-1537, Part 2, Section 12.1, “Organization,” Acceptance Criteria, states, in part, that “[t]he applicant should discuss the training of personnel, should reference the operator training program and the operator requalification program, and should include a review of compliance with the requirements of 10 CFR Part 55” [“Operators’ Licenses”].

SHINE PSAR, Section 12.1.4, “Selection and Training Of Personnel,” states, in part, that “SHINE establishes and maintains formal and informal indoctrination and training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. The Training Manager (TM) is responsible to the PM [Plant Manager] for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety.” However, SHINE PSAR, Section 12.1.4, does not include a reference to the operator requalification program or a review of compliance with the requirements of 10 CFR Part 55, as applicable.

Additional information was required for the staff to make a determination on the acceptability of the training of personnel. In RAI 12.1-2 (Reference 14), the staff requested that the applicant:

- a) Include a reference to the operator training program and the operator requalification program.
- b) Provide a review of SHINE’s compliance with the requirement of 10 CFR Part 55.
- c) Indicate if minimum requirements exist for the facility staff.

In response to RAI 12.1-2 (Reference 20), the applicant stated that the SHINE FSAR will do the following:

- a) State that the licensed operator training program, including the requalification training program, will be developed and implemented in accordance with 10 CFR Part 55 as it pertains to non-power facilities.
- b) State that SHINE will comply with the requirements of 10 CFR Part 55 as it pertains to non-power facilities.
- c) Provide the required minimum qualifications for facility staff.

SHINE stated they have initiated an IMR to track these updates.

On the basis of its review, the staff finds the information to be included in SHINE PSAR Section 12.1 to be acceptable to support the issuance of a construction permit because the information to be added to the FSAR will state that the licensed operator training program and the requalification training program will be developed and implemented in accordance with 10 CFR Part 55. The FSAR will also describe how SHINE will comply with 10 CFR Part 55 requirements and provide the required minimum qualifications for facility staff. The staff will confirm that this issue has been resolved during the evaluation of the SHINE FSAR.

12.4.2 Review and Audit Activities

The staff evaluated the sufficiency of the preliminary design of the SHINE review and audit activities, as described in SHINE PSAR Section 12.2, in part, by reviewing the composition and qualification of the committee members, charter and rules of the committee, conduct of the review function, and conduct of the audit function, using the guidance and acceptance criteria from Section 12.2, "Review and Audit Activities," of NUREG-1537, Parts 1 and 2. The staff also used the guidance and acceptance criteria of Chapter 14, "Technical Specifications," of NUREG-1537, Part 2, to ensure that the applicant sufficiently described a basis for the technical specifications requirements for the review and audit function.

While the above referenced PSAR sections describe the SHINE review and audit activities, some further clarifications were needed.

NUREG-1537, Part 1, Section 12.2, "Review and Audit Activities," notes that the applicant should explicitly state who holds the approval authority and should specify how the review and audit committees communicate and interact with facility management and corporate management.

SHINE PSAR, Section 12.2, "Review and Audit Activities," discusses the establishment of the review and audit committees and states they report to Executive Management. However, approval authority is not addressed. Therefore, in RAI 12.2-1 (Reference 14), the staff requested that the applicant provide the following additional information:

- a) State who holds approval authority.
- b) Provide additional detail on how the review and audit committees interact with management.

In response to RAI 12.2-1 (Reference 20), the applicant provided the following information:

- a) The PM holds approval authority for review and audit activities.
- b) The review and audit committees' interaction with facility management was detailed.

SHINE stated they will update Section 12.2 in the FSAR to incorporate the above details of who has approval authority and how the review and audit committees interact with facility management. The applicant also stated that IMRs have been initiated by the applicant to track the updates to Section 12.2.

NUREG-1537, Part 2, Section 12.2, "Review and Audit Activities," Acceptance Criteria, states, in part, that "[t]he applicant should give the details of the review function...The reviews should include 10 CFR 50.59[,"Changes, tests, and experiments"] safety reviews." SHINE PSAR, Section 12.2.3, "Review Function," did not include this in the list of items required to be reviewed. In RAI 12.2-2 (Reference 14), the staff requested that the applicant add 10 CFR 50.59 safety reviews to the list of items to be reviewed or justify their exclusion.

In response to RAI 12.2-2 (Reference 20), the applicant stated that, the list of items in PSAR Section 12.2.3 requiring review by the SHINE review and audit committee will be updated in the SHINE FSAR to include 10 CFR 50.59 safety reviews. The applicant stated that an IMR has been initiated to track the inclusion of 10 CFR 50.59 safety reviews in the list.

NUREG-1537, Part 2, Section 12.2, “Review and Audit Activities,” Acceptance Criteria, states, in part, that “[t]he applicant should give the details of the audit function. The minimum list of items to be audited should be that given in ANSI/ANS 15.1-1990 [‘The Development of Technical Specifications for Research Reactors’],.... The audit of facility operations should include items such as organization and responsibilities, training, reactor operations, procedures, logs and records, experiments, health physics, technical specification compliance, and surveillances.”

In addition, NUREG-1537, Part 1, Section 12.2.4, “Audit Function,” states, in part, that “[t]he applicant should list and discuss the items that must be audited by the committee. In addition to audits by the facility committee, the licensee may consider entering into an auditing agreement with other non-power reactor facilities to bring in staff members from other non-power reactors to perform an audit.”

SHINE PSAR, Section 12.2.4, “Audit Function,” includes a list of examples of activities to be audited, but did not include details addressing the items above. Therefore, in RAI 12.2-3 (Reference 14), the staff asked the applicant to provide additional information expanding PSAR Section 12.2.4 to include the details addressing the items above, or justify their exclusion.

In response to RAI 12.2-3 (Reference 20), the applicant stated it will update Section 12.2.4 of the FSAR to expand on the description of SHINE activities to be audited, the audit frequencies, and information on the reporting of audit findings. SHINE stated they will work to establish relationships with other entities to participate in audits of the facility. The applicant also stated an IMR has been initiated to track the update to Section 12.2.4.

On the basis of its review, the staff finds the information to be included in SHINE FSAR Section 12.2 is sufficient and meet the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Following receipt of the SHINE FSAR, the staff will confirm that the above issues have been resolved.

12.4.3 Procedures

The staff evaluated the sufficiency of the preliminary design of the SHINE procedures, as described in SHINE PSAR Section 12.3, using the guidance and acceptance criteria from Section 12.3, “Procedures,” in NUREG-1537, Part 1 and 2. The staff also used the guidance and acceptance criteria of Chapter 14, “Technical Specifications,” of NUREG-1537, Part 2, and ANSI/ANS 15.1-2007 (Reference 55), to ensure that the applicant sufficiently described a basis for the technical specifications requirements for procedures.

While the above referenced PSAR sections describe the SHINE procedure activities, some further clarification was needed.

NUREG-1537, Part 1, Section 12.3, “Procedures,” states, in part, that “[t]he applicant should discuss the basic topics that the procedures do or will cover...The applicant should discuss the methodology used for developing procedures, including the approval process. The applicant should also discuss the process required to make changes to procedures including substantive and minor permanent changes, as defined in ANSI/ANS 15.1[-2007 (Reference 55)], and temporary deviations to deal with special or unusual circumstances during operation. The applicant should note that 10 CFR 50.59 may apply to changes to procedures.”

NUREG-1537, Part 2, Section 12.3, "Procedures," Acceptance Criteria, states, in part, that "[t]he applicant should discuss the method for the review and approval of procedures. The method should involve staff from reactor operations, radiation protection, and reactor administration and the review committee, as appropriate to the procedure under review and approval." Section 12.3 also states, in part, that "[t]he applicant should propose a method for making changes to procedures. This method should cover minor changes with little or no safety significance, substantive changes that are safety significant, and temporary deviations caused by operational needs." SHINE PSAR, Section 12.3, "Procedures," discusses operating procedures and the procedure program. It generally discusses the use of procedures and that the process for making changes and revisions is documented. However, additional detail was needed for the staff to assess the adequacy of the SHINE preliminary operating procedures and procedure program.

Therefore, in RAI 12.3-1 (Reference 14), the staff asked that the applicant:

- a) Discuss the basic topics the procedures address or will cover.
- b) Discuss the method for the review and approval of procedures.
- c) Discuss the process required to make changes to procedures noting that 10 CFR 50.59 may apply to changes to procedures.

In response to RAI 12.3-1 (Reference 20), the applicant provided the following:

- a) A list of the basic topics that SHINE procedures will cover, which will be developed in accordance with Section 2.5 of the SHINE QAPD.
- b) A description of the method for the initial review and approval of procedures activities listed in Part (a) of the SHINE response to RAI 12.3-1 was given. The applicant stated that this same method also applies when there are substantive changes to the procedures.
- c) A discussion concerning the process required to make changes to procedures. The applicant stated that revisions to procedures related to activities listed in Part (a) of the SHINE Response to RAI 12.3-1 are initiated and tracked via the SHINE Information Management System.

Procedure revisions will receive a technical review, which will include a screening for 10 CFR 50.59 applicability, and will then be reviewed and approved as described in Part (b) of the SHINE response to RAI 12.3-1.

SHINE stated they will update Section 12.3 in the FSAR to expand on the description of the applicant's method for the review and approval of procedures, as was described. An IMR has been initiated to track the update to FSAR Section 12.3.

On the basis of its review, the staff finds that the information included in SHINE's PSAR Section 12.3, as supplemented by SHINE's response to RAIS, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Following receipt of the SHINE FSAR, the staff will confirm that the above issues have been resolved.

12.4.4 Required Actions

The staff evaluated the sufficiency of the preliminary design of the SHINE required actions, as described in SHINE PSAR Section 12.4, using the guidance and acceptance criteria from Section 12.4, “Required Actions,” in NUREG-1537, Part 1 and 2.

As stated in SHINE PSAR Section 12.4, “[r]equired actions to be taken in the event of a violation of a facility safety limit or the occurrence of a reportable event will be developed for the FSAR.”

The staff has considered the statement in the PSAR and verified that information on required actions is not needed for issuance of the CP.

Therefore, the staff finds deferring the details on required actions, as described in SHINE PSAR 12.4, can reasonably be left for later consideration when it will be supplied in the FSAR.

12.4.5 Reports

The staff evaluated the sufficiency of the preliminary design of the SHINE reports, as described in SHINE PSAR Section 12.5, using the guidance and acceptance criteria from Section 12.5, “Reports,” in NUREG-1537, Part 1 and 2.

As stated in SHINE PSAR Section 12.5, “[a] detailed discussion of reports that will be submitted to the NRC will be provided in the FSAR.”

The staff has considered the statement in the PSAR and verified that information on reports is not needed for issuance of the CP.

Therefore, the staff finds deferring the details on reports, as described in SHINE PSAR 12.5, can reasonably be left for later consideration when it will be supplied in the FSAR.

12.4.6 Records

The staff evaluated the sufficiency of the preliminary design of the SHINE records, as described in SHINE PSAR Section 12.6, using the guidance and acceptance criteria from Section 12.6, “Records,” in NUREG-1537, Part 1 and 2.

As stated in SHINE PSAR Section 12.6, “[t]he SHINE records management program defines the process for managing SHINE records. The records management program includes the identification, generation, authentication, maintenance, and disposition of records. A detailed discussion of records management will be provided in the FSAR.”

The staff has considered the statement in the PSAR and verified that information on records is not needed for issuance of the CP.

Therefore, the staff finds deferring the details on records, as described in SHINE PSAR 12.6, can reasonably be left for later consideration when it will be supplied in the FSAR.

12.4.7 Emergency Planning

The staff evaluated the sufficiency of the SHINE Preliminary Emergency Plan, in part, against applicable regulatory requirements using regulatory guidance and standards to assess the sufficiency of the preliminary emergency plan.

Parts of the SHINE Preliminary Emergency Plan and the staff's evaluation are withheld from public disclosure under 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." A publicly available summary of the staff's evaluation follows.

The regulations in 10 CFR Part 50, Appendix E, Part II, "The Preliminary Safety Analysis Report," (PSAR) state that the PSAR should address the site layout and location, consideration of access routes, surrounding population distribution, land use, and jurisdictional boundaries. NUREG-1537, Part 2, Chapter 12, "Conduct of Operations," Section 12.1, "Introduction," provides the guidelines for reviewing applications and references NUREG-0849 (Reference 52) for the review and evaluation of emergency plans at non-power reactors. The planning standard provided in NUREG-0849, Section 1.0, "Introduction," calls for the emergency plan to provide a description of the reactor – in this case the TSV - including authorized power level, location, and access routes to the facility. The owner and operator of the facility should be identified, and the objectives of the emergency plan explained.

The staff reviewed the information provided in Section 1.0, "Introduction," of the SHINE Preliminary Emergency Plan, including associated figures, site layout, and maps provided in the application.

In the course of reviewing the SHINE construction permit application, the NRC staff determined that additional information was required to prepare a safety evaluation report. In an RAI dated September 19, 2014 (Reference 14), the staff requested that the applicant provide a legible figure of the facility and/or an electronic copy that could be manipulated to facilitate resolution of building names/numbers and labels, roads and parking lots, site boundaries showing fences and gates, major site features, access routes, and water bodies within approximately 1 mile of the site.

In an October 15, 2014, response to RAI-12.7-1 (Reference 20), the applicant provided a legible copy of Figure 1-1 of the SHINE Preliminary Emergency Plan, including building names/numbers and labels, roads and parking lots, site boundaries showing fences and gates, and major site features, including access routes. The applicant also stated there are no bodies of water within one mile of the SHINE site.

The staff reviewed the response to RAI 12.7-1 and concluded that the information provided is consistent with the guidelines in NUREG-0849. Therefore, this RAI is closed.

There are no specific regulatory requirements in 10 CFR 50, Appendix E, Part II, "The Preliminary Safety Analysis Report," related to definitions. NUREG-1537, Part 2, Chapter 12, "Conduct of Operations," Section 12.2, "Definitions," provides the guidelines for reviewing applications and references NUREG-0849 for the review and evaluation of emergency plans at non-power reactors. Section 2.0, "Definitions," of NUREG-0849, states that the emergency plan should provide definitions for terms that are unique to the facility and should include phrases with meanings specific to the facility.

The staff reviewed the terms defined as having special meaning and the list of acronyms and abbreviations provided in the SHINE Preliminary Emergency Plan, Rev. 0, and observed the use of these terms, acronyms, and abbreviations throughout the document.

The staff found the defined terms, acronyms, and abbreviations to be complete and used consistently throughout the document. The staff finds the information acceptable and determined that the definitions, acronyms, and abbreviations are consistent with the guidelines provided in NUREG-0849, Section 2.0, "Definitions." The staff concludes that the preliminary information provided in this section meets the applicable regulatory requirements and acceptance criteria and is therefore sufficient to support the issuance of a construction permit. Further evaluation of this section will occur following the receipt of the SHINE FSAR and emergency plan submitted in support of the operating license.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section A require a description of the onsite and offsite organizations for coping with emergencies and the means for notification in the event of an emergency, and of persons assigned to the emergency organization. The guidance in NUREG-0849 and NUREG-1537, Part 2, Section 3.0, "Organization and Responsibilities," identifies criteria for evaluating the emergency organization including the onsite emergency organization and any augmentation from offsite groups, and the identification, by normal everyday title, of all persons or groups that will fill positions in the emergency organization. These criteria include:

- A description of the emergency planning functions of Federal, State, and local government agencies, and identification of the assistance they would provide and of the applicant's emergency organization, including augmentation of the operations staff to provide assistance during an emergency, recovery from the emergency, and maintaining emergency preparedness.
- The arrangements and written agreements with local support organizations that would augment and extend the capability of the facility's emergency organization.
- A block diagram illustrating the interrelationship of the facility emergency organization to the total emergency response effort. Specification of the interface between the onsite emergency organization and offsite local support organizations and agencies.
- The identification by title of the individuals in charge of directing emergency operations; for coordinating emergency preparedness planning, updating emergency plans and procedures, and coordinating plans with other supporting organizations; for relating information about the emergency to the news media and the public, and of the individual in charge of both onsite and offsite radiological assessments including a line of succession, and responsibilities and authorities and those responsibilities which may not be delegated (such as notification and protective action decisions).
- The identification by title of the individuals providing onsite and offsite dose assessments and recommended protective actions, authorizing reentry into radiological controlled areas or portions of the facility that may have been evacuated during the emergency; terminating an emergency and initiating recovery actions and informing the emergency organization of planned organizational actions or changes, and authorizing volunteer emergency workers to incur radiation exposures in excess of normal occupational limits.

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- The identification by title of the individuals who will declare an alert or site area emergency, activate the onsite ERO during all shifts, promptly notify offsite response authorities that an alert of site area emergency has been declared, notify the NRC Operations Center, initiate onsite and offsite protective actions, request support from offsite organizations, and either terminate the emergency or enter recovery mode.

The staff reviewed Section 3.0, "Organization and Responsibilities," of the SHINE Preliminary Emergency Plan, Rev. 0, to evaluate the emergency organization, and in an RAI letter dated September 19, 2014 (Reference 14), submitted six RAIs related to this subsection. The applicant's responses to RAI 12.7-2 through 12.7-7 are contained in Reference 20.

In RAI 12.7-2, the staff requested that the applicant clarify if letters of agreements, with developed procedures for emergency response with local emergency response agencies, would be submitted with the SHINE OL Application. In response, the applicant confirmed that letters of agreement with local support organizations who could augment and extend the capability of the facility's emergency organization will be provided in the emergency plan, which will be provided as part of the SHINE OL Application. The applicant initiated an IMR to ensure the letters of agreement are provided. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.3-01. Following receipt of the SHINE Emergency Plan and FSAR prepared in support of the operating license, the staff will confirm that this issue has been resolved.

In RAI 12.7-3, the staff requested that the applicant clarify if the Operators and ERO staff positions will be filled by the same individuals and to describe the positions, duties, and responsibilities of the ERO staff. In response, the applicant stated that the positions, duties, and responsibilities of the ERO staff will be described in the SHINE Emergency Plan submitted with the SHINE OL Application. The applicant initiated an IMR to ensure the positions, duties, and responsibilities of the ERO staff are described in the SHINE Emergency Plan and provided as part of the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.3-02. Following receipt of the SHINE Emergency Plan and FSAR submitted with the SHINE OL Application, the staff will confirm that this issue has been resolved.

In RAI 12.7-4, the staff requested that the applicant describe the actions the on-shift operators will take if they cannot ensure that their activities can be placed in a safe condition before reporting to the on-site assembly area. In response to RAI 12.7-4, the applicant stated that equipment operators in the field would either place their activities in a safe condition or take whatever possible actions and report to the on-site assembly area and to the **ED**.

However, the applicant's response to RAI 12.7-4 did not address on-shift operator actions, such as the actions taken by the shift supervisor, senior facility operator, and facility operator. In follow-up RAI 12.7-35, dated January 6, 2015 (Reference 15), the staff requested that the applicant address the actions of the on-shift operators. In response to RAI 12.7-35 (Reference 22), the applicant stated they would revise Section 3.3 of the SHINE Emergency Plan to clarify this issue. The applicant initiated an IMR to ensure the emergency plan was appropriately revised to address this issue. The staff is tracking this issue as Commitment 12.7.3-03. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the operating license, the staff will confirm that this issue has been resolved.

In RAI 12.7-36, dated March 25, 2015 (Reference 16), the staff requested that the applicant provide additional information on the actions on-shift operators will take if an emergency was

declared, considering design basis, beyond design basis, security, and unplanned onsite and offsite events, if their activities could not be placed in a safe condition. The staff also requested that the applicant describe the programmatic processes for individuals as well as the safety systems necessary to maintain safe shutdown. In the **April 14, 2015, email response**, the applicant stated they have initiated three IMRs to ensure the SHINE Emergency Plan provided as part of the SHINE OL Application will address these issues. The staff is tracking this issue as Commitment 12.7.3-04. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the operating license, the staff will confirm that these issues have been resolved.

In RAI 12.7-5, the staff requested that the applicant clarify the lines of succession for the shift supervisor if the shift supervisor is acting as the ED. In response to RAI 12.7-5, the applicant clarified the lines of succession. The staff finds the response to be acceptable to support the issuance of a construction permit.

In RAI 12.7-6, the staff requested that the applicant describe a line of succession for the responsibilities of the Emergency Preparedness Manager. In response to RAI 12.7-6, the applicant clarified that the Emergency Preparedness Manager is part of the SHINE management team and the responsibilities are outside the actual ERO framework and no line of succession will be required. The applicant stated that the Emergency Preparedness Manager is responsible for overall emergency plan maintenance and coordination, and that this position could respond to emergencies as part of the ERO. The staff finds the response to be acceptable to support the issuance of a construction permit.

In RAI 12.7-7, the staff noted that the applicant did not include the Emergency Preparedness Manager in organization charts. In response to RAI 12.7-7, the applicant clarified that the responsibilities of the Emergency Preparedness Manager fits within the Chief Operating Officer's (COO's) chain of command, but there is no direct reporting relationship to the COO. The applicant also clarified that the Emergency Preparedness Manager is not in the line of succession for the **ED**. The staff finds this to be an acceptable response to support the issuance of a construction permit

Emergency planning is programmatic and the information in this subsection pertains to the operations of the SHINE facility. Specific details regarding the organization and responsibilities are not necessary to support the issuance of a construction permit. In the responses to RAIs 12.7-2, RAI 12.7-3, and RAI's 12.7-4/RAI 12.7-35, the applicant has stated it would provide additional information regarding the organization and responsibilities in the SHINE Emergency Plan and FSAR submitted with the OL application. Therefore, the staff has deferred a more detailed evaluation of this subsection until receipt of the SHINE Emergency Plan and FSAR supporting an operating license. These issues are being tracked as Commitments 12.7.3.01, 12.7.3-02, 12.7.3-03, and 12.7.3-04. Following receipt of the SHINE Emergency Plan and FSAR for the operating license, staff will confirm that these issues have been resolved. The Commitment Items for the emergency plan and FSAR related to this subsection are briefly summarized below:

Commitment Items

Commitment Item 12.7.3-01: The SHINE Emergency Plan provided as part of the SHINE OL Application will include letters of agreement made with local support organizations.

Commitment Item 12.7.3-02: The SHINE Emergency Plan provided as part of the SHINE OL Application will describe the positions, duties, and responsibilities of the ERO Staff.

Commitment Item 12.7.3-03: The SHINE Emergency Plan, Section 3.3 will be revised to clarify the actions that on-shift operators will take if they cannot ensure their activities can be placed in a safe condition before reporting to on-site assembly areas.

Commitment Item 12.7.3-04: The SHINE Emergency Plan provided with the SHINE OL Application will describe the actions on-shift operators will take if their activities cannot be placed in a safe condition considering a design basis, beyond design-basis, security, and unplanned events. The SHINE Emergency Plan will also address the programmatic process for individuals to follow, as well as the safety systems necessary to maintain safe shutdown in the event of an emergency.

The staff concludes that the information provided in the SHINE Preliminary Emergency Plan, Rev. 0, Section 3.0, "Organization and Responsibility," is not necessary to meet regulatory requirements and acceptance criteria in support of the issuance of a construction permit. Further evaluation of this subsection will occur following the receipt of the SHINE Emergency Plan and FSAR submitted with the OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, require that a PSAR provide sufficient information to ensure the compatibility of the proposed emergency plan with onsite areas and the proposed design features. Section C requires that protective measures be taken within the site boundary to protect health and safety in the event of an accident. Section H requires a preliminary analysis reflecting the need to include methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations within and outside the site boundary and assessing/recommending protective actions.

The acceptance criteria in NUREG-0849, Appendix 12.2, Section 4.0, "Emergency Classification System," and from NUREG-1537, Part 2, Section 12.7, "Emergency Planning," Sub-section 4.0, "Emergency Classification System," state, in part, that the emergency plan should contain:

- An emergency classification system consistent with the planning standard.
- The emergency plan implementing procedures (EIPs) should be contained in an appendix to the emergency plan.
- The emergency plan should include both an alert and site area emergency classification.
- The emergency plan should identify the classification of each accident identified in the emergency plan.

The staff reviewed Section 4.0, "Emergency Classification System," of the SHINE preliminary Emergency Plan which states the classification scheme will be based on three guidance documents (Regulatory Guide 2.6 [Reference 53], ANSI/ANS-15.16-2008 [Reference 56], and NUREG-0849 [Reference 52]), will cover the range of events described in Chapter 13 of the PSAR and that a listing of EIPs, by title, will be provided with the FSAR. In RAI 12.7-8, dated September 19, 2014 (Reference 14), the staff requested that the applicant provide a listing by title, and description, of implementing procedures for each class of emergency in accordance with NUREG-0849 or to explain why this information is not necessary. In response to RAI 12.7-8 (Reference 20), the applicant stated that it would provide an Appendix to the Emergency Plan, listing by title, with description, EIPs for each class of emergency in the SHINE Emergency Plan provided as part of the SHINE OL Application. The staff finds this to be an

acceptable response to support the issuance of a construction permit. The applicant initiated an IMR to ensure an appendix containing a listing of EIPs with descriptions for each class of emergency is provided with the SHINE Emergency Plan submitted in support of the SHINE OL Application. The staff is tracking this issue as Commitment 12.7.4-01.

Emergency planning is programmatic and the information in this subsection pertains to the operations of the SHINE facility. Specific details regarding the emergency classification scheme are not necessary to support the issuance of a construction permit. In the response to RAI 12.7-8, the applicant stated it will provide an Appendix to the SHINE Emergency Plan submitted with the OL application that lists, by title, with description, the EIPs for each class of emergency. Therefore, the staff has deferred a more detailed evaluation of this subsection until receipt of the SHINE Emergency Plan and FSAR supporting an operating license. Commitment 12.7.4-01 is being tracked to ensure that EIPs are provided. Following receipt of the SHINE Emergency Plan and FSAR for the operating license, staff will confirm that this issue has been resolved. The Commitments for the emergency plan related to this subsection are briefly summarized below:

Commitment 12.7.4-01: The SHINE Emergency Plan provided as part of the SHINE OL Application will include an appendix to the emergency plan that lists the EIPs by title and description.

The staff concludes that the information provided in the SHINE Preliminary Emergency Plan, Rev. 0, Section 4.0, “Emergency Classification System,” is not necessary to meet regulatory requirements and acceptance criteria in support of the issuance of a construction permit. Further evaluation of this subsection will occur following the receipt of the SHINE Emergency Plan and FSAR submitted with the SHINE OL Application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section H require a preliminary analysis reflecting the need to include methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations within and outside the site boundary and assessing recommended protective actions.

The acceptance criteria in NUREG-0849, Appendix 12.2, Section 5.0, “Emergency Action Levels,” and from NUREG-1537, Part 2, Section 12.7, “Emergency Planning,” Sub-section 5.0, “Emergency Action Levels,” state, in part, that:

- The emergency action levels (EALs) should be appropriate to the specific facility and consistent with the emergency classes discussed in Section 12.7.4, and to the extent possible, specify the effluent monitors used to project dose rates and radiological effluent releases at the site boundary.
- The EALs should be comparable to the U.S. Environmental Protection Agency’s protective action guides (PAGs) described in [EPA 400-R-92-001](#).

The staff reviewed Section 5.0, “Emergency Action Levels,” of the SHINE Preliminary Emergency Plan and submitted three RAIs (Reference 14) related to EALs. The applicant’s responses to RAI 12.7-9 through 12.7-11 are contained in Reference 20.

In RAI 12.7-9, the staff requested that the applicant explain why an inadvertent criticality event was not considered in the accident analyses. In its response, the applicant clarified its approach to the consideration of a criticality event and committed to revise Table 5-1, “Postulated Accidents for the SHINE Facility Emergency Classification, Maximum Off-site and

Worker Dose, and Corresponding Emergency Action Level,” as appropriate. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.5-01. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the operating license, the staff will confirm that this issue has been resolved.

In RAI 12.7-10, the staff noted that Table 5-1 did not include a full list of EALs for each accident condition and requested that the applicant confirm that Table 5-1 would be provided with a full list of EALs for each accident condition. In response to RAI 12.7-10, the applicant committed to revise Table 5.1 to include a full list of EALs for each accident condition, in the SHINE Emergency Plan submitted in support of the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.5-02. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the operating license, the staff will confirm that this issue has been resolved.

In RAI 12.7-11, the staff requested that the applicant specify effluent monitors that would be used to project dose rates and radiological effluent releases and include EALs to initiate protective actions per the guidance in NUREG-0849. In response to RAI 12.7-11, the applicant stated that the specific values/setpoints used for emergency classification will be provided in the SHINE Emergency Plan submitted as part of the SHINE OL Application. The applicant initiated an IMR to ensure the specific values/setpoints are provided with the SHINE Emergency Plan, submitted with the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit and is tracking this issue as Commitment 12.7.5-03. Following receipt of the SHINE Emergency Plan and FSAR submitted with the SHINE OL Application, staff will confirm that this issue has been resolved.

Emergency planning is programmatic and the information in this subsection pertains to the operations of the SHINE facility. Specific details regarding the EALs are not necessary to support the issuance of a construction permit. In the responses to RAI 12.7-9, 12.7-10, and 12.7-11, the applicant has stated it will revise the SHINE Emergency Plan submitted with the OL application to consider a criticality event, to identify EALs for each identified accident condition, and to identify specific values/set points. Therefore, the staff has deferred a more detailed evaluation of this subsection until receipt of the SHINE Emergency Plan and FSAR supporting an operating license. Commitments 12.7.5-01 through 12.7.5-03 are being tracked to ensure these issues are resolved in the emergency plan and FSAR submitted in support of the operating license. Following receipt of the SHINE Emergency Plan and FSAR for the operating license, the staff will confirm that these issues have been resolved. The Commitments for the emergency plan related to this subsection are briefly summarized below:

Commitment 12.7.5-01: The SHINE Emergency Plan provided as part of the SHINE OL Application will include a revised Table 5-1 that considers a criticality event.

Commitment 12.7.5-02: The SHINE Emergency Plan provided as part of the SHINE OL Application will include a revised Table 5.1, “Postulated Accidents for the SHINE Facility, Emergency Classification, Maximum Off-site and Worker Dose, and Corresponding Emergency Action Level,” that provides a full list of EALs for each accident condition.

Commitment 12.7.5-03: The SHINE Emergency Plan provided as part of the SHINE OL Application will provide specific values/setpoints for emergency classification.

The staff concludes that the information provided in the SHINE Preliminary Emergency Plan, Rev. 0, Section 4.0, “Emergency Classification System,” is not necessary to meet regulatory requirements and acceptance criteria in support of the issuance of a construction permit. Further evaluation of this subsection will occur following the receipt of the SHINE Emergency Plan and FSAR submitted with the SHINE OL Application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section H require a preliminary analysis reflecting the need to include methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations within and outside the site boundary, including the capabilities for dose projection and dispatch of radiological monitoring teams within the EPZs.

The acceptance criteria from NUREG-0849, Appendix 12.2, Section 6.0 for the “Emergency Planning Zones,” NUREG-1537, Part 2, Section 12.7, “Emergency Planning,” Sub-section 6.0, “Emergency Planning Zones,” and in Regulatory Guide 2.6 supplementing ANSI/ANS-15.16-2008, Section 3.4, states in part, that:

- The emergency plan should identify the EPZ.
- The emergency plan should provide an acceptable basis for the EPZ.
- The size of the EPZ should be established so that the dose to individuals beyond the EPZ is not projected to exceed the PAGs.

The potential radiological hazards to the public associated with the operation of research and test reactors and fuel facilities licensed under 10 CFR Part 50 involve considerations different than those associated with nuclear power reactors. As endorsed by Regulatory Guide 2.6, ANSI/ANS-15.16 describes an acceptable approach for emergency planning commensurate with the potential risk involved for facilities of various authorized power level. This approach to an acceptable EPZ size is also described in NUREG-0849, Appendix II, and was adopted by the applicant.

The staff reviewed Section 6.0, “Emergency Planning Zones,” of the SHINE preliminary Emergency Plan, which states the applicant could not define a credible accident scenario that would result in radiological emergencies that involve an off-site plume exposure exceeding 1 rem whole body or 5 rem thyroid. Therefore, the applicant did not identify EPZs for the SHINE facility.

In RAI 12.7-12 dated September 19, 2014 (Reference 14), the staff noted that the applicant had not identified the size of the EPZ consistent with the criteria in the cited guidance in ANSI/ANS-15.16-2008 and in NUREG-0849. In response to RAI 12.7-12 (Reference 21), the applicant responded by stating, in part, that

SHINE has performed calculations as part of the accident analysis, and the calculation results are described in Chapter 13 of the PSAR. SHINE has concluded that the radiological releases and consequences to workers and the public are maintained within 10 CFR 20 limits (i.e., 100 millirem to the general public and five rem to the worker). For this reason, Section 6.0 of the SHINE Preliminary Emergency Plan [Reference 3] states, in part, that :

“As described in Chapter 13 of the SHINE PSAR (Reference 11.8), no credible accident scenarios at the SHINE facility result in radiological emergencies that involve an off-site plume exposure exceeding 1 rem

whole body or 5 rem thyroid. Therefore, in accordance with ANSI/ANS-15.16-2008 (Reference 11.1) and NUREG-0849 (Reference 11.3), no EPZs have been identified for the SHINE facility.”

Based on the above information, SHINE concludes that an emergency planning zone (EPZ) is not required at the SHINE facility, and the guidance and information contained in ANSI/ANS-15.16-2008 and NUREG-0849 align with this position. There is no radiological emergency which would result in off-site plume exposures exceeding one rem whole body or five rem thyroid.

The staff finds this to be an acceptable response to support the issuance of a construction permit.

Emergency planning is programmatic and the information in this subsection pertains to the operations of the SHINE facility. Specific details regarding the emergency planning zone are not necessary to support the issuance of a construction permit. In the responses to RAI 12.7-12, the applicant has concluded that no credible accident scenarios at the SHINE facility result in radiological emergencies that involve an off-site plume exposure exceeding 1 rem whole body or 5 rem thyroid. Therefore, in accordance with ANSI/ANS-15.16-2008 (Reference 54) and NUREG-0849 (Reference 52), no EPZs have been identified for the SHINE facility, and that an emergency planning zone is not required. Therefore, the staff has deferred a more detailed evaluation of this subsection until receipt of the SHINE Emergency Plan and FSAR supporting an operating license application.

The regulations in 10 CFR 50 Appendix E, Part II, “The Preliminary Safety Analysis Report,” Sections C, D, and E, require that emergency response measures be identified for each emergency. These response measures should be related to the emergency class and action levels that specify what measures are to be implemented. NUREG-1537, Part 2, Chapter 12, “Conduct of Operations,” Section 12.7, “Emergency Response,” provides the guidelines for reviewing applications and references NUREG-0849 provides the guidelines for the review and evaluation of emergency plans at non-power reactors. NUREG-0849, Section 7.0, “Emergency Response,” provides criteria for emergency response measures that should be identified for each emergency. NUREG-0849 and NUREG-1537, Part 2, acceptance criteria included the review and evaluation of:

- The notification information for emergency response including the actions to notify and mobilize the emergency organization and the applicable offsite support organizations for each emergency class and the location of current notification lists. Initial and follow-up emergency messages to the NRC and to offsite authorities, as applicable, should include: caller information such as name, title, and telephone number, a description of the emergency event, date and time of incident initiation, the location of the incident and the emergency class, quantity and type of radionuclides released or expected to be released, and the impact of releases and recommended offsite emergency actions. A method to ensure that offsite authorities have received the initial message and that it is authentic and that appropriate follow-up messages to offsite authorities are issued promptly.
- The methods for gathering and processing information for assessment actions should be described in the emergency plan, and PAGS are available and used by the appropriate personnel in a timely manner.

- The actions that could be taken to mitigate or correct the problem for each emergency class should be summarized in the emergency plan.
- The emergency plan should describe protective actions appropriate for the emergency class and should include: conditions for either partial or complete onsite evacuation, evacuation routes, and primary and alternate assembly areas; methods to ensure personnel accountability and the segregation of potentially contaminated personnel; protective measures and exposure guidelines for emergency personnel; provisions for isolating and access control of facility areas to minimize exposures to radiation and the spread of radioactive contamination; and the methods for monitoring radiation dose rates and contamination levels, both onsite and offsite, including provisions for transmitting collected information and data to those responsible for accident assessment.
- The emergency plan should describe the ability to promptly and effectively assess a release of radioactive material or hazardous chemicals including a description of procedures for estimating or measuring the release rate or source term; a description of the computer codes used to project doses along with supporting justifications, and discuss the validity of assumptions, and describe the method for assessing collateral damage to the facility.

The staff reviewed Section 7.0, “Emergency Response,” of the SHINE Emergency Plan to evaluate the applicant’s emergency preparedness, and in an RAI dated September 19, 2014 (Reference 14), submitted nine RAIs related to this subsection. The staff determined that the applicant did not adequately describe emergency response measures for each class of emergency and specify what measures should be implemented to promptly and effectively assess the release of radioactive material or hazardous chemicals. The applicant’s responses to RAI 12.7-13 through 12.7-21 are contained in Reference 20.

In RAI 12.7-13, the staff requested that the applicant clarify who has the responsibility to classify an emergency event and to incorporate the clarification into the next revision of the SHINE Emergency Plan. In response to RAI 12.7-13, the applicant stated that the ED has the responsibility to classify an emergency event, and that clarifying language will be provided in the SHINE Emergency Plan submitted with the SHINE OL Application. The applicant initiated an IMR to ensure the clarifying language is provided in the SHINE Emergency Plan. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.7-01. Following receipt of the SHINE Emergency Plan and FSAR, the staff will confirm that this issue has been resolved.

In RAI 12.7-14, the staff requested a summary description of those actions that the applicant could take to mitigate or correct the problem for each emergency class. In response to RAI 12.7-14, the applicant stated that a summary description of those actions that could be taken to mitigate or correct the problem for each class of emergency will be provided with the SHINE Emergency Plan, provided as part of the SHINE OL Application. The applicant initiated an IMR to ensure the summary descriptions are provided in the SHINE Emergency Plan. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.7-02. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the operating license, the staff will confirm that this issue has been resolved.

In RAI 12.7-15, the staff requested that the applicant describe the method(s) to assess collateral damage to the facility. In response to RAI 12.7-15, the applicant stated they will describe the

methods for assessing collateral damage to the SHINE facility in the SHINE Emergency Plan submitted with the SHINE OL Application. The applicant initiated an IMR to ensure the methods for assessing collateral damage to the facility are described in the SHINE Emergency Plan. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.7-03. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the operating license, the staff will confirm that this issue has been resolved.

In RAI 12.7-16, the staff requested that the applicant confirm that alternate assembly areas and evacuation routes will be provided in the FSAR. In response to RAI 12.7-16, the applicant clarified that alternate assembly areas and evacuation routes will be identified in the SHINE Emergency Plan, provided as part of the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.7-04. Following receipt of the SHINE Emergency Plan and FSAR, staff will confirm that this issue has been resolved. No IMR was initiated by the applicant.

In RAI 12.7-17, the staff requested that the applicant describe the “contamination controls” that will be in place throughout the facility and in close proximity to a contaminated area, or describe where this information can be found in the emergency plan. In response to RAI 12.7-17, the applicant stated that they will include this information in the SHINE Emergency Plan submitted with the SHINE OL Application. The applicant initiated an IMR to ensure that contamination controls are described in the SHINE Emergency Plan. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.7-05. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the operating license, the staff will confirm that this issue has been resolved.

In RAI 12.7-18, the staff requested that the applicant define the thresholds for categorizing personnel being surveyed and evacuated through control points as “contaminated” and “decontaminated” before release. In response to RAI 12.7-18, the applicant stated that these thresholds will be defined in the SHINE EIPs. The applicant initiated an IMR to ensure that the thresholds to categorize personnel being surveyed and evacuated through control points as “contaminated,” and to be decontaminated before release, is defined in the SHINE EIPs. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.7-06. Following receipt of the SHINE Emergency Plan and FSAR, staff will confirm that this issue has been resolved.

In RAI 12.7-19, the staff requested that the applicant describe protective measures and exposure guidelines for emergency personnel. In response to RAI 12.7-19, the applicant stated they will include protective measures and exposure guidelines for emergency personnel in the SHINE Emergency Plan submitted with the SHINE OL Application. The applicant initiated an IMR to track the inclusion of protective measures and exposure guidelines for emergency personnel in the SHINE Emergency Plan. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.7-07. Following receipt of the SHINE Emergency Plan and FSAR, the staff will confirm that this issue has been resolved.

In RAI 12.7-20 the staff requested that the applicant describe the methods that would be used to transmit radiation dose rates and contamination levels to onsite and offsite individuals involved in accident assessment. In response to RAI 12.7-20, the applicant stated that the methods for transmitting radiation dose rates and contamination levels onsite and offsite to those personnel

involved in accident assessment will be described in the SHINE Emergency Plan submitted with the SHINE OL Application. The applicant initiated an IMR to ensure a description of these methods is provided in the SHINE Emergency Plan. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.7-08. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the operating license, the staff will confirm that this issue has been resolved.

In RAI 12.7-21, the staff requested that the applicant provide the valid computer code(s) that will be used to project doses or concentrations to the public or environment including the assumptions made for purposes of analysis and the supporting justification. In response to RAI 12.7-21, the applicant stated that they do not plan to provide real-time dose projections. The applicant clarified that actual indications from installed instruments will be used for emergency classifications. Dose projections will be based on worst-case accident scenarios/calculations. The staff finds this to be an acceptable response to support the issuance of a construction permit. Following receipt of the SHINE Emergency Plan and FSAR, the staff will confirm that this issue has been resolved.

Emergency planning is programmatic and the information in this subsection pertains to the operations of the SHINE facility. Therefore, specific details regarding emergency response are not necessary to support the issuance of a construction permit. In the responses to RAIs 12.7-13 through RAI 12.7-21, the applicant states that it will provide additional information regarding emergency response in the SHINE Emergency Plan and FSAR submitted with the OL application. Therefore, the staff has deferred a more detailed evaluation of this subsection until receipt of the SHINE Emergency Plan and FSAR supporting the application for an operating license. These issues are being tracked as Commitments 12.7.7-01 through 12.7.7-08. Following receipt of the SHINE Emergency Plan and FSAR for the operating license, the staff will confirm that these issues have been resolved. The commitment items for the emergency plan and FSAR related to this subsection are briefly summarized below:

Commitment Item 12.7.7-01: The SHINE Emergency Plan submitted in support of the operating license will be revised to clarify that the ED will have the responsibility to declare an emergency event.

Commitment Item 12.7.7-02: The SHINE Emergency Plan submitted in support of the operating license will describe those actions that could be taken to mitigate or correct the problem for each class of emergency.

Commitment Item 12.7.7-03: The SHINE Emergency Plan submitted in support of the operating license will be revised to describe the methods for assessing collateral damage to the SHINE facility.

Commitment Item 12.7.7-04: The SHINE Emergency Plan submitted in support of the operating license will identify alternate assembly areas and evacuation routes. [No IMR initiated by applicant.]

Commitment Item 12.7.7-05: The SHINE Emergency Plan submitted in support of the operating license will describe the contamination controls used throughout the facility and in close proximity to a contaminated area.

Commitment Item 12.7.7-06: The applicant stated that the EIPs will define the threshold to categorize surveyed personnel evacuated through control points as “contaminated,” and to be

decontaminated prior to release in accordance with Section V of Appendix E to 10 CFR 50 and the EIPs.

Commitment Item 12.7.7-07: The SHINE Emergency Plan submitted in support of the operating license will include protective measures and exposure guidelines for emergency personnel.

Commitment Item 12.7.7-08: The SHINE Emergency Plan submitted in support of the operating license will describe the methods for transmitting radiation dose rates and contamination levels to both onsite and offsite accident assessment personnel.

The staff finds that the information provided in the SHINE Preliminary Emergency Plan, Rev. 0, Section 7.0, "Emergency Response," is not necessary to meet regulatory requirements and acceptance criteria in support of the issuance of a construction permit. Further evaluation of this subsection will occur following the receipt of the SHINE Emergency Plan and FSAR submitted in support of the OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, require that a PSAR provide sufficient information to ensure the proposed emergency plan is compatible with proposed design features. Section H requires there is an onsite facility for use in assessing the consequences of a potential radiological accident. The acceptance criteria for information on emergency facilities and equipment from **NUREG-0849, Appendix 12.2** are:

- The emergency plan describes an ESC.
- Representative types of monitoring and sampling equipment that would be used for accident assessment and their location are described. For each type of accident identified, the emergency plan should describe the means of detecting the accident, the means of detecting any release of radioactive material or hazardous chemicals incident to the processing of licensed material, and the means of alerting operating staff.
- The sampling and monitoring equipment types should include portable and fixed radiation monitors, sampling equipment, equipment for personnel monitoring, equipment for specific radionuclide identification and analysis, and to assess the release to the environment of radioactive or hazardous chemicals incident to the processing of license material. The plan should also describe nonradiological monitors or indicators such as fire detectors, earthquake sensors, etc.
- The emergency plan should identify those measures that would be used to provide assistance to injured persons or those exposed to radiation. The capability to decontaminate, administer first aid, transport injured personnel, and arrange for treatment should be described including a description of both onsite and offsite services that support emergency response such as first aid personnel, firefighters, law enforcement assistance, and ambulance service. A list and description of both onsite and offsite emergency facilities, by location and purpose should be provided.
- The emergency plan should identify the emergency communications systems that would be available to communicate instructions and information both onsite and offsite throughout the course of an emergency.

The staff reviewed Section 8.0, "Emergency Facilities and Equipment," of the SHINE Preliminary Emergency Plan to ensure emergency facilities and equipment will be available, and in an RAI dated September 19, 2014 (Reference 14), submitted seven RAIs related to this subsection. The applicant's responses to RAI 12.7-22 through 12.7-28 are contained in Reference 20.

In RAI 12.7-22, the staff requested a more complete description of the ESC since Sections 7.2.2 and 8.2 of the SHINE Preliminary Emergency Plan, Rev. 0, do not clearly describe whether the ESC is either a fixed area or mobile, nor were the capabilities and equipment described. In response to RAI 12.7-22, the applicant stated they will provide a more complete description of the ESC including its primary location, back-up location, capabilities, equipment, and size in the SHINE Emergency Plan to be submitted as part of the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. The applicant initiated an IMR for this topic and the staff has identified this as Commitment 12.7.8-01. Following receipt of the SHINE Emergency Plan and FSAR, the staff will confirm that this issue has been resolved.

In RAI 12.7-23, the staff requested that the applicant describe the means of detecting accident conditions, the means of detecting any release of radioactive material or hazardous materials, and the means of alerting the operations staff of an accident. The staff asked the applicant to confirm that for each accident identified in Table 5-1 of the SHINE Preliminary Emergency Plan, Revision 0, the means of detecting accident conditions, the means of detecting any release of radioactive material or hazardous materials, and the means of alerting the operations staff of the accident conditions be provided in the FSAR. In response to RAI 12.7-23, the applicant stated that for each accident identified in Table 5.1 of the SHINE Preliminary Emergency Plan, the applicant will provide the means of detecting accident conditions, the means of detecting release of either radioactive or hazardous materials, and the means of alerting the operations staff of the accident conditions with the FSAR. The staff finds this to be an acceptable response to support the issuance of a construction permit. The applicant initiated an IMR for this topic to update the SHINE Emergency Plan to include the requested information. The staff has identified this as Commitment 12.7.8-02. Following receipt of the SHINE Emergency Plan and FSAR, staff will confirm that this issue has been resolved.

In RAI 12.7-24, the staff requested that the applicant describe in the emergency plan the specific facility locations of first aid equipment. In response to RAI 12.7-24, the applicant stated they will describe the locations of first aid equipment in the SHINE Emergency Plan provided as part of the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. The applicant initiated an IMR for this topic to ensure the location of first aid equipment is described in the SHINE Emergency Plan. The staff has identified this as Commitment 12.7.8-03. Following receipt of the SHINE Emergency Plan and FSAR for the operating license, the staff will confirm that this issue has been resolved.

RAI 12.7-25 requested that the applicant identify the facilities, and to provide the written letters of agreement with hospitals to ensure the medical staff is prepared to handle radiological emergencies. In response to RAI 12.7-25, the applicant stated they will identify the facilities in which arrangements have been made to ensure that medical services are available and that the medical staff are prepared to handle radiological emergencies in the emergency plan submitted with the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. The applicant initiated an IMR to ensure the facilities are identified and written agreements are provided as part of the SHINE OL Application. The staff is tracking this item as Commitment 12.7.8-04. Following receipt of the SHINE Emergency Plan and FSAR, the staff will confirm that this issue has been resolved.

In RAI 12.7-26, the staff requested that the applicant describe who will be responsible for decontaminating an ambulance, medical personnel, and the medical facility and identify the procedures, and their location, that will be used for decontamination of emergency medical

services/equipment/personnel. In response to RAI 12.7-26, the applicant stated they will identify the responsible person and the location of procedures for decontamination of emergency medical services/equipment/personnel in the SHINE Emergency Plan, provided as part of the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. The applicant initiated an IMR for this topic which the staff is tracking as Commitment 12.7.8-05. Following receipt of the SHINE Emergency Plan and FSAR, staff will confirm that this issue has been resolved

In RAI 12.7-27, the staff requested that the applicant confirm that a description of the backup off-site communications system be provided in the FSAR. In response to RAI 12.7-27, the applicant stated they will provide a description of the backup off-site communications system in the SHINE Emergency Plan provided as part of the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. The staff is tracking this issue as Commitment 12.7.8-06. Following receipt of the SHINE Emergency Plan and FSAR, the staff will confirm that this issue has been resolved.

The SHINE Preliminary Emergency Plan, Revision 0, Section 8.6, "Contingency Planning," addresses arrangements made with alternate facilities and sources of alternate equipment. In RAI 12.7-28 the staff requested that the applicant confirm that arrangements will have been made with alternate facilities and to ensure the availability of equipment from multiple sources. In the response to RAI 12.7-28, the applicant stated they will confirm that arrangements have been made with alternate facilities and that sources of alternate equipment are available, if needed, in the SHINE Emergency Plan submitted as part of the OL application. The staff finds this to be an acceptable response to support the issuance of a construction permit. The applicant initiated an IMR for this topic. The staff is tracking this issue as Commitment 12.7.8-07. Following receipt of the SHINE Emergency Plan and FSAR, staff will confirm that this issue has been resolved.

Emergency planning is programmatic and the information in this subsection pertains to the operations of the SHINE facility. Specific details regarding emergency facilities and equipment are not necessary to support the issuance of a construction permit. In the response to RAIs 12.7-22 through RAI 12.7-28, the applicant has stated it will provide additional information regarding emergency facilities and equipment in the SHINE Emergency Plan and FSAR submitted with the OL application. Therefore, the staff has deferred a more detailed evaluation of this subsection until receipt of the SHINE Emergency Plan and FSAR supporting an operating license. These issues are being tracked as Commitments 12.7.8-01 through 12.7.8-07. Following receipt of the SHINE Emergency Plan and FSAR for the operating license, staff will confirm that these issues have been resolved. The commitments for the emergency plan and FSAR related to this subsection are briefly summarized below:

Commitment 12.7.8-01: The SHINE Emergency Plan submitted as part of the OL license will provide a complete description of the ESC including its primary location, back-up location, capabilities, and size.

Commitment 12.7.8-02: Table 5.1 of the SHINE Emergency Plan will be revised to provide the means of detecting accident conditions, the means of detecting a release of either radioactive or hazardous materials, and the means of alerting the operations staff of the accident conditions.

Commitment 12.7.8-03: The SHINE Emergency Plan submitted as part of the OL license application will specifically describe the location of first aid equipment.

Commitment 12.7.8-04: The applicant will confirm that arrangements have been made with alternate facilities, and ensure alternate sources of equipment as part of the SHINE OL Application.

Commitment 12.7.8-05: The SHINE Emergency Plan submitted as part of the OL license application will describe both who has the responsibility for decontaminating an ambulance, medical personnel, and medical facility, and the location of the procedures for decontamination of emergency medical services/equipment/personnel. [No IMR initiated by applicant]

Commitment 12.7.8-06: The SHINE Emergency Plan submitted as part of the OL license application will describe the backup off-site communications system.

Commitment 12.7.8-07: The SHINE Emergency Plan submitted as part of the OL license application will include written Letters of Agreement with alternate facilities that will describe services, equipment, and provisions to be provided in the event of an emergency.

The staff concludes that the information provided in the SHINE Preliminary Emergency Plan, Rev. 0, Section 8.0, “Emergency Facilities and Equipment,” is not necessary to meet regulatory requirements and acceptance criteria in support of the issuance of a construction permit. Further evaluation of this section will occur following the receipt of the SHINE Emergency Plan and FSAR submitted with the OL application.

The regulations in 10 CFR Part 50, Appendix E, Part II, Section C requires that a PSAR provide sufficient information on protective measures to be taken within the site boundary to protect human health and safety in the event of an accident. Section H requires that a PSAR provide a preliminary analysis to identify the scope of potential radiological accidents. The acceptance criteria for information on recovery from NUREG-0849, Appendix 12.2 and NUREG-1537, Part 2 include:

- The emergency plan specifies that recovery procedures will be written and approved as required.
- The emergency plan describes the procedures for promptly determining the actions necessary to reduce any ongoing releases of radioactive material or hazardous chemicals incident to the processing of licensed material and to prevent further incidents.
- The emergency plan describes the provisions for promptly and effectively accomplishing required restoration plans.

The staff reviewed Section 9.0, “Recovery,” of the SHINE Preliminary Emergency Plan to ensure that the applicant considered the recovery phase of an accident, and in a RAI letter dated September 19, 2014 (Reference 14), submitted three RAIs related to this subsection. The applicant’s responses to RAI 12.7-29 through 12.7-31 are contained in Reference 20.

In RAI 12.7-29, the staff requested that the applicant explain the bases for presenting a recovery condition that is different than that provided by the guidance. In response to RAI 12.7-29, the applicant stated that it would clarify its characterization of recovery in the SHINE Emergency Plan submitted as part of the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. The applicant initiated an IMR for this topic which the staff has identified as Commitment 12.7.9-01. Following receipt of the SHINE Emergency Plan and FSAR submitted in support of the SHINE OL Application, the staff will confirm that this issue has been resolved.

In RAI 12.7-30, the staff requested that the applicant identify the section within the SHINE Preliminary Emergency Plan that described the SHINE plans to restore the facility after an accident and to recover after an emergency. The staff also requested that the applicant describe the methods and responsibilities for assessing both the damage to the facility and the status of the facility's capabilities to safely control radioactive material or hazardous chemicals. In response to RAI 12.7-30, the applicant stated they would describe in the SHINE Emergency Plan, provided as part of the SHINE OL Application, the methods and responsibilities for assessing the damage to the facility and status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with the process. The staff finds this to be an acceptable response to support the issuance of a construction permit. The applicant initiated an IMR for this topic which the staff has identified as Commitment 12.7.9-02. Following receipt of the SHINE Emergency Plan and FSAR, staff will confirm that this issue has been resolved.

In RAI 12.7-31, the staff requested that the applicant identify who will write and approve the recovery plans and procedures, what elements will be included, and to identify the location of the plans. In response to RAI 12.7-31, the applicant initiated an IMR to ensure an explanation is provided in the SHINE Emergency Plan submitted with the SHINE OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.9-03. Following receipt of the SHINE Emergency Plan, the staff will confirm that this issue has been resolved.

Emergency planning is programmatic and the information in this subsection pertains to the operations of the SHINE facility. Specific details regarding recovery are not necessary to support the issuance of a construction permit. In the responses to RAIs 12.7-29, RAI 12.7-30, and RAI 12.7-31, the applicant has stated it would provide additional information regarding recovery in the SHINE Emergency Plan and FSAR submitted with the OL Application. Therefore, the staff has deferred a more detailed evaluation of this subsection until receipt of the SHINE Emergency Plan and FSAR supporting an operating license application. These issues are being tracked as Commitments 12.7.9-01 through 12.7.9-03. The commitments for the emergency plan related to this subsection are briefly summarized below:

Commitment 12.7.9-01: Section 9.0 of the SHINE Emergency Plan submitted as part of the OL license application will be revised to clarify the characterization of recovery.

Commitment 12.7.9-02: The SHINE Emergency Plan submitted as part of the OL license application will describe the methods and responsibilities for assessing the damage to the SHINE facility and status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with the process.

Commitment 12.7.9-03: The SHINE Emergency Plan submitted as part of the OL license application will describe who will write and who will approve recovery plans and procedures, what elements will be included, and where the plans will be kept.

Following receipt of the SHINE Emergency Plan and FSAR for the operating license, staff will confirm that these issues have been resolved.

The staff concludes that the information provided in the SHINE Preliminary Emergency Plan, Rev. 0, Section 9.0, "Recovery," is not necessary to meet regulatory requirements and acceptance criteria in support of the issuance of a construction permit. Further evaluation of

this section will occur following the receipt of the SHINE Emergency Plan and FSAR submitted with the OL application.

Appendix E, Part II, Section F of 10 CFR Part 50 describes the requirement for both employee training for those employees required to respond to an emergency and for nonemployees who might be called upon in the event of an emergency. The acceptance criteria for information on training from NUREG-0849, Appendix 12.2 and the ISG for NUREG-1537, Part 2 include:

- The emergency plan should describe initial and periodic training for emergency response employees assigned functions for decision making and instructions, accident assessment, radiological monitoring and analysis teams, and for personnel involved in first aid and rescue, medical support, police, security, and ambulance and firefighting personnel.
- The emergency plan should describe the conduct of annual onsite emergency drills, include provisions for drill critiques including timely evaluation of observer comments and correction of identified deficiencies, and discuss the development of written scenarios for the conduct of annual action drills.
- The emergency plan should provide for a biennial review and update of the emergency plan and implementing procedures and agreements with offsite support organizations and agencies that includes review and approval by those responsible for emergency planning, incorporating modifications resulting from drill results or changes to the facility, and timely forwarding changes to the plan and implementing procedures, and agreements to the appropriate individuals, agencies, and supporting organizations.
- The emergency plan should describe the provisions to ensure the operational readiness of emergency communications and emergency health physics equipment including the required maintenance and minimum calibration frequency, functional testing, and inventory of equipment and supplies.

The staff reviewed Section 10.0, “Maintaining Emergency Preparedness,” of the SHINE Preliminary Emergency Plan to evaluate the applicant’s maintenance of emergency preparedness and in a RAI letter dated September 19, 2014 (Reference 14), submitted three RAIs related to this subsection. The applicant’s responses to RAI 12.7-32 through 12.7-34 are contained in Reference 20.

In RAI 12.7-32, the staff requested that the applicant confirm that the list of specific training topics described in subsection 10.1.2 of the SHINE Preliminary Emergency Plan, Revision 0, will include training targeted to the following personnel:

- those responsible for decision-making and transmitting emergency information and instructions,
- those responsible for accident assessment, radiological monitoring and analysis teams, and
- those involved in first aid and rescue, medical support and police, security, ambulance and firefighting personnel.

In response to RAI 12.7-32, the applicant stated they will update Section 10.1 of the SHINE Preliminary Emergency Plan to list training targeted to personnel responsible for decision making; for transmitting emergency information and instructions; for accident assessment; radiological monitoring and analysis teams; and personnel associated with first aid and rescue medical support, and police, security, ambulance, and firefighting personnel, provided in support

of the SHINE OL Application and FSAR. The applicant initiated an IMR to track the update to Section 10.1 of the emergency plan. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.10-01. Following receipt of the SHINE Emergency Plan and FSAR, staff will confirm that this issue has been resolved.

In RAI 12.7-33, the staff requested that the applicant describe how emergency drills demonstrate personnel protection measures during fires, medical emergencies, mitigation activities, search and rescue, and other similar events, and to identify where this information can be found in the emergency plan.

In response to RAI 12.7-33, the applicant stated that it will describe how emergency drills demonstrate personnel protection measures such as controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, and search and rescue in the SHINE Emergency Plan provided as part of the SHINE OL Applicant. The applicant initiated an IMR to ensure a description of how emergency drills demonstrate personnel protection measures is provided in the SHINE Emergency Plan submitted in support of the OL Application. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.10-02. Following receipt of the SHINE Emergency Plan and FSAR, the staff will confirm that this issue has been resolved.

In RAI 12.7-34, the staff requested that the applicant provide information on the frequency, performance objectives, and plans for the emergency response training that will be provided to workers. The staff requested information on the general content and topics for training programs to be given to both onsite and offsite emergency response personnel; and the administration of the training program including responsibility for training, positions requiring training, schedule, frequency, use of team training, hours required for training/retraining, required training for onsite personnel who are not member of the emergency planning staff, and special instruction and tours provided to offsite personnel who might be asked to respond in the event of an emergency. In response to RAI 12.7-34, the applicant stated they will provide information on the topics and general content of the training programs for both onsite and offsite personnel, provide details on the administration of the training program, on training on the use of protective equipment, on training for onsite personnel who are not members of the emergency staff, and on training for offsite personnel such as fire, police, and medical staff who might be called upon to assist in an emergency as part of the SHINE OL Application. The applicant initiated an IMR to ensure this information will be provided in the SHINE Emergency Plan submitted with the OL application. The staff finds this to be an acceptable response to support the issuance of a construction permit. This issue has been identified as Commitment 12.7.10-03. Following receipt of the SHINE Emergency Plan and FSAR, staff will confirm that this issue has been resolved.

Emergency planning is programmatic and the information in this subsection pertains to the operations of the SHINE facility. Specific details regarding maintenance of emergency preparedness are not necessary to support the issuance of a construction permit. In the responses to RAIs 12.7-32, RAI 12.7-33, and RAI 12.7-34, the applicant has stated it will provide additional information regarding maintaining emergency preparedness in the SHINE Emergency Plan and FSAR submitted with the OL application. Therefore, the staff has deferred a more detailed evaluation of this subsection until receipt of the SHINE Emergency Plan and FSAR supporting an operating license. These issues are being tracked as Commitments 12.7.10-01 through 12.7.10-03. The commitments for the emergency plan and FSAR related to this subsection are briefly summarized below:

Commitment 12.7.10-01: Section 10.1 of the SHINE Emergency Plan provided as part of the OL application will include training targeted to personnel responsible for decision making, accident assessment, and for radiological monitoring and analysis teams; and for personnel involved in first aid and rescue, medical support, and training for police, security, ambulance, and firefighting personnel.

Commitment 12.7.10-02: The SHINE Emergency Plan provided as part of the OL application will demonstrate how emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue and other similar events.

Commitment 12.7.10-03: The SHINE Emergency Plan provided as part of the OL application will provide the topics and general content of the training programs for both onsite and offsite emergency response personnel; the administration of the training program including responsibility for training, identification of positions requiring training, use of team and hours of training; training on the use of protective equipment such as respirators, protective clothing, monitoring devices, and other equipment used in emergency response; training for onsite staff who are not members of the emergency staff; and special instructions/tours the licensee would offer to non-licensee emergency personnel such as fire, police, and medical staff, and other non-licensee emergency personnel who might be asked to provide emergency assistance to ensure they know the emergency plan, assigned duties, and effective response to an actual emergency.

Following receipt of the SHINE Emergency Plan and FSAR for the operating license, staff will confirm that these issues have been resolved.

The staff concludes that the information provided in the SHINE Preliminary Emergency Plan, Rev. 0, Section 10.0, "Maintaining Emergency Preparedness," is not necessary to meet regulatory requirements and acceptance criteria in support of the issuance of a construction permit. Further evaluation of this section will occur following the receipt of the SHINE Emergency Plan and FSAR submitted with the OL application.

12.4.8 Security Planning

The staff evaluated the sufficiency of the preliminary design of the SHINE security planning, as described in SHINE PSAR Section 12.8, using the guidance and acceptance criteria from Section 12.8, "Security Planning," in NUREG-1537, Part 1 and 2.

As stated in SHINE PSAR Section 12.8, "[t]he security plan will be developed using the guidance provided in Regulatory Guide 5.59, Revision 1 [Reference 56]."

The staff has considered the statement in the PSAR and verified that the security plan is not needed for issuance of the CP.

Therefore, the staff finds deferring the security plan, as described in SHINE PSAR 12.8, can reasonably be left for later consideration when it will be supplied in the FSAR.

12.4.9 Quality Assurance

The staff evaluated the sufficiency of the preliminary design of the SHINE QAPD, as described in Appendix C of SHINE PSAR Chapter 12, in part, by reviewing how the relevant requirements of 10 CFR 50.34(a)(7) were satisfied and by using the guidance and acceptance criteria from Section 12.9, "Quality Assurance," of NUREG-1537, Parts 1 and 2, which provides a basis for the staff's review of QA programs based on ANSI/ANS-15.8. The following is an evaluation of the SHINE QAPD as described in Appendix C of SHINE PSAR Chapter 12.

Section 12.9, "Quality Assurance," of SHINE PSAR states that the "SHINE QA-1, Quality Assurance Program Description (QAPD), is based on ANSI/ANS 15.8-1995 [Reference 57]) (ANSI/ANS, 1995), 'Quality Assurance Program Requirements for Research Reactors,' with guidance from Regulatory Guide 2.5, Revision 1." However, it is not clear to what extent ANSI/ANS 15.8-1995 has been applied to the development of the SHINE QAPD for the facility.

Therefore, in RAI 12C.1-1 (Reference 14) the staff requested that the applicant confirm to what extent the SHINE QAPD implemented the guidance provided in ANSI/ANS-15.8-1995 across the facility, identifying and justifying any deviations from the guidance. In response to RAI 12C.1-1 (Reference 20), the applicant stated, in part, that according to Regulatory Guide 2.5 (Reference 58) ANSI/ANS-15.8-1995 provides an acceptable method of complying with the program requirements of 10 CFR 50.34, and was used by SHINE for developing the QAPD for the entire facility. The staff reviewed the SHINE response to RAI 12C.1-1 and determined that additional information was required to complete the review. Therefore, staff issued additional RAIs on January 6, 2015 (Reference 15).

In RAI 12C.1-3, part (a) (Reference 15), the staff requested that the applicant further clarify its response to RAI 12C.1-1, by explaining whether SHINE had verified that ANSI/ANS-15.8-1995 is sufficient for use in the development of the SHINE QAPD. In response to RAI 12C.1-3, part (a) (Reference 22) the applicant stated that SHINE had revised the Executive Summary of the SHINE QAPD to state that "SHINE had determined that ANSI/ANS 15.8-1995 is appropriate to use in the design of the facility even though the standard was written for research reactors." The staff reviewed the SHINE response to RAI 12C.1-3, part (a), and determined that additional information was required to complete the review.

In RAI 12C.1-5 (Reference 16), the staff requested that the applicant further clarify its response to RAI 12C.1-3, part (a), by explaining if SHINE had determined whether ANSI/ANS 15.8-1995 is sufficient for use in the development of the SHINE QAPD, which is to be applied in the design, fabrication, construction, and operation of the SHINE facility.

The applicant's response to RAI 12C.1-5 (Reference 24), indicated that SHINE had revised the Executive Summary of the SHINE QAPD to state that "SHINE has determined that ANSI/ANS-15.8-1995 is sufficient for use in the development of the SHINE QAPD, which is to be applied to the design, fabrication, construction, and operation of the SHINE facility."

The staff reviewed the SHINE response to RAI 12C.1-5 and verified that the revised Executive Summary of the SHINE QAPD was appropriately updated, based on the RAI response. The staff finds that the Executive Summary adequately describes the application of guidance provided in ANSI/ANS-15.8-1995 in the development of the SHINE QAPD.

In RAI 12C.1-3, part (b) (Reference 15), the staff requested the applicant to clarify if the "SHINE

QA-1” referred to in the first paragraph of Section 12.9 of the SHINE PSAR is, in fact, SHINE QAPD document number 2000-09-01. In response to RAI 12C.1-3 (Reference 22), the applicant stated that the naming convention of the QAPD had been changed from “SHINE-QA-1,” to document number 2000-09-01. The applicant further stated that they will update Section 12.9 of the PSAR in the FSAR to refer to the current naming convention of the SHINE QAPD. Following receipt of the SHINE FSAR, the staff will confirm that this issue has been resolved.

Section 1.1, “Scope,” of SHINE QAPD describes the administrative and engineered controls to be used during the design, construction, and operation of the facility.

In RAI 12C.5-1 (Reference 15), the staff requested that SHINE provide additional information regarding the quality assurance requirements that apply during the decommissioning phase. In response to RAI 12C.5-1 (Reference 22), the applicant stated that they had removed the term “decommissioning” from Sections 1.1 and 1.2 of the QAPD, and revised Section 5, “Decommissioning,” of the SHINE QAPD, to state that it will be updated at a later date. The SHINE commitment to update the QAPD at a later date, to address the requirements for decommissioning, is acceptable to the staff.

The SHINE QA program, as described in Section 1.2, “Application,” of the SHINE QAPD, will be applied to SHINE activities, consistent with their importance to safety and reliability. Such activities will include, at a minimum, those related to irradiation unit safety and protection system, material processing safety, criticality safety, engineered safety features, and applicable radiation monitoring systems. SHINE will apply a graded approach to those items and activities that could affect the quality of safety-related SSCs and other components not designated as safety-related. SHINE activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

The staff determined that description of the SHINE QA program application met the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

In Section 1.3, “Definitions,” the SHINE QAPD provided a list of key definitions used throughout the document. In RAI 12C.1-4 (Reference 15), the staff requested that the applicant clarify what definition of “safety-related” was provided in the SHINE stand-alone Administrative Procedure (AP) 2000-10-01, and where that definition was included in the SHINE QAPD. In addition, the staff requested additional information discussing why it was acceptable to maintain key definitions that were used in the SHINE QAPD, in a stand-alone administrative procedure. The applicant responded (Reference 22) that the following definition for safety-related SSCs was provided in the SHINE AP 2000-10-01 and revised Section 1.3 of the QAPD to include it, as follows:

Safety-related SSC – those SSCs that are relied upon to remain functional during normal conditions and during and following design basis events to assure:

1. The integrity of the primary system boundary;
2. The capability to shutdown the target solution vessel (TSV) and maintain the target solution in a safe shutdown (SSD) condition;
3. The capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20;
4. That the potential for an inadvertent criticality accident is not credible;

5. That acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area; or
6. That an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur.

In the same response, the applicant also stated that Section 1.3 of the QAPD was revised to include all applicable ANSI/ANS-15.8-1995 (R2013) definitions. The response also stated that all definitions included in the SHINE QAPD are consistent with those provided in Section 1.3 of ANSI/ANS-15.8-1995 (R2013), with the following exceptions:

1. Modified the definition of “commissioning” by replacing the word “reactor” with “irradiation facility;”
2. The definition of “experiment” was not included in the SHINE QAPD;
3. Modified the definition of “management” by replacing the words “research reactor” with “SHINE;”
4. The definitions of “non-power reactor,” “research reactor,” and “test reactor” were not included in the SHINE QAPD; and
5. The definition of “safety-related SSCs” was modified as described above.

The inclusion of applicable ANSI/ANS-15.8-1995 definitions in the revised SHINE QAPD addressed staff’s concern with maintaining key definitions in a stand-alone administrative procedure, thus allowing for appropriate control of definitions that are important to establishing the QA program at SHINE. The modification of the definition of “commissioning” and “management” as described above is acceptable to the staff, as these changes are appropriate for the SHINE facility, which does not meet the definition of a “reactor.” Further, the exclusion of definitions of “non-power reactor,” “research reactor,” and “test reactor” is also acceptable to the staff because these definitions do not apply to SHINE.

In RAI 12C.1-6, part (a) (Reference 16), the staff asked the applicant to clarify the basis for not including the definition of “experiment” in the QAPD, since conduct of experiments and use of experimental equipment are discussed in Sections 2.10 and 2.19 of the QAPD, respectively. The applicant’s response to RAI 12C.1-6, part (a) (Reference 24), indicated that SHINE did not plan on conducting experiments or utilizing experimental equipment, and the definition of “experiment” was, therefore, not included in the SHINE QAPD. Further, SHINE had revised Section 2.10 to remove the phrase “experiment fabrication” and had removed Section 2.19, Experimental Equipment, from the SHINE QAPD. The staff reviewed the SHINE response to RAI 12C.1-6, part (a) and verified that the SHINE QAPD was appropriately updated, based on the RAI response. The staff finds the SHINE response to be acceptable.

In RAI 12C.1-6, part (b) (Reference 16), the staff asked the applicant to provide additional information regarding the definitions of “audit,” as used in the SHINE QAPD Sections 2.7, “Control of Purchased Items and Services,” and 2.7.3, “Verification Activities,” and “assessment,” as used in Section 2.18, “Assessment,” and provide clarification as to the difference between the two definitions. The applicant’s response to RAI 12C.1-6, part (b) (Reference 24), stated that the SHINE definitions of “assessment” and “audit” are identical and SHINE used the terms interchangeably. SHINE further stated that they define both “assessment” and “audit” as “[a] planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance

with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation.” The staff finds the applicant’s response to be acceptable.

In RAI 3.5-6, part (a) (Reference 16), the staff asked the applicant to provide a performance-based definition for the fourth part (i.e., “[t]hat the potential for an inadvertent criticality accident is not credible”) of the six-part definition of the “safety-related SSCs,” or provide a discussion as to why it is not necessary. Further, in part (b) of the same RAI, the staff asked the applicant to discuss how the SHINE definition of “safety-related SSCs” aligns with the definition of “basic component” provided in 10 CFR 21.3. The applicant’s response to RAI 3.5-6, part (a) (Reference 24), stated that SHINE had revised the definition of “safety-related,” to read:

Safety-related SSCs: Those SSCs that are relied upon to remain functional during normal conditions and during and following design basis events to assure:

1. The integrity of the primary system boundary;
2. The capability to shutdown the target solution vessel (TSV) and maintain the target solution in a safe shutdown (SSD) condition;
3. The capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20;
4. That all nuclear processes are subcritical, including use of an approved margin of criticality;
5. That acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area; or
6. That an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur.

The staff verified that the SHINE QAPD was appropriately updated, based on the RAI response. The staff finds the SHINE response to be acceptable.

Further, the SHINE response to RAI 3.5-6, part (b), stated that SHINE considers safety-related SSCs, as defined in part (a) of the RAI response, to be basic components, as defined in 10 CFR 21.3. The staff reviewed the SHINE response to RAI 3.5-6, part (b) and found that the SHINE proposed definition of “safety-related structures, systems, and components” and treatment of “basic component” are acceptable.

The SHINE QAPD is a top-level policy document that describes the requirements and tasks assigned to the various organizational elements, to achieve the SHINE objectives in assurance of quality. The SHINE overall philosophy regarding the achievement and assurance of quality is described in the QAPD, while implementing documents assign more specific responsibilities and duties for conducting activities within the scope of the QAPD.

Section 2.1, “Organization,” of the SHINE QAPD describes the SHINE organizational structure, functional responsibilities, levels of authority, and lines of communication for establishing, executing, and verifying implementation of activities within the scope of the QAPD.

The Quality Manager is responsible for the development and verification of implementation of the QAPD. The Quality Manager reports to the Chief Operating Officer (COO), an adequately

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authoritative level of management. The Quality Manager also has the ability and responsibility to report to Chief Executive Officer (CEO), who has overall responsibility for the SHINE QA program. The SHINE QAPD further establishes that the CEO delegates the necessary responsibility and authority, to ensure that quality is achieved and maintained by those who have been assigned responsibility for performing work, and that quality achievement is verified by persons not directly performing the work.

The QAPD establishes that the COO has access to work areas and encourages managers and employees to identify problems, initiate, recommend, or provide corrective action, and ensure corrective action implementation.

The SHINE QAPD establishes independence between the organizations responsible for performing a function and oversight activities performed by the quality organization (i.e., quality assurance and quality control).

The staff determined that the SHINE organizational controls are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

The SHINE QAPD documents the requirements for establishing, implementing, and managing the QA program. The program implements a graded approach to quality, as described in Enclosure 2 of the SHINE QAPD. Quality Level (QL)-1 classification implements the full measure of the SHINE QAPD and will be applied to all safety-related SSCs. QL-2 classification will include the non-safety related activities performed by SHINE, and that are deemed necessary to ensure the manufacture and delivery of highly reliable products and services, to meet or exceed customer requirements and expectations.

All SHINE activities and tasks will be performed in accordance with approved implementing procedures. SHINE procedures will be delineated, managed, and maintained by the Quality Manager, with support from SHINE staff.

The program provides for the appropriate and necessary indoctrination and training of personnel who perform activities affecting quality, to ensure that suitable proficiency is achieved and maintained. When required, qualification and selection of personnel will be conducted in accordance with requirements established in applicable SHINE procedures. The scope of indoctrination will include administrative and technical objectives, as well as the requirements of applicable codes, standards, and the SHINE QAPD. Records of personnel training and qualification will be maintained.

In RAI 12C.E2-6, part (a) (Reference 16), the staff asked the applicant to clarify if the QL-1 classification applies to safety-related activities, as well as safety-related SSCs. In addition, in part (b) of the same RAI, the staff asked SHINE to clarify how the definition of the QL-2 classification is based on safety significance considerations. Further, in part (c) of the same RAI, the staff asked SHINE to explain if the QL-2 classification is intended to be applied only to selected non-safety related SSCs and activities.

The SHINE response to RAI 12C.E2-6 (Reference 24), part (a) indicated that SHINE had revised the definition of the QL-1 classification to apply to safety-related activities, as well as safety-related SSCs. The staff reviewed the SHINE response to RAI 12C.E2-6, part (a) and verified that the revised definition of the QL-1 classification in Enclosure 2 of the SHINE QAPD was appropriately updated, based on the RAI response.

The SHINE response to RAI 12C.E2-6, part (b) indicated that SHINE had revised the definition of the QL-2 classification, to be based on safety significance considerations and the application of the full scope of the SHINE QAPD to the activities affecting quality. Further, the response stated that SHINE had added a new QL-3 classification, to be applied to non-safety related SSCs or activities that do not support or protect the safety function of safety-related SSCs or activities. The staff reviewed the SHINE response to RAI 12C.E2-6, part (b) and verified that the revised definition of the QL-2 classification and the new definition of the QL-3 classification were appropriately included in Enclosure 2 of the SHINE QAPD, based on the RAI response.

In response to RAI 12C.E2-6, part (c), SHINE stated that the QL-2 classification is intended to be applied only to selected non-safety related SSCs and activities. The staff reviewed the SHINE response to RAI 12C.E2-6, part (c), and found it to be acceptable.

The staff finds that the revised QL-1, QL-2, and QL-3 classifications adequately represent a graded approach to quality, as described in Section 2.2 and Enclosure 2 of the SHINE QAPD. The staff determined that the SHINE programmatic controls are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

In Section 2.3, “Design Control,” the SHINE QAPD establishes a design control process to control the design, design changes, and modifications subject to the provisions of the QAPD. The SHINE QAPD states that procedures will identify the process and include the provisions for the control of design documents, control of software, and implementation of required rules, regulations, codes, and standards.

As described below, the staff determined that the SHINE design controls are in accordance with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8.

Section 2.3.1, “Design Requirements,” of the SHINE QAPD establishes that applicable design inputs, including design bases, performance requirements, regulatory requirements, codes, and standards, are to be identified and documented.

Section 2.3.2, “Design Process,” states that SHINE is responsible for identifying and controlling the design interfaces and will coordinate activities among participating organizations. The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, will be verified for each application. Deviations from the established design inputs will be documented and controlled.

The design organization will ensure that final design is relatable to the design input by adequate documentation. Computer design programs used to develop any portion of the facility design or to analyze the design will be controlled. When a design program must be developed, the program will be controlled to ensure that it is fully documented and validated. When changes to previously validated computer programs are made, documented re-validation will be performed for the change and include appropriate benchmark testing.

Section 2.3.3, “Design Verification,” describes how the SHINE independent design reviews will be performed to verify the adequacy of design. Design verification will be performed by competent persons other than those who designed the item. Design verification will be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations. Qualification testing will be defined in formal test plans and will include appropriate acceptance criteria. Testing will demonstrate the adequacy of

performance that simulates the most adverse design conditions. Test results will be documented and verified to have met the test requirements.

Section 2.3.4, "Design Documents and Records," describes the SHINE process to ensure that design documents and records will provide evidence that the design and design verification processes were performed. Such documents and records will be collected, stored, and maintained for the life of the safety-related item.

Section 2.3.5, "Commercial Grade Items," states that SHINE will have procedures in place, to provide for reviews and evaluations of commercial grade items, to be used in safety-related applications. If a commercial grade item is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the item will be identified in a different manner that is traceable to a documented description of the difference.

Section 2.3.6, "Change Control," describes how modifications to the SHINE facility's SSCs will be procedurally controlled. Design changes will be documented, justified, and subject to control measures commensurate with those applied to the original design. These measures will include assurance that the design analyses for SSCs or computer codes are still valid. When a significant design change is necessary because of an incorrect design, the design organization will review and modify the design process and verification procedure, as necessary.

In Section 2.4, "Procurement Document Control," the SHINE QAPD describes a process to ensure that procurement documents contain sufficient technical and quality requirements to ensure that the items and services satisfy the needs of SHINE. The SHINE QAPD stipulates that procurement documents at all procurement levels identify the documentation required to be submitted for information, review, or approval by SHINE. The procurement documents will require access to the supplier's facility and records by designated individuals. Procurement documents will require the supplier to report non-conformances associated with the items or services being procured.

The staff determined that the SHINE procurement document controls are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and therefore acceptable.

Section 2.5, "Procedures, Instructions, and Drawings," describes the SHINE measures to ensure that quality activities are based on documented instructions, procedures, or drawings, as appropriate. These documents will include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

The staff determined that the SHINE controls for instructions, procedures, and drawings are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

Section 2.6, "Document Control," describes the SHINE process to control the review, approval, and distribution of documents, including changes thereto, which prescribe activities affecting quality. The program and implementing procedures will establish the requirements for identification, review and approval, and distribution of documents. Major changes to controlled documents will be reviewed and approved by the same organizations that performed the review of the original issue.

The staff determined that the SHINE document controls are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

Section 2.7, “Control of Purchased Items and Services,” describes the SHINE measures to ensure that purchased items and services conform to procurement documents. These measures include supplier evaluation and selection, source surveillance and inspection, and audits and review of supplier documents, as applicable.

The staff determined that the SHINE controls for purchased items and services are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

As described, in Section 2.7.1, “Supplier Selection,” the SHINE QAPD requires that the selection of suppliers be based on evaluation of their capabilities to provide items or services in accordance with the requirements of the procurement documents.

In Section 2.7.2, “Work Control,” the SHINE QAPD requires that measures be established to control the supplier’s performance. Controls may include review of test plans and supplier’s submitted documents, source surveillance and inspection, and other technical and administrative interfaces with the supplier, in accordance with the procurement documents.

Section 2.7.3, “Verification Activities,” states that SHINE will require that suppliers verify and provide evidence of the quality of their products. SHINE will establish methods to control and approve supplier-generated documents. Based on the complexity of the product and importance to safety, SHINE will independently verify the quality of supplier’s product using source surveillances, inspections, audits, or review of supplier’s non-conformances, dispositions, waivers, and corrective actions.

Section 2.7.4, “Item or Service Acceptance,” describes the SHINE process to ensure that purchased items and services conform to procurement specifications. SHINE will use one or more of the following methods to accept an item or service: supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test. Receiving inspection will include, as appropriate, verification by objective evidence such features as proper configuration, identification and cleanliness, shipping damage, and indication of fraud or counterfeit.

Section 2.8, “Identification and Control of Items,” describes the SHINE measures for item identification, traceability, and control purposes. The type of identification is established by specifications, codes, or standards. Items, including materials, will be identified by appropriate means. Where physical identification on the item is either impractical or insufficient, physical separation will be used. Items having a limited shelf and service life will be identified and controlled.

The staff determined that the SHINE controls for identification of items are in accordance with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

Section 2.9, “Control of Special Processes,” describes the SHINE measures to ensure that approved special process procedures are used by qualified personnel, and in accordance with specified codes and standards, including acceptance criteria for the process. Special processes at SHINE will be controlled by instructions, procedures, drawings, checklists, travelers, or other

appropriate means. Records for qualified personnel, processes, and equipment associated with special processes will be maintained, as appropriate.

The staff determined that the SHINE controls for special processes are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

Section 2.10, "Inspections," describes the SHINE inspection process to verify the quality and conformance of the item to specified requirements. The inspection process will be applicable to procurement, construction, modification, maintenance, and experiment fabrication. Inspections will be performed by persons other than those who performed the work being inspected, but may be from the same organization. Measuring and Test Equipment (M&TE) used to perform inspections will be identified in inspection documentation, for traceability of inspection results. Only items that have passed the required inspections and tests will be used, installed, or operated. Inspection results will be documented. Acceptance of items will be documented and approved by authorized personnel. Verification of conformance of work activities for the purpose of acceptance will be performed by qualified personnel.

SHINE will determine the need for formal training and conduct such training, as required, to qualify inspection and test personnel. SHINE will provide on-the-job training, as appropriate. Records of inspection personnel's qualification will be established and maintained by SHINE or the appropriate contractor.

The staff determined that the SHINE controls for inspection are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

Section 2.11, "Test Control," describes the SHINE measures to demonstrate that SSCs will perform satisfactorily in service. Test results will be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Computer programs to be used for operational control will be tested in accordance with an approved verification and validation plan and will demonstrate required performance over the range of operation of the controlled function or process.

The staff determined that the SHINE controls for testing are in accordance with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

Section 2.12, "Control of Measuring and Test Equipment," describes the SHINE measures to ensure that tools, gauges, instruments, and other M&TE used for activities affecting quality are controlled, calibrated, or adjusted at specified periods, to maintain accuracy within specified limits.

Out-of-calibration devices will be tagged and segregated, until calibration has been restored. Records of calibration traceable to individual M&TE will be maintained. Calibration and control measures will not be required when normal commercial equipment provides adequate accuracy.

The staff determined that the SHINE controls for M&TE are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

In Section 2.13, "Handling, Storage, and Shipping," the SHINE QAPD requires that handling, storage, and shipping of items be performed in accordance with work and inspection instructions, drawings, specifications, shipping instructions, or other pertinent documents or procedures.

The staff determined that the SHINE controls for handling, storage, and shipping are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and therefore acceptable.

In Section 2.14, “Inspection, Test, and Operating Status,” the SHINE QAPD requires that the status of inspection and test activities be identified on the items or in documents traceable to the items. Identification of inspection and test status will ensure that required inspection and test were performed and prevent inadvertent installation or operation of items that have not passed the required inspections or tests.

The staff determined that the SHINE controls for inspection, test, and operating status are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and therefore acceptable.

In Section 2.15, “Control of Nonconforming Items and Services,” the SHINE QAPD described the necessary measures to control nonconforming items, to prevent their inadvertent use or installation. These controls include measures for identification, documentation, evaluation, segregation (as appropriate), and disposition of nonconforming items. Recommended dispositions, such as “use-as-is,” “reject,” “repair,” or “rework,” will be identified, documented, and approved.

SHINE will document the technical justification for the acceptability of a nonconforming item dispositioned as “repair” or “use-as-is.” Non-conformances to design requirements of items dispositioned as “repair” or “use-as-is” will be subject to design control measures commensurate with those applied to the original design. Nonconforming items dispositioned as “repair” or “rework” will be re-examined in accordance with applicable procedures and appropriate acceptance criteria.

The staff determined that the SHINE controls for nonconforming items and services are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and therefore acceptable.

In Section 2.16, “Corrective Actions,” the SHINE QAPD requires that conditions adverse to quality be identified promptly and corrected as soon as practical. The corrective actions will be in accordance with the design requirements, unless those requirements were faulty.

In the case of a significant condition adverse to quality, the cause of the condition will be investigated and corrective action to prevent recurrence will be taken.

The staff determined that the SHINE controls for corrective action are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and therefore acceptable.

In Section 2.17, “Quality Records,” the SHINE QAPD describes the necessary measures to ensure that, at minimum, sufficient records of the following activities be maintained and appropriately stored: inspection and test results, results of quality assurance reviews, quality assurance procedure, and engineering reviews and analyses in support of design or changes and modifications. The SHINE records system or systems will be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

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Some records will be maintained by or for the plant owner for the life of the item while it is installed in the plant or stored for future use. Such records will be classified in accordance with applicable documented classification criteria. Other records will be retained for a shorter period, as determined by SHINE.

Records will be stored in a location that provides damage prevention from moisture, temperature, and pestilence. Provisions will be specified for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage. SHINE requires that records that be maintained by a supplier be accessible to SHINE.

The staff determined that the SHINE controls for quality records are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995.

In Section 2.18, "Assessments," the SHINE QAPD describes the necessary measures for conducting periodic assessments of quality-affecting activities during design, construction, modification, and operations, to evaluate the effectiveness of the quality program implementation.

Assessments will be performed in accordance with written procedures or checklists. Assessment results will be documented and reviewed by the management personnel responsible for the area assessed. Management of the assessed organization will investigate adverse findings and schedule corrective actions. The adequacy of the responses will be evaluated by the assessing organization. Assessment records will include plans, reports, written replies, and records of completion of corrective actions.

SHINE requires that personnel conducting assessments have the requisite training and experience.

The staff determined that the SHINE controls for assessments are consistent with the guidance provided in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995 and therefore acceptable.

Section 3, "Facility Operations," of the SHINE QAPD describes the elements of a quality assurance program for conduct of operation at the SHINE facility. The SHINE QAPD also establishes that some requirements of the QA program for operations may be found in other documents, such as the Training Program, Emergency Plan, Security Plan, Technical Specifications, and the Radiation Protection Program, and would not be duplicated in the quality assurance program.

The information provided in Section 3, "Facility Operations," of the SHINE QAPD, including its subsections, pertains to the operations of the SHINE facility, and specific details are not necessary to support the issuance of a construction permit. Therefore, the staff has deferred a more detailed evaluation of this section until the receipt of an FSAR supporting an operating license application.

Section 5, "Decommissioning," of the SHINE QAPD, pertains to decommissioning of the SHINE facility, and is not necessary to support the issuance of a construction permit. SHINE stated in Section 5 of the SHINE QAPD that this section would be updated at a later date. Therefore, the staff has deferred the review of this section until the receipt of an FSAR supporting an operating license application. Following receipt of the SHINE FSAR, staff will confirm that this issue has been resolved.

Due to limited information provided in the SHINE PSAR regarding the SHINE quality assurance program requirements during operations and decommissioning, further evaluation of the SHINE QAPD will occur following the receipt of the SHINE FSAR.

On the basis of its review, the staff finds the information to be included in SHINE FSAR Section 12.9, “Quality Assurance,” is sufficient and meet the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35.

12.4.10 Operator Training and Requalification

The staff evaluated the sufficiency of the preliminary design of the SHINE operator training and requalification program, as described in SHINE PSAR Section 12.10, using the guidance and acceptance criteria from Section 12.10, “Operator Training and Requalification,” in NUREG-1537, Part 1 and 2.

As stated in SHINE PSAR Section 12.10a, “[t]his section is not applicable as the SHINE irradiation unit is not a reactor,” and Section 12.10b, “[t]he SHINE facility operator training and requalification program will be described in the FSAR.”

The staff has considered the statements in the PSAR and verified that the operator training and qualification program is not needed for issuance of the CP; however, the staff have not made a determination on whether the operator training and qualification program is applicable to the SHINE IF. This will be reviewed and evaluated when SHINE submits the FSAR.

Therefore, the staff finds deferring the operator training and requalification program, as described in SHINE PSAR 12.10, can reasonably be left for later consideration when it will be supplied in the FSAR.

12.4.11 Startup Plan

The staff evaluated the sufficiency of the preliminary design of the SHINE startup plan, as described in SHINE PSAR Section 12.11, using the guidance and acceptance criteria from Section 12.11, “Startup Plan,” in NUREG-1537, Part 1 and 2.

As stated in SHINE PSAR Section 12.11, “The startup plan will be described in the FSAR.”

The staff has considered the statement in the PSAR and verified that the startup plan is not needed for issuance of the CP.

Therefore, the staff finds deferring the startup plan, as described in SHINE PSAR 12.11, can reasonably be left for later consideration when it will be supplied in the FSAR.

12.4.12 Environmental Reports

Section 12.4.12, “Environmental Reports,” has been superseded by Chapter 19, “Environmental Review,” and is therefore vacated.

Results of the staff review of the environmental report is provided in the SHINE Final Environmental Impact Statement (Reference 59).

12.4.13 Material Control and Accounting Plan

The staff evaluated the sufficiency of the preliminary design of the SHINE material control and accounting (MC&A) plan, as described in SHINE PSAR Section 12.13, using the guidance and acceptance criteria from Section 12.13, "Material Control and Accounting Plan," in the ISG Augmenting NUREG-1537, Part 1 and 2.

As stated in SHINE PSAR Section 12.13, "[t]he material, control, and accountability program will be provided in the FSAR."

The staff has considered the statement in the PSAR and verified that the startup plan is not needed for issuance of the CP.

Therefore, the staff finds deferring the MC&A plan, as described in SHINE PSAR 12.13, can reasonably be left for later consideration when it will be supplied in the FSAR.

12.5 Summary and Conclusions

SHINE PSAR Chapter 12 describes the conduct of operations for the IUs and RPF, therefore, the technical evaluation of the SHINE conduct of operations, described in SHINE PSAR, Chapter 12, applies to both the IUs and RPF.

The staff evaluated the descriptions and discussions of the SHINE organization, including probable subjects of technical specifications, as described in Chapter 12 of the SHINE PSAR and supplemented by the applicant's responses to RAIs, and finds that the preliminary design of the SHINE organization meets the applicable guidelines of ISG Augmenting NUREG-1537, Parts 2 and NUREG-1537, Part 2, as follows:

- The applicant has presented an organizational structure that reflects the complete facility organization from the official license holder to the reactor operations staff. All organizational relationships important to safety have been shown, including that of the review and audit function and the radiation safety function. The organization meets the non-power reactor standards in ANSI/ANS 15.1-2007, "The Development of Technical Specifications for Research Reactors," and ANSI/ANS 15.4-2007.
- The applicant has described the responsibilities of the persons in the organizational structure. The responsibility for safe operation of the facility and for the protection of the health and safety of the staff and the public has been shown.
- The applicant has described facility staffing requirements that demonstrate its ability to safely operate the facility and protect the health and safety of the staff and the public. The staffing meets the requirements of the regulations.
- Facility staff will be selected that meet minimum qualifications acceptable for non-power reactors. Operators will be trained in a program that meets the standards for non-power reactors and the requirements of the regulations. Radiation protection training and specialized training will be conducted at an acceptable level.

- The applicant has described a radiation safety organization that is acceptable to the staff. This organization has direct access to upper management and the review and audit committee to express concerns, if necessary. The radiation safety staff has the authority to interdict or terminate activities to ensure safety.
- The applicant has proposed a review and audit function for the facility. The committee members appear to be well qualified, with a wide spectrum of expertise. The committee membership includes persons from outside the university (or corporation). The staff has determined that the committee membership is acceptable.
- The review and audit committee has proposed a charter and rules that describe the number of times the committee meets, the way the committee conducts business, the requirements for a quorum when voting, and the way the committee distributes its reports and reviews to the applicant. The staff has determined that the charter and rules for the committee are acceptable.
- The applicant has proposed a list of items that the committee will review. The staff has determined that this list is comprehensive and acceptable. The applicant has proposed a list of items that the committee will audit. The staff has determined that this list is complete and acceptable.
- The applicant has proposed a set of required procedures that is appropriate to operation of the facility as proposed in the SAR and is acceptable to the staff.
- The applicant has described the review and approval process for procedures and has also described the method for making minor and substantive changes to existing procedures and for the temporary deviation from procedures during operations. The staff has determined that the process and method described by the applicant will ensure proper management control and proper review of procedures.
- The staff finds the information on required actions, reports, and records may reasonably be left for later consideration in the FSAR.
- The staff identified 29 commitments related to the review of SHINE PSAR Section 12.7, “Emergency Planning,” and the SHINE Preliminary Emergency Plan. The staff noted that the information in this section pertains more specifically to the operations of the SHINE facility, and the remaining commitment items are not necessary to be resolved to support the issuance of a construction permit. SHINE stated that it would provide the requested information in the SHINE Emergency Plan and FSAR supporting an operating license application. The staff finds that the information in this section meets the regulatory requirements and acceptance criteria in support of the issuance of a construction permit. Further evaluation of this section will occur following the receipt of the SHINE FSAR and Emergency Plan supporting an operating license application.
- The staff finds the information on security planning may reasonably be left for later consideration in the FSAR.
- The staff finds the information to be included in SHINE PSAR Section 12.9, “Quality Assurance,” is sufficient and meet the applicable regulatory requirements and guidance for the issuance of a CP, however, due to limited information provided in the SHINE

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PSAR regarding the SHINE quality assurance program requirements during operations and decommissioning, further evaluation of the SHINE QAPD will occur following the receipt of the SHINE FSAR.

- The staff finds the information on the operator training and requalification program, startup plan, and MC&A plan may reasonably be left for later consideration in the FSAR.

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

- (1) SHINE has described the proposed design of the conduct of operations and has identified the major elements incorporated therein for the protection of the health and safety of the public;
- (2) Further design information required to complete the safety analysis of the conduct of operations may reasonably be left for later consideration in the FSAR;
- (3) Taking into consideration the site criteria contained in part 100, there is reasonable assurance that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

