

## **12.0 CONDUCT OF OPERATIONS**

The conduct of operations involves the administrative aspects of facility operation, the facility emergency plan, the quality assurance plan, the security plan, the operator requalification plan, and the startup plan. The administrative aspects of facility operations are the facility organization, review and audit activities, organizational aspects of radiation safety, facility procedures, required actions in case of license or technical specifications violations, reporting requirements, and recordkeeping.

This chapter of the SHINE operating license application safety evaluation report (SER) describes the review and evaluation by the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of the final design of the SHINE conduct of operations as presented in Chapter 12, "Conduct of Operations," of the SHINE Final Safety Analysis Report (FSAR), as supplemented by the applicant's response to NRC requests for additional information (RAIs).

### **12.1 Areas of Review**

SHINE FSAR Chapter 12 describes the conduct of operations for the SHINE facility. SHINE FSAR Chapter 12 is applicable to both the SHINE irradiation facility (IF) and radioisotope production facility (RPF). The NRC staff reviewed SHINE FSAR Chapter 12 against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the SHINE conduct of operations.

### **12.2 Summary of Application**

SHINE FSAR Chapter 12 describes the SHINE 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. The organizational aspects of the radiation protection program, the production facility safety program, staffing, and selection and training of personnel are also included in the conduct of operations. This discussion is included in SHINE FSAR Sections 12.1, "Organization," Section 12.2, "Review and Audit Activities," Section 12.3, "Procedures," Sections 12.4, "Required Actions," 12.5, "Reports," 12.6, "Records," Section 12.7, "Emergency Planning," Section 12.8, "Security Planning," Section 12.9, "Quality Assurance," 12.10, "Operator Training and Requalification," 12.11, "Startup Plan," and 12.13, "Material Control and Accountability Program."

SHINE FSAR Section 12.12, "Environmental Reports," is vacated. SHINE submitted its supplement to the applicant's environmental report (ADAMS Accession No. ML21320A066). The NRC staff's evaluation of this is documented in NUREG-2183, "Supplement 1 – Environmental Impact Statement Supplement Related to the Operating License for the SHINE Medical Isotope Production Facility."

### **12.3 Regulatory Requirements and Guidance and Acceptance Criteria**

The NRC staff reviewed SHINE FSAR Chapter 12 against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the

sufficiency of the bases and the information provided by SHINE for the issuance of an operating license.

### **12.3.1 Applicable Regulatory Requirements**

The applicable regulatory requirements for the evaluation of SHINE's conduct of operations are as follows:

10 CFR 50.34, "Contents of applications; technical information," paragraph (b)(6).

10 CFR 50.40, "Common standards."

10 CFR 50.54, "Conditions of licenses," paragraphs (i), (j), (k), (l), and (m)(1).

10 CFR 50.57, "Issuance of operating license."

10 CFR Part 20, "Standards for Protection Against Radiation."

### **12.3.2 Applicable Regulatory Guidance and Acceptance Criteria**

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

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

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

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

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

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

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

## **12.4 Review Procedures, Technical Evaluation, and Evaluation Findings**

The NRC staff performed a review of the technical information presented in SHINE FSAR Chapter 12, as supplemented, to assess the sufficiency of the conduct of operations for the issuance of an operating license. The sufficiency of the conduct of operations is determined by ensuring that it meets applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 12.3, "Regulatory Requirements and Guidance and Acceptance Criteria," of this SER. The findings of the NRC staff review are described in SER Section 12.5, "Review Findings."

### **12.4.1 Organization**

The NRC staff evaluated the sufficiency of SHINE's organization, as presented in SHINE FSAR Section 12.1, using the applicable guidance and acceptance criteria from Section 12.1, "Organization," of NUREG-1537, Parts 1 and 2, and of the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with the review criteria in Chapter 14, "Technical Specifications," of NUREG-1537, Part 2, Section 12.1, and ANSI/ANS 15.1-2007, "The Development of Technical Specifications for Research Reactors," the NRC staff evaluated the description of the SHINE review and audit activities to ensure that the FSAR provides a basis for the technical specification requirements for the organization activities.

SHINE FSAR Section 12.1.1, "Structure," as accompanied by SHINE FSAR Figure 12.1-1, "SHINE Operational Organization Chart," provides a multi-level functional organization description, consistent with ANSI/ANS 15.1-2007. The organization chart in SHINE FSAR Figure 12.1-1 shows the various levels of the organization, including reporting and communication lines between operations staff, supervisors, managers, and committees.

Therefore, the NRC staff finds that SHINE has presented an organizational structure that reflects the complete facility organization from the license holder to the operations staff. All organizational relationships important to safety have been shown, including the review and audit function and the radiation safety function. The organization meets the standards in ANSI/ANS 15.1-2007 and ANSI/ANS 15.4-2016, "Selection and Training of Personnel for Research Reactors."

In SHINE FSAR Section 12.1.2, "Responsibility," SHINE describes the responsibilities of the persons in the organizational structure described in SHINE FSAR Section 12.1.1 and Figure 12.1-1 consistent with ANSI/ANS 15.4-2016. Therefore, the NRC staff finds that the responsibility for the safe operation of the facility and for the protection of the health and safety of the SHINE staff and the public has been shown.

In SHINE FSAR Section 12.1.3, "Staffing," SHINE describes the facility staffing requirements that demonstrate its ability to safely operate the facility and protect the health and safety of the

SHINE staff and public consistent with ANSI/ANS 15.4-2016. Consistent with the requirements of 10 CFR 50.54, paragraphs (i), (j), (k), (l), and (m)(1), SHINE's minimum staffing ensures that manipulation of controls of the facility will be performed by licensed operators or senior operators as provided in 10 CFR Part 55; manipulation of apparatus and mechanisms other than controls that may affect reactivity or power level will only be performed with the knowledge and consent of a licensed operator or senior operator pursuant to 10 CFR Part 55; an operator or senior operator licensed pursuant to 10 CFR shall be present at the controls at all times during operation; individuals shall be designated to be responsible for directing licensed activities of license operators; and a senior operator shall be present at the facility or readily available on call at all times during operation and as prescribed in the facility license.

Therefore, the NRC staff finds that the SHINE staffing meets the requirements of the NRC's regulations.

In SHINE FSAR Section 12.1.4, "Selection and Training of Personnel," SHINE describes the minimum qualification for each level of personnel. Consistent with ANSI/ANS 15.4-2016, SHINE describes the necessary experience, education, and training for each of the four qualifications levels and other technical personnel. SHINE also provides for radiation training consistent with the requirements in 10 CFR 19.12, "Instruction to Workers."

Therefore, the NRC staff finds that SHINE will select staff that meet minimum qualifications acceptable for non-power production and utilization facilities. Radiation protection training and specialized training will be conducted at an acceptable level. SHINE describes its initial training and requalification program in SHINE FSAR Section 12.10, which is evaluated by the NRC staff in Section 12.4.10 of this SER.

In SHINE FSAR Section 12.1.5, "Radiation Safety," SHINE refers to the information in SHINE FSAR sections 12.1.1 and 12.1.2 for the organizational structure and responsibilities for radiation safety. As depicted in SHINE FSAR Figure 12.1-1, the Radiation Safety Function has communication lines established with the Chief Executive Officer, Review and Audit Committee, and Shift Supervisor, which are separate from its reporting line to the Diagnostics General Manager. Consistent with the acceptance criteria in NUREG-1537, Part 2, Section 12.1, "Organization," SHINE states the following:

RP [Radiation Projection] staff maintain the ability to raise safety issues with the review and audit committee or executive management. The RP staff encompasses the clear responsibility and ability to interdict or terminate licensed activities that it believes are unsafe. This does not mean that the RP staff possesses absolute authority. If facility managers, the review and audit committee, and executive management agree, the decision of the RP staff could be overruled. However, this would be a rare occurrence that would be carefully analyzed and considered.

Therefore, the NRC staff finds that SHINE has described a radiation safety organization that is acceptable. 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.

## **12.4.2 Review and Audit Activities**

The NRC staff evaluated the sufficiency of SHINE's review and audit activities, as presented in SHINE FSAR Section 12.2, using the applicable guidance and acceptance criteria from Section 12.2, "Review and Audit Activities," of NUREG-1537, Parts 1 and 2. Consistent with the review criteria in Chapter 14 of NUREG-1537, Part 2, Section 12.2, and ANSI/ANS 15.1-2007, the NRC staff evaluated the description of the SHINE review and audit activities to ensure that the FSAR provides a basis for the technical specification requirements for the review and audit function.

In SHINE FSAR Section 12.2.1, "Composition and Qualifications," SHINE describes a review and audit function for the facility. Consistent with ANSI/ANS 15.1-2007, the committee members appear to be well qualified, with a wide spectrum of expertise. The committee membership includes provisions for including persons from outside the company. Therefore, the NRC staff has determined that the committee membership is acceptable.

In SHINE FSAR Section 12.2.2, "Charter and Rules," SHINE describes the charter for the review and audit committee. Consistent with ANSI/ANS 15.1-2007, SHINE 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. Therefore, the NRC staff has determined that the charter and rules for the committee are acceptable.

In SHINE FSAR Sections, 12.2.3, "Review Function," and 12.2.4, "Audit Function," SHINE provides lists of the minimum items to be reviewed and audited, respectively. Except as described below, SHINE has followed the guidance in ANSI/ANS 15.1-2007 for establishing its lists of items to be reviewed and audited.

With respect to reviews, the NRC staff finds it acceptable that SHINE has excluded experiments from its list of items to be reviewed since it will not be conducting experiments at its facility. With respect to audits, the NRC staff finds it acceptable that SHINE has included its quality assurance program description, physical security plan, and nuclear criticality safety program within the scope of items to be audited as this goes beyond the minimum provided in ANSI/ANS 15.1-2007.

Therefore, the NRC staff finds that SHINE has proposed a comprehensive and acceptable list of items that the committee will review and audit.

### **12.4.3 Procedures**

The NRC staff evaluated the sufficiency of the SHINE procedures, as presented in SHINE FSAR Section 12.3, using the applicable guidance and acceptance criteria from Section 12.3, "Procedures," in NUREG-1537, Part 1 and 2. Consistent with the review criteria of Chapter 14 of NUREG-1537, Part 2, Section 12.3, and ANSI/ANS 15.1-2007, the NRC staff evaluated the description of the SHINE procedure activities to ensure that the FSAR provides a basis for the technical specification requirements for procedures.

In SHINE FSAR Section 12.3, SHINE describes the review and approval process for procedures and also describes the method for making minor and substantive changes to existing procedures and for the temporary deviation from procedures during operation. Except as described below, SHINE has followed the guidance in ANSI/ANS 15.1-2007 for describing its review and approval process; methodology for making changes or deviations; and the topics for which written procedures will be prepared, reviewed, and approved.

Because SHINE is not a reactor, the NRC staff finds it acceptable that the topics for which written procedures will be prepared, reviewed, and approved, will include topics related to SHINE's IUs and target solution. The NRC staff also finds that it is acceptable for SHINE to exclude topics related to experiments since it will not be conducting experiments at its facility.

Therefore, the NRC staff finds that SHINE has proposed a set of required procedures that is appropriate to operation of the facility, and that the process and method described by SHINE will ensure proper management control and proper review of procedures.

#### **12.4.4 Required Actions**

The NRC staff evaluated the sufficiency of the SHINE required actions, as presented in SHINE FSAR Section 12.4, using the applicable guidance and acceptance criteria from Section 12.4, "Required Actions," in NUREG-1537, Part 1 and 2. Consistent with the review criteria of Chapter 14 of NUREG-1537, Part 2, Section 12.4, and ANSI/ANS 15.1-2007, the NRC staff evaluated the description of the SHINE required actions to ensure that the FSAR provides a basis for the technical specification requirements for required actions.

In SHINE FSAR Section 12.4, SHINE describes the required actions, as provided in the technical specifications, to be taken in the event of either a safety limit violation or an occurrence requiring a special report other than a safety limit violation. Except as described below, SHINE has followed the guidance in ANSI/ANS 15.1-2007 for defining reportable events and the actions to be taken should a reportable event occur.

Because SHINE is not a reactor, the NRC staff finds it acceptable for SHINE to use language encompassing operations and processes within both its IF and RPF as being within scope of reportable events and actions to be taken should a reportable event occur.

Therefore, the NRC staff finds that SHINE has defined a group of incidents as reportable events and has described the required actions it will take if the reportable event occurs. The definition of reportable events gives reasonable assurance that safety-significant events will be reported by the applicant. The staff also finds that SHINE has proposed actions to be taken if a safety limit is violated or a reportable event occurs. The NRC staff has determined that SHINE will take whatever actions are necessary to protect the health and safety of the public.

#### **12.4.5 Reports**

The NRC staff evaluated the sufficiency of the SHINE reports, as presented in SHINE FSAR Section 12.5, using the applicable guidance and acceptance criteria from Section 12.5, "Reports," in NUREG-1537, Part 1 and 2. Consistent with the review criteria of Chapter 14 of NUREG-1537, Part 2, Section 12.5, and ANSI/ANS 15.1-2007, the NRC staff evaluated the description of the SHINE reports to ensure that the FSAR provides a basis for the technical specification requirements for reports.

In SHINE FSAR Section 12.5, SHINE provides listings of both the content and timing of submission to the NRC of annual operating reports and special reports for unplanned events or planned major facility and administrative changes. Except as described below, SHINE has followed the guidance in ANSI/ANS 15.1-2007 for the content, timing of submittals, and distribution of its operating and special reports.

For annual operating reports, the NRC staff finds the following deviations from ANSI/ANS 15.1-2007 acceptable:

- Exclusion of the tabulation of new tests or experiments because SHINE will not be performing tests or experiments at its facility
- Providing results of individual monitoring carried out by SHINE for each individual for whom monitoring is required by 10 CFR 20.1502, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," because this is more conservative than the criterion provided in ANSI/ANS 15.1-2007

Therefore, the NRC staff finds that SHINE has described the content, the timing of the submittal, and the distribution of the reports to ensure that important information will be provided to the NRC in a timely manner.

#### **12.4.6 Records**

The NRC staff evaluated the sufficiency of the SHINE records, as presented in SHINE FSAR Section 12.6, using the applicable guidance and acceptance criteria from Section 12.6, "Records," in NUREG-1537, Part 1 and 2. Consistent with the review criteria of Chapter 14 of NUREG-1537, Part 2, Section 12.6, and ANSI/ANS 15.1-2007, the NRC staff evaluated the description of the SHINE records to ensure that the FSAR provides a basis for the technical specification requirements for records.

In SHINE FSAR Section 12.6, SHINE describes the scope of its record management program from identification to disposition, as well as the storage method of keeping records in the SHINE electronic data management system. Except as described below, SHINE has provided a list of records to maintained for one of the following time periods consistent with ANSI/ANS 15.1-2007: 1) lifetime of the SHINE facility, 2) five years or for the life of the component involved if less than five years, or 3) at least one operator certification cycle.

For the records to be maintained for five years or for the life of the component involved if less than five years, the NRC staff finds the following deviations from ANSI/ANS 15.1-2007 acceptable:

- Exclusion of records for experiments because SHINE will not be performing experiments at its facility
- Maintaining records for radioactive material inventories rather than fuel inventories because SHINE will have special nuclear material in the form of an aqueous target solution rather than heterogeneous fuel

Therefore, the NRC staff finds that SHINE has described the types of records that will be retained by the facility and the period of retention to ensure that important records will be retained for an appropriate time.

#### **12.4.7 Emergency Planning**

#### **12.4.8 Security Planning**

#### **12.4.9 Quality Assurance**

#### **12.4.10 Operator Training and Requalification**

#### **12.4.11 Startup Plan**

#### **12.4.12 Environmental Reports**

SHINE FSAR Section 12.12, "Environmental Reports," is vacated. SHINE submitted its supplement to the applicant's environmental report separately. The NRC staff's evaluation of this is documented in NUREG-2183, "Supplement 1 – Environmental Impact Statement Supplement Related to the Operating License for the SHINE Medical Isotope Production Facility."

#### **12.4.13 Material Control and Accounting Plan**

### **12.5 Review Findings**

The NRC staff reviewed the descriptions and discussions of SHINE's conduct of operations, as described in SHINE FSAR Chapter 12, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the FSAR and independent confirmatory review, the NRC staff determined that:

- (1) SHINE described the conduct of operations and identified the major features or components incorporated therein for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

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