12.0 CONDUCT OF OPERATIONS

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

This chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) 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 SHINE conduct of operations, as presented in chapter 12, “Conduct of Operations,” of the SHINE final safety analysis report (FSAR) and supplemented by the applicant’s response to staff 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 and 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 section 12.1, “Organization,” section 12.2, “Review and Audit Activities,” section 12.3, “Procedures,” section 12.4, “Required Actions,” section 12.5, “Reports,” section 12.6, “Records,” section 12.7, “Emergency Planning,” section 12.8, “Security Planning,” section 12.9, “Quality Assurance,” section 12.10, “Operator Training and Requalification,” section 12.11, “Startup Plan,” and section 12.13, “Material Control and Accountability Plan.”

SHINE FSAR section 12.12, “Environmental Reports,” is vacated. By letter dated November 16, 2021, SHINE submitted Revision 7 of its operating license stage supplement to its construction permit stage environmental report for the SHINE facility (Agencywide Documents Access and Management System Accession No. ML21320A066). The NRC staff’s evaluation of the environmental, economic, technical, and other benefits against the environmental and other costs of the proposed action of deciding whether to issue an operating license for the SHINE facility, based, in part, on SHINE’s supplemental environmental report, is documented in NUREG-2183, Supplement 1, “Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility.”

12.3 <u>Regulatory Requirements and Guidance and Acceptance Criteria</u>

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 information regarding SHINE's conduct of operations 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:

- Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34, "Contents of applications; technical information," paragraph (b)(6)

- 10 CFR 50.36, "Technical specifications"

- 10 CFR 50.40, "Common standards"

- 10 CFR 50.57, "Issuance of operating license"

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

- 10 CFR 70.22, "Contents of applications," paragraph (k)

- 10 CFR 70.34, "Amendment of licenses"

- 10 CFR 73.67, "Licensee fixed site and in-transit requirements for the physical protection
- n of special nuclear material of moderate and low strategic significance," paragraphs (a), (c), (d) and (e)

- 10 CFR 73.57, "Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information"

- 10 CFR 73.71, "Reporting of Safeguards Events"

- 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"

As discussed below, the NRC staff determined that the licensed operator requirements of 10 CFR Part 55, "Operators' Licenses," applicable to test and research/non-power reactors must apply at the SHINE facility to provide, in part, reasonable assurance that the activities authorized by the operating license can be conducted without endangering the health and safety of the public. Accordingly, the conditions in every nuclear power reactor operating license issued under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," that are generally related to licensed operators at facilities with 10 CFR Part 50 operating licenses, 10 CFR 50.54(i), (i-1), (k), (l), and (m)(1) must also be conditions in the SHINE operating license. Therefore, the NRC conditions the SHINE operating license as follows:

> The requirements of 10 CFR Part 55 applicable to test and research/non-power reactors apply at the SHINE facility. Accordingly, this license shall also be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(i), (i-1), (k), (l) and (m)(1).

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 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.

- Regulatory Guide (RG) 5.59, Revision 1, “Standard Format and Content for Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance” (ML100341301).

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

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

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 SHINE’s conduct of operations for the issuance of an operating license. The sufficiency of SHINE’s 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 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 these guidance and acceptance criteria, the staff used chapter 14, “Technical Specifications,” of NUREG-1537, ANSI/ANS-15.1-2007, “The Development of Technical Specifications for Research Reactors,” and ANSI/ANS-15.4-2016, “Selection and Training of Personnel for Research Reactors,” to evaluate the description of the SHINE organization to ensure that the SHINE FSAR provides a basis for the TS requirements for the organization.

SHINE FSAR section 12.1.1, “Structure,” including 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 shows the various levels of the organization, including reporting and communication lines between operations staff, supervisors, managers, and committees.

Based on its review, the NRC staff determined that SHINE presented an organizational structure that reflects the complete SHINE facility organization from the license holder to the operations staff. All organizational relationships important to safety are 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 and is, therefore, acceptable.

SHINE FSAR section 12.1.2, “Responsibility,” describes the responsibilities of the persons in the organizational structure described in SHINE FSAR section 12.1.1 and SHINE FSAR 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 SHINE facility and for the protection of the health and safety of the workers and the public has been shown.

SHINE FSAR section 12.1.3, “Staffing,” describes the SHINE facility staffing requirements that demonstrate the ability to safely operate the facility and protect the health and safety of the workers and the public consistent with ANSI/ANS-15.4-2016. SHINE’s minimum staffing ensures that the manipulation of the controls of the facility will be performed by licensed operators or senior operators as provided in 10 CFR Part 55; an operator or senior operator licensed pursuant to 10 CFR Part 55 will be present at the controls at all times during operation; licensed senior operators will be designated to be responsible for directing licensed activities of license operators; and a senior operator will 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 applicable acceptance criteria in NUREG-1537, Part 2, and the ISG augmenting NUREG-1537, Part 2, for the issuance of an operating license.

SHINE FSAR section 12.1.4, “Selection and Training of Personnel,” 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 for 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 acceptable minimum qualifications. Also, radiation protection training and specialized training will be conducted at an acceptable level. SHINE describes its initial training and requalification program for licensed operators in SHINE FSAR section 12.10, which is evaluated by the staff in section 12.4.10 of this SER.

SHINE FSAR section 12.1.5, “Radiation Safety,” 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 section 12.1 of NUREG-1537, Part 2, SHINE stated the following:

> RP [Radiation Protection] 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, and of the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE review and audit activities to ensure that the SHINE FSAR provides a basis for the TS requirements for the review and audit function.

SHINE FSAR section 12.2.1, “Composition and Qualifications,” describes a review and audit function for the facility. Consistent with ANSI/ANS-15.1-2007, the review and audit 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 finds that the committee membership is acceptable.

SHINE FSAR section 12.2.2, “Charter and Rules,” describes the charter for the review and audit committee. Consistent with ANSI/ANS-15.1-2007, SHINE 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 finds that the charter and rules for the committee are acceptable.

SHINE FSAR sections 12.2.3, “Review Function,” and 12.2.4, “Audit Function,” provide lists of the minimum items to be reviewed and audited, respectively. Except as described below, SHINE 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 excluded experiments from its list of items to be reviewed since SHINE will not be conducting experiments at its facility. With respect to audits, the staff finds it acceptable that SHINE 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 items in ANSI/ANS-15.1-2007.

Therefore, the NRC staff finds that SHINE 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 SHINE’s procedures, as presented in SHINE FSAR section 12.3, using the applicable guidance and acceptance criteria from section 12.3, “Procedures,” of NUREG-1537, Parts 1 and 2 and of the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE procedures to ensure that the SHINE FSAR provides a basis for the TS requirements for procedures.

SHINE FSAR section 12.3 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 followed the guidance in ANSI/ANS-15.1-2007 for describing its review and approval process for procedures; methodology for making changes to or deviations from procedures; and the topics for which written procedures will be prepared, reviewed, and approved.

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

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

12.4.4 Required Actions

The NRC staff evaluated the sufficiency of SHINE's 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, Parts 1 and 2 and from the ISG augmenting NUREG--1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS--15.1-2007 to evaluate the description of the SHINE required actions to ensure that the SHINE FSAR provides a basis for the TS requirements for required actions.

SHINE FSAR section 12.4 describes the required actions, as provided in the TSs, 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 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 the SHINE facility is not a reactor, the NRC staff finds it acceptable for SHINE to use language encompassing operations and processes within both the IF and RPF as being within the scope of reportable events and the actions to be taken should a reportable event occur.

Therefore, the NRC staff finds that SHINE defined specific incidents as reportable events and described the required actions to be taken if a reportable event occurs. The definition of reportable events provides reasonable assurance that safety-significant events will be reported by the applicant. The staff also finds that SHINE proposed actions to be taken if a safety limit is violated or a reportable event occurs. Based on the above, the staff concludes that SHINE will take the actions necessary to protect the health and safety of the public.

12.4.5 Reports

The NRC staff evaluated the sufficiency of SHINE's reports, as presented in SHINE FSAR section 12.5, using the applicable guidance and acceptance criteria from section 12.5, "Reports," in NUREG-1537, Parts 1 and 2 and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE reports to ensure that the SHINE FSAR provides a basis for the TS requirements for reports.

SHINE FSAR section 12.5 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 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

- Provision of 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 adequately 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 SHINE’s records, as presented in SHINE FSAR section 12.6, using the applicable guidance and acceptance criteria from section 12.6, “Records,” in NUREG-1537, Parts 1 and 2 and from the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used chapter 14 of NUREG-1537 and ANSI/ANS-15.1-2007 to evaluate the description of the SHINE records to ensure that the SHINE FSAR provides a basis for the TS requirements for records.

SHINE FSAR section 12.6 describes the scope of the SHINE 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 provided a list of records to be maintained for one of the following time periods consistent with ANSI/ANS-15.1-2007: (1) the 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 of records for radioactive material inventories rather than for 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 adequately described the types of records that will be retained by the facility and their period of retention to ensure that important records will be retained for an appropriate time.

12.4.7 Emergency Planning

The NRC staff evaluated the SHINE Emergency Plan, presented in document EMG-01-01, Revision 2, “Emergency Plan” (ML22202A451), (the SHINE Emergency Plan), against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess its sufficiency. Previously, the staff reviewed the SHINE Preliminary Emergency Plan (ML13269A378), submitted as part of SHINE’s construction permit application. In its safety evaluation report associated with the construction permit application (ML16229A140), the staff identified several regulatory commitments concerning the emergency plan that the applicant was to address in the SHINE Emergency Plan and in the SHINE FSAR supporting the operating license application. The staff confirmed that all of the regulatory commitments previously identified have been satisfactorily addressed. The specific regulatory commitments are not individually documented in this SER, as the review effort was conducted to ensure that the SHINE Emergency Plan satisfies the appropriate regulatory guidance and acceptance criteria and, therefore, meets the applicable regulatory requirements.

Section 50.34(b)(6)(v) of 10 CFR requires that each application for an operating license include an FSAR that contains, among other things, the applicant’s plans for coping with emergencies, including the items specified in appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities,” to 10 CFR Part 50.

Footnote 2 to section I.3 of appendix E to 10 CFR Part 50 specifies that RG 2.6 will be used as guidance for the acceptability of research and test reactor emergency response plans. RG 2.6, Revision 2, “Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities” (ML17263A472), in turn endorses ANSI/ANS-15.16-2015, “Emergency Planning for Research Reactors.” This standard identifies the elements of an emergency plan for minimizing the accident consequences at non-power reactors.

The NRC staff evaluated the sufficiency of the SHINE Emergency Plan using the applicable guidance and acceptance criteria from section 12.7, “Emergency Planning,” of NUREG-1537, Parts 1 and 2 and of the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used ANSI/ANS-15.16-2015, NUREG-0849, “Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors” (ML062190191), and NUREG-1520, Revision 2, “Standard Review Plan for Fuel Cycle Facilities License Applications” (ML15176A258), as appropriate, to evaluate the SHINE Emergency Plan.

12.4.7.1 Introduction

The guidance in section 1.0, “Introduction,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.1, “Introduction,” of ANSI/ANS-15.16-2015 provides that the emergency plan should contain a description of the facility including the authorized power level of the facility, the location of the facility, and the access routes to the facility. The owner and operator of the facility should be identified, and the objectives of the emergency plan explained.

The NRC staff reviewed section 1, “Introduction,” of the SHINE Emergency Plan, including associated figures, site layout, and maps provided in the plan. The SHINE Emergency Plan provides that the SHINE facility is owned and operated by SHINE Medical Technologies, LLC and is located at 4021 South US Highway 51, Janesville WI, 53546.

The SHINE facility includes the following structures:

- Main production facility,
- Resource building,
- Material staging building,
- Storage building, and
- Nitrogen purge system structure

The SHINE facility involves the use of a non-reactor based, subcritical fission process for the purpose of manufacturing medical isotopes. The SHINE facility contains IUs, each with a target solution vessel with a licensed fission power of 125 kilowatts-thermal, located in the IF area of the main production facility. Also located in the IF are rooms and cells housing off-gas handling equipment, cooling equipment, tritium purification equipment, and an area for servicing neutron drivers.

The RPF area of the main production facility contains a hot cell bank; below-grade vaults containing tanks, other process components, and storage space; two laboratories; and areas for waste handling, cooling, and other equipment. The remaining areas of the facility (the control room area and the administrative annex area) contain the control room, electrical equipment, additional auxiliary equipment, and other miscellaneous areas.

The SHINE site consists of an approximately 91-acre parcel in the City of Janesville, Rock County, Wisconsin and is accessed from U.S. Highway 51. Figure 1, “SHINE Facility Site Layout,” of appendix 1, “Figures,” to the SHINE Emergency Plan depicts the site boundary, fences, gates, roads and parking lots on site, onsite structures and tanks, and U.S. Highway 51. Figure 2, “SHINE Main Production Facility General Arrangement,” depicts the general arrangement layout of the main production facility, which includes the IF, RPF, control room area, and administrative annex area. Figure 3, “SHINE Site Buildings and Surrounding Area,” provides an aerial view of the area surrounding the SHINE site, including the location of onsite structures and sensitive facilities near the SHINE site (0-1 mile), including churches, parks, residences, airstrips, and educational facilities. Farms are distributed throughout the one-mile radius of the SHINE site. There are no medical facilities within one mile of the SHINE site. Figure 4, “SHINE Site General Area Map,” contains a general area map constructed from U.S. Geological Survey topographical quadrangles and includes the SHINE facility site boundary.

The major activities conducted at the SHINE facility are: (1) preparation and irradiation of uranyl sulfate target solution and (2) extraction, purification, and packaging of medical isotopes from irradiated target solution inside hot cells. The SHINE facility contains radioactive and hazardous materials that are part of the overall medical isotope production process. Appendix 2, “Radioactive and Hazardous Materials,” to the SHINE Emergency Plan provides the types, quantities, and locations of radioactive and hazardous materials normally on the SHINE site.

The SHINE main production facility contains a facility vent stack for facility emissions. The stack uses high efficiency particulate air filters and single stage high efficiency gas adsorption filter equipment for emission control. There is a stack release monitor that provides information on radiation released from the facility stack.

Section 1.9, “Accident Summary,” of the SHINE Emergency Plan describes the general types of accidents that may require the implementation of protection actions. Additional information on potential facility accidents is contained in chapter 13, “Accident Analysis,” of the SHINE FSAR. Measures and equipment used to respond to and detect accidents and releases are described in section 9, “Emergency Facilities and Equipment,” of the SHINE Emergency Plan.

The NRC staff finds that the information in the SHINE Emergency Plan concerning the site layout and location, consideration of access routes, surrounding population distribution, land use and jurisdictional boundaries, authorized power level, identification of the owner and operator of the facility, and an explanation of the objectives of the emergency plan are acceptable and meet the relevant standards set forth in NUREG-0849 and the ISG augmenting NUREG-1537. The staff concludes that this information meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.2 Definitions

The guidance in section 2.0, “Definitions,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.2, “Definitions,” of ANSI/ANS-15.16-2015 provides that the emergency plan should identify definitions for terms that are unique to the facility and should include phrases with meanings specific to the facility.

The NRC staff reviewed section 2, “Definitions” of the SHINE Emergency Plan, which describes the terms defined as having special meaning unique to the facility, as well as acronyms and abbreviations used throughout the document. The staff finds the defined terms, acronyms, and abbreviations to be complete and to be used consistently throughout the document. The staff finds the information acceptable and determined that the definitions, acronyms, and abbreviations are consistent with the guidance in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.3 Organization and Responsibilities

The guidance in section 3.0, “Organization and Responsibilities,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.3, “Organization and Responsibilities,” of ANSI/ANS-15.16-2015 provides that the emergency plan should identify the emergency organization, including the onsite emergency organization, 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, including 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; of coordinating emergency preparedness planning, updating emergency plans and procedures, and coordinating plans with other supporting organizations; of relating information about the emergency to the news media and the public, and 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.

- The identification by title of the individuals who will declare an alert or site area emergency classification, activate the onsite emergency response organization (ERO) during all shifts, promptly notify offsite response authorities that an alert or site area emergency classification 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.

Section 3.1, "Emergency Response Organization," of the SHINE Emergency Plan states that the ERO is responsible for taking actions in an emergency to avoid an accident or to mitigate the consequences of one. At the SHINE facility, the ERO would be staffed with trained and qualified personnel that would be required to attend formal initial and continuing training, as well as participate in drills and exercises. In addition, the applicant explained that the ERO at the SHINE facility would consist of two groups of personnel: (1) the normal facility operating organization and (2) the facility emergency organization.

As summarized below, the on-shift personnel present at the site will initially staff the facility emergency organization. Upon activation of the ERO, designated off-shift personnel will be notified to report to the Emergency Support Center (ESC), once it has been activated, or to the control room if the ESC has not yet been activated. Section 7, "Activation of the ERO and Notification," of the SHINE Emergency Plan further describes this response effort.

The NRC staff reviewed section 3, "Organization and Responsibilities," of the SHINE Emergency Plan. The organization for managing and operating the SHINE facility is provided in figure 10, "SHINE Normal Facility Operation Organization Chart," of Appendix 1 to the SHINE Emergency Plan and is summarized below.

Chief Executive Officer (CEO): The CEO is responsible for the overall management and leadership of the company.

Diagnostics General Manager: The Diagnostics General Manager is responsible for operational aspects of the diagnostics division.

Director of Plant Operations: The Director of Plant Operations is responsible for the overall operation of the facility.

Director of Corporate Support: The Director of Corporate Support is responsible for facility radiation protection, security, and training.

Operations: The facility operations personnel are responsible for the operation of the facility and safe, reliable, and efficient plant operations.

Security: The facility security personnel are responsible for the physical security of the facility.

Engineering: The facility engineering personnel are responsible for providing technical expertise and support of facility operation and maintenance, and for controlling the physical facility configuration to ensure that facility operation, maintenance, and configuration are maintained in accordance with the design basis.

Radiation Protection: The facility radiation protection personnel, which are part of the facility technical staff, are responsible for the handling and monitoring of radioactive materials.

Maintenance: The facility maintenance personnel are responsible for performing maintenance on facility equipment in accordance with facility procedures, instructions, and technical requirements.

Chemistry: The facility chemistry personnel, which are part of the facility technical staff, are responsible for sampling, analysis, and product quality control activities.

Executive, support, administrative, and other personnel ("support personnel"): These individuals have various responsibilities involving procurement, licensing, quality, finance, etc., and may include personnel normally stationed offsite.

<u>On-shift personnel</u>

Shift supervisor: A senior licensed operator responsible for the safe operation of the facility.

Licensed operators (including any additional on-shift senior licensed operators, if present): Responsible for ensuring that licensed activities are conducted safely and in accordance with the facility license and procedures.

Non-licensed operating staff: Responsible for conducting operations in the facility in accordance with procedures and under the direction of licensed operators.

Security personnel: Responsible for the physical security of the facility.

Radiation protection individual: At least one individual capable of monitoring radiation dose rates and contamination levels is present on each shift.

During an emergency, personnel may deviate from actions described in the SHINE Emergency Plan for unusual or unanticipated conditions. The ERO at the SHINE facility is comprised of the following individuals, as illustrated by figure 11, “SHINE Facility Emergency Organization,” of Appendix 1 to the SHINE Emergency Plan:

- Emergency Director: The Emergency Director is authorized to and responsible for directing and coordinating the overall emergency response. The Emergency Director has the following non-delegable responsibilities:

  - Emergency event classification and decision to declare an emergency;
  - Decision to activate the ERO;
  - Decision to initiate on-site protective actions;
  - Decision to notify off-site response authorities;
  - Decision to request support from off-site organizations;
  - Authorization of reentry into portions of the facility or site that may have been evacuated during the emergency;
  - Authorization of volunteer emergency workers to incur radiation exposures in excess of normal 10 CFR Part 20 occupational limits; and
  - Decision to terminate the emergency and initiate recovery actions.

The Emergency Director may delegate the following responsibilities, based on his/her decision (as stated above):

  - Notifying the appropriate personnel to activate the ERO;
  - Performing the notification of offsite response authorities within 15 minutes of when a Notification of Unusual Event, Alert, or Site Area Emergency classification;
  - Notification of the NRC Operations Center within one hour of declaring the emergency;
  - Assessment of damage to and status of the facility’s capabilities to safely control radioactive material or hazardous chemicals associated with licensed activities;
  - Prioritizing responses to concurrent emergencies; and
  - Informing the ERO of planned emergency organization actions or changes.

- Shift Supervisor: The Shift Supervisor acts as the initial Emergency Director upon declaration of an emergency. Additionally, the Shift Supervisor has the following responsibilities:

  - Implementing immediate actions to respond to the emergency in accordance with facility emergency procedures;
  - Directing and supervising the activities of the control room staff; and
  - Safe operation of the plant in compliance with the facility NRC operating license, technical specifications, facility operating procedures, and the requirements for their use.

- Emergency Communicator: The Emergency Communicator assists in the execution of the Emergency Director’s duties. The Emergency Communicator is responsible for:

- Exchanging information with offsite authorities responsible for coordinating and implementing off-site emergency measures, including transmitting dose projections, and monitoring and surveying information;
- Relating information about the emergency situation to the news media and the public; and
- Ensuring a record of the events during and following the emergency is maintained.

- Radiation Safety Coordinator: The Radiation Safety Coordinator is responsible for making radiological assessments and advising the Emergency Director, including responsibility for the following tasks:

  - Making on-site and off-site dose assessments and projections;
  - Recommending protective actions; and
  - Identifying exposed personnel and determining their radiation dose.

- Technical Support Coordinator: The Technical Support Coordinator is responsible for coordinating the technical response to the event, including:

  - Performing technical assessments of facility emergencies;
  - Assisting the Emergency Director and Radiation Safety Coordinator in technical matters; and
  - Coordinating the technical staff to augment the ERO on an as-needed basis to support accident assessment and mitigation activities.

- Criticality Safety Engineer: A criticality safety engineer is called-in upon activation of the ERO, at the discretion of the Emergency Director or Technical Support Coordinator, if a criticality event is suspected or confirmed. The Criticality Safety Engineer is responsible for the following tasks:

  - Advising and assisting the Emergency Director in responding to the criticality accident; and
  - Assisting the Radiation Safety Coordinator in conducting a radiological dose assessment appropriate for a criticality accident.

- Security personnel: Security personnel that are present at the facility when an emergency is declared will implement emergency plan implementing procedures (EPIPs) appropriate to the event classification. Security personnel are responsible for the following tasks:

  - Performing personnel Accountability, if required; and
  - Implementing access control of facility areas at the direction of the Emergency Director, if required.

- Operations personnel: Operations personnel that are present at the facility when an emergency is declared will implement EPIPs appropriate to the event classification. Operations personnel are responsible for performing the following tasks:

  - Monitoring facility instrumentation and reporting results to the Emergency Director; and
  - Implementing corrective actions at the direction of the Emergency Director.

- Assessment Teams: Assessment Teams are comprised of facility operations, technical staff, or support personnel that may be called upon by the Emergency Director following activation of the ERO. Assessment Teams are responsible for the following tasks:

  - Collecting on-site and off-site field monitoring data;
  - Monitoring radiation dose rates and contamination levels; and
  - Assessing collateral damage to the facility.

- Reentry and Damage Control Teams: Reentry and Damage Control Teams are comprised of facility operations, technical staff, or support personnel who may be called-in by the Emergency Director upon activation of the ERO. Reentry and Damage Control Teams are responsible for the following tasks:

  - Reentering an immediate evacuation zone during the emergency on a voluntary basis after being informed of the potential hazards and risks; and
  - Performing actions at the direction of the Emergency Director associated with controlling and stabilizing emergency events in-progress.

Section 3.4, “Emergency Support Organizations,” of the SHINE Emergency Plan states that in the event that the Emergency Director makes the decision to request support from offsite organizations, the following offsite support agencies and organizations would aid:

- Janesville Fire Department: Fire support, first aid support, ambulance services, and hazardous materials response;

- Janesville Police Department: Law enforcement support;

- SSM [Sisters of St. Mary] Health St. Mary’s Hospital: Support services for any radiation exposed or contaminated injured individuals transported from the site;

- Rock County Emergency Management: Responsible for coordinating major emergencies, disaster response, and recovery efforts in support of county and local governments; and

- The State of Wisconsin: Has the general authority and responsibility to assist local units of government and local law enforcement agencies in responding to a disaster or the imminent threat of a disaster. The State of Wisconsin coordinates its response with Rock County Emergency Management as needed.

SHINE stated that local government agencies and organizations, as described above, will be initially notified as described in section 7 of the SHINE Emergency Plan by contacting the Rock County 911 Communications Center. The applicant further explained that the SHINE facility does not anticipate the need for State or Federal assistance. The NRC staff confirmed that Appendix 3, “Agreement Letters” to the SHINE Emergency Plan provides arrangements and agreements with the support organizations described above that would augment and extend the capability of the facility's emergency organization as specified in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537.

Section 3.3, paragraph (2) of ANSI/ANS-15.16-2015 states, in part, that the organizational description shall include, as applicable, the authority and responsibility of each support agency or organization (local, county, state, or all three) having radiological emergency responsibilities for emergency preparedness planning and emergency response assistance. Section 3.4 of the SHINE Emergency Plan states, in part, that in the event that the decision is made by the Emergency Director to request support from those offsite agencies and organizations, assistance as outlined above would be provided. The applicant further stated that the State of Wisconsin has the general authority and responsibility to assist local units of government and local law enforcement in responding to a disaster or the imminent threat of a disaster and will coordinate its response with Rock County Emergency Management, as needed.

Section 3.7.1, "Activation of emergency organization," of ANSI/ANS-15.16-2015 states the specific actions to take to notify and mobilize the emergency organization and the applicable offsite support organizations for each emergency class. Section 7.3, "Notification of Off-site Organizations," of the SHINE Emergency Plan states that the Emergency Director ensures that emergency notifications are promptly made to offsite emergency response organizations and that a notification will be made to the State of Wisconsin promptly after notification to the NRC.

Section 3.5, "Maintaining Emergency Preparedness," of the SHINE Emergency Plan describes the roles and responsibilities of individuals that have roles related to maintaining emergency preparedness. The SHINE Emergency Plan provides a description of how the effectiveness of the emergency plan will be maintained, including training, review, and update of the emergency plan and associated implementing procedures along with maintenance and inventory of equipment and supplies that would be used in an emergency.

Section 3.10.1, "Training and drills," of ANSI/ANS-15.16-2015 identifies and describes training and drill criteria to demonstrate emergency preparedness. Section 3.10.1 states that at least every two years, exercise drills shall contain provisions for coordination with off-site emergency personnel. Section 11.4.2, "Planning and Controlling Drills and Exercises," of the SHINE Emergency Plan states that off-site organizations or governments, including city, county, and State agencies, shall be invited and allowed to participate in drills or exercises at their request.

Based on the above, the NRC staff finds that section 3 of the SHINE Emergency Plan provides an adequate description of the emergency organization that would be activated to cope with radiological emergencies as it pertains to the onsite emergency organization and any augmentation necessary from offsite groups. Personnel or groups that will fill positions in the emergency organization are adequately identified by title and described within the SHINE Emergency Plan as specified in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.4 Emergency Classification System

The guidance in section 4.0, "Emergency Classification System," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.4, "Emergency Classification System," of ANSI/ANS-15.16-2015 provides the following standard emergency classifications; however, it states that each emergency plan shall include only those standard classifications appropriate for dealing with accident consequences determined to be credible for the specific facility:

- Notification of Unusual Event;
- Alert;
- Site Area Emergency; and
- General Emergency.

The NRC staff reviewed section 4, “Emergency Classification System,” of the SHINE Emergency Plan. The SHINE Emergency Plan provides for the classification of emergencies according to the severity of offsite radiological consequences. The standard classifications for the SHINE facility are: Notification of Unusual Event; Alert; and Site Area Emergency, which is consistent with the guidance in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015. SHINE identified no credible accidents for the SHINE facility that would result in radiological levels exceeding the action levels for a General Emergency classification level at the site boundary. As a result, the SHINE Emergency Plan does not include provisions for a General Emergency classification.

Section 4.2, “Emergencies Less Severe Than Notification of Unusual Events,” of the SHINE Emergency Plan also recognizes emergencies of lesser consequences than the Notification of Unusual Event classification level. SHINE explained that these include physical occurrences within the facility requiring facility emergency organization response. Responses to these emergencies of lesser consequence than a Notification of Unusual Event are based on the recognition of immediate need for onsite staff to implement emergency measures to provide aid to affected persons or to mitigate the consequences of damage to equipment, coupled with assessing radiological monitors to determine if the possibility of a more serious emergency is present. Situations of lesser consequence than Notification of Unusual Events that may warrant implementation of portions of the SHINE Emergency Plan or select EPIPs are identified within section 4.2 of the plan.

Section 4.3, “Notification of Unusual Event,” of the SHINE Emergency Plan defines a Notification of Unusual Event, also referred to as an Unusual Event, as man-made events and natural phenomena creating a significant hazard potential that was previously non-existent. At the Unusual Event classification level, time is expected to be available to take precautionary and corrective steps to prevent the escalation of the accident or to mitigate the consequences should it occur. As a result, no releases of radioactive or hazardous materials requiring offsite responses are anticipated.

Section 4.4, “Alert,” of the SHINE Emergency Plan defines an Alert classification level as an event that may occur, is in progress, or has occurred, that could lead to a release of radioactive material or hazardous chemicals incident to the processing of licensed materials. However, a release is not expected to require a response by an offsite response organization to protect persons offsite. The applicant explained that substantial modification of facility operating status at the Alert classification level is a highly probable corrective action.

Section 4.5, “Site Area Emergency,” of the SHINE Emergency Plan defines this emergency classification level as an event that may occur, is in progress, or has occurred that could lead to a significant release of radioactive material or hazardous chemicals incident to the processing of licensed material and that could require a response by offsite emergency response organizations to protect persons offsite. The applicant stated that a Site Area Emergency may be initiated when events such as major damage of primary boundaries containing radioactive or hazardous materials incident to the processing of licensed material have occurred and actual or imminent failure of other physical barriers preventing releases have occurred and the projected offsite radiological consequences exceed the action levels for a Site Area Emergency classification level at the site boundary. The offsite radiological doses are listed in Appendix 4, “Emergency Action Levels,” of the SHINE Emergency Plan. The applicant explained that monitoring at the site boundary will be conducted to assess the need for offsite protective actions and protective measures onsite will be implemented, as necessary.

Section 4.0 of NUREG-0849 states that the submitted emergency plan should include an appendix that contains titles and descriptions of implementing procedures for each emergency class described above. Appendix 5, “Emergency Plan Implementing Procedure (EPIP) List,” to the SHINE Emergency Plan provides a listing by title of implementing procedures for each class of emergency at the SHINE facility. The NRC staff confirmed that the EPIPs as described would adequately provide the facility personnel with the guidance on actions to provide a graded response in order of increasing severity based on the standard of emergency classifications at the site in the event of an emergency.

The NRC staff confirmed that the emergency classifications identified in the SHINE Emergency Plan are consistent with the guidance in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015 and are in conformance with Appendix I, “Emergency Classes,” of NUREG-0849. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.5 Emergency Action Levels

The guidance in section 5.0, “Emergency Action Levels,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.5, “Emergency Action Levels (EAL),” of ANSI/ANS-15.16-2015 provides that the emergency plan should 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 guidance states, in part, that:

- The emergency action levels (EALs) should be appropriate to the specific facility and consistent with the emergency classes;

- To the extent possible, the EALs should specify the effluent monitors used to project dose rates and radiological effluent releases at the site boundary;

- The emergency plan should include EALs to initiate protective actions for facility staff and members of the general public onsite, and

- The protective action guides shall be 10 milliSievert (mSv) deep dose (1 rem whole body) or 50 mSv (5 rem) thyroid.

The NRC staff reviewed section 5, “Emergency Action Levels,” of the SHINE Emergency Plan. The SHINE Emergency Plan does not identify any events that could lead to a release of hazardous chemicals incident to the processing of licensed material that would require activation of the SHINE ERO to protect persons onsite, or that would require a response by an offsite response organization (ORO) to protect persons offsite. For this reason, the applicant did not identify any EALs related to releases of hazardous chemicals incident to the processing of licensed material.

Appendix 4, "Emergency Action Levels," to the SHINE Emergency Plan provides a full list of events under the three standard classifications of emergencies at the SHINE facility: Notification of Unusual Event; Alert; and Site Area Emergency. Included in Appendix 4 are specific dose values/set points used for emergency classification. The NRC staff confirmed that the information contained in Appendix 4 is consistent with the emergency classifications identified in section 4 of the SHINE Emergency Plan. The staff also determined that the EALs have been established in terms of effluent monitors and other facility parameters from which the dose rates and radiological effluent releases at the site boundary can be projected. The staff finds that the SHINE Emergency Plan adequately includes appropriate EALs that contain specific values and setpoints used for determining when and what type of protective actions are necessary to protect the health and safety of the facility staff onsite. The protective actions identified by the applicant are defined by the protective action guides (PAGs) identified in U.S. Environmental Protection Agency (EPA) document EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents."

Section 7, "Activation of the ERO and Notification," of the SHINE Emergency Plan provides that elements of the ERO will be activated or notified to increase the state of readiness as warranted by the circumstances. Although the situation may not have resulted in damage to the facility, it may warrant preventative or mitigative actions or interruption of nonessential routine functions. As a result, SHINE explained that protective evacuations or isolation of certain areas of the facility may be necessary.

The NRC staff verified that Appendix 4 to the SHINE Emergency Plan describes the classes of emergency situations covering the spectrum of emergency conditions that involve the alerting or activating of progressively larger segments of the emergency organization. The staff also verified that for each class of emergency associated with an EAL there was a particular immediate action to provide an appropriate graded response. The NRC staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.6 Emergency Planning Zones

The guidance in section 6.0, "Emergency Planning Zones," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.6, "Emergency Planning Zones," of ANSI/ANS-15.16-2015 provides, in part, that:

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

The potential radiological hazards to the public associated with the operation of research and test reactors and fuel cycle facilities licensed under 10 CFR Part 50 involve considerations different than those associated with nuclear power reactors. As endorsed by RG 2.6 and referenced to by the ISG augmenting NUREG-1537, ANSI/ANS-15.16-2015 describes an acceptable approach for emergency planning commensurate with the potential risk involved for facilities of various authorized power levels. This approach to an acceptable EPZ size is also described in NUREG-0849, Appendix II, and was adopted by the applicant.

The NRC staff reviewed section 6, “Emergency Planning Zones,” of the SHINE Emergency Plan, which states that there are no identified radiological emergencies at the SHINE facility that would result in offsite plume exposure exceeding 1 rem whole body or 5 rem thyroid. Therefore, the EPZ for the SHINE facility is identified as the operational boundary. Consistent with the guidance in NUREG-0849 and ANSI/ANS-15.16-2015, for a facility with the authorized power level of the SHINE facility, the NRC finds that an acceptable EPZ size is the SHINE operational boundary.

Based on the above, the NRC staff finds that the information provided adequately addresses the establishment of an appropriate EPZ for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.7 Emergency Response

The guidance in section 7.0, “Emergency Response,” of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.7, “Emergency Response,” of ANSI/ANS-15.16-2015 provides criteria for emergency response measures that should be identified for each emergency. The criteria include the review and evaluation of the following:

- 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; the 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 adequate justifications to show the validity of the assumptions; and a description of the method for assessing collateral damage to the facility.

SHINE addressed these criteria in section 7, "Activation of the ERO and Notification," and section 8, "Emergency Response," of the SHINE Emergency Plan.

The NRC staff reviewed section 7 of the SHINE Emergency Plan to evaluate the applicant's planned emergency response measures related to activation and notification of the ERO. Section 7 identifies that the Shift Supervisor will become the Emergency Director when conditions exist that exceed EALs, or other conditions exist that warrant activation of the facility emergency organization. Notification of the emergency declaration will be made in accordance with established EPIPs. Rosters for emergency notifications are maintained in the control room and the ESC, and in controlled copies of the EPIPs. Progressive notifications to ERO members are planned dependent on classification of the emergency with full activation at the Site Area Emergency classification. The ESC is to be activated at an Alert or higher classification level. The OROs are activated by calling the Rock County 911 Communications Center, using established EPIPs, which contain message authentication instructions. Notifications to OROs are to be made within 15 minutes of an emergency declaration. Notifications to the NRC Operations Center are to be made within one hour after event declaration. Preformatted messages and reporting checklists are used and include information consistent with that called for in guidance documents. After notification of the Rock County 911 Communication Center and the NRC, the State of Wisconsin will be promptly notified following the declaration of an emergency.

The NRC staff reviewed section 8 of the SHINE Emergency Plan to evaluate the applicant's planned emergency response measures. This section sets forth voluntary emergency work exposure guidelines that the Emergency Director can authorize when called for. The use of respiratory protection and protective clothing is outlined.

Actions that the applicant will take in response to events to assess the event and activate appropriate facilities and notify personnel, and corrective actions that could be taken for events and personnel protective actions, are discussed for each emergency classification level. Consideration of evacuation of personnel from impacted areas of the facility, along with assembly and accountability processes are described. The control room, main production facility break room, and main production facility conference room are identified as primary assembly areas for ERO personnel onsite and non-essential personnel. The main production facility conference room is designated as the alternate onsite assembly area for non-essential personnel. Back-up assembly locations in the storage building office area and the SHINE Headquarters breakroom are also identified.

The SHINE Emergency Plan identifies provisions for isolation and access control of facility areas to minimize exposures to radiation and the spread of contamination. It describes methods for monitoring radiation dose rates and contamination levels both onsite and offsite using installed monitoring equipment and portable survey equipment.

Section 8.7.3, "On-site and Off-site Surveying," of the SHINE Emergency Plan states, in part, that "Monitoring outside the facility and at the site boundary shall be implemented within two hours of declaring a Site Area Emergency involving a potential or actual release." Per section 3.3.4, "Radiation Safety Coordinator," of the SHINE Emergency Plan, the Radiation Safety Coordinator has the responsibility of making onsite and offsite dose assessments and projections. The role of the Radiation Safety Coordinator is initially filled by an onsite individual with radiation protection experience. A relief Radiation Safety Coordinator may be called in as part of the activation of the ERO, if required. Additionally, section 3.3.9, "Assessment Teams," of the SHINE Emergency Plan identifies collecting onsite and offsite field monitoring data as one of the responsibilities of an Assessment Team, which will assist the Radiation Safety Coordinator in making radiological assessments by monitoring or collecting radiation dose rates and contamination levels.

In addition, section 8.7, "Assessment Action Information," and section 9.4, "Assessment Facilities and Equipment," of the SHINE Emergency Plan provide protective actions in conformance with section 8.4.3.1.7, "Assessment of Releases," of NUREG-1520.

Based on the above, the NRC staff finds that the information provided in sections 7 and 8 of the SHINE Emergency Plan adequately addresses the emergency response measures for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.8 Emergency Facilities and Equipment

The guidance in section 8.0, "Emergency Facilities and Equipment," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.8, "Emergency Facilities and Equipment," of ANSI/ANS-15.16-2015 provides criteria for emergency facilities, and the type of equipment and their location that should be addressed in the emergency plan. The acceptance criteria for information on emergency facilities and equipment 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 licensed material. The plan should also describe non-radiological monitors or indicators such as fire detectors, earthquake sensors, etc.

- The emergency plan should identify those measures that would be used to aid 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 NRC staff reviewed section 9, “Emergency Facilities and Equipment,” of the SHINE Emergency Plan to evaluate the emergency facilities and equipment that are available at the SHINE facility. The SHINE Emergency Plan identifies the control room as the centralized onsite location from which effective control can be provided during an emergency. The plan also describes an ESC, both a primary and back-up location, to oversee operations in the control room and the rest of the facility in emergency conditions. The ESC is sized for at least six people.

The assessment of conditions of the facility and identification of emergency events is aided by the use of installed radiological instrumentation, a criticality accident alarm system, area radiation monitors, process radiation monitors, process tritium monitoring, a continuous air monitoring system, criticality accident dosimeters, and the ability to collect environmental monitoring information. Portable radiological monitoring equipment is available, as well as sampling kits and hand-held lights.

Two onsite laboratory facilities are available with instrumentation for specific radionuclide identification and analysis.

Non-radiological monitors and instrumentation for fire detection and seismic monitoring are available. Weather band radio receiver in the control room allows for the assessment of potential meteorological threats to the facility.

Section 9.5, “Decontamination Facilities, Supplies, and Controls,” of the SHINE Emergency Plan states that personnel are considered contaminated if they are found by direct frisk or use of a portal monitor to have contamination above background levels, as defined in the EPIP addressing emergency radiation exposure control. Equipment is considered contaminated if a survey of accessible surfaces results in contamination above background levels, as defined in the EPIP addressing emergency radiation exposure control.

A decontamination room is provided at the main exit from the radiologically controlled area of the facility. Supplies for temporary decontamination areas are available if needed. The normal personnel monitoring equipment used by the SHINE facility staff is also used in emergency conditions, supplemented with any additional specialized dosimetry deemed necessary. Emergency support organization personnel are provided dosimetry prior to entering affected areas.

First aid supplies are maintained in the control room, ESC, the storage building office, and the main production facility shipping and receiving dock area. Offsite medical arrangements with the City of Janesville Fire Department and SSM Health St. Mary's Hospital are described in the SHINE Emergency Plan.

Communications systems using the normal facility phone system, which has a battery backup power supply, are relied upon for most communications in the event of an emergency. A public address system is also available throughout the facility. Sound powered phones are available in four strategic locations if needed. Handheld radios and base stations are also available and serve as a backup communications system. Radios are also capable of communication with the police and fire departments in Janesville, Wisconsin. The facility maintains an emergency mobile phone in the control room, and personal mobile phones are expected to be available if needed.

Based on the above, the NRC staff finds that the information provided in section 9 of the SHINE Emergency Plan adequately addresses the emergency facilities and equipment for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.9 Recovery

The guidance in section 9.0, "Recovery," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.9, "Recovery," of ANSI/ANS-15.16-2015 provides the criteria for recovery and reentry planning that should be addressed in the emergency plan, which are:

- The emergency plan specifies that recovery procedures will be written and approved as needed.

- 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 NRC staff reviewed section 10, "Recovery," of the SHINE Emergency Plan to ensure that the applicant appropriately considered the recovery phase of an accident. Section 10 states that the Emergency Director will determine, using criteria provided in the SHINE Emergency Plan, when emergency conditions no longer exist and recovery can begin. Assessment Teams, using established procedures, will conduct recovery assessments. Recovery plans and procedures will be prepared by facility technical staff based on current conditions and approved by an individual qualified as an Emergency Director at the facility. Personnel will be trained in specific recovery actions.

Based on the above, the NRC staff finds that the information provided in section 10 of the SHINE Emergency Plan adequately addresses recovery actions for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.10 Maintaining Emergency Preparedness

The guidance in section 10.0, "Maintaining Emergency Preparedness," of NUREG-0849, as supplemented by section 12.7 of the ISG augmenting NUREG-1537, and section 3.10, "Maintaining Emergency Preparedness," of ANSI/ANS-15.16-2015 provides the criteria for maintaining an acceptable state of emergency preparedness, which are:

- The emergency plan should describe initial and periodic training for emergency response employees assigned functions for decision making and transmitting instructions and accident assessment, radiological monitoring and analysis teams, for personnel involved in first aid and rescue and medical support, and 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 OROs 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 of 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 NRC staff reviewed section 11, "Maintaining Emergency Preparedness," of the SHINE Emergency Plan, to evaluate the applicant's maintenance of emergency preparedness and training of facility staff. The plan calls for initial (eight hours) and annual refresher (four hours) training on topics such as an overview of the emergency plan, emergency procedure usage, facility layout, characteristics of a criticality event, radiation safety, first aid, and the use of protective equipment and monitoring devices. Position-specific training is also provided for members of the ERO.

Training is offered annually to off-site emergency support organization personnel. This training may include facility tours for familiarization, reentry procedures, facility hazards, access control, permitted fire suppression techniques, potential accident scenarios, emergency action levels, notification procedures, exposure guidelines, personnel monitoring devices, communications, contamination control, and the responding organizations' roles in emergency conditions.

Radiological and SHINE facility orientation opportunities are offered biannually to local service personnel, such as news media and local government officials.

The SHINE Emergency Plan states that drills are primarily onsite tests of one or more portions of the integrated capability of emergency response plans, equipment, and organizations, with offsite support functions being simulated. An exercise is a type of drill that is a full-scale test of the ERO, in which offsite organizations are invited to participate. Drills of the onsite ERO are to be conducted annually and exercises where the OROs will be invited to participate are to be conducted every two years. Critiques of drills and exercises are to be conducted to identify items that need correction. An annual review of the emergency plan, EPIPs, and EALs will be conducted. A review of agreement letters, the emergency plan, and EPIPs will also be conducted every two years with responsible OROs.

Based on the above, the NRC staff finds that the information provided in section 11 of the SHINE Emergency Plan adequately addresses the elements necessary for maintaining an acceptable state of emergency preparedness for the SHINE facility. The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

12.4.7.11 Conclusion

Based on the above conclusions, the NRC staff finds that the SHINE Emergency Plan meets the guidance in NUREG-0849, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.16-2015. Therefore, the staff concludes that SHINE has satisfied the applicable requirement of 10 CFR 50.34(b)(6)(v) that each application for an operating license include an FSAR that contains, among other things, the applicant’s plans for coping with emergencies, including the items specified in Appendix E to 10 CFR Part 50.

12.4.8 Security Planning

The SHINE’s physical security plan contains security-related information are protected from public disclosure.

The NRC staff evaluated the SHINE’s physical security plan to ensure that it meets the requirements for physical protection of special nuclear material (SNM) at fixed sites. Specifically, the staff reviewed the PSP to determined whether the relevant requirements of 10 CFR 70.22(k); 10 CFR 73.67, paragraphs (a), (c), (d) and (e);10 CFR 73.57; 10 CFR 73.71 and 10 CFR 37 are met. In addition, the staff used RG 5.59, to inform its evaluation to determine whether SHINE meets the applicable 10 CFR Part 73 requirements.

The NRC staff determined that to ensure adequate protection, additional supplement security measures (SSMs) were required beyond the physical protection requirements in 10 CFR 73.67. The additional SSMs were developed in coordination with SHINE using the general SSMs discussed in a Commission paper titled “Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99.” The staff plans to incorporate the SSMs into the operating license by adding the following license condition:

> “The licensee shall fully implement and maintain, in effect, all provisions of the Commission-approved physical security plan (PSP), entitled “SHINE Physical Security Plan,” designated Revision 2, and dated October 12, 2021, and all changes made thereto pursuant to the authority of 10 CFR 50.90 and 50.54(p). The site-specific supplemental security measures (SSMs) in Appendix [C] are hereby incorporated into this license. The licensee shall fully implement and maintain in effect all of the SSMs in Appendix [C]. They must describe how the SSMs will be implemented. The PSP and Appendix [C] contain Safeguards Information protected under 10 CFR 73.21.”

The NRC staff has reviewed SHINE's physical security plan. The NRC staff has determined that the proposed physical protection activities at the SHINE facility meet the applicable regulatory requirements and applicable portions of the SSMs. The method and procedures outlined in SHINE's physical security plan satisfy the performance objectives, systems capabilities, and reporting requirements specified in the applicable NRC regulations and license conditions. Therefore, staff finds that SHINE's physical security plan is acceptable and provides reasonable assurance that SHINE's physical protection of SNM is not inimical to the common defense and security and does not constitute an unreasonable risk to public health and safety.

12.4.9 Quality Assurance

The NRC staff evaluated the sufficiency of the SHINE Quality Assurance Program Description (QAPD), Revision 19 (ML22164A053), by reviewing whether the relevant requirements of 10 CFR 50.34(b)(6)(ii) are satisfied by using the applicable guidance and acceptance criteria from section 12.9, "Quality Assurance," of NUREG-1537, Parts 1 and 2, and of the ISG augmenting NUREG-1537, Parts 1 and 2. Consistent with these guidance and acceptance criteria, the staff used ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," as endorsed in RG 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors" (ML093520099).

As part of its review of the SHINE construction permit application, the NRC staff approved the SHINE QAPD, Revision 7, as documented in NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility" (ML16229A140). For the SHINE operating license application, the staff reviewed Revision 19 of the QAPD. The substantive changes to the SHINE QAPD from Revision 8 to Revision 19 are the following:

- QAPD revision log was added that provides the history of changes;

- Section 1.3, "Definitions," was revised to add definitions derived from 10 CFR 21.3, "Definitions," related to commercial grade dedication of equipment and to delete the definition of safety-related structure, system, or component (SSC) and replace it with the definition of safety-related items.

- Section 2.1, "Organization," was revised with roles and responsibilities changes that were administrative improvements.

- Section 3, "Facility Operations," was added to include a description of the operational QA program.

- Enclosure 1, "SHINE Functional Organizational Chart," was revised to make it consistent with the information provided in Section 2.1 of the QAPD.

- Enclosure 2, "Graded Approach to Quality," was revised by deleting the definition of Quality Level-3.

- Enclosure 3, "Procedure that Implement the QAPD," was revised to include additional procedures and implementing procedure numbers with titles for SHINE and its contractor.

The NRC staff reviewed the revision log added to the SHINE QAPD and finds that it accurately describes the history of the changes to the QAPD and, therefore, is acceptable.

The NRC staff reviewed the definitions derived from 10 CFR 21.3 related to commercial grade dedication of equipment that were added to section 1.3 of the SHINE QAPD, which are basic component, commercial grade item, critical characteristics, dedication, and dedicating entity. The staff previously reviewed and approved these SHINE-specific definitions (as an exemption from the requirements of 10 CFR 21.3), as documented in an NRC Safety Assessment, dated April 30, 2021 (ML21076A519). In that review, the staff concluded that the use of the SHINE-specific definitions and, consequently, the use of commercial grade items by SHINE dedicated consistent with the definitions, did not adversely affect the public health and safety. Further, the staff considered the requirements of 10 CFR 21.7 and concluded that granting the exemption was authorized by law and would not endanger life or property or the common defense and security and was otherwise in the public's interest. The staff finds that the definitions added to Revision 19 of the SHINE QAPD are the same as those definitions that were previously approved. Therefore, the staff concludes that their addition is acceptable, and that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

The NRC staff reviewed the replacement in section 1.3 of the SHINE QAPD of the previously approved definition of safety-related SSC with the definition of safety-related items. The definition of safety-related items explicitly addresses items whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public. While the safety-related items definition no longer contains explicit thresholds in determining the acceptability of the consequences of a postulated event, SHINE has retained similar safety criteria for the classification of physical SSCs in the licensing basis, specifically, as described in section 3.1, “Design Criteria,” of the SHINE FSAR. The staff determined that the replacement of the definition of safety-related SSC with the definition of safety-related items is acceptable because this definition is appropriate for the SHINE facility and is consistent with the ANSI/ANS-15.8-1995 (R2013). The staff concludes that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license

The NRC staff reviewed section 2.1 of the SHINE QAPD in which SHINE made the following administrative changes since the staff's previous review to reflect SHINE organizational changes: removing the role of the Chief Financial Officer; removing the role of the Director of Engineering Support and Auxiliary Systems and replacing it with the Engineering Support Manager; deleting Chief Operating Officer; adding Diagnostics General Manager; deleting Plant Manager; adding Director of Plant Operations; and adding Director of Corporate Support. SHINE also replaced the role of Director of Process Engineering with the role of Vice President of Engineering (VPE) and changed the VPE role reporting to the Chief Executive Officer, replaced the role of Procurement Manager with Supply Chain Director, replaced the role of Information Technology Manager with Vice President of Cybersecurity and Information Technology, changed the Director of Engineering Support and Auxiliary Systems reporting to the VPE, and modified the programmatic responsibility for Document Control and Records Management from the Director of Engineering Support to the Chief Operating Officer. Enclosure 1 of the QAPD was updated to reflect the administrative title changes. In addition, Enclosure 3 was revised to identify additional procedures and to update procedure numbers and titles of SHINE implementing procedures.

The NRC staff determined that SHINE's changes to the QAPD to reflect organizational changes represent administrative improvements with organizational revisions that continue to maintain persons and organizations performing QA functions having the requisite authority and organizational freedom. The changes to Enclosure 3 are consistent with commitments made in previous revisions of the QAPD. The staff noted that implementing procedures were added to all activities included in section 2, "Design, Construction, and Modifications," of the QAPD except for "Control of Special Processes." The implementing procedures will be reviewed as part of the staff's inspection of SHINE's implementation of the QAPD. Based on the above, the staff concludes that these changes are acceptable and that the information provided meets the applicable acceptance criteria and is, therefore, sufficient for the issuance of an operating license.

The NRC staff previously determined in NUREG-2189 that sections 2.2 through 2.18 of the SHINE QAPD are acceptable. The staff notes that SHINE did not make any changes to these sections. Therefore, the staff concludes that the information provided by these sections meets the applicable acceptance criteria and is sufficient for the issuance of an operating license.

Section 3 of the SHINE QAPD describes the elements of a QA program for the conduct of operations at the SHINE facility. The SHINE QAPD also establishes that some requirements of the QA program for operations may be found in documents other than the QAPD, such as the Training Program, Emergency Plan, Security Plan, Technical Specifications, and Radiation Protection Program, and are, therefore, not duplicated in the QA program. The NRC staff notes that there is no specific requirement to place these programs, plans, or technical specifications in the QA program. SHINE established its facility operations QA program based on ANSI/ANSI-15.8-1995 (R2013).

The NRC staff evaluated the sufficiency of the SHINE QA program controls for the conduct of operations at the SHINE facility against applicable regulatory requirements using appropriate regulatory guidance and acceptance criteria. On the basis of its review, the staff determined that the level of SHINE's commitment to establish a QA program for the conduct of facility operations is adequate and supports applicable acceptance criteria in section 12.9 of NUREG--1537, Part 2, as supplemented by section 12.9 of the ISG augmenting NUREG-1537, Part 2 and ANSI/ANSI-15.8-1995 (R2013). Accordingly, the staff concludes that the information provided satisfies the relevant requirements of 10 CFR 50.34(b)(6)(ii) and is, therefore, sufficient for the issuance of an operating license.

Section 4, "Applicability to Existing Facilities," of the SHINE QAPD states that "The SHINE facility will be a newly constructed facility and this section does not apply." The NRC staff determined that the SHINE facility will only include structures that are newly constructed. Therefore, the staff concludes that a discussion of the applicability of the QA program to existing facilities is not necessary to include in the QAPD.

Section 5, "Decommissioning," of the SHINE QAPD states that this section will be updated at a later date. The NRC staff defers the review of this section until the receipt of a decommissioning plan under 10 CFR 50.82(b). Following receipt of the decommissioning plan, the staff will confirm that this issue has been resolved.

Based on its evaluation of the SHINE QAPD, Revision 19, described in section 12.9 of the SHINE FSAR, and its previous evaluation in NUREG-2189, the NRC staff finds that the SHINE QA program meets the guidance in section 12.9 of NUREG-1537, as supplemented by the ISG augmenting NUREG-1537, and ANSI/ANS-15.8-1995, endorsed by the NRC in RG 2.5, Revision 1. Therefore, the staff concludes that the SHINE QA program satisfies the relevant requirements of 10 CFR 50.34(b)(6)(ii) for the design, fabrication, construction, and operation of the SHINE facility.

12.4.10 Operator Training and Requalification

The NRC staff evaluated the sufficiency of the SHINE licensed operator requalification training program, as described in section 12.10, “Operator Training and Requalification,” of the SHINE FSAR and in Enclosure 12, “Licensed Operator Continuing Training Program” (ML19211C141), to the SHINE operating license application, using the applicable guidance and acceptance criteria from section 12.10, “Operator Training and Requalification,” of NUREG-1537, Parts 1 and 2, and of the ISG augmenting NUREG-1537, Parts 1 and 2. During the staff review, SHINE provided responses to staff requests for additional information (ML21307A306 and ML21350A191), which were incorporated into revisions to the licensed operator requalification training program, where appropriate. The staff reviewed Revision 2 (ML21350A191) of the licensed operator requalification training program for this technical evaluation.

Additionally, SHINE submitted a licensed operator initial training program, as described in section 12.10 of the SHINE FSAR and in Enclosure 13, “Licensed Operator Initial Training Program” (ML19211C144), to the SHINE operating license application. The NRC staff evaluated the sufficiency of this training program using the applicable guidance and acceptance criteria from section 12.10 of NUREG-1537, Parts 1 and 2, and of the ISG augmenting NUREG-1537, Parts 1 and 2. During the staff review, SHINE provided a revision to the licensed operator initial training program along with the aforementioned responses to staff requests for additional information. The staff reviewed Revision 1 (ML21307A306) of the licensed operator initial training program for this technical evaluation.

12.4.10.1 Licensed Operator Requalification Training Program

Under 10 CFR 50.34(b)(8), each application for a facility operating license must include a description and plans for implementation of a licensed operator requalification program that must as a minimum meet the requirements contained in 10 CFR 55.59, “Requalification.” section 1.1, “Purpose,” of the SHINE licensed operator continuing training program states that this program is in accordance with ANSI/ANS-15.4-2016, “Selection and Training of Personnel for Research Reactors,” and SHINE proposed TS 5.1.4, “Selection and Training of Personnel,” states that ANSI/ANS-15.4-2016 is used in the requalification programs for licensed operators. Accordingly, the NRC staff evaluated the sufficiency of this program using the applicable regulations, using the applicable guidance and acceptance criteria from section 12.10 of NUREG-1537, Parts 1 and 2, and of the ISG augmenting NUREG-1537, Parts 1 and 2, for consistency with the applicable guidance in ANSI/ANS-15.4-2016, and for appropriateness for the SHINE facility.

<u>Chapter 1 – Introduction</u>

Chapter 1, “Introduction,” of the SHINE licensed operator continuing training program discusses purpose and scope, overview, applicability and effectiveness, evaluations and revisions, and document reviews. The information in this chapter is administrative in nature, with the exception of one more substantive issue, which is discussed next.

Section 1.3, “Overview,” of the SHINE licensed operator continuing training program states that licensed operators will be enrolled into the licensed operator continuing training program within three months after their operating license is issued. The NRC staff notes that there are no specific requirements in 10 CFR Part 55 and no specific guidance in ANSI/ANS-15.4--2016 related to the timing of a newly licensed operator's enrollment in a requalification program. 10 CFR 55.53(h) requires, as a condition of their licenses, that licensed operators complete a requalification program as described by 10 CFR 55.59, which, in turn, states that licensed operators must successfully complete a requalification program developed by the facility licensee. NUREG-1262, "Answers to Questions at Public Meetings Regarding Implementation of Title 10, Code of Federal Regulations, Part 55 on Operators' Licenses" (ML15198A217), provides that facilities have flexibility with respect to the implementation of requalification programs as long as the program meets its objectives. Therefore, the staff determined that this enrollment timeframe is adequate and acceptable.

Based on its review, the NRC staff finds that the information in chapter 1 of the SHINE licensed operator continuing training program is acceptable because it is administrative in nature and not contrary to the NRC's regulations or the guidance in ANSI/ANS-15.4-2016 and because it adequately describes the elements and objectives of the program in sufficient detail for the staff to review the rest of the program. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 2 – Definitions

Chapter 2, "Definitions," of the SHINE licensed operator continuing training program describes terms having special meaning unique to the SHINE facility or that are necessary to understand aspects of the program. Specifically, the following definitions are included: annual requalification cycle, biennial requalification cycle, controls, graded approach to training, on-the-job training, quarterly, and simulation-based learning. The NRC staff reviewed these definitions for conformance with regulatory requirements and consistency with guidance, as applicable.

The proposed definition for "annual requalification cycle" is "[t]ime period corresponding to a 12-month interval comprising half of a biennial requalification cycle per ANSI/ANS-15.4-2016 Section 6.2." The NRC staff determined that this definition conforms with requirements in 10 CFR Part 55 and is consistent with the guidance in section 6.2 of ANSI/ANS-15.4-2016; therefore, it is adequate and acceptable.

The proposed definition for "biennial requalification cycle" is "[t]ime period corresponding to a 24-month interval that the requalification program is conducted in per ANSI/ANS-15.4-2016 section 6.2. Each biennial requalification cycle is immediately followed by another 24-month cycle." The NRC staff determined that this definition conforms with 10 CFR 55.59(c)(1), "Schedule," meets the acceptance criteria for program duration in section 12.10 of NUREG-1537, Part 2, and of the ISG augmenting NUREG-1537, Part 2, and is consistent with the guidance in section 6.2 of ANSI/ANS-15.4-2016; therefore, it is adequate and acceptable.

The proposed definition for "controls" is "1) Apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of an Irradiation Unit (IU). 2) Apparatus and mechanisms, the manipulation of which could affect the chemical, physical, metallurgical, or nuclear process of the facility in such a manner as to affect the protection of health and safety against radiation." The NRC staff determined that the first definition of controls conforms with 10 CFR 50.2, "Definitions," and 10 CFR 55.4, "Definitions," as applicable to the SHINE facility, because it is consistent with those definitions except for omitting the phrase "when used with respect to a nuclear reactor" and changing "of the reactor" to "of an Irradiation Unit (IU)." This definition is appropriate for the SHINE facility because, although their reactivity and power level may be affected, the SHINE facility IUs are not nuclear reactors or reactors as those terms are used in 10 CFR 50.2 and 10 CFR 55.4. The staff also determined that the second definition of controls conforms with 10 CFR 50.2 because it uses the same language as the second definition of controls in 10 CFR 50.2 and this definition is appropriate for the SHINE facility. Therefore, the definition is adequate and acceptable.

The proposed definition for “graded approach to training” is “[a] method of streamlining parts of the systematic approach to training (SAT) process, tying each of the five phases of SAT together in more efficient information management.” The NRC staff verified that, for SHINE, there are no applicable regulatory requirements or guidance associated with this term or definition. Therefore, the definition is adequate and acceptable.

The proposed definition for “on-the-job training” is “[p]erformance-based training (conducted in environment that replicates as much as possible the actual task conditions) through which trainees learn how to perform a task, and the task related knowledge and skills.” 10 CFR 55.4 does not contain a definition for “on-the-job training.” 10 CFR 55.59(c)(3), “On-the-job training,” requires that the requalification program include on-the-job training and 10 CFR 55.59(c)(3)(i)-(v) provides specific types of on-the-job training that must be completed by licensed operators, as applicable. ANSI/ANS-15.4-2016 defines “on-the-job training” as “a systematic, structured method using a qualified person to provide the required job-related knowledge and skills to a trainee, usually in the actual workplace, with proficiency documented.” Section 2.2, “Definitions,” of ANSI/ANS-15.4-2016 provides definitions that “will be useful in understanding this [standard] and companion or reference standards,” but these definitions do not necessarily constitute a requirement or recommendation. Although the SHINE definition of “on-the-job training” is different than that in ANSI/ANS-15.4-2016, it is not contrary to the discussion of on-the-job training in the NRC’s regulations. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The proposed definition for “quarterly” is “[t]ime period corresponding to a calendar quarter.” The NRC staff determined that this definition conforms with requirements in 10 CFR Part 55 and is consistent with the guidance in section 6.5 of ANSI/ANS-15.4-2016; therefore, it is adequate and acceptable.

The proposed definition for “simulation-based learning” is “[a] technique to replace and amplify real experiences with guided ones, often ‘immersive’ in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion. Simulation-based learning may or may not include an actual simulation device.” 10 CFR 55.4 does not contain a definition for “simulation-based learning.” 10 CFR 55.59(c)(3)(v) states, in part, that “[i]f the simulator or simulation device is used to administer operating tests for a facility, as provided in [10 CFR] 55.45(b)(1), the device approved to meet the requirements of [10 CFR] 55.45(b)(1) must be used for credit to be given for meeting the requirements of [10 CFR 55.59(c)(3)(i)(G)-(AA)].” 10 CFR 55.59(c)(4)(iv) states, in part, that “[i]f a simulator is used in meeting the requirements of [10 CFR 55.59(c)(4)(iii)], it must accurately reproduce the operating characteristics of the facility involved and the arrangement of the instrumentation and controls of the simulator must closely parallel that of the facility involved.” Although SHINE has not submitted a request for approval of a simulator or simulation device, the definition provides SHINE with the future flexibility of incorporating a simulation device. Based on the above, the staff did not identify this definition as contrary to the NRC’s regulations. Therefore, the staff determined that this definition is adequate and acceptable.

Based on its review, the NRC staff finds that the definitions in chapter 2 of the SHINE licensed operator continuing training program are not contrary to the NRC's regulations or the guidance in ANSI/ANS-15.4-2016 and are appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 3 – Responsibilities

Chapter 3, "Responsibilities," of the SHINE licensed operator continuing training program contains program-applicable positions and position responsibilities. The information in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information in chapter 3 is acceptable because it is administrative in nature and not contrary to the NRC's regulations or the guidance in ANSI/ANS-15.4-2016 and because it adequately describes the responsibilities of those individuals involved in the continuing training program in sufficient detail for the staff to review the rest of the program. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 4 – Program Requirements

Chapter 4, "Program Requirements," of the SHINE licensed operator continuing training program contains several different categories of requalification requirements. The NRC staff reviewed the program requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 55.59(c)(2), "Lectures," the requalification program must include preplanned lectures on a regular and continuing basis throughout the license period in those areas where operator and senior operator written examinations and facility experience indicate that emphasis in scope and depth of coverage is needed for the subjects listed in 10 CFR 55.59(c)(2)(i)-(ix). Table 4-1, "Continuing Training Program Requirements," of the SHINE licensed operator continuing training program provides that training lectures will be performed on a quarterly periodicity. Section 4.3, "Training Scope," states that licensed operator continuing training includes knowledge of topics listed in Attachment A to the program, which are modified for applicability to the SHINE facility. SHINE stated that the specific content of the training sessions will be based on a number of items that can be considered facility operating experience. The NRC staff determined that this conforms with 10 CFR 55.59(c)(2) and meets the acceptance criteria for preplanned lectures contained in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(i), the requalification program must include on-the-job training so that each licensed operator manipulates the plant controls and each licensed senior operator either manipulates the controls or directs the activities of individuals during plant control manipulations during the term of the licensed operator's or senior operator's license that are applicable to the plant design and involve reactivity control manipulations. Chapter 4 of the SHINE licensed operator continuing training program provides that the program will be administered, in part, through on-the-job training. Table 4-1 provides that ten reactivity manipulations will be performed once per annual requalification cycle. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(i) and meets the acceptance criteria for on-the-job training contained in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(ii), the requalification program must include on-the-job training so that each licensed operator and senior operator has demonstrated satisfactory understanding of the operation of the apparatus and mechanisms associated with the control manipulations in 10 CFR 55.59(c)(3)(i) applicable to the facility and knows the operating procedures in each area for which the operator or senior operator is licensed. Section 4.3 of the SHINE licensed operator continuing training program states that the scope of the training includes knowledge of topics listed in Attachment A to the program, which include facility design and operating procedures. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(ii) and meets the acceptance criteria for on-the-job training contained in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(iii), the requalification program must include on-the-job training so that each licensed operator and senior operator is cognizant of facility design changes, procedure changes, and facility license changes. Section 1.3 of the SHINE licensed operator continuing training program states that document reviews will be conducted to ensure that licensed individuals are cognizant of all design, procedure, and license changes, as appropriate. Table 4-1 provides that continuing training on facility design, procedure, and license changes will be performed on an as applicable periodicity. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(iii) and meets the acceptance criteria for on-the-job training contained in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(iv), the requalification program must include on-the-job training so that each licensed operator and senior operator reviews the contents of all abnormal and emergency procedures on a regularly scheduled basis. Table 4-1 of the SHINE licensed operator continuing training program provides that abnormal and emergency procedure reviews will be performed once per annual requalification cycle. Additionally, as discussed previously, document reviews related to any procedure changes are performed on an as applicable periodicity. The NRC staff determined that this conforms with 10 CFR 55.59(c)(3)(iv) and meets the acceptance criteria for on-the-job training contained in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(3)(v), a simulator may be used in meeting the requirements of 10 CFR 55.59(c)(3)(i) and (ii). SHINE has not provided any additional information on the use of a simulator or simulation device. Additionally, as discussed previously, the NRC staff noted that SHINE has not submitted a request for approval of a simulator or simulation device.

Under 10 CFR 55.59(c)(4)(i), comprehensive requalification written examinations and annual operating tests are required to determine areas in which retraining is needed for licensed operator and senior operator knowledge. Section 5.1 and 5.2 of the SHINE licensed operator continuing training program provides that an annual operating evaluation and biennial written examinations will be used to verify operator knowledge. For the operating exam, this evaluation requires that operators demonstrate an understanding of and an ability to perform the actions necessary to accomplish a broad sample of topics listed in 10 CFR 55.45(a)(1) through (13), as applicable. The biennial written examinations will be used to verify operator knowledge, and preplanned training sessions will be used to address any deficiencies identified through the written exam. Section 5.2 provides that a score of 70% on the written examination requires no additional retraining. A score of 65%-69% will require retraining in areas or topics where weaknesses or deficiencies were identified. A score lower than 65% will require an evaluation by the Operations Manager within 30 days to identify the deficiencies requiring remediation, with the removal of the operator from licensed duties pending completion of retraining and retesting. The NRC staff determined that the program implementation of annual operating examinations and biennial written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(i) and meets the acceptance criteria contained in section 12.10 of NUREG-1537, Part 2, and of the ISG augmenting NUREG-1537 Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(ii), written examinations determine the licensed operator and senior operator knowledge of subjects covered in the requalification program and provide a basis for evaluating their knowledge of abnormal and emergency procedures. Section 4.2 of the SHINE licensed operator continuing training program provides that the scope of training includes knowledge of topics listed in Attachment A, which includes abnormal and emergency procedures. Additionally, Table 4-1 in section 4 states that abnormal and emergency procedure reviews will be completed annually. The NRC staff determined that the program implementation of biennial written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(ii) and meets the acceptance criteria contained in section 12.10 of NUREG-1537, Part 2, and of the ISG augmenting NUREG-1537 Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(iii), the requalification program must include systematic observation and evaluation of the performance and competency of licensed operators and senior operators by supervisors and/or training staff members, including evaluation of actions taken or to be taken during actual or simulated abnormal and emergency procedures. Section 4.3 of the SHINE licensed operator continuing training program provides that observations of operator performance will be made and that weaknesses in the training program or operator knowledge as determined by operating events, examination results, and crew or individual performance gaps will be identified. Section 4.3 further provides that the scope of training includes knowledge of topics listed in Attachment A and that the sequence and methodology of training will be based upon training approach (e.g., simulation). Attachment A includes emergency and abnormal operating procedures, conditions of license (e.g., job observations), and emergency plan. Additionally, chapter 6, “Program Review and Evaluation,” of the SHINE licensed operator continuing training program states that training effectiveness will be determined throughout the continuing training cycle based primarily on operator performance and oversight of the Operations Department by management, training, and supervisory personnel. The NRC staff determined that the program implementation of systematic observations and evaluations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(iii) and meets the acceptance criteria contained in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(iv), the requalification program must include simulation of emergency or abnormal conditions that may be accomplished by using the control panel of the facility involved or by using a simulator. Section 4.3 of the SHINE licensed operator continuing training program states that the scope of training includes knowledge of topics listed in Attachment A and that the sequence and methodology of the training will be based upon the training approach (e.g., simulation). Attachment A includes emergency and abnormal operating procedures, conditions of license (e.g., job observations), and emergency plan. As the NRC staff evaluated above, SHINE proposed a definition for “simulation-based learning” that may or may not include an actual simulation device and SHINE has not submitted a request for approval of a simulator or simulation device. The staff determined that the program implementation of simulation of emergency or abnormal conditions conforms with the applicable requirements of 10 CFR 55.59(c)(4)(iv) and meets the acceptance criteria contained in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Chapter 4 of the SHINE licensed operator continuing training program includes additional items specific to 10 CFR Part 55.41 and 55.45, modified for applicability to SHINE, for the scope of licensed operator continued training requirements for operators and senior operators. These items are based in part on the content of regulatory requirements for written examinations and operating examinations for reactor operators and senior reactor operators. The NRC staff reviewed the program requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 55.53(e), to maintain their license in active status, a licensed operator or a licensed senior operator is required to actively perform licensed functions for a specified number of hours per calendar quarter. Under 10 CFR 55.53(f), to restore a license to active status, a licensed operator or a licensed senior operator is required to perform a minimum number of hours of licensed functions under the direction of another operator. Table 4-1 of the SHINE licensed operator continuing training program provides that operators are to perform four hours of licensed duties on a quarterly basis, which is consistent with the timing requirements specific to research and test reactors in 10 CFR 55.53(e). Additionally, chapter 4 states that "[l]icensed operators and senior licensed operators who have not met the periodicity requirements for proficiency in Table 4-1 will perform a minimum of six hours of licensed duty under the direction of a qualified individual holding the same or higher-level license prior to being reinstated," which is consistent with the timing requirements specific to research and test reactors in 10 CFR 55.53(f)(2). Since the SHINE facility is not a research and test reactor, SHINE submitted a request for exemption from the requirements of 10 CFR 55.53(e) and 10 CFR 55.53(f) in order to allow it to use the timing requirements specific to research and test reactors as opposed to the timing requirements applicable to all other facilities (ML21350A190). The NRC staff review of that exemption follows.

The NRC has acknowledged the similarities of the SHINE facility and test and research reactors, including similarities among size, scope, and safety considerations. While the IUs represent new technology, the accelerator and neutron multiplier add sufficient external neutrons to the TSV to achieve a fission rate with a thermal power level comparable to non-power reactors typically licensed under 10 CFR Part 50 as utilization facilities (5 watts to 20 megawatts). The thermal power level of SHINE's IUs is 125 kilowatts, which is comparable to non-power reactors and of smaller size and scope than power reactors. This smaller scope is demonstrated by the fact that there are no postulated accident sequences that credit operator actions to mitigate the consequences of an event.

Additionally, the IUs have many similar safety considerations as those of non-power reactors, including:

- Provisions for fission heat removal during operation
- Considerations of decay heat generation after shutdown
- Similarity of reactivity feedback mechanisms to non-power reactors

- Control of fission gas release during operation and subsequent gas management engineering safety features

- Control of fission product inventory buildup

- Accident scenarios similar to non-power reactors, such as loss of coolant, reactivity additions, and release of fission products.

Application of the minimum hour requirements for licensed operators at non-power reactors is consistent with NRC application guidance relative to the SHINE facility (section 12.10 of NUREG-1537 Part 1, section 12.10 of NUREG-1537 Part 2, and section 12.10 of the Final Interim Staff Guidance (ISG) Augmenting NUREG-1537 Parts 1 and 2).

Approval of this exemption request will not endanger life, property, or the common defense and security, and will ensure that licensed reactor operators and senior reactor operators will reasonably maintain or restore active status given the SHINE facility's projected operating cycle. Additionally, approval of this exemption will allow the SHINE facility to maintain licensed operator active status requirements in a cost-efficient manner to support the domestic commercial production of molybdenum-99, which is in the interest of public health, with no loss of safety.

Based on the above, the NRC staff determined that the licensed operator requirements of 10 CFR Part 55.53(e) and (f) applicable to test and research reactors must apply at the SHINE facility to provide, in part, reasonable assurance that the activities authorized by the operating license can be conducted without endangering the health and safety of the public, and is therefore adequate and acceptable.

Under 10 CFR 55.21 and 10 CFR 55.53(i), a licensed operator or licensed senior operator is required to have a medical examination by a physician every two years. Section 4.1 of the SHINE licensed operator continuing training program states that a medical evaluation is required for licensed operators and licensed senior operators once every 2 years with the periodic examination being completed no later than the last day of the 12th month of the second year in accordance with section 7.1.2 of ANSI/ANS-15.4-2016. The NRC staff notes that this reflects that the medical examination must be completed within a two-year period from the date of the initial or previous medical examination and that the periodicity is not extendable by an additional grace period. The staff determined that the program implementation of medical examinations for licensed operators and licensed senior operators conforms with the applicable requirements of 10 CFR 55.21 and 10 CFR 55.53(i) and, therefore, is adequate and acceptable.

Section 8, "Fitness for Duty," of ANSI/ANS-15.4-2016 describes elements of a program or policy to assure that licensed individuals are fit to perform licensed duties. Additionally, ANSI/ANS-15.4-2016 states that all licensed personnel shall adhere to the established policy or program, including drug testing if required. Under 10 CFR 55.53(j), licensed operators and licensed senior operators shall not use, possess, or sell any illegal drugs and shall not perform activities authorized by their license while under the influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect their ability to safely and competently perform licensed duties. Section 4.2 of the SHINE licensed operator continuing training program states that licensed operators are required to adhere to fitness for duty requirements as described in the SHINE employee handbook. The NRC staff determined that this conforms with the applicable requirements of 10 CFR 55.53(j) and is consistent with ANSI/ANS-15.4-2016. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 50.74, facility licensees are required to notify the NRC within 30 days of a change in licensed operator or licensed senior operator status. Section 4.4 of the SHINE licensed operator continuing training program states that the changes in operator status, as outlined in 10 CFR 50.74, will be communicated to the NRC within 30 days. The NRC staff determined that this conforms with 10 CFR 50.74 and, therefore, is adequate and acceptable.

Based on its review, the NRC staff finds that the program requirements in chapter 4 meet the applicable regulatory requirements and acceptance criteria and are appropriate for the SHINE facility. Therefore, the program requirements are sufficient for the issuance of an operating license.

Chapter 5 – Examinations

Chapter 5, "Examinations," of the SHINE licensed operator continuing training program contains requalification requirements related to evaluations. The NRC staff reviewed these requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 55.59(c)(4)(i), the requalification program must include, in part, comprehensive requalification written examinations that determine areas in which retraining is needed to upgrade licensed operator and licensed senior operator knowledge. Under 10 CFR 55.59(c)(4)(ii), the requalification program must include written examinations that determine licensed operators' and licensed senior operators' knowledge of subjects covered in the program and provide a basis for evaluating their knowledge of abnormal and emergency procedures. Under 10 CFR 55.59(a)(2)(i), the written examination must sample the items specified in 10 CFR 55.41 and 10 CFR 55.43, to the extent applicable to the facility, the licensee, and any limitation of the license under 10 CFR 55.53(c). Section 5.2 of the SHINE licensed operator continuing training program states that biennial written examinations will be used to verify the operator's knowledge and that preplanned training sessions will be used to retrain those operators who demonstrate deficiencies in any part of the examination. Section 4.3 states that the scope of training includes the topics listed in Attachment A of the program, which are based, in relevant part, on the requirements of 10 CFR 55.41, modified for applicability to the SHINE facility. The NRC staff determined that Attachment A provides a list of licensed operator training material applicable to both licensed operators and licensed senior operators that is consistent with the topics in 10 CFR 55.41, to the extent applicable to SHINE, and a list of senior licensed operator training material applicable to licensed senior operators that is consistent with the topics in 10 CFR 55.43, to the extent applicable to SHINE. The staff determined that the program implementation of written examinations conforms with the applicable requirements of 10 CFR 55.59(c)(4)(i), 10 CFR 55.59(c)(4)(ii), and 10 CFR 55.59(a)(2)(i) and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(i), the requalification program must include, in part, annual operating tests that determine areas in which retraining is needed to upgrade licensed operator and licensed senior operator knowledge. Under 10 CFR 55.59(a)(2)(i) the operating test must require the operator or senior operator to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a comprehensive sample of items specified in 10 CFR 55.45(a)(2)-(13) inclusive to the extent applicable to the facility. Section 5.1 of the SHINE licensed operator continuing training program states that an annual operating evaluation is administered to each licensed operator and licensed senior operator consisting of a broad sample of applicable items specified in 10 CFR 55.45(a)(1)-(13) inclusive to the extent applicable. Section 4.3 states that the scope of training includes the topics listed in Attachment A of the program, which are based, in relevant part, on the requirements of 10 CFR 55.45, modified for applicability to the SHINE facility. The NRC staff determined that Attachment A provides a list of licensed operator and senior licensed operator training material topics applicable to licensed operators and licensed senior operators that is consistent with the topics in 10 CFR 55.45, to the extent applicable to SHINE. The staff determined that the program implementation of annual operating tests conforms with the applicable requirements of 10 CFR 55.59(c)(4)(i) and 10 CFR 55.59(a)(2)(i) and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Under 10 CFR 55.59(c)(4)(v), the requalification program must include provisions for each licensed operator and licensed senior operator to participate in an accelerated requalification program where performance evaluations conducted pursuant to 10 CFR 55.59(c)(4)(i)-(iv) clearly indicate the need. Section 6.3, “Evaluation and retraining,” of ANSI/ANS-15.4-2016 describes the scoring criteria for requalification. Section 5.5 of the SHINE licensed operator continuing training program outlines provisions for accelerated requalification if performance evaluations indicated the need. Specifically, sections 5.4 and 5.5 discuss acceptance criteria for all graded examinations, operator status during retraining, performance evaluation and retraining time frames, determination of retraining content, and acceptance criteria to complete retraining. The NRC staff determined that the program implementation of accelerated requalification conforms with the applicable requirements of 10 CFR 55.59(c)(4)(v), is consistent with ANSI/ANS-15.4-2016, and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Based on its review, the NRC staff finds that the implementation of examinations in chapter 5 meets the applicable regulatory requirements and acceptance criteria and is appropriate for the SHINE facility. Therefore, the implementation of examinations is sufficient for the issuance of an operating license.

Chapter 6 – Program Review and Evaluation

Chapter 6, “Program Review and Evaluation,” of the SHINE licensed operator continuing training program contains information on programmatic evaluation. The NRC staff reviewed this information for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 50.36(c)(5), TSs must include items in the category of administrative controls, which includes provisions relating to review and audit necessary to assure operation of the facility in a safe manner. The foreword of ANSI/ANS-15.4-2016 provides that administrative and organizational requirements and structures, including reviews and audits, are found in companion standard ANSI/ANS-15.1-2007 (R2013). Section 6.2.4, “Audit function,” of ANSI/ANS-15.1-2007 describes the review and audit functions that are to be established, which include, in relevant part, audits for the retraining and requalification program for the operating staff to be conducted at least once every other calendar year with the interval between audits not to exceed 30 months. SHINE proposed TS 5.2.4.1.b incorporates this audit function into the SHINE licensing basis. Separately, section 6 of the SHINE licensed operator continuing training program states that the program is assessed at least once every biennium, with an interval between assessments not to exceed 24 months. The NRC staff notes that although it is inconsistent with the SHINE proposed TSs and ANSI/ANS-15.1-2007, the periodicity of the programmatic evaluation in the SHINE licensed operator continuing training program is more conservative than the TSs and ANSI/ANS-15.1-2007. The staff determined that the program implementation of programmatic evaluation conforms with the applicable requirements of 10 CFR 50.36(c)(5) and meets the acceptance criteria in section 12.10 of NUREG-1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable and sufficient for the issuance of an operating license.

Chapter 7 – Records

Chapter 7, "Records," of the SHINE licensed operator continuing training program contains requirements related to recordkeeping. The NRC staff reviewed these requirements for conformance with regulatory requirements and consistency with guidance, as applicable.

Under 10 CFR 55.59(c)(5), "Records," the types and retention period of requalification program documentation are specified. Sections 7.1, 7.2, and 7.3 of the SHINE licensed operator continuing training program provide information on the record storage system, record formats, and an illustrative list of the programmatic and individual records that will be retained. Section 7.4 states that "[r]ecords of training and qualification of Operations Department personnel shall be maintained for the duration of the currently valid license." SHINE proposed TS 5.9.2 states, in part, that records of meeting and audit reports of the review and audit committee will be maintained for a period of at least five years. SHINE proposed TS 5.9.3 states that records of retraining and requalification of operations personnel who are licensed pursuant to 10 CFR Part 55 shall be maintained at all times while the individual is employed as a licensed operator or until the license is renewed. The NRC staff determined that the program implementation of recordkeeping conforms with the applicable requirements of 10 CFR 55.59(c)(5) and meets the acceptance criteria in section 12.10 of NUREG--1537, Part 2 and of the ISG augmenting NUREG-1537, Part 2. Therefore, the staff determined that this is adequate and acceptable.

Based on its review, the NRC staff finds the implementation of recordkeeping in chapter 6 meets the applicable regulatory requirements and acceptance criteria and is appropriate for the SHINE facility. Therefore, the implementation of recordkeeping is sufficient for the issuance of an operating license.

Conclusion

The NRC staff reviewed the SHINE licensed operator continuing training program. The staff determined that the program conforms with the applicable regulations, meets the acceptance criteria in NUREG-1537 and in the ISG augmenting NUREG-1537, is consistent with the applicable guidance, and is appropriate for the SHINE facility. Therefore, the staff concludes that in accordance with 10 CFR 50.34(b)(8) SHINE has included a description and plans for implementation of a licensed operator requalification program that meets the applicable requirements contained in 10 CFR 55.59.

12.4.10.2 Licensed Operator Initial Training Program

Under 10 CFR 50.34(b)(6)(i), each application for a facility operating license must include information concerning facility operation, including personnel qualifications requirements. Under 10 CFR Part 55, the NRC establishes the criteria for the issuance of licenses to operators and senior operators of utilization facilities, including the requirement that applicants for an operator or senior operator license successfully complete the facility licensee's requirements to be licensed as an operator or senior operator and that evidence of this may be in the form of a certification that the applicant has successfully completed a Commission-approved training program that is based on a systems approach to training. The SHINE licensed operator initial training program describes how applicants for operator and senior operator licenses at the SHINE facility will be prepared for licensure under 10 CFR Part 55. Section 1.2, "Scope," of the program states that this program complies with the applicable portions of 10 CFR Part 55 and follows the guidance of ANSI/ANS-15.4-2016 and SHINE proposed TS 5.1.4 states that ANSI/ANS-15.4-2016 is used in the initial program for licensed operators. Accordingly, the NRC staff evaluated the sufficiency of this program using the applicable regulations, using the applicable guidance and acceptance criteria from section 12.10 of NUREG-1537, Parts 1 and 2, and of the ISG augmenting NUREG-1537, Parts 1 and 2, for consistency with the applicable guidance in ANSI/ANS-15.4-2016, and for appropriateness for the SHINE facility.

Chapter 1 – Introduction

Chapter 1, "Introduction," of the SHINE licensed operator initial training program discusses the purpose, scope, and an overview of this program. The information in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information in chapter 1 is acceptable because it is administrative in nature, not contrary to the NRC's regulations, consistent with the guidance in ANSI/ANS-15.4-2016, and adequately describes the objectives of the program in sufficient detail for the staff to review the rest of the program. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 2 – Definitions

Chapter 2, "Definitions," of the SHINE licensed operator initial training program describes terms having special meaning unique to the SHINE facility or that are necessary to understand aspects of the program. Specifically, the following definitions are included: controls, graded approach to training, on-the-job training, and simulation-based training. The NRC staff reviewed these definitions for conformance with regulatory requirements and consistency with guidance, as applicable.

The proposed definition for "controls" is "1) Apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of an Irradiation Unit (IU). 2) Apparatus and mechanisms, the manipulation of which could affect the chemical, physical, metallurgical, or nuclear process of the facility in such a manner as to affect the protection of health and safety against radiation." The NRC staff determined that the first definition of controls conforms with 10 CFR 50.2 and 10 CFR 55.4, as applicable to the SHINE facility, because it is consistent with those definitions except for omitting the phrase "when used with respect to a nuclear reactor" and changing "of the reactor" to "of an Irradiation Unit (IU)." This definition is appropriate for the SHINE facility because, although their reactivity and power level may be affected, the SHINE facility IUs are not nuclear reactors or reactors as those terms are used in 10 CFR 50.2 and 10 CFR 55.4. The staff also determined that the second definition of controls conforms with 10 CFR 50.2 because it uses the same language as the second definition of controls in 10 CFR 50.2 and this definition is appropriate for the SHINE facility. Therefore, the definition is adequate and acceptable.

The proposed definition for "graded approach to training" is "[a] method of streamlining parts of the systematic approach to training (SAT) process, tying each of the five phases of SAT together in more efficient information management." The NRC staff verified that, for SHINE, there are no applicable regulatory requirements or guidance associated with this term or definition. Therefore, the definition is adequate and acceptable.

The proposed definition for “on-the-job training” is “[p]erformance-based training (conducted in environment that replicates as much as possible the actual task conditions) through which trainees learn how to perform a task, and the task related knowledge and skills.” 10 CFR 55.4 does not contain a definition for “on-the-job training.” 10 CFR 55.59(c)(3), “On-the-job training,” requires that a requalification program include on-the-job training and 10 CFR 55.59(c)(3)(i)-(v) provides specific types of on-the-job training that must be completed by licensed operators, as applicable. ANSI/ANS-15.4-2016 defines “on-the-job training” as “a systematic, structured method using a qualified person to provide the required job-related knowledge and skills to a trainee, usually in the actual workplace, with proficiency documented.” Section 2.2, “Definitions,” of ANSI/ANS-15.4-2016 provides definitions that “will be useful in understanding this [standard] and companion or reference standards,” but these definitions do not necessarily constitute a requirement or recommendation. Although the SHINE definition of “on-the-job training” is different than that in ANSI/ANS-15.4-2016, it is not contrary to the discussion of on-the-job training in the NRC’s regulations. Therefore, the NRC staff determined that this definition is adequate and acceptable.

The proposed definition for “simulation-based learning” is “[a] technique to replace and amplify real experiences with guided ones, often ‘immersive’ in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion. Simulation-based learning may or may not include an actual simulation device.” 10 CFR 55.4 does not contain a definition for “simulation-based learning.” However, 10 CFR 55.4 contains a definition for “simulation facility” and 10 CFR 55.46, “Simulation facilities,” contains requirements for Commission acceptance of the use of simulation facilities. Although SHINE has not submitted a request for approval of a simulator or simulation device, the definition provides SHINE with the future flexibility of incorporating a simulation device. Based on the above, the staff did not identify this definition as contrary to the NRC’s regulations. Therefore, the staff determined that this definition is adequate and acceptable.

Based on its review, the NRC staff finds that the definitions in chapter 2 of the SHINE licensed operator initial training program are not contrary to the NRC’s regulations, are consistent with the guidance in ANSI/ANS-15.4-2016, and are appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 3 – Responsibilities

Chapter 3, “Responsibilities,” of the SHINE licensed operator initial training program contains program-applicable positions and position responsibilities. The information in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information in chapter 3 is acceptable because it is administrative in nature, not contrary to the NRC’s regulations, consistent with the guidance in ANSI/ANS-15.4-2016, and adequately describes the responsibilities of those individuals involved in the initial training program in sufficient detail for the staff to review the rest of the program. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 4 – Training

Chapter 4, “Training,” of the SHINE licensed operator initial training program contains information related to program implementation, which SHINE stated, in section 4.1, “Program

Requirements," meets the requirements of 10 CFR Part 55 and follows the guidance of ANSI/ANS-15.4-2016. The NRC staff reviewed this information for conformance with regulatory requirements and consistency with guidance, as applicable, and for appropriateness for the SHINE facility.

Section 4.2, "Analysis," of the SHINE licensed operator initial training program states that the actual manipulation of facility equipment by licensed operator candidates is conducted under the cognizance of a licensed operator. The NRC staff determined that this conforms with 10 CFR 55.13, "General exemptions," and is consistent with ANSI/ANS- 15.4-2016. Therefore, the staff determined that this is adequate and acceptable.

Section 4.3, "Reactivity Manipulations," of the SHINE licensed operator initial training program states that each licensed operator candidate will perform a minimum of five reactivity control manipulations with at least one startup and one shutdown of an IU. The NRC staff determined that this conforms with the regulatory requirements in paragraph (a)(5) of 10 CFR 55.31, "How to apply," as appropriate for the SHINE facility. Section 4.3 also states that each senior licensed operator candidate may receive credit for supervising and directing the performance of these activities, which will be considered as actual performance. The NRC staff will determine whether this conforms with the requirement of 10 CFR 55.31(a)(5) that "the applicant, as a trainee, … successfully manipulated the controls of … the facility" upon its review of any application for a senior operator license that takes credit for supervising and directing the performance of control manipulations or whether this would require an exemption in conformance with 10 CFR 55.11. Since exemptions are provided for in 10 CFR Part 55, the staff determined that this information is adequate and acceptable.

Section 4.4, "Exemptions," of the SHINE licensed operator initial training program provides a process to account for previous experience and training. The NRC staff notes that the use of the term "exemption" by the applicant is specific to the initial training program and does not appear to be synonymous with a request for a specific exemption in accordance with 10 CFR 55.11 or a waiver in accordance with 10 CFR 55.47. The staff determined that this use of a process to account for previous experience and training is consistent with ANSI/ANS-15.4-2016 and, therefore, is adequate and acceptable.

Section 4.5, "Observation and Evaluation of Candidates," of the SHINE licensed operator initial training program provides that candidates will be evaluated through observations, oral boards, examinations, and an NRC exam eligibility review. The NRC staff determined that this candidate evaluation process is consistent with ANSI/ANS-15.4-2016 and, therefore, is adequate and acceptable.

Section 4.6, "Training Scope," of the SHINE licensed operator initial training program provides training topics and a training schedule overview and states that the depth of the training is based on the trainee's performance and experience. The NRC staff determined that the training topics listed in Attachment A are consistent with the areas covered in 10 CFR 55.41, 55.43, and 55.45, to the extent applicable to the SHINE facility. The staff also determined that the training scope is consistent with ANSI/ANS-15.4-2016. Therefore, it is adequate and acceptable.

Section 4.7, "Senior Licensed Operator Specific Training," of the SHINE licensed operator initial training program provides information on the additional training consistent with the appropriate knowledge, skills, and abilities for the licensed senior operator position, to the extent applicable to the SHINE facility. The NRC staff determined that the development of position-specific training is consistent with ANSI/ANS-15.4-2016 and, therefore, is adequate and acceptable.

Based on its review, the NRC staff finds that the information in chapter 4 of the SHINE licensed operator initial training program is acceptable because it is not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 5 – Medical Certification and Fitness for Duty

Chapter 5, "Medical Certification and Fitness for Duty," of the SHINE licensed operator initial training program states that licensed operator candidates will successfully complete a medical examination and evaluation prior to initial licensing, that licensed operator medical requirements follow the standards established in ANSI/ANS-15.4-2016, and that licensed operators are required to adhere to fitness for duty requirements per ANSI/ANS-15.4-2016 and that SHINE's fitness for duty policy is described in the employee handbook. The NRC staff reviewed this information for conformance with regulatory requirements and consistency with guidance, as applicable, and for appropriateness for the SHINE facility. Based on its review, the staff finds that this information is not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility. Therefore, this information is sufficient for the issuance of an operating license.

Chapter 6 – Candidate Selection

Chapter 6, "Candidate Selection," of the SHINE licensed operator initial training program contains information related to personnel selection and qualifications. The NRC staff reviewed this chapter for conformance with regulatory requirements and consistency with guidance, as applicable, and for appropriateness for the SHINE facility.

Section 6.1, "Licensed Operator," section 6.2, "Senior Licensed Operator (Instant)," and section 6.3, "Senior Licensed Operator (Upgrade)," of the SHINE licensed operator initial training program provide position-specific qualification criteria. The NRC staff determined that these criteria are consistent with ANSI/ANS-5.4-2016 and, therefore, are adequate and acceptable.

Based on its review, the NRC staff finds that the information in chapter 6 is acceptable because it is not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility.

Chapter 7 - Examinations

Chapter 7, "Examinations," of the SHINE licensed operator initial training program contains information on methods, acceptance criteria, and review of written, oral, and on-the-job evaluations performed with trainees. Based on its review, the NRC staff finds that the information in chapter 7 is acceptable because it is not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS15.4-2016, and is appropriate for the SHINE facility.

The basis for implementation of written examinations and operating tests are established in 10 CFR 55.40(a), (b), and (c) for power reactor facilities and 55.40(d) for non-power reactor facilities. Since the SHINE facility is neither a power reactor nor a non-power reactor facility, SHINE has requested a License Condition that will allow them to prepare, proctor, and grade the written examinations and operating tests. The proposed License Condition to address the non-applicability to 10 CFR 55.40 is as follows:

> SHINE must comply with the requirements of 10 CFR Part 55, “Operators’ Licenses,” to the same extent as would a test and research/non-power reactor licensee, with the exception of 10 CFR 55.40. In lieu of 10 CFR 55.40, SHINE will prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and will prepare the operating tests required by 10 CFR 55.45, subject to the following conditions:
>
> a. SHINE shall prepare the required examinations and tests in accordance with the content requirements of 10 CFR 55.41(b), 55.43(b), and 55.45(a);
> b. Pursuant to 10 CFR 55.49, SHINE shall establish, implement, and maintain procedures to control examination security and integrity;
> c. An authorized representative of SHINE shall approve the required examinations and tests before they are submitted to the Commission for review and approval;
> d. SHINE shall establish acceptance criteria for preparation and approval of written examinations and operating tests, and submit the acceptance criteria to the NRC in writing no later than 120 days before the first scheduled examination date;
> e. SHINE shall submit any subsequent changes to the acceptance criteria to the NRC in writing no later than 120 days before any scheduled examination dates;
> f. SHINE must receive Commission approval of its proposed written examinations and operating tests; and
> g. In lieu of conditions (a) through (f) and upon written request from an authorized representative of SHINE pursuant to 10 CFR 55.31(a)(3), the Commission shall, for SHINE, prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and the operating tests required by 10 CFR 55.45. In addition, the Commission may exercise its discretion to itself prepare, proctor, and grade the required written examinations and operating tests for SHINE.
>
> This license shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(i), (i-1), (k), and (l).

The NRC staff reviewed the proposed license condition and determined that it is adequate and acceptable.

<u>Chapter 8 – Training Review and Evaluation</u>

Chapter 8, “Training Review and Evaluation,” of the SHINE licensed operator initial training program contains information on periodic program review. Based on its review, the NRC staff finds that the information in chapter 8 is acceptable because it is not contrary to the NRC’s regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility.

Chapter 9 - Records

Chapter 9, "Records," of the SHINE licensed operator initial training program contains information on recordkeeping. Based on its review, the NRC staff finds that the information in chapter 9 is acceptable because it is not contrary to the NRC's regulations, is consistent with the guidance in ANSI/ANS-15.4-2016, and is appropriate for the SHINE facility.

Conclusion

The NRC staff reviewed the SHINE licensed operator initial training program. The staff determined that the program is not contrary to the applicable regulations, meets the acceptance criteria in NUREG-1537 and in the ISG augmenting NUREG-1537, is consistent with the applicable guidance, and is appropriate for the SHINE facility. Therefore, the staff concludes that in accordance with applicable requirements of 10 CFR 50.34(b)(6)(i) SHINE has included information concerning licensed operator and licensed senior operator qualifications requirements and the staff approves the SHINE licensed operator initial training program.

Based on the above, the NRC staff determined that the licensed operator requirements of 10 CFR Part 55 applicable to test and research/non-power reactors must apply at the SHINE facility to provide, in part, reasonable assurance that the activities authorized by the operating license can be conducted without endangering the health and safety of the public. Accordingly, the conditions in every nuclear power reactor operating license issued under 10 CFR Part 50 that are generally related to licensed operators at facilities with 10 CFR Part 50 operating licenses, 10 CFR 50.54(i), (i-1), (k), and (l), must also be conditions in the SHINE operating license. Therefore, the NRC conditions the SHINE operating license as follows:

The requirements of 10 CFR Part 55 applicable to test and research/non-power reactors §§ 55.5(a) and (b)(3), 55.53(e), (f), (j), and (k), 55.59(c)(7), and 55.61(b)(5), also apply to the SHINE facility. Accordingly, this license shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(i), (i-1), (k), and (l). Additionally, a senior operator licensed pursuant to 10 CFR Part 55 shall be present at the SHINE facility as required by Technical Specification 5.1.3(1).

12.4.11 Startup Plan

The NRC staff evaluated the sufficiency of SHINE's startup plan, as presented in SHINE FSAR section 12.11, using the applicable guidance and acceptance criteria from section 12.11, "Startup Plan," in NUREG-1537, Parts 1 and 2 and from the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 12.11 describes at a high-level the tests necessary to verify key system parameters required for the safe handling of nuclear material and operation of the facility. SHINE FSAR section 12.11.1, "Administration of the Startup Testing Program," describes testing that will occur in accordance with a startup test schedule to ensure that all required systems are tested to confirm operability prior to facility startup. SHINE FSAR section 12.11.1 states that SHINE will use approved test procedures that will describe the personnel qualifications, conduct of testing, documenting of deficiencies, and corrective actions. Test results will be documented, including comparison of test data with acceptance criteria and disposition of any discrepancies. Along with test procedures, SHINE FSAR section 12.11.1 states that SHINE will use approved test plans to conduct pre-operational testing. The test plans will describe testing methods and objectives, acceptance criteria, hazards controls, and instructions for accomplishing the test. Subsequent to the completion of testing, SHINE will submit a startup report to the NRC in accordance with the timeframe established in SHINE proposed TS 5.8.4, “Startup Report.” The startup report will contain the information described in SHINE FSAR section 12.11.1.2, “Startup Test Report.”

SHINE FSAR sections 12.11.2.1, “Facility Startup Tests,” and 12.11.2.2, “Irradiation Unit Startup Tests,” provide an overview of the facility and irradiation unit startup tests, which involve tests in the following areas:

- Preparation for uranium handling
- Receipt, unpacking, and internal transfer of uranium
- Preparation of uranyl sulfate
- Preparation for reuse
- Process vessel vent system
- Transfer of target solution
- Packaging at end of solution life
- Radiation measurements
- Ventilation systems
- Electrical systems
- Instrumentation and controls
- Tritium purification system
- Detector calibration
- Irradiation unit fill and drain systems
- Subcritical assembly system nuclear physics parameters
  - Uranium concentration
  - Critical height
  - Calculational bias
  - Temperature coefficients
  - Void coefficient
  - Flux distribution
- Neutron driver assembly system
- Target solution vessel off-gas system
- Primary closed loop cooling system

The NRC staff determined that although the SHINE FSAR does not provide detailed information on the testing methods and acceptance criteria, it does state that SHINE will develop acceptance criteria using the applicable design specifications, design documents, drawings, TSs, manufacturer instructions, etc. SHINE stated that it will describe these acceptance criteria in test plans for the tests listed in SHINE FSAR sections 12.11.2.1 and 12.11.2.2. For the startup tests described in SHINE FSAR sections 12.11.2.1 and 12.11.2.2, SHINE referenced design details in the following FSAR sections to support the development of the startup test acceptance criteria:

- Section 4a2.3, “Neutron Driver Assembly System,”
- Section 4a2.6, “Nuclear Design,”
- Section 4a2.8, “Gas Management System,”
- Section 4b.2, “Radioisotope Production Facility Biological Shield,”
- Section 4b.4, “Special Nuclear Material Processing and Storage,”
- Section 5a2.2, “Primary Closed Loop Cooling System,”

- Section 7.2.1, “System Description,”
- Section 7.4.5, “Highly Integrated Protection System Design,”
- Section 9a2.1, “Heating, Ventilation, and Air Conditioning Systems,”
- Section 9a2.7, “Other Auxiliary Systems,”
- Section 9b.2, “Handling and Storage of Target Solution,”
- Section 9b.6, “Cover Gas Control in the Radioisotope Production Facility,” and
- Section 9b.7, “Other Auxiliary Systems.”

The NRC staff determined that the licensee provided references to applicable sections of the SHINE FSAR that describe the design details to support the development of the startup plan acceptance criteria. Additionally, the NRC staff determined that SHINE identified startup tests to measure operational nuclear physics parameters, to perform radiation surveys to compare with expected values, for handling uranium and target solution, and to calibrate detectors based on manufacturer instructions.

SHINE FSAR sections 12.11.2.1.1 through 12.11.2.1.4 and sections 12.11.2.1.6 and 12.11.2.1.7 describe the plan for preparation, receipt, unpacking, transfer, and reuse of uranium. The SHINE FSAR details the uranium testing to include verifying concentration, enrichment, temperature, pH, and volume. Before the initial receipt of uranium, the availability and calibration of required testing equipment are verified. Based on the above information, the NRC staff reviewed the information in the FSAR and finds that SHINE has plans for receiving, handling, and performing quality assurance checks on the uranium. Further, the NRC staff finds that SHINE testing equipment will be calibrated to support testing the uranium.
SHINE FSAR section 12.11.2.1.5, “Process Vessel Vent System,” describes that PVVS operational parameters are measured and compared to design parameters. SHINE identifies the key parameters as temperatures, pressures, flow rates, and effective operation of the carbon guard and delay beds. Based on the above information, the NRC staff finds that the PVVS is tested prior to routine operations.

SHINE FSAR section 12.11.2.1.8, “Radiation Measurements,” describes the that installed radiation monitors, such as the continuous airborne monitor and facility stack monitor are calibrated and tested prior to startup. Further, radiation measurements are taken and compared to expected values. SHINE FSAR also states, in part, that the area radiation measurements are taken to confirm the adequacy of the biological shielding. Based on the above information, the NRC staff finds that area and effluent radiation surveys will be conducted to confirm expected values and verify adequacy of the biological shield.

SHINE FSAR section 12.11.2.1.9, “Ventilation Systems,” describes that ventilation system parameters, such as pressures, temperatures, and flowrates, used to control airborne contamination are measured and compared to expected to values. Based on the above information, the NRC staff finds that ventilation systems will be tested before routine operations.

SHINE FSAR section 12.11.2.1.10, “Electrical Systems,” states, in part, that startup testing verifies the UPSS is capable of providing power to safety-related equipment in the absence of offsite power or the standby generator. Based on the above information, the NRC staff finds that electrical systems will be tested before routine operations.

SHINE FSAR section 12.11.2.1.11, “Instrumentation and Controls,” states, in part, that testing of instrument and control (I&C) systems includes calibration, establishing and verifying setpoints, and testing system actuations. Further, the SHINE FSAR states, in part, that detectors are calibrated in accordance with the manufacture instructions or as described in FSAR section 12.11.2.2.1. THE SHINE FSAR describes that the I&C acceptance criteria are developed based on design details in FSAR chapter 7. Based on the above information, the NRC staff finds that electrical systems will be tested before routine operations.

SHINE FSAR section 12.11.2.1.12, “Tritium Purification System,” states, in part, TPS leak rates are measured and compared to predetermined acceptance criteria, which are developed based on design details provided in FSAR section 9a2.7. Based on the above information, the NRC staff finds that Tritium Purification System will be tested before routine operations.

SHINE FSAR section 12.11.2.2.1, “Detector Calibration,” states that detectors are calibrated using an isotopic method in accordance with implementing procedures. Further, the SHINE FSAR states, in part, that detector calibration acceptance criteria are developed based on manufacturer instructions and are provided in test plans. Based on the above information, the NRC staff finds that detectors will be calibrated before routine operations.

SHINE FSAR section 12.11.2.2.2, “Irradiation Unit Fill and Drain System,” states, in part, the IU fill and drain mechanisms are tested to include key parameters such as fill flow rate and dump valve timing. Further, the SHINE FSAR states, in part, that measured dump valve opening time and time to empty the TSV with one dump line are compared to the acceptance criteria. Based on the above information, the NRC staff finds that Irradiation Unit Fill and Drain System will be tested before routine operations.

SHINE FSAR section 12.11.2.2.3, “Subcritical Assembly System Nuclear Physics Parameters,” states, in part, that the subcritical assembly system (SCAS) nuclear physics parameters are tested in order to develop appropriate operational parameters, such as uranium concentration and TSV fill height, and to ensure operability of the SSCs. SHINE plans on measuring uranium concentration by using a controlled approach towards criticality (1/M approach). SHINE will also use a series of tests to determine critical solution height in the TSV, neutronic bias, temperature coefficients, void coefficients, and flux distribution. These measured values will be compared to acceptance criteria developed based on design information in the FSAR. Based on the above information, the NRC staff finds the critical mass will be determined and that measurements are planned to determine operational nuclear physics parameters with the results compared to acceptance criteria.

SHINE FSAR section 12.11.2.2.4, “Neutron Driver Assembly System,” states, in part, that the neutron driver is tested for operability, stability, and neutron yield prior to placement in the IU cell. The neutron driver is run without target solution in the TSV to evaluate stability of the neutron flux prior to operation with target solution. The neutron driver startup test acceptance criteria are developed based on design details provided in section 4a2.3 and are provided in test plans. Based on the above information, the NRC staff finds that Neutron Driver Assembly System will be tested before routine operations and measurements are planned to determine operational nuclear physics parameters.

SHINE FSAR section 12.11.2.2.5, “Target Solution Vessel Off-Gas System,” states, in part, TSV off-gas system (TOGS) parameters are tested in order to characterize operational parameters, such as TOGS water holdup and worth, and ensure the operability of safety functions. TOGS pressure boundary leak integrity, sweep gas flow rate, and effectiveness of iodine removal are measured and compared to predetermined acceptance criteria. TOGS is tested for its leak tightness to prevent the release of radioactive material. TOGS is also tested for its ability to maintain the sweep gas flow rate within setpoints and produce an IU cell safety actuation and an IU Cell Nitrogen Purge if outside setpoints. The iodine removal function is also tested to ensure that iodine removal is performing adequately. The hydrogen recombination and heat removal functions are tested to demonstrate the recombiner efficiency and cooling capacity. The reactivity worth of TOGS water holdup will be measured. The TOGS startup test acceptance criteria are developed based on design details provided in FSAR sections 4a2.6 and 4a2.8 and are provided in test plans. Based on the above information, the NRC staff finds that TOGS will be tested before routine operations and measurements are planned to determine operational nuclear physics parameters.

SHINE FSAR section 12.11.2.2.6, “Primary Closed Loop Cooling System,” states, in part, primary closed loop cooling system (PCLS) parameters are tested in order to determine operational parameters, such as PCLS reactivity worth, and ensure operability of safety functions. PCLS is tested for its ability to maintain temperature and flow rate within limits and produce a Driver Dropout and an IU Cell Safety Actuation if outside setpoints. Additionally, PCLS worth is measured. Filling PCLS is calculated to result in a negative reactivity insertion that is measured by filling the TSV with PCLS empty then filling PCLS while measuring neutron flux. The PCLS startup test acceptance criteria are developed based on design details provided in sections 4a2.6 and 5a2.2 and are provided in test. Based on the above information, the NRC staff finds that PCLS will be tested before routine operations and measurements are planned to determine operational nuclear physics parameters.

Based on the above, the NRC staff determined that there is reasonable assurance that SHINE will develop appropriate startup plan acceptance criteria based on the approved applicable design specifications as described in the SHINE FSAR, design documents, drawings, TSs, and manufacturer instructions, as stated in SHINE FSAR section 12.11. The staff finds that the information meets the guidance in NUREG-1537, Part 2, and that the implementation of the startup plan will provide reasonable assurance that the facility is operating as described and analyzed in the FSAR.

12.4.12 Environmental Reports

SHINE FSAR section 12.12 is vacated. By letter dated November 16, 2021, SHINE submitted Revision 7 of its operating license stage supplement to its construction permit stage environmental report for the SHINE facility. The NRC staff’s evaluation of the environmental, economic, technical, and other benefits against the environmental and other costs of the proposed action of deciding whether to issue an operating license for the SHINE facility, based, in part, on SHINE’s supplemental environmental report, is documented in NUREG-2183, Supplement 1, “Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility.”

12.4.13 Material Control and Accounting Plan

The NRC staff evaluated the sufficiency of Revision 5 of SHINE’s Material Control and Accounting (MC&A) Plan, as described in SHINE FSAR section 12.13, “Material Control and Accounting Plan,” against the applicable regulatory requirements.

Under 10 CFR 70.22(b), an applicant for a license to possess special nuclear material (SNM) or to possess and use at any one time and location SNM in a quantity exceeding one effective kilogram must submit, as part of its application for a license, a full description of its program for control and accounting of the SNM that will be in its possession under its license to show how compliance with the requirements of 10 CFR 74.31, 74.33, 74.41, or 74.51, as applicable, will be accomplished. Of those requirements, 10 CFR 74.31 will not apply because the SHINE facility is a production and utilization facility that will be licensed pursuant to 10 CFR parts 50 or 70 and will not possess more than one effective kilogram of SNM of low strategic significance; 10 CFR 74.33 will not apply because SHINE will not be authorized to possess equipment capable of enriching uranium or to operate an enrichment facility; and 10 CFR 74.51 will not apply because SHINE will not be authorized to possess five or more formula kilograms of strategic SNM. SHINE will, however, be authorized to possess SNM of moderate strategic significance. Therefore, to comply with 10 CFR 70.22(b), the SHINE MC&A Plan must show how compliance with the requirements of 10 CFR 74.41 will be accomplished. Accordingly, the SHINE MC&A Plan describes how SHINE's program for the control and accounting of SNM meets the performance objectives of 10 CFR 74.41(a) and the system features and capabilities requirements of 10 CFR 74.41(c).

As an initial matter, SHINE has not yet submitted its application for a license to possess SNM and to possess and use at any one time and location SNM in a quantity exceeding one effective kilogram, which means that 10 CFR 70.22(b) does not currently apply to SHINE. The NRC staff, however, understands that SHINE intends to submit a 10 CFR Part 70 application. As the staff understands it, upon submitting its 10 CFR Part 70 application, SHINE intends to combine this application with its 10 CFR Part 50 application in accordance with 10 CFR 50.31, "Combining applications." Given this, and the fact that SHINE has submitted its MC&A Plan as part of its 10 CFR Part 50 application, the staff is reviewing that plan against the relevant regulatory requirements.

Chapter 1 – Introduction

Chapter 1, "Introduction," of the SHINE MC&A Plan contains the purpose and scope of the MC&A Plan, facility description, process description, and a description of the forms of SNM to be processed at the SHINE facility. The information in this chapter is supplemental and administrative in nature. Based on its review, the NRC staff finds that the information in chapter 1 is acceptable because it is administrative in nature, not contrary to the NRC's regulations, and adequately describes the facility processes and the SNM processed at the facility in sufficient detail for the staff to review the rest of the SHINE MC&A Plan.

Chapter 2 – General Performance Objectives

The purpose of the general performance objectives in 10 CFR 74.41(a) is to maintain current information, verify the presence of all SNM held by the licensee, and to detect the occurrence of any significant loss, including possible theft or diversion. To maintain current information, the applicant should have in place a program that provides timely, accurate, and reliable information about the quantity and location of SNM in its possession (10 CFR 74.41(a)(1)). To meet the requirements of 10 CFR 74.41(a)(2)-(3), the applicant should have a formalized program to promptly investigate and resolve an anomaly that may indicate a possible loss of SNM. Resolution of such anomalies means that the applicant has made a rapid determination about whether an actual loss of a significant quantity of SNM has occurred, including possible theft or diversion. If the NRC or other government agency deems it necessary to conduct an investigation of actual (or highly suspected) events concerning missing material, the licensee should provide any information it deems relevant to the recovery of material involved in a loss, theft, or diversion, as required by 10 CFR 74.41(a)(4).

SHINE addressed the general performance objectives throughout the SHINE MC&A Plan. An overview of the basis for the SHINE MC&A program is described in chapter 2, "General Performance Objectives." Chapter 4, "Measurements," and chapter 5, "Measurement Control

System," describe the measurement program and controls that ensure SNM quantities are accurate, current, and reliable. Chapter 7, "Physical Inventory Program," describes the inventory program that confirms the quantities and presence of all SNM at the facility. Chapter 8, "Item Control Program," describes controls in place to ensure current knowledge on SNM in items, and to ensure that items are stored, handled, and measured in a manner that will ensure detection of unauthorized or unrecorded removal of SNM. Chapter 13, "Resolving Indications of Loss, Theft, Diversion or Misuse of Special Nuclear Material," describes how SHINE will investigate and resolve indications of loss, theft, diversion, or misuse of SNM. Chapter 14, "Aiding Investigation and Recovery of Missing Special Nuclear Material," describes SHINE's program for aiding the investigation and recovery of missing SNM. Chapter 15, "Recordkeeping," describes how SHINE establishes and maintains records that demonstrate how the general performance objectives and system capabilities are met.

The NRC staff reviewed SHINE's strategy for meeting the general performance objectives as provided in the SHINE MC&A Plan. This review is discussed throughout this SER. On the basis of that review, the NRC staff determined that SHINE's overall MC&A program includes processes and procedures to ensure accurate, current, and reliable information on all SNM; to confirm the presence of SNM; to investigate and resolve anomalies; to permit rapid determination of whether a significant loss of SNM has occurred; and to generate information to aid in the investigation and recovery of missing SNM. The NRC staff finds that SHINE's program for meeting the overall general performance objectives includes the appropriate components to meet the requirements in 10 CFR 74.41(a) and is, therefore, acceptable.

<u>Chapter 3 – Management Structure</u>

Under 10 CFR 74.43(a) and (b)(1)–(4), licensees subject to 10 CFR 74.41 must implement internal controls laid out in 10 CFR 74.43(b)(1)–(4) that relate to management structure. The management structure requirements are meant to separate the performance of key MC&A functions from each other to incorporate checks and balances that increase MC&A system reliability and make the theft or diversion of SNM less likely. These functions are then overseen by a single individual as specified by 10 CFR 74.43(b)(2). This separation at the performance level is also meant to free MC&A management personnel from conflicts of interest with other major functions, such as production, and ensure independence of action and objectiveness of decisions. An effective management structure also relies on the adequate review, approval, and use of written MC&A procedures, and the training and qualification of personnel in key positions to maintain a high level of safeguards awareness.

Chapter 3, "Management Structure," of the SHINE MC&A Plan describes the management structure, including the facility organization, MC&A organization, procedures, and training and qualifications. Section 3.2, "Facility Organization," and section 3.3, "MC&A Organization," describe the various facility organizations as they relate to MC&A and discuss the positions responsible for the MC&A functions, including accounting, measurement, control, and custodianship. Chapter 3 discusses the overall responsibility for MC&A, independence from manufacturing responsibilities, and separation of key responsibilities, which ensures that the individual with overall responsibility for the MC&A program will function with independence of action and objectiveness of decisions. Section 3.3.5, "MC&A Procedures," provides information related to the adequate review, approval, and use of written procedures which cover all aspects of the MC&A program. MC&A procedures are listed in Appendix 16.4, "List of MC&A Procedures," of the SHINE MC&A Plan. Section 3.4, "Training and Qualification Requirements," describes MC&A training for the general employee, training and qualification for employees with specific MC&A tasks, and minimum qualifications for positions with significant MC&A

responsibilities. SHINE stated that personnel who work in key positions involving MC&A are trained to maintain a high level of safeguards awareness.

The NRC staff finds that the plan for the management structure for the SHINE facility provided in chapter 3, “Management Structure,” of the SHINE MC&A Plan incorporates clear overall responsibility for MC&A functions, independence from production and manufacturing, separation of key responsibilities, and overall responsibility for MC&A vested in a single individual at a level sufficient to ensure independence of action and objectiveness of decisions to meet the requirements in 10 CFR 74.43(b)(1)–(2). SHINE’s plan for review, approval, and use of written procedures, and assurance that personnel who work in key positions are trained to a high level of safeguards awareness meets the requirements of 10 CFR 74.43(b)(3)–(4). Therefore, SHINE’s plan for these internal controls is acceptable.

Chapter 4 – Measurements

Under 10 CFR 74.45(b), licensees must establish, maintain, and use a program for the measurement of all SNM (both element and fissile isotope) received, produced, transferred between internal control areas, on inventory, or shipped, discarded, or otherwise removed from inventory, with certain exceptions. Licensees must develop and follow approved written procedures related to reference standards, measurement system calibrations, performing measurements, obtaining samples, performing laboratory analyses, and recording, reviewing, and reporting measurements.

Chapter 4, “Measurements,” of the SHINE MC&A Plan describes the SHINE SNM measurement program. Systems are in place for quantifying the mass of all SNM received, shipped, discarded, transferred between internal control areas (ICAs), or listed in the physical inventory. Section 4.1, “Measurement Points,” lists the items/containers that will be onsite and the measurements to be taken. Section 4.1 also shows in Table 4-1a measurements of SNM between ICAs. Section 4.2, “Measurement Systems,” describes the various measurement systems used at the SHINE facility, including analytical measurements, sampling, mass measurements, volume, and nondestructive assay measurements. Section 4.4, “Measurement Procedures,” states that approved, written procedures are used for all accountability measurement methods, including sampling. Approved written procedures are also used for control and reference standards and for calibrating measurement systems.

The NRC staff finds that SHINE’s plan for the measurement program provided in chapter 4, Measurements,” of the SHINE MC&A Plan includes sufficient detail on the measurement points and measurement systems that will be used at the SHINE facility, and on the program for the development and use of written procedures for all aspects of its measurement program, for the staff to determine that it meets the requirements in 10 CFR 74.45(b). Additionally, although the SHINE MC&A plan did not explicitly address SNM “otherwise removed from inventory” this would be accounted for because all material removed from inventory would have a measured value on inventory. Further, although SHINE would produce very small quantities of plutonium, these quantities are so small they would not be measured, they would be calculated. Therefore, while the SHINE MC&A Plan does not address SNM produced by SHINE, it does not need to because SHINE will not produce any SNM that would be measured. It is, therefore, acceptable. The calculated quantities of plutonium are discussed in section 4.1.3, “Quantity of Pu,” of the SHINE MC&A Plan.

Chapter 5 – Measurement Control System

Under 10 CFR 74.45(c)(1) – (11), licensees must ensure that measurement systems used to establish SNM accountability quantities are controlled by a formal measurement control program that ensures measurement quality is maintained and measurement uncertainty values are estimated. Chapter 5 of the SHINE MC&A Plan describes the measurement control program.

Under 10 CFR 74.45(c)(1) licensees must assign responsibility for planning, developing, coordinating, and administering a measurement control program to an individual who has no direct responsibility for performing measurements or for SNM processing or handling, and who holds a position at an organizational level which permits independence of action and has adequate authority to obtain all the information required to monitor and evaluate measurement quality.

Section 5.1, “Organization and Management,” and chapter 3, “Management Structure” (as discussed above), of the SHINE MC&A Plan provides a description of the organization and management of the measurement control program, which includes personnel from the MC&A organization that are responsible for the oversight and implementation of the program, as well as the personnel outside of the MC&A organization that are responsible for performing measurement control activities. SHINE stated that the MC&A Manager is responsible for implementing the overall MC&A program, including planning and coordination, and for administering the measurement control program. SHINE stated that oversight of the measurement control program is provided by the MC&A organization, which is independent of the organizations that perform measurements and measurement control activities.

The NRC staff finds that the organization and management of the measurement control program for the SHINE facility provided in section 5.1, “Organization and Management,” and chapter 3, Management Structure,” of the SHINE MC&A Plan are sufficiently independent from performing measurements and from SNM processing and handling to meet the measurement control requirement of 10 CFR 74.45(c)(1) and are, therefore, acceptable.

Under 10 CFR 74.45(c)(2) licensees must ensure that any contractor who performs MC&A measurement services conforms with the applicable measurement control requirements in 10 CFR 74.45(c)(5), (6), (7), (10), and (11), and that conformance includes reporting of sufficient measurement control data to allow the licensee to calculate the associated measurement uncertainties.

Section 5.1, “Organization and Management,” of the SHINE MC&A Plan states that outside contractors and offsite laboratories used to provide measurement services for SHINE are reviewed to ensure measurement control systems are in place and adequate to meet the requirements of 10 CFR 74.45(c)(2). SHINE also stated that the outside contractor program is audited annually. Additionally, Section 10.5, “Assessment of Outside Contractor,” of the SHINE MC&A Plan states that the outside contractor or laboratory’s measurement services will be assessed as part of the independent assessment of the SHINE MC&A program, as described in chapter 10, “Assessment and Review of the MC&A Program,” of the SHINE MC&A Plan.

The NRC staff finds that SHINE’s plan for evaluating and reviewing contractors that provide MC&A measurement services for SHINE provided in sections 5.1, Organization and Management,” and 10.5, “Assessment of Outside Contractor,” of the SHINE MC&A Plan is sufficiently comprehensive to meet the measurement control requirement in 10 CFR 74.45(c)(2) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(3) licensees must identify potential sources of sampling error and ensure that samples are representative by performing process sampling tests using well characterized materials to establish or verify the applicability of utilized procedures for sampling SNM and for maintaining sample integrity during transport and storage. Licensees are also required to conduct sampling tests whenever a new sampling procedure or technique is used, or new sampling equipment is installed; a sampling procedure, technique, or sampling equipment is modified; or sample containers, sample transport methods, or sample storage conditions are modified.

Section 4.2.5, “Sampling Systems,” of the SHINE MC&A Plan describes the potential sources of sampling error and the performance of sampling tests to ensure that solutions are homogeneous and samples are representative. SHINE stated that sampling tests are also performed when modifications are made to a sampling system, a new sampling procedure is used, a sampling technique is modified, sample containers are modified, or sample storage is modified. The NRC staff understands a sampling technique or system, as those terms are used by SHINE, to include sampling equipment and sampling transportation methods. This is similar to the use of the term “measurement system,” as defined in 10 CFR 74.4, where measurement system is defined as “all the apparatus, equipment, instruments and procedures used in performing a measurement.” While there is no definition of “sampling system” in 10 CFR 74.4, analogous reasoning would define sampling system as all of the apparatus, equipment, instruments, and procedures used in sampling.

The NRC staff finds that SHINE’s plan for sampling tests in Section 4.2.5, “Sampling Systems,” of the SHINE MC&A Plan includes sufficient descriptions of possible sampling errors, sampling tests, and when sampling tests would be used to allow the staff to determine that the program meets the measurement control requirement in 10 CFR 74.45(c)(3) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(4) licensees must establish and maintain a measurement control program so that for each inventory period the standard of error for the inventory difference (SEID) is less than 0.125 percent of the active inventory and assure that any MC&A measurements performed under contract are controlled so that the licensee can satisfy this requirement.

Chapter 5, “Measurement Control System,” and section 6.2.2, “Estimating the Standard Error of the Inventory Difference,” of the SHINE MC&A Plan state that measurement uncertainty is controlled so that the SEID, based on all measurement contributions, is less than 0.125 percent of the active inventory. Chapter 5, “Measurement Control System,” also states that the same measurement control requirements must be met for outside contractors or offsite laboratories providing accountability measurement services, and that these outside organization measurement programs are subject to review before use and by annual audits.

The NRC staff finds that SHINE’s plan for establishing and maintaining a measurement control program provided in Chapters 5, “Measurement Control System,” and 6, “Statistics,” of the SHINE MC&A Plan presents sufficient explanation of its approach for controlling measurement uncertainty to allow the staff to determine that the program meets the measurement control requirement in 10 CFR 74.45(c)(4) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(5) licensees must generate current data on the performance of each measurement system used during each material balance period in order to establish measured values and uncertainties, including bias, variance components for calibration, sampling, and replicate measurements.

Section 3.3.2, “Nuclear Material Measurement Responsibilities,” of the SHINE MC&A Plan states that the measurement control program coordinator has responsibility for oversight of MC&A measurements and implementation of the measurement control program. Chapter 5, “Measurement Control System,” describes the activities involved in monitoring measurement systems, including calibrations; use of control standards to ensure systems are in control and to estimate bias; and the use of replicate samples and measurements to estimate sampling uncertainties and random errors. Section 5.1, “Organization and Management,” states that the MC&A organization is responsible for analyzing measurement control data and evaluating measurement performance. Section 3.3, “MC&A Organization,” states that Operations and Radiation Protection generate the source data upon which the records in the accounting system are based, including measurement and measurement control data. Section 5.1, Organization and Management,” also states that Operations, Radiation Protection, and the Laboratories are responsible for performing control measurements and providing the control measurement results to the MC&A organization. Chapter 6, “Statistics,” describes the statistical methods used to determine measurement uncertainties and to identify biases.

The NRC staff finds that SHINE’s plan for generating and monitoring current measurement control data provided in chapters 3, “Management Structure,” 5, “Measurement Control System,” and 6, “Statistics,” of the SHINE MC&A Plan includes sufficient details on generating the data, estimating and controlling bias and measurement uncertainties through calibration, sampling, and replicates to allow the staff to determine that the program meets the measurement control requirement in 10 CFR 74.45(c)(5) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(6) licensees must use standards on an ongoing basis for the calibration and control of all measurement systems used for SNM accountability. Additionally, 10 CFR 74.45(c)(6) requires licensees ensure that:

- Calibrations are repeated whenever any significant change occurs in a measurement system or when program data indicate a need for recalibration;

- Calibrations and control standard measurements are based on standards whose assigned values are traceable to certified reference standards or certified standard reference materials; and

- Control standards are representative of the process material or items being measured by the measurement system in question.

Section 5.2, “Calibrations,” of the SHINE MC&A Plan describes the use of calibration standards and methods for laboratory instruments, scales and balances, and tanks and other vessels. SHINE stated that calibrations are repeated when a significant change to a measurement system occurs and when control standard measurements fail to meet acceptance criteria. Chapter 5, “Measurement Control System,” and section 4.2, “Measurement Systems,” of the SHINE MC&A Plan state that calibration standards are traceable to nationally recognized standards.

Section 5.3, “Control Standards,” of the SHINE MC&A Plan describes the use of control standards to ensure measurement systems are in control. SHINE stated that control standard measurements are used to verify the performance of each measurement system that is not point-calibrated, and the control standards are traceable to nationally recognized standards. SHINE also stated that control standards are representative of the process material being measured.

The NRC staff finds that SHINE’s plan for the use of calibration and control standards in sections 5.2, “Calibrations,” and 5.3, “Control Standards,” of the SHINE MC&A Plan sufficiently utilizes these standards to meet the measurement control requirements in 10 CFR 74.45(c)(6) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(7) licensees must conduct control measurements to provide current data for the determination of random error behavior. The program must also, on a predetermined schedule, include the following, as appropriate:

- Replicate analyses of individual samples;
- Analysis of replicate process samples;
- Replicate volume measurements of bulk process batches;
- Replicate weight measurements of process items and bulk batches, or alternatively, the use of data generated from the replicate weighing of control standard weights as derived from the control standard program; and
- Replicate nondestructive assay (NDA) measurements of individual process containers or items, or alternatively, the use of data generated from the replicate measurements of NDA control standards as derived from the control standard program.

Section 5.4, “Replicate Measurements,” of the SHINE MC&A Plan describes the replicate measurement program used to determine random error behavior. SHINE discussed the use of duplicate or replicate samples to estimate combined analytical plus sampling error. SHINE stated that for mass measurements, replicate measurements are taken of control standards. SHINE stated that NDA replicates are not taken due to the low quantity of SNM in waste measured by NDA. SHINE also stated that volume replicates are not taken since the replicates would not be independent of each other and would therefore not be statistically appropriate.

The NRC staff finds that SHINE’s plan for the replicate program to determine random error behavior provided in section 5.4, “Replicate Measurements,” of the SHINE MC&A Plan includes sufficient description of its approach to conducting control measurements, including limitations due to small quantities of SNM in some material areas, to allow the staff to determine that the program meets the measurement control requirement in 10 CFR 74.45(c)(7) and is, therefore, acceptable.

Under 10 CFR 74.45(c)(8) licensees must use all measurements and measurement controls generated during the current material balance period for the estimation of the SEID.
Under 10 CFR 74.45(c)(9) licensees must evaluate with appropriate statistical methods all measurement system data generated pursuant to 10 CFR 74.45(c)(5) to determine significant contributors to the measurement uncertainties associated with inventory differences and

shipper-receiver differences so that if SEID exceeds specified limits established in 10 CFR 74.45(c)(4), the cause of the excessive SEID can be identified for corrective action with respect to controlling the standard error within applicable limits.

Section 6.2.2, “Estimating the Standard Error of the Inventory Difference,” of the SHINE MC&A Plan describes the approach used to determine the various components of the SEID. SHINE stated that the SEID takes into account all measurement error contributions to the components of the inventory difference, and that measurement uncertainty is controlled so that SEID does not exceed 0.125 percent of active inventory. Determination of the measurement errors, both random and systematic, is described in section 6.1.2, “Estimating Random Uncertainty,” and section 6.1.3, “Estimating Systematic Uncertainty.” Section 6.1, “Determination of Measurement Uncertainties,” of the SHINE MC&A Plan states that measurement uncertainties are estimated using measurement control data (control standards and replicates) as described in chapter 5, “Measurement Control System,” of the SHINE MC&A Plan. SHINE stated that established statistical techniques are used to analyze measurement data to provide random and systematic error variances in the measurement method. Section 7.7, “SEID Limit and Response Actions,” states that if a calculated SEID exceeds the limit of 0.125 percent of active inventory, an investigation will be initiated to determine which measurement systems(s) were the source of the excessive SEID.

The NRC staff finds that SHINE’s plan for the use of measurements and measurement controls to estimate SEID along with its plan for the use of appropriate statistical methods to evaluate all measurements and measurement controls in estimating the SEID in chapters 5, “Measurement Control System,” 6, “Statistics,” and 7, “Physical Inventory Program,” of the SHINE MC&A Plan includes appropriate data and calculations to meet the measurement control requirements in 10 CFR 74.45(c)(8) and (9), including calculating SEID and identifying the cause of excessive SEID for corrective action, and is, therefore, acceptable.

Under 10 CFR 74.45(c)(10) licensees must establish and maintain a statistical control system, including control charts, formal statistical procedures, and control limits (established at the 0.05 and 0.001 significance levels or their equivalent) designed to monitor the quality of each measurement device or system. Under 10 CFR 74.45(c)(11) licensees must promptly investigate and take any appropriate corrective action whenever a control datum exceeds an 0.05 control limit, and whenever a control datum exceeds an 0.001 control limit, the measurement system that generated the datum shall immediately be placed out-of-service with respect to MC&A measurements until the deficiency has been corrected and the system brought into control within the 0.05 control limits.

Section 5.5, “Control Limits,” of the SHINE MC&A Plan states that control limits are established at the 0.05 (warning limit) and 0.001 (alarm limit) significance levels, and statistical analyses are performed to evaluate a measurement system’s performance, including the use of control charts. SHINE described the response activities when control limits are exceeded, including remeasurements when the warning limits are exceeded and removal of the measurement system from service when the control standard result is out-of-control (exceeds the alarm limit). SHINE stated that the system will not be returned to service until the measurement system has been returned to statistical control. Section 3.3.2, “Nuclear Material Measurement Responsibilities,” of the SHINE MC&A Plan states that the measurement control coordinator monitors control standard results from measurement systems to ensure that no accountability values were established using an out-of-control system. Section 5.1, “Organization and Management,” of the SHINE MC&A Plan states that all facility procedures that address measurement include a section on measurement control, if applicable, and are subject to approval by the MC&A Manager.

The NRC staff finds that SHINE's plan to establish and maintain a statistical control system to monitor the quality of each measurement system provided in sections 3.3.2, "Nuclear Measurement Responsibilities," 5.1, "Organization and Management," and 5.5, "Control Limits," of the SHINE MC&A Plan includes procedures, control charts, and the appropriate calculations, alarm levels, and alarm responses to meet the measurement control requirements in 10 CFR 74.45(c)(10) and (11) and is, therefore, acceptable.

Chapter 6 – Statistics

Proper use of statistics is important to ensure that the regulatory requirements in 10 CFR 74.43, "Internal controls, inventory, and records," and 10 CFR 74.45, "Measurements and measurement control," are met. An effective statistical program will ensure that measurement uncertainties are estimated and propagated; the inventory difference (ID) and SEID are properly determined; and bias corrections are appropriately estimated and applied.

Chapter 6, "Statistics," of the SHINE MC&A Plan describes the use of statistics in the SHINE MC&A program. This chapter describes how both random and systematic measurement uncertainties are determined and the sources of the uncertainties. Calculation of the ID and SEID are described in section 6.2, "Determination of Inventory Statistics." SHINE described the calculation of the active inventory (used in evaluating the SEID) and stated that common items are appropriately removed from the active inventory equation. Section 6.3, "Bias Corrections," describes how SHINE corrects for bias and states that significant biases are corrected in each measurement value or as a total in the inventory difference equation.

The NRC staff finds that SHINE's statistical programs include the appropriate consideration of uncertainties and use of calculations and meet the system capabilities requirements in 10 CFR 74.43 and 10 CFR 74.45. Therefore, SHINE's statistical programs are acceptable.

Chapter 7 – Physical Inventory Program

The regulations in 10 CFR 74.43(c)(1)–(8) describe licensee requirements related to inventory control and physical inventories. Chapter 7 of the SHINE MC&A Plan describes the physical inventory program for the SHINE facility.

Under 10 CFR 74.43(c)(1) licensees must provide unique identification for each item on inventory and maintain inventory records showing the identity, location, and quantity of SNM for these items.

Section 7.1, "General Description," of the SHINE MC&A Plan provides a general description of the physical inventory. SHINE stated that a book inventory list includes all SNM items that records indicate should be present, and that the list indicates the current status of all items. Section 8.3, "Item Identity Controls,"of the SHINE MC&A Plan indicates that all SNM containers have a unique identity that cannot be altered. Section 15.1, "Description of Records," of the SHINE MC&A Plan describes the Item History Form, which is the primary record used to account for SNM. The form includes item identity, current location, and quantity of SNM.

The NRC staff finds that the item identity controls used for item control and inventory control, as provided in sections 7.1, "General Description," 8.3, "Item Identity Controls," and 15.1, “Description of Records,” of the SHINE MC&A Plan, include the item identity, location, and quantity to meet the inventory control requirement in 10 CFR 74.43(c)(1) and are, therefore, acceptable.

Under 10 CFR 74.43(c)(2) licensees must document all transfers of SNM between designated internal control areas within the licensee’s site.

Section 3.6, “Material Control Boundaries,” of the SHINE MC&A Plan describes the internal control areas to be used to facilitate control of SNM. SHINE stated that records are prepared to document movement of SNM between the areas. Section 3.3.4, “Nuclear Material Custodians,” of the SHINE MC&A Plan states that the nuclear material custodians are responsible for ensuring that transfers of SNM out of the area to which they are assigned have been approved and ensuring that all activities involving SNM are documented. Section 15.1, “Description of Records,” of the SHINE MC&A Plan describes the primary forms used to document history and movement of SNM items. The Item History Form follows the item, including location, from receipt and throughout its existence. The SNM Transfer Form records relocation of items.

The NRC staff finds that the transfer documentation controls used for item control and inventory control, as provided in sections 3.6, “Material Control Boundaries,” 3.3.4, “Nuclear Material Custodians,” and 15.1, “Description of Records,” of the SHINE MC&A Plan, including assigning transfer control responsibilities to nuclear material custodians, provide for documentation of all transfers of SNM to meet the inventory control requirement in 10 CFR 74.43(c)(2) and are, therefore, acceptable.

Under 10 CFR 74.43(c)(3) licensees must maintain and follow procedures for tamper-safing of containers or vaults containing SNM, if tamper-safe seals are to be used for assuring the validity of prior measurements. The procedures must include control of access to, and distribution of, unused seals and to records showing the date and time of seal application.

SHINE’s tamper-safing program is described in chapter 11, “Tamper-Safing,” of the SHINE MC&A Plan. The NRC staff’s review of this program can be found in “Chapter 11 – Tamper-Safing,” of this section of the SER.

Under 10 CFR 74.43(c)(4) licensees must maintain and follow procedures for confirming the validity of prior measurements associated with unencapsulated and unsealed items on ending inventory.

Section 11.1, “Characteristics of Tamper-Safing Devices,” of the SHINE MC&A Plan states that tamper-indicating devices (TIDs) are used on containers of SNM to ensure that no tampering has occurred with the contents. SHINE stated that TIDs are used on containers of SNM that are stored onsite and when they are in transit. Section 8.4, “Storage Controls,” of the SHINE MC&A Plan describes storage of SNM items and states that the containers are tamper-safed. Section 7.3, “Typical Inventory Composition,” of the SHINE MC&A Plan states that any SNM items that were measured prior to the inventory-taking are not re-measured if a TID was applied and the TID remains intact. In addition, any SNM included in the inventory that has not previously been measured is measured for the inventory. Section 7.5, “Conducting Physical Inventories,” of the SHINE MC&A Plan states that during inventory-taking, the TID integrity and identification number are confirmed, and that any discrepancies that are identified during the inventory are investigated and resolved. Based on these measures, the SHINE MC&A plan indicates that there will be no unencapsulated or unsealed items on ending inventory.

The NRC staff finds that SHINE's program for confirmation of the validity of prior measurements used for item control and inventory control, as provided in sections 11.1, "Characteristics of Tamper-Safing Devices," 8.4, "Storage Controls," 7.3, "Typical Inventory Composition," and 7.5, "Conducting Physical Inventories," of the SHINE MC&A Plan, includes the use of TIDs to ensure that no items are unencapsulated or unsealed on ending inventory. This meets the inventory control requirement in 10 CFR 74.43(c)(4) and is, therefore, acceptable.

Under 10 CFR 74.43(c)(5) licensees must maintain and follow physical inventory procedures to ensure that the requirements in 10 CFR 74.43(c)(5)(i)–(vi) are met. Under 10 CFR 74.43(c)(6) licensees must conduct physical inventories according to written instructions which meet the requirements in 10 CFR 74.43(c)(6)(i)–(iv).

Concerning the inventory procedure requirements in 10 CFR 74.43(c)(5), section 7.1, "General Description," of the SHINE MC&A Plan states that all aspects of SHINE's physical inventory program are contained in the SHINE MC&A procedure, "Physical Inventory Taking." Chapter 7, "Physical Inventory Program," of the SHINE MC&A Plan describes the physical inventory program, including the general description, organization, procedures, inventory composition, and conduct of the inventory. Sections 7.3, "Typical Inventory Composition," and 7.5, "Conducting Physical Inventories," state that the physical inventory is a measured inventory, that any SNM not previously measured is measured for inventory, and that every item is accounted for and no item is counted more than once by using controlled inventory tags. Cutoff procedures for transfers and processing, and for records and reports, are established as described in sections 7.3, "Typical Inventory Composition," and 7.5, "Conducting Physical Inventories," of the SHINE MC&A Plan. As stated in section 7.3, "Typical Inventory Composition," of the SHINE MC&A Plan, any SNM not previously measured is measured for the inventory, and the measurements are completed as soon as possible after the inventory listing. Section 7.5, "Conducting Physical Inventories," of the SHINE MC&A Plan states that following the physical inventory, the book and inventory records are reconciled with, and adjusted to, the results of the physical inventory for each internal control area.

Concerning the inventory written instructions requirements in 10 CFR 74.43(c)(6), section 7.5, "Conducting Physical Inventories," of the SHINE MC&A Plan states that detailed inventory instructions are issued prior to the start of each inventory and are approved by the MC&A manager. Section 7.5, "Conducting Physical Inventories," of the SHINE MC&A Plan also states that facility staff with inventory responsibilities are named in the instructions and trained to perform their inventory activities. SHINE stated that the instructions include a timeline of activities including cutoff times for SNM movement and processing, steps taken to clean out processing equipment, and the timing and performance of various inventory steps. Section 7.3, "Typical Inventory Composition," of the SHINE MC&A Plan provides a list of every inventory stratum and how those strata are handled during inventory. Section 7.3 also states that SNM items measured prior to inventory are not remeasured if a TID was applied at the time of measurement and if inspection of the item and the TID indicates the contents (measured quantity and its limit of error) are intact. If there is evidence of tampering, the contents will be remeasured. The inventory instructions identify specific points where measurements should be made and detail any deviation from normal inventory procedures. As discussed in the previous paragraphs, the SHINE MC&A plan also includes normal inventory procedures.

The NRC staff finds that the inventory procedures and instructions used for inventory control, as described in sections 7.1, "General Description," 7.3, "Typical Inventory Composition," and 7.5, "Conducting Physical Inventories," of the SHINE MC&A Plan, sufficiently address the inventory control requirements in 10 CFR 74.43(c)(5) and (6) and are, therefore, acceptable.

Under 10 CFR 74.43(c)(7) licensees must conduct physical inventories of all SNM possessed at intervals not to exceed nine calendar months. Under 10 CFR 74.43(c)(8) licensees must, within 60 calendar days after the start of the physical inventory required by 10 CFR 74.43(c)(7), calculate, for the material balance period terminated by the physical inventory, the ID and associated SEID for both element and isotope; reconcile and adjust the book record of quantity of element and isotope, as appropriate, to the results of the physical inventory; and investigate and report to the Director, NRC Office of Nuclear Material Safety and Safeguards, any occurrence where the ID or the SEID exceed limits specified in 10 CFR 74.43(c)(8)(iii) and include a statement of the probable reasons for the excessive inventory difference and the corrective actions taken or planned. The regulations in 10 CFR 74.13, "Material status reports," require, in part, licensees to submit material balance reports and physical inventory listings for each physical inventory performed within 60 calendar days of the beginning of the physical inventory. The regulations in paragraph (b) of 10 CFR 74.17, "Special nuclear material physical inventory summary report," require, in part, licensees to report the results of each physical inventory using NRC Form 327, "Special Nuclear Material (SNM) and Source Material (SM) Physical Inventory Summary Report," not later than 60 calendar days from the start of each physical inventory required by 10 CFR 74.43(c)(7).

Chapter 7, Physical Inventory Program," of the SHINE MC&A Plan provides a description of the physical inventory program for the SHINE facility. Section 7.1, "General Description," of the SHINE MC&A Plan states that a physical inventory of all SNM at the facility is conducted at intervals not to exceed 9 calendar months, and that differences between the accounting records and the physical inventory are investigated and reconciled. Details of the physical inventory process, including reconciliation activities to align the accounting records and the physical inventory, are provided in section 7.5, "Conducting Physical Inventories," of the SHINE MC&A Plan.

Section 7.1, "General Description," of the SHINE MC&A Plan states that material balance reports (DOE/NRC Form 742, misidentified in the MC&A Plan as material status reports), which are a type of material status report, and physical inventory listings, and the inventory summary report (NRC Form 327) are submitted within 60 days of the start of the physical inventory in the proper formats. Calculation of the ID and the associated SEID are described in section 6.2, "Determination of Inventory Statistics," of the SHINE MC&A Plan. Section 7.6, "Inventory Limits and Response Actions," of the SHINE MC&A Plan describes the calculation of the ID limits and response actions when the ID exceeds the limits specified in 10 CFR 74.43(c)(8)(iii), including reporting to the NRC. Section 7.7, "SEID Limit and Response Actions," of the SHINE MC&A Plan states that if the SEID exceeds its 10 CFR 74.43(c)(8)(iii) control limit an investigation will be conducted and the NRC will be notified. Finally, as stated in chapter 7, "Physical Inventory Program," of the SHINE MC&A Plan, calculation of ID and SEID; relevant reconciliation activities; and investigation and reporting of SEID and ID exceeding relevant limits will be completed within 60 calendar days after the start of each physical inventory.

The NRC staff finds that SHINE's plan for conducting inventories and reporting results of the inventories, as provided in chapter 7, "Physical Inventory Program," and section 6.2, "Determination of Inventory Statistics," of the SHINE MC&A Plan, includes sufficient explanation of how and when SHINE will conduct inventories and the associated reporting to allow the staff to determine that the program meets the inventory control requirements in 10 CFR 74.43(c)(7) and (8), 10 CFR 74.13, and 10 CFR 74.17 and is, therefore, acceptable.

Chapter 8 – Item Control Program

Under 10 CFR 74.43(b)(5) licensees must establish, document, and maintain an item control program to protect against and detect unauthorized and unrecorded removal of items, or of material from items. This includes providing current knowledge of SNM items with respect to identity, element and isotope content, and stored location. Further, 10 CFR 74.43(b) exempts certain items from the requirements of 10 CFR 74.42(b)(5). An item, as defined in 10 CFR 74.4, “Definitions,” means any discrete quantity or container of SNM or source material, not undergoing processing, having a unique identity and also having an assigned element and isotope quantity.

Chapter 8, “Item Control Program,” of the SHINE MC&A Plan describes the item control program at the SHINE facility. The organizational responsibilities for the item control program are provided in section 8.1, “Organization,” as well as sections 3.3.1, “Nuclear Material Accounting Responsibilities,” 3.3.3, “Nuclear Material Control Responsibilities,” and 3.3.4, “Nuclear Material Custodians,” of the SHINE MC&A Plan. A general description of the item control program is provided in section 8.2, “General Description,” of the SHINE MC&A Plan which states that the item control program is designed to provide current knowledge of items and ensures detection of unauthorized or unrecorded removal of SNM. Chapter 8, “Item Control Program,” of the SHINE MC&A Plan also describes item identity and storage controls, which ensures that items have unique identities and are protected during storage, and item monitoring procedures, which confirm that items are stored and identified as indicated in the records. Section 8.6, “Investigation and Resolution of Item Discrepancies,” of the SHINE MC&A Plan states the type of discrepancies identified by item monitoring tests and that all discrepancies are investigated and resolved. Other sections of the SHINE MC&A Plan discuss activities that support item control. Sections 9.1, “Receiving Procedures,” and 9.5, “Shipments,” of the SHINE MC&A Plan discuss controls for receipts and shipments to ensure that they are properly tracked and controlled. Chapter 11, “Tamper-Safing,” of the SHINE MC&A Plan discusses tamper-safing, which ensures the integrity of the contents of items. Chapter 12, “Designation of Material Balance Areas, Item Control Areas, and Custodians,” of the SHINE MC&A Plan discusses the designation of material balance areas and custodians to facilitate SNM control. Chapter 15, “Recordkeeping,” of the SHINE MC&A Plan discusses recordkeeping, including the use of two forms: the item history form to track an item throughout its existence and the SNM transfer form to document relocations of SNM.

The NRC staff finds that SHINE’s program for item control for the SHINE facility, as provided in chapters 8, “Item Control Program,” 9, “Receiving and Shipping Program,” 11, “Tamper-Safing,” 12, “Designation of Material Balance Areas, Item Control Areas, and Custodians,” and 15, “Recordkeeping,” of the SHINE MC&A Plan, adequately describes how the program provides current knowledge of, protects, and detects missing SNM items to allow the staff to determine that the program meets the item control requirements in 10 CFR 74.43(b)(5), as modified by the 10 CFR 74.43(b)(6) exemption, and is, therefore, acceptable.

Chapter 9 – Receiving and Shipping Program

Under 10 CFR 74.43(b)(7) licensees must conduct and document shipper-receiver comparisons for all SNM receipts, both on an individual batch basis and a total shipment basis, and ensure that any shipper-receiver difference that is statistically significant and exceeds twice the estimated standard deviation of the difference estimator and 200 grams of plutonium or uranium-233 or 300 grams of uranium-235 is investigated and resolved;

Chapter 9, “Receiving and Shipping Program,” of the SHINE MC&A Plan describes the conduct of shipper–receiver comparisons, including receiving procedures and how the receiver’s values are determined. Section 9.3, “Evaluation of Shipper-Receiver Differences,” of the SHINE MC&A Plan discusses the statistical evaluation of SRDs, including how the combined standard error is determined, and the criteria for finding an SRD significant. Investigation and resolution of significant SRDs is described in section 9.4, “Resolution of Significant Shipper-Receiver Differences,” of the SHINE MC&A Plan including steps taken to investigate a significant SRD and possible causes. SHINE stated that any SRD that is statistically significant and exceeds twice the estimated standard deviation of the difference estimator and 300 grams of U-235, for both total receipt and individual containers, is investigated and resolved. Section 15.1, “Description of Records” of the SHINE MC&A Plan states that MC&A records include records related to the calculation of SRDs.

The NRC staff finds that SHINE’s program for conducting shipper–receiver comparisons for the SHINE facility, as provided in chapter 9, “Receiving and Shipping Program,” of the SHINE MC&A Plan, adequately addresses the calculation of SRD and resulting actions to meet the shipper–receiver requirement in 10 CFR 74.43(b)(7) and is, therefore, acceptable.

Chapter 10 - Assessment and Review of the MC&A Program

Under 10 CFR 74.43(b)(8) licensees are required to perform independent assessments of the MC&A program at least every 18 months. This assessment must assess the performance of the MC&A program, review its effectiveness, and document management’s action on prior assessment recommendations and identified deficiencies. The assessment must also include a review and evaluation of any contractor who performs SNM accountability measurements for the licensee.

Chapter 10, “Assessment and Review of the MC&A Program,” of the SHINE MC&A Plan describes the assessment and review of the SHINE MC&A program. Chapter 10 describes the makeup and responsibilities of the assessment team, a comprehensive list of the areas to be reviewed, the review process, including timing of the review and distribution of the report, and the review and response to the report findings. SHINE stated that the assessment evaluates the performance and overall effectiveness of the SHINE MC&A program every 18 months, and documents management action on prior assessment recommendations and deficiencies. SHINE also stated that the assessment includes an evaluation of any contractor who performs SNM accountability measurements for SHINE.

The NRC staff finds that SHINE’s program for independent assessment of the MC&A program for the SHINE facility, as provided in chapter 10, “Assessment and Review of the MC&A Program,” of the SHINE MC&A Plan, sufficiently describes the approach to allow the staff to determine that the assessment meets the assessment program requirement in 10 CFR 74.43(b)(8) and is, therefore, acceptable.

Chapter 11 – Tamper-Safing

Under 10 CFR 74.43(c)(3) licensees must maintain and follow procedures for tamper-safing of containers or vaults containing SNM, if tamper-safe seals are to be used for assuring the validity of prior measurements. The procedures must include control of access to, and distribution of, unused seals and records showing the date and time of seal application.

Chapter 11, "Tamper-Safing," of the SHINE MC&A Plan describes the tamper-safing program. SHINE described the types of TIDs used at the SHINE facility and the testing of the TIDs to ensure that removal would be detected. SHINE further described TID control and usage, inventory of unused and unissued TIDs, the proper application of TIDs, and training of authorized users in the application and destruction of TIDs. Chapter 11, "Tamper-Safing," of the SHINE MC&A Plan also describes the records that are prepared to document TID activities. The SHINE tamper-safing program ensures that procedures are maintained and followed for tamper-safing, and includes control of access to, and distribution of, unused seals and records showing the date and time of seal application.

The NRC staff finds that SHINE's tamper-safing program for the SHINE facility, as provided in chapter 11, "Tamper-Safing," of the SHINE MC&A Plan, adequately describes the use of TIDs to allow the staff to determine that the program meets the tamper-safing requirement in 10 CFR 74.43(c)(3) and is, therefore, acceptable.

Chapter 12 – Designation of Material Balance Areas, Item Control Areas, and Custodians

As discussed above, because of the material that SHINE expects to possess, it is governed by 10 CFR 74.41, 10 CFR 74.43, and 10 CFR 74.45. Although these regulations do not require material balance areas (MBAs), item control areas, and the designation of custodians, SHINE has voluntarily decided to designate an MBA and to designate custodians as part of its MC&A Plan. That said, regulations related to measurements in 10 CFR 74.45(b) and to inventory in 10 CFR 74.43(c) do require "internal control areas," and licensees use internal control areas (ICAs) in some form to facilitate control of SNM.

Chapter 12, "Designation of Material Balance Areas, Item Control Areas, and Custodians," of the SHINE MC&A Plan describes the designation of material control boundaries—which is a generic term SHINE uses to refer to both MBAs and ICAs—and custodians. Due to the size of the SHINE facility, only one MBA is designated. However, to facilitate control, localize losses, and aid in the resolution of MC&A anomalies, the one MBA is divided into five ICAs. Chapter 3, "Management Structure," of the SHINE MC&A Plan contains additional information on ICAs and custodial responsibilities. The ICAs are characterized by the form of material and by the physical location of the material. The SHINE MC&A Plan also states that custodial responsibility is assigned to one individual for each ICA.

As noted above, SHINE is not required to identify material balance areas, item control areas, or designate custodians. That said, nothing in the regulations prevents SHINE from going beyond the regulatory requirements. The NRC staff reviewed the SHINE MC&A plan and finds that SHINE's plan for designation of MBAs, ICAs, and custodians for the SHINE facility, as provided in chapter 12, "Designation of Material Balance Areas, Item Control Areas, and Custodians," and chapter 3, "Management Structure," of the SHINE MC&A Plan, is not contrary to regulatory requirements.

Chapter 13 – Resolving Indications of Loss, Theft, Diversion, or Misuse of Special Nuclear Material

Under the general performance objectives in 10 CFR 74.41(a)(2) and (3) licensees should be able to promptly conduct investigations and resolve anomalies indicating a possible loss of SNM, and rapidly determine whether an actual loss of a significant quantity of SNM, as defined in 10 CFR 74.41(a)(3)(i)-(ii), has occurred.

Chapter 13, “Resolving Indications of Loss, Theft, Diversion, or Misuse of Special Nuclear Material,” of the SHINE MC&A Plan describes the resolution program. SHINE described methods and procedures for identifying indicators and the actions taken when an alarm occurs. Chapter 13 provides a list of the types of indicators investigated, describes the information needed for an investigation, and describes the steps taken in the investigation and resolution process. SHINE described the criteria for determining that an indicator is resolved, the timing of the investigation, and notifications to the NRC. Chapter 13 also describes response actions for unresolved indicators, including escalating the response actions and the level of management involved, and conducting a possible cleanout inventory. Section 13.2, “System and Procedures for Investigating and Resolving Loss Indicators,” of the SHINE MC&A Plan states the time allowed for resolution, and states that if the indicator is true or SHINE is unable to determine that it is not true, notification is made to the NRC in accordance with 10 CFR 74.11, “Reports of loss or theft or attempted theft or unauthorized production of special nuclear material.” Section 13.2, “System and Procedures for Invesigating and Resolving Indicators,” of the SHINE MC&A Plan defines “true” and “not true” indicators such that they align with the reporting requirements in 10 CFR 74.11. Section 13.4, “Documentation Requirements,” of the SHINE MC&A Plan states the documentation required for the investigation and resolution of an indicator.

The NRC staff finds that SHINE’s resolution program for the SHINE facility, as provided in chapter 13, “Resolving Indications of Loss, Theft, Diversion or Misuse of Special Nuclear Material,” of the SHINE MC&A Plan, adequately describes its criteria and process for resolving indications to allow the staff to determine that the program meets the resolution program requirements in 10 CFR 74.41(a)(2) and (3) and 10 CFR 74.11 and is, therefore, acceptable.

Chapter 14 – Aiding Investigation and Recovery of Missing Special Nuclear Material

The general performance objective in 10 CFR 74.41(a)(4) requires licensees to generate information to aid in the investigation and recovery of missing SNM in the event of an actual loss.

Chapter 14, “Aiding Investigation and Recovery of Missing Special Nuclear Material,” of the SHINE MC&A Plan describes the program for aiding investigation and recovery of missing SNM. SHINE described the types of information available to aid in the investigation and recovery, lists the sources of information indicating that a loss or theft may have occurred, and lists additional information that may be useful in resolving indications of missing SNM. chapter 14, “Aiding Investigation and Recovery of Missing Special Nuclear Material,” of the SHINE MC&A Plan states that records are prepared and maintained for all activities and are available to the NRC and any other government investigators to assist in any investigation relating to actual or suspected missing material.

The NRC staff finds that SHINE’s program for providing information to aid in the investigation and recovery of missing SNM, as provided in chapter 14, “Aiding Investigation and Recovery of Missing Special Nuclear Material,” of the SHINE MC&A Plan, is sufficiently complete to meet the investigational aid requirement in 10 CFR 74.41(a)(4) and is, therefore, acceptable.

Chapter 15 – Recordkeeping

Under 10 CFR 74.43(d)(5) licensees must establish and maintain records that demonstrate that the general performance objectives of 10 CFR 74.41(a)(1) – (4) and the system capabilities of 10 CFR 74.43(b) and (c) and 10 CFR 74.45(b) and (c) have been met. Further, in accordance with 10 CFR 74.43(d)(5), licensees must retain these records for a minimum of 3 years (or longer if specifically required by 10 CFR 74.19(b), 10 CFR Part 75, “Safeguards on Nuclear Material—Implementation of Safeguards Agreements between the United States and the International Atomic Energy Agency,” or by a specific license condition). Additionally, under 10 CFR 74.43(d)(1) – (3) licensees must maintain records documenting receipt, shipment, disposal, and current inventory associated with all possessed SNM; quantities of SNM added to and removed from process; and all shipper–receiver evaluations associated with SNM receipts.

Under 10 CFR 74.43(d)(4) licensees must retain records pertaining to the receipt and disposal of SNM until the Commission terminates the license. In addition to meeting the recordkeeping requirements of 10 CFR 74.43(d), the licensee’s MC&A system must, in accordance with 10 CFR 74.41(c)(1) and (2), incorporate checks and balances that are sufficient to detect falsification of data and reports that could conceal diversion of SNM by: (1) a single individual, including an employee in any position; or (2) collusion between two individuals, one or both of whom have authorized access to SNM.

Chapter 15, “Recordkeeping,” of the SHINE MC&A Plan describes the recordkeeping program. SHINE listed the records, forms, reports, and procedures that are considered to be MC&A records; listed records generated by other facility organizations that are necessary for MC&A; and described retention periods for the records. SHINE stated that MC&A records, forms, reports, and procedures are retained for a minimum of 3 years or longer if specifically required by 10 CFR Part 75, and that records pertaining to receipt and disposal of SNM are retained until the NRC terminates the license. Chapter 15, “Recordkeeping,” of the SHINE MC&A Plan describes the program and controls for ensuring an accurate and reliable record system, including: access to records; storage controls; redundancy of records; controls to protect computerized records; and checks and balances to detect destruction or falsification of records, such as signature by two individuals. In addition, section 3.3, “MC&A Organization,” section 3.5, “MC&A Program Description,” and section 3.7, “Commitments and Acceptance Criteria,” of the SHINE MC&A Plan describe the SHINE MC&A program and organizational elements that ensure that checks and balances are in place to detect falsification of data and reports that could conceal diversion of SNM.

The NRC staff finds that SHINE’s recordkeeping program, as provided in chapter 15, “Recordkeeping,” and chapter 3, “Management Structure,” of the SHINE MC&A Plan, includes the appropriate records, retention periods, and checks and balances to meet the recordkeeping requirements in 10 CFR 74.43(d) and 10 CFR 74.41(c)(1) and (2) and is, therefore, acceptable.

Chapter 16 – Appendix

Chapter 16, “Appendix,” of the SHINE MC&A Plan contains supplemental information including: site layout; production facility layout; organization chart; list of MC&A procedures; list of MC&A forms; item history form; and SNM transfer form. The information in this chapter is administrative in nature. Based on its review, the NRC staff finds that the information in chapter 16, “Appendix,” of the SHINE MC&A Plan is acceptable because it is administrative in nature and not contrary to the NRC’s regulations.

Conclusion

The NRC staff evaluated the sufficiency of the SHINE MC&A Plan, as described in SHINE FSAR section 12.13 and provided in Revision 5 of the SHINE MC&A Plan, against the applicable regulatory requirements. The staff determined that the SHINE MC&A Plan describes acceptable methods for achieving the general performance objectives in 10 CFR 74.41(a) and the system features and capabilities requirements of 10 CFR 74.43 and 10 CFR 74.45. Therefore, the staff concludes that the SHINE MC&A Plan is acceptable.

12.4.14 Cybersecurity

There are currently no NRC regulations regarding cybersecurity that apply to non-power production and utilization facilities intending to produce molybdenum-99 (Mo-99) like the SHINE facility. Therefore, in “Staff Requirements – SECY-18-0063 – Response to Staff Requirements Memorandum (SRM)-COMSECY-17-0008 on Physical Protection for Non-Power Production and Utilization Facilities Intending to Produce Molybdenum-99,” dated September 26, 2019, the Commission directed the NRC staff to address cybersecurity at these facilities through subsequent development of appropriate license conditions based on the facilities’ operating license applications. The staff determined that the best approach to develop such risk-informed site-specific license conditions to establish an adequate level of protection for the SHINE facility would be to use, as a starting point, the cybersecurity requirements for similar types of facilities.

The NRC staff reviewed the SHINE FSAR to determine if it includes an adequate level of cybersecurity protections to ensure that, in accordance with 10 CFR 50.57(a)(6), the issuance of an operating license for the SHINE facility will not be inimical to the common defense and security or to the health and safety of the public. The staff also performed a regulatory audit to determine what cybersecurity practices are being applied at the SHINE facility. The staff issued RAIs to SHINE to help gather further information, to which SHINE provided responses (ML21315A003). After completing this review, the staff determined that additional cybersecurity program elements were needed to provide reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks.

To ensure adequate protection at the SHINE facility, and consistent with SRM-SECY-18-0063, the NRC staff drew upon its review of the SHINE FSAR and lessons learned from the cybersecurity programs at nuclear power reactor facilities and the draft fuel cycle facility cybersecurity rulemaking (ML17018A218) to develop a list of important cybersecurity program elements applicable to the SHINE facility. These elements are included in the below risk-informed license condition that allows SHINE to apply a graded approach to cybersecurity based on the consequences of concern specific to the SHINE facility. The term “consequences of concern” is explained below. Specifically, the license condition requires SHINE to have a cybersecurity plan (CSP) that describes how the facility’s cybersecurity program provides reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks. The license condition also requires that the cybersecurity program elements described in the CSP include the elements determined by the staff to be important and applicable to the SHINE facility. The staff determined that this license condition, in addition to the supplemental information provided by SHINE that is discussed immediately below, will ensure, in part, that the issuance of the operating license will not be inimical to the common defense and security or to the health and safety of the public. Therefore, the issuance of a SHINE operating license, as conditioned, in part, by the below license condition, meets the requirements of 10 CFR 50.57(a)(6).

On July 6, 2022, SHINE submitted a revision to its responses to RAIs related to cybersecurity (ML22223A066) that provides information regarding the design, administrative, and programmatic controls that the SHINE CSP will provide. This includes how consequences of concern will be identified, how critical digital assets (CDAs) will be determined, how cybersecurity controls will be applied, and other programmatic controls to ensure that the cybersecurity program is documented and maintained. The NRC staff determined that, through the combination of this information and the below cybersecurity license condition, once the SHINE CSP is implemented, there will be sufficient cybersecurity program elements in place to provide reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks. The staff also reviewed the consequences of concern identified by SHINE in its July 6, 2022, revised responses to RAIs and determined that protecting CDAs associated with these consequences of concern provides reasonable assurance that issuance of the operating license will not be inimical to the common defense and security or to the health and safety of the public.

A consequence of concern is an event that occurs as a result of the compromise of a CDA that has the potential to adversely impact the public health and safety or the common defense and security. Licensees must identify and document those digital assets that, if compromised by a cyberattack, would result in a consequence of concern. Such digital assets that are then determined to be CDAs must be protected by the application of appropriate cybersecurity controls. A consequence of concern can be active or latent. In the case of an active consequence of concern, the compromise of the digital asset from a cyberattack directly results in a radiological or chemical exposure exceeding the safety criteria limits specified in a licensee's Final Safety Analysis Report. In the case of a latent consequence of concern, a digital asset is compromised but there is no direct impact on a safety, security, or safeguards function until a secondary event occurs (i.e., an initiating event separate from the cyberattack). The combination of the compromise of the digital asset from the cyberattack (i.e., the latent consequence of concern) and the secondary event must both occur for there to be a significant impact on public health and safety or common defense and security.

For facilities intending to produce Mo-99 such as the SHINE facility, the following consequences of concern must be considered (but may not necessarily apply):

> Latent Safeguards: The concern involves the compromise as a result of a cyberattack of a digital asset performing a security function, which would allow a malicious actor to exploit the degraded security function that was put in place to prevent the unauthorized removal of SNM of moderate strategic significance or the loss of MC&A for SNM of moderate strategic significance.
>
> Active Safety: In this situation, the cyberattack compromises the function of a digital asset and directly leads to safety-related consequences as defined in the safety criteria found in the licensee's Final Safety Analysis Report.
>
> Latent Safety or Security: The attack renders one or more digital assets incapable of performing its intended function. When called upon to respond to an event, separate from the cyberattack, the digital asset does not operate as expected and therefore the supported safety or security function is compromised, resulting in safety-related consequences like above, or loss or unauthorized disclosure of classified information or classified matter. In addition, MC&A functions whose compromise could lead to a latent safety consequence of concern, would need to be protected from a cyberattack.

Based on the above, the SHINE operating license is conditioned as follows:

The licensee must have a cybersecurity plan (CSP) that describes how the facility's cybersecurity program provides reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks. The cybersecurity program elements described in the CSP must include but are not limited to the following:

(1) Establishing a team with working knowledge in information and digital system technology, facility operations, engineering, safety, and the facility's physical security and emergency preparedness to identify the relevant consequences of concern, including latent safeguards, active safety, and latent safety or security consequences of concern, as applicable, as defined in the NRC safety evaluation of the SHINE facility operating license application, and make informed cybersecurity decisions. Alternatively, establish equivalent individual roles and responsibilities in the CSP that ensure that informed cybersecurity decisions are made.

(2) Identifying digital assets that, if compromised by a cyberattack, would result in a consequence of concern.

(3) Determining which of these assets are critical digital assets (CDAs) that need to be protected to meet the cybersecurity program performance objectives of the facility.

(4) Identifying a set of cybersecurity controls for CDAs and applying them so that there is reasonable assurance that the facility is adequately protected against cyberattacks.

(5) Implementing site-specific defense-in-depth protective strategies that ensure that the failure of a single protective strategy or security control will not result in a consequence of concern by describing how the licensee delays, detects, prevents, responds to, and recovers from cyberattacks on CDAs, as applicable.

(6) Providing temporary compensatory measures to meet the cybersecurity program performance objectives when the cybersecurity controls are degraded.

(7) Establishing and maintaining a configuration management system to ensure that any changes to the facility are monitored and evaluated for potential cybersecurity impacts prior to implementation so that there is reasonable assurance that the facility is adequately protected against cyberattacks.

(8) Periodically reviewing the effectiveness of the cybersecurity program to provide reasonable assurance that the cybersecurity program performance objectives of the facility are continuously met.

(9) Tracking and reporting cybersecurity events.

The licensee may make changes to the CSP provided that the above cybersecurity program elements and the performance objectives of the CSP remain met and that these changes are made with the knowledge of the team, or its equivalent, of program element (1).

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, as appropriate, the 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 applicable regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected.

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

Based on the above determinations, the NRC staff finds that the descriptions and discussions of 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.