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## ACRONYMS AND ABBREVIATIONS

<b><u>Acronym/Abbreviation</u></b>	<b><u>Definition</u></b>
ALARA	as low as reasonably achievable
ANSI	American National Standards Institute
ANS	American Nuclear Society
CEO	Chief Executive Officer
DGM	Diagnostics General Manager
DPO	Director of Plant Operations
EAL	emergency action level
EDMS	electronic data management system
EPZ	emergency planning zone
GED	general education development
gU/L	grams uranium per liter
I&C	instrumentation and control
IU	irradiation unit
MC&A	material control and accounting
MCNP	Monte Carlo N-Particle Transport Code
NDAS	neutron driver assembly system

## ACRONYMS AND ABBREVIATIONS

<b><u>Acronym/Abbreviation</u></b>	<b><u>Definition</u></b>
OM	Operations Manager
QAPD	Quality Assurance Program Description
PCLS	primary closed loop cooling system
PVVS	process vessel vent system
RLWI	radioactive liquid waste immobilization
RP	radiation protection
RPP	Radiation Protection Program
SCAS	subcritical assembly system
SNM	special nuclear material
SSC	structure, system, and component
TM	Training Manager
TOGS	TSV off-gas system
TPS	tritium purification system
TSV	target solution vessel
UPSS	uninterruptible electrical power supply system
VTS	vacuum transfer system

## CHAPTER 12 – CONDUCT OF OPERATIONS

### 12.1 ORGANIZATION

This section describes the SHINE organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure. The SHINE organizational structure implements a conduct of operations philosophy of working in a formalized, disciplined manner to achieve operational excellence, which emphasizes safety in every aspect of plant operations. The organizational aspects of the radiation protection (RP) program (RPP), the production facility safety program, staffing, and selection and training of personnel will also be discussed in this section.

#### 12.1.1 STRUCTURE

Responsibility for the safe operation of the SHINE facility shall be with the chain of command established in the SHINE operational organization chart provided in [Figure 12.1-1](#). The individuals at the various management levels, in addition to having responsibility for the policies and operation of the SHINE facility, shall be responsible for safeguarding the public and facility personnel from undue radiation exposures and for adhering to the requirements of the operating license and technical specifications.

SHINE management functional levels and assignments of responsibility are described below:

- Level 1: Individuals responsible for the medical isotope facility license
- Level 2: Individuals responsible for the facility operation
- Level 3: Individuals responsible for day-to-day operation or shift
- Level 4: Operating staff

Alternates may perform the functions required in the absence of the normal designee.

Facility operators (i.e., senior licensed operators, licensed operators, and field operators) (Level 4) report directly to the shift supervisors (Level 3). The personnel performing the radiation safety function have communication lines with the shift supervisors and executive management. The shift supervisors report directly to the Operations Manager (OM) (Level 2). The OM reports to the Director of Plant Operations (DPO) (Level 2). The review and audit committee is chaired by the Diagnostics General Manager (DGM) or designee and has communication lines with the DPO and executive management. The DPO reports to the DGM (Level 1). The DGM reports to the Chief Executive Officer (CEO) (Level 1).

#### 12.1.2 RESPONSIBILITY

##### 12.1.2.1 SHINE Medical Technologies, LLC

SHINE Medical Technologies, LLC is the entity with legal responsibility for holding the facility operating license.

### 12.1.2.2 Chief Executive Officer (CEO)

The CEO is responsible for the overall design, management, and technical leadership of the company and is also responsible for all technical and administrative support activities provided by SHINE. The CEO reports to the Board of Directors with respect to all matters.

### 12.1.2.3 Diagnostics General Manager (DGM)

The DGM is responsible for operational aspects of the division including safety, management, and training. The DGM is also responsible for matters regarding environment, safety, and health. The DGM delegates sufficient responsibility and authority to direct reports that ensures appropriate controls have been established and for verifying that activities have been correctly performed. The DGM encourages managers and employees to identify problems and initiate, recommend, or provide corrective action, and ensures corrective action implementation. The DGM reports to the CEO.

### 12.1.2.4 Director of Plant Operations (DPO)

The DPO is responsible for the operation and management of the SHINE facility. The DPO reports to the DGM.

### 12.1.2.5 Operations Manager (OM)

The OM is responsible for safe, reliable, and efficient plant operations within the constraints of the operating license and regulatory requirements. This position is also responsible for the development and implementation of appropriate operational controls in accordance with the Quality Assurance Program Description (QAPD). The OM reports to the DPO.

### 12.1.2.6 Shift Supervisors

The shift supervisors are senior licensed operators and are responsible for the safe day-to-day operation of the facility. The shift supervisors report to the OM.

### 12.1.2.7 Senior Licensed Operators, Licensed Operators, and Field Operators

Senior licensed operators, licensed operators, and field operators are responsible for conforming to applicable rules, regulations, and procedures for operation of the facility. Senior licensed operators are responsible for safe and efficient operation of a portion of the facility when designated by the shift supervisor. Senior licensed operators and licensed operators are responsible for maintaining senior licensed operator and licensed operator status, respectively. Field operators are non-licensed operations personnel. Senior licensed operators, licensed operators, and field operators report to shift supervisors.

### 12.1.2.8 Radiation Safety Function

The radiation protection organization fulfills the radiation safety function and is responsible for establishing and implementing the RPP, monitoring worker doses, and the calibration and quality assurance of health physics instrumentation. The radiation protection organization is described in [Subsection 11.1.2.1.1](#).

### 12.1.2.9 Review and Audit Committee

The review and audit committee is responsible for the independent review and audit of the safety aspects of the SHINE facility operations. The review and audit committee is described in [Section 12.2](#).

### 12.1.3 STAFFING

SHINE provides sufficient resources in personnel and materials to safely conduct operations.

- (1) The minimum staffing when the facility is not secured shall be:
  - (a) A senior licensed operator present in the facility,
  - (b) A licensed operator or second senior licensed operator present in the control room, and
  - (c) An additional designated person present at the facility able to carry out prescribed written instructions.Unexpected absence of the position described in (1)(a) for as long as 30 minutes to accommodate a personal emergency may be acceptable provided immediate action is taken to designate a replacement. Unexpected absence of the position described in (1)(c) for as long as two hours to accommodate a personal emergency may be acceptable provided immediate action is taken to obtain a replacement.
- (2) A list of facility personnel by name and telephone number shall be readily available in the control room for use by the operator. The list shall include:
  - (a) Management personnel,
  - (b) Radiation safety personnel, and
  - (c) Other operations personnel.

Staffing requirements are included in the technical specifications.

The role of the operator in the SHINE facility is to perform the manual actions required to safely and efficiently manufacture medical isotopes. There are no postulated accident sequences that credit operator action to mitigate the consequences of the event after initiation of the event. Should an initiating event of a postulated accident sequence occur, operator actions provide a defense-in-depth, nonsafety-related, diverse means of actuating components.

### 12.1.4 SELECTION AND TRAINING OF PERSONNEL

SHINE establishes and maintains training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. The Training Manager (TM) reports to the Director of Corporate Support (DCS) and is responsible for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety. American National Standards Institute/ American Nuclear Society (ANSI/ANS) 15.4-2016 is used in the selection and training of personnel (ANSI/ANS, 2016a). Records of personnel training and qualification are maintained.

In general, operations personnel have the combination of academic training, job-related experience, health, and skills commensurate with their level of responsibility that provides reasonable assurance that decisions and actions during normal and abnormal conditions are

such that the facility is operated in a safe manner. The minimum qualification level of personnel is defined as follows:

#### Level 1

At the time of appointment, Level 1 personnel receive briefings sufficient to provide an understanding of the general operational and emergency aspects of the facility.

#### Level 2

At the time of appointment to the position, Level 2 personnel have a minimum of six years nuclear experience. The individual has a recognized baccalaureate or higher degree in engineering or scientific field. The degree may fulfill up to four years of the six years of nuclear experience required. Education and/or experience that is job related may be substituted for a degree on a case-by-case basis. Appropriate facility-specific training occurs upon a comparison of the individual's background and abilities with the responsibilities and duties of the position. Because of the educational and experience requirements of the position, continued formal training may not be required. If this individual is also to be licensed, the licensing requirements of the respective position and responsible authority are met by the individual.

#### Level 3

At the time of appointment to the position, the individual has sufficient training at the facility or elsewhere to satisfy the requirements for licensing as a senior licensed operator. This individual also has three years nuclear experience. A maximum of two years equivalent full-time academic training may be substituted for two of the three years required nuclear experience. Individuals in Level 3 positions have a high-school diploma or have successfully completed a General Education Development (GED) test.

#### Level 4

At the time of appointment to the position, the individual has sufficient training at the facility or elsewhere to satisfy the requirements for licensing at the appropriate level. Individuals assigned to Level 4 positions have a high-school diploma or have successfully completed a GED test. Individuals without a high-school diploma or GED are not excluded. Previous job-related experience or education is considered. Successfully completing the training for the Level 4 position and satisfying all job performance requirements determine qualification for appointment to the position.

#### Other Technical Personnel

Technical support personnel are those individuals not directly involved in the management and operation of the facility but who provide technical support. Examples are laboratory technicians, instrument technicians, and health physics personnel. Technical support personnel have a minimum of one year of working experience in their specialty or craft and are qualified to perform the work for the position. Relevant education may be substituted for the experience requirements on a case-by-case basis.

#### 12.1.4.1 Initial Training and Requalification

The licensed operator training program, including the requalification training program, is implemented in accordance with 10 CFR Part 55 as it pertains to non-power facilities and the guidance provided in ANSI/ANS 15.4-2016 (ANSI/ANS, 2016a). The SHINE facility operator training and requalification programs are described in [Section 12.10](#).

#### 12.1.4.2 10 CFR Part 19 Training

Individuals whose assigned duties involve exposure to radiation or radioactive material, and in the course of their employment are likely to receive, in a year, an occupational dose of radiation greater than 100 millirem (mrem) (1 millisievert [mSv]), receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12.

The design and implementation of the radiation protection training program complies with the requirements of 10 CFR 19.12.

#### 12.1.5 RADIATION SAFETY

The RPP is described in greater detail in [Subsection 11.1.2](#). The RPP meets the requirements of 10 CFR Part 20, Subpart B, and is consistent with the guidance provided in Regulatory Guide 8.2, Revision 1, Administrative Practices in Radiation Surveys and Monitoring, and ANSI/ANS 15.11-2016, Radiation Protection at Research Reactor Facilities (ANSI/ANS, 2016b). Development and implementation of the RPP is commensurate with the risks posed by a medical isotope production facility. Procedures and engineering controls are based upon sound RP principles to achieve occupational doses to on-site personnel and doses to members of the public that are as low as reasonably achievable (ALARA).

The organizational structure and responsibilities, including the radiation safety function, are described in [Sections 12.1.1](#) and [12.1.2](#).

The RP Department is independent of facility operations. This independence ensures that the RP Department maintains its objectivity and is focused only on implementing sound RP principles necessary to achieve occupational doses and doses to members of the public that are ALARA.

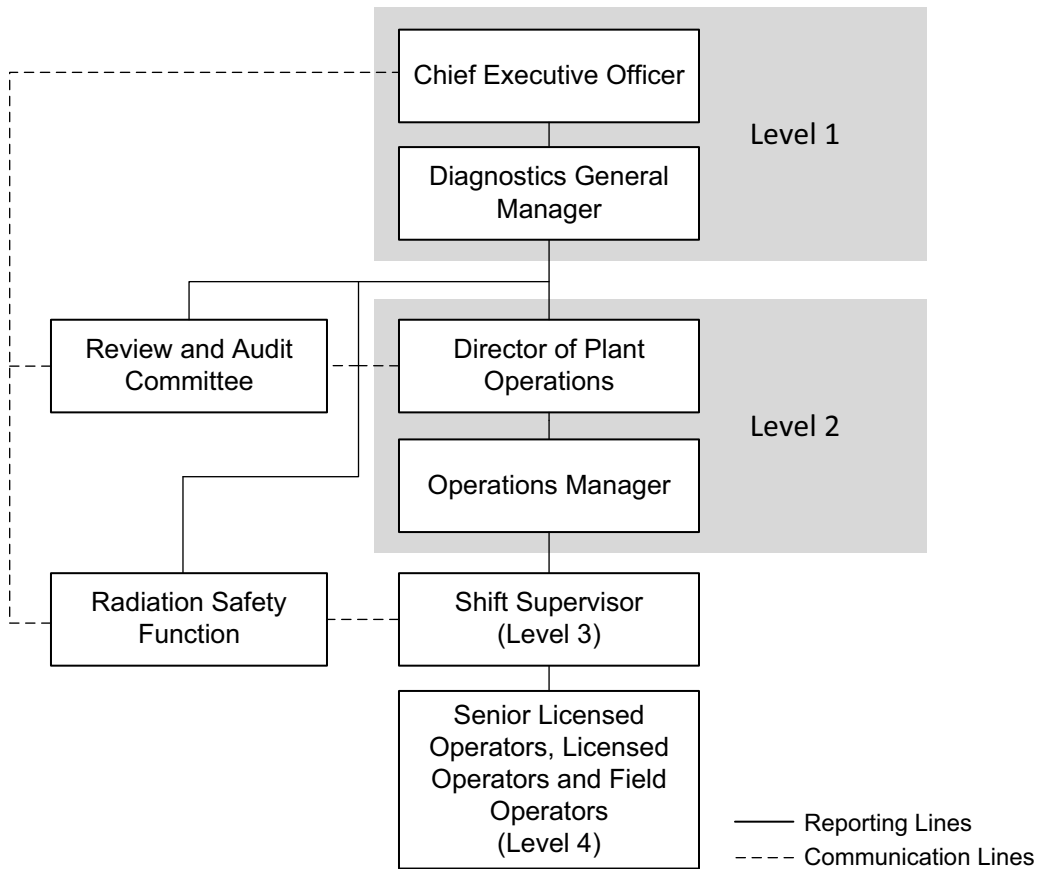
RP staff maintain the ability to raise safety issues with the review and audit committee or executive management. The RP staff encompasses the clear responsibility and ability to interdict or terminate licensed activities that it believes are unsafe. This does not mean that the RP staff possesses absolute 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.

#### 12.1.6 NUCLEAR SAFETY PROGRAM

The production facility safety program is implemented within the nuclear safety program and developed using methodologies as described in 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 (USNRC, 2012a); and 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 (USNRC, 2012b). The nuclear safety program is described in [Chapter 13](#).

**Figure 12.1-1 – SHINE Operational Organization Chart**



## 12.2 REVIEW AND AUDIT ACTIVITIES

The Diagnostics General Manager (DGM) establishes the review and audit committee and ensures that the appropriate technical expertise is available for review and audit activities. The DGM holds approval authority for review and audit activities. Independent audits of the SHINE facility are conducted periodically.

The review and audit committee will interact with facility management through the dissemination of meeting minutes and meeting reports. SHINE will submit a written report or minutes of the findings and recommendations of the review group to Level 1 management and the review and audit group members in a timely manner after the review has been completed. SHINE will immediately report deficiencies uncovered that affect nuclear safety to Level 1 management.

### 12.2.1 COMPOSITION AND QUALIFICATIONS

The review and audit committee shall have the appropriate expertise and experience such that members provide the SHINE management an independent assessment of the operation. The DGM or designee chairs the review and audit committee and appoints additional members. The minimum number of the members shall be three. The qualifications for the review and audit committee members shall include a broad spectrum of technical, operational, and managerial expertise. At a minimum, the committee shall include members with expertise in facility operations, engineering, and radiation protection. Non-SHINE employees may be appointed as committee members, at the discretion of the chair. Assignment of non-SHINE employees to the committee will be necessary in circumstances when the required expertise to perform an activity is not available from SHINE employees (e.g., to perform an audit of an area where the only personnel with expertise in that area are immediately responsible for that area).

### 12.2.2 CHARTER AND RULES

The charter for the review and audit committee requires at least one meeting per year, with a quorum being a minimum of 50 percent of the voting committee membership where the facility operations personnel do not constitute a majority. Facility operations personnel consist of all facility personnel organizationally subordinate to, and including, the Director of Plant Operations (DPO). Dissemination, review, and approval of minutes shall occur within three months. The review and audit committee charter shall include provisions for the use of subgroups. Committee reports and reviews shall be distributed by memorandum to Level 1 management and other management as designated in the charter. Voting may be conducted at the meeting or by polling members with a majority required for approval.

### 12.2.3 REVIEW FUNCTION

At a minimum, the following items shall be reviewed:

- Determinations that proposed changes in equipment, systems, test, or procedures are allowed without prior authorization by the NRC (e.g., 10 CFR 50.59 safety reviews);
- All new procedures and major revisions having safety significance;
- Proposed changes in facility equipment or systems having safety significance;
- Proposed changes in technical specifications or license;
- Violations of technical specifications or license;
- Violations of internal procedures or instructions having safety significance;

- Operating abnormalities having safety significance;
- Reportable occurrences; and
- Audit/Assessment reports.

Upon completion of a review, a written report of any findings and recommendations of the review and audit committee shall be provided to SHINE executive management.

#### 12.2.4 AUDIT FUNCTION

The audit function will include selective (but comprehensive) examination of operating records, logs, and other documents. Discussions with personnel and observation of operations will be used as appropriate. In no case will the individual immediately responsible for the area perform an audit in that area. SHINE will work to establish relationships with other entities to participate in audits of the facility. The following items will be audited:

- Facility operations for conformance to the technical specifications and applicable license conditions (including organization and responsibilities, training, operations, procedures, logs and records, health physics, technical specification compliance, and surveillances): at least once per calendar year (interval between audits not to exceed 15 months).
- The retraining and requalification program for the operating staff: at least once every other calendar year (interval between audits not to exceed 30 months).
- The results of action taken to correct those deficiencies that may occur in the main production facility equipment, systems, structures, or methods of operations that affect nuclear safety: at least once per calendar year (interval between audits not to exceed 15 months).
- The SHINE facility emergency plan and implementing procedures: at least once every other calendar year (interval between audits not to exceed 30 months).
- The radiation protection plan: at least once per calendar year (interval between audits not to exceed 15 months).
- The quality assurance program description: at least once every other calendar year (interval between audits not to exceed 30 months).
- The physical security plan: at least once every other calendar year (interval between audits not to exceed 30 months).
- The nuclear criticality safety program: at least once every third calendar year (interval between audits not to exceed 36 months).
- The nuclear safety program and SHINE safety analysis summary report: at least once every third calendar year (interval between audits not to exceed 45 months).

Deficiencies identified during the audit will be entered into the corrective action program. Deficiencies uncovered that affect nuclear safety shall immediately be reported to Level 1 management. A written report of the findings of the audit shall be submitted to Level 1 management and the review and audit committee members within three months after the audit has been completed.

### 12.3 PROCEDURES

Procedures for the operation and use of the SHINE facility provide appropriate direction to ensure that the facility is operated normally within its design basis and in compliance with technical specifications. Procedures also provide guidance for addressing abnormal and emergency situations. These procedures are written, reviewed, and approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct, and the wording and format are clear and concise.

The process required to make changes to procedures, including substantive and minor permanent changes, and temporary deviations to accommodate special or unusual circumstances during operation is documented and includes a screening for 10 CFR 50.59 applicability.

SHINE will prepare, review, and approve written procedures for the following topics:

1. startup, operation, and shutdown of the irradiation unit (IU);
2. target solution fill, draining, and movement within the main production facility;
3. maintenance of major components of systems that may have an effect on nuclear safety;
4. surveillance checks, calibrations and inspections required by the technical specifications;
5. personnel radiation protection, consistent with applicable regulatory guidance. The procedures shall include management commitment and programs to maintain exposures and releases as low as reasonably achievable in accordance with ANSI/ANS 15.11-2016, Radiation Protection at Research Reactor Facilities (ANSI/ANS, 2016b);
6. administrative controls for operations and maintenance and for the conduct of irradiations that could affect nuclear safety;
7. implementation of required plans (e.g., emergency, security); and
8. use, receipt, and transfer of byproduct material.

The specific procedures within these topic areas are developed in accordance with the SHINE Quality Assurance Program Description (QAPD).

SHINE shall review and approve written procedures prior to initiating any of the activities listed above. The procedures shall be reviewed by the SHINE review and audit committee and approved by Level 2 management or designated alternates, and such reviews and approvals shall be documented in a timely manner.

Substantive changes to procedures related to the activities listed above shall be made effective only after documented review by the SHINE review and audit committee and approval by Level 2 management or designated alternates. Minor modifications to the original procedure that do not change their original intent may be made by Level 3 management or higher, but the modifications must be approved by Level 2 or designated alternates. Temporary deviations from the procedures may be made by a senior licensed operator or higher individual present, in order to accommodate special or unusual circumstances or conditions. Such deviations shall be documented and reported within 24 hours or the next working day to Level 2 management or designated alternates. Review and approval of procedural changes shall be documented in a timely manner, in accordance with the SHINE document control procedure.

Revisions to the procedures for the operation and use of the SHINE facility are initiated and tracked through the document control processes. Following preparation, procedure revisions

receive a technical review, which will include a screening for 10 CFR 50.59 applicability and are then reviewed and approved as described above.

Prior to a new or revised procedure being issued for use, the procedure is verified and validated to ensure it will accomplish its intended purpose.

The extent of detail in a procedure is dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error. The process for making changes and revisions to procedures is documented. A controlled copy of all operations procedures is maintained in the control room. Activities and tasks are performed in accordance with approved implementing procedures.

## 12.4 REQUIRED ACTIONS

### 12.4.1 SAFETY LIMIT VIOLATION

As described in the technical specifications, in the event of a safety limit violation:

1. The SHINE facility operations related to medical isotope production shall be shut down immediately and operation shall not be resumed until authorized by the NRC.
2. The safety limit violation shall be promptly reported to Level 2 management or designated alternates.
3. The safety limit violation shall be reported to the NRC.
4. A safety limit violation report shall be prepared. The report shall describe the following:
  - a. Applicable circumstances leading to the violation including, when known, the cause and contributing factors;
  - b. Effect of the violation upon facility structures, systems, and components (SSCs) and on the health and safety of personnel and the public; and
  - c. Corrective action to be taken to prevent recurrence.

The report shall be reviewed by the review and audit committee, and any follow-up report shall be submitted to the NRC when authorization is sought to resume operation of the SHINE facility.

### 12.4.2 OCCURRENCES REQUIRING SPECIAL REPORTS OTHER THAN A SAFETY LIMIT VIOLATION

In the event of an occurrence requiring a special report, as defined in technical specifications, other than a violation of a safety limit:

1. The affected processes or areas of the facility shall be returned to normal conditions or shut down. If it is necessary to shut down processes to correct the occurrence, operation of those affected processes shall not be resumed unless authorized by Level 2 management or designated alternates.
2. The occurrence shall be reported to Level 2 management or designated alternates and to the NRC as required by the technical specifications.
3. The occurrence shall be reviewed by the review and audit committee at its next scheduled meeting.

## 12.5 REPORTS

### 12.5.1 OPERATING REPORTS

An annual report covering the operation of the facility during the previous calendar year will be submitted to the NRC Document Control Desk within 30 days of the end of the calendar year providing the following information:

- A narrative summary of operating experience including the energy produced by each irradiation unit (IU) or the hours each IU was operating, or both.
- The unscheduled shutdowns including, where applicable, corrective action taken to preclude recurrence.
- Tabulation of major preventative and corrective maintenance operations having safety significance.
- Tabulation of major changes in the facility and procedures, including a summary of the evaluation leading to the conclusions that they are allowed under 10 CFR 50.59.
- A summary of the nature and amount of radioactive effluents released or discharged to environs beyond SHINE's effective control, as determined at, or before, the point of such release or discharge. The summary will include to the extent practicable an estimate of individual radionuclides present in the effluent. If the estimated average release after dilution or diffusion is less than 25 percent of the concentration allowed or recommended, a statement to this effect is sufficient.
- A summarized result of environmental surveys performed outside the facility.
- Results of individual monitoring carried out by SHINE for each individual for whom monitoring was required by 10 CFR 20.1502.

### 12.5.2 SPECIAL REPORTS

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

There will be a report not later than the following working day by telephone and confirmed in writing by electronic mail or similar conveyance to the NRC Operations Center, to be followed by a written report to the NRC Document Control Desk that describes the circumstances of the event within 14 days of any of the following:

- Violation of a safety limit;
- Release of radioactivity from the site above allowed limits;
- Operations with actual safety system settings for required systems less conservative than the limiting safety system settings specified in the technical specifications;
- Operation in violation of limiting conditions for operation established in the technical specifications unless prompt remedial action is taken;
- A safety system component malfunction that renders or could render the safety system incapable of performing its intended safety function, as described in the technical specifications;
- Abnormal and significant degradation of the primary system boundary (including minor leaks);
- Abnormal and significant degradation in the primary closed loop cooling system (PCLS) and the light water pool (excluding minor leaks); and

- An observed inadequacy in the implementation of administrative or procedural controls such that the inadequacy causes or could have caused the existence or development of an unsafe condition with regard to operations.

There will be a written report within 30 days to the NRC Document Control Desk of the following:

- Permanent changes in the facility organization involving Level 1 or Level 2 management, and
- Significant changes in the accident analysis as described in the Final Safety Analysis Report (FSAR).

## 12.6 RECORDS

The SHINE records management program includes the identification, generation, authentication, maintenance, and disposition of records. Records will be stored in the electronic data management system (EDMS) and may be in the form of logs, data sheets, or other suitable forms. The required information may be contained in single or multiple records, or a combination thereof.

Records of the following activities shall be maintained and retained for the periods specified below.

### 12.6.1 LIFETIME RECORDS

The following records are to be retained for the lifetime of the SHINE facility:

1. Gaseous and liquid radioactive effluents released to the environs;
2. Off-site environment-monitoring surveys required by the technical specifications;
3. Radiation exposure for all monitored personnel;
4. Drawings of the SHINE facility; and
5. Records of reportable occurrences involving violations of safety limits, limiting safety system settings, and limiting conditions for operation.

Applicable annual reports, if they contain all of the required information, may be used as records in this section.

### 12.6.2 FIVE YEAR RECORDS

The following records are to be maintained for a period of at least five years or for the life of the component involved if less than five years:

1. Normal SHINE facility operation (but not including supporting documents such as checklists, log sheets, etc., which shall be maintained for a period of at least one year or one NRC inspection cycle, whichever is longer);
2. Principal maintenance operations;
3. Reportable occurrences (except those required to be retained for the lifetime of the SHINE facility);
4. Surveillance activities required by the technical specifications;
5. Facility radiation and contamination surveys where required by applicable regulations;
6. Radioactive material inventories, receipts, and shipments;
7. Approved changes in operating procedures; and
8. Records of meeting and audit reports of the review and audit committee.

### 12.6.3 RECORDS TO BE RETAINED FOR AT LEAST ONE CERTIFICATION CYCLE

Records of retraining and requalification of operations personnel who are licensed pursuant to 10 CFR 55 shall be maintained at all times while the individual is employed as a licensed operator or until the license is renewed.

## 12.7 EMERGENCY PLANNING

The SHINE Emergency Plan describes the essential elements of advance planning and necessary provisions for coping with and mitigating the consequences of emergencies within and beyond the SHINE site boundary. The Emergency Plan is primarily focused on situations that may cause or threaten to cause radiological hazards that could affect employee or public health and safety. The Emergency Plan also includes provisions for other on-site emergency situations commensurate with their severity.

The Emergency Plan was written to conform to 10 CFR 50, Appendix E, following the guidance of:

- Regulatory Guide 2.6, Revision 2, Emergency Planning For Research And Test Reactors and Other Non-Power Production And Utilization Facilities (USNRC, 2017);
- American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.16-2015, Emergency Planning for Research Reactors (ANSI/ANS, 2015);
- ANSI/ANS 8.23-2007, Nuclear Criticality Accident Emergency Planning and Response (ANSI/ANS, 2007b); and
- NUREG-0849, Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors (USNRC, 1983a).

The Emergency Plan includes the following:

- Descriptions of the facility and site to provide a general orientation and common understanding about the facility and the Emergency Plan;
- Definitions of terms unique to the SHINE facility and the Emergency Plan;
- Organizational descriptions and responsibilities for SHINE personnel and off-site supporting organizations and agencies responsible for planning and implementing the Emergency Plan;
- Descriptions of classes of emergency situations and the Emergency Action Levels (EALs) and criteria for classifying emergency situations;
- Identification of an Emergency Planning Zone (EPZ), where protective actions may be implemented;
- Descriptions of emergency response measures for each class of emergency, including assessment actions, activation of the emergency organization and notification procedures;
- Descriptions of emergency facilities and equipment;
- Processes for recovery from emergencies; and
- Provisions for training and maintaining emergency preparedness.

## 12.8 SECURITY PLANNING

The Physical Security Plan was developed following the guidance in Regulatory Guide 5.59, Revision 1, Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance (USNRC, 1983b).

The Physical Security Plan provides a comprehensive description of the security program for the SHINE facility, which addresses the following:

- Use and storage area requirements,
- Detection devices and procedures,
- Access control,
- Security organization,
- Communications,
- Response procedures,
- Material transportation requirements,
- Receiver requirements,
- In-transit physical protection requirements,
- Transfer and control requirements,
- Export requirements,
- Import requirements, and
- Requirements for compliance with orders to delay strategic special nuclear material.

## 12.9 QUALITY ASSURANCE

The SHINE Quality Assurance Program Description (QAPD), was developed using the guidance in American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.8-1995, Quality Assurance Program Requirements for Research Reactors (ANSI/ANS, 1995), and Regulatory Guide 2.5, Revision 1, Quality Assurance Program Requirements for Research and Test Reactors (USNRC, 2010).

## 12.10 OPERATOR TRAINING AND REQUALIFICATION

The initial training program was developed to conform to the requirements of 10 CFR Part 55, as it pertains to non-power facilities, following the guidance of American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.4-2016, Selection and Training of Personnel for Research Reactors (ANSI/ANS, 2016a). The initial training program addresses the following:

- Training methods, including classroom methods, self-study methods, on-the-job-training methods, and other methods;
- Examinations, including examination administration and evaluation;
- Medical examination; and
- Licensing.

In addition to the general and specific training requirements for licensing operators contained in 10 CFR Part 55 and the guidance contained in ANSI/ANS 15.4-2016, the initial training program will contain the following additional topics:

- Theory and principles of radioisotope production process involving special nuclear materials (SNM),
- Theory and principles of radioisotope extraction and purification processes,
- Facility design and operating characteristics,
- Instrumentation and control systems,
- Engineered safety features,
- Technical specifications,
- Criticality control features and management measures required for processes involving SNM, and
- Normal and emergency operating procedures.

The requalification training program for licensed operators and senior licensed operators describes the essential training required to maintain a license in active status. The requalification training program is administered over a requalification period of 24 months. The program was developed to conform to the programmatic requirements described in 10 CFR 55.59(c), following the guidance of ANSI/ANS 15.4-2016. The requalification training program addresses the following:

- Refresher training,
- Written examination,
- Medical examination,
- Reactivity control manipulations,
- Operating test or evaluation, and
- Document review.

## 12.11 STARTUP PLAN

The SHINE Startup Testing Program outlines the tests and measurements necessary to: (1) verify key parameters necessary for the safe operation of an irradiation unit (IU), (2) verify key parameters necessary for the safe handling of special nuclear material (SNM) outside of the IUs, and (3) ensure that operating characteristics are well understood. Some startup testing is used to confirm calculational parameters while other tests establish or aid in establishing operational parameters, such as setpoints or valve positions. Proposed startup tests are identified in [Section 12.11.2](#).

### 12.11.1 ADMINISTRATION OF THE STARTUP TESTING PROGRAM

Implementing procedures address the scheduling of startup tests. The startup test schedule ensures that the safety of the plant is not dependent on the performance of untested structures, systems, and components (SSCs).

Startup testing is conducted in accordance with approved test procedures. Administrative controls are in place to ensure that: (1) testing is performed by personnel qualified in accordance with implementing procedures, (2) testing is conducted in accordance with approved test plans, and (3) that deficiencies discovered during testing are documented and dispositioned in accordance with the corrective action program. In addition, implementing procedures ensure that modifications and repairs are made as required and retesting is conducted.

Results of tests are documented, and documentation includes, at minimum, a comparison of applicable test data with the related acceptance criteria and disposition of any deficiencies discovered during testing.

#### 12.11.1.1 Test Plans

Test plans are developed based upon guidance provided in the Startup Testing Program and implementing procedures. Startup tests will be planned prior to being conducted, and startup test plans will include, at a minimum, the following:

- Testing methods and objectives;
- Testing acceptance criteria;
- Identification of hazards associated with the test, and controls of those hazards; and
- Instructions for accomplishing the test.

Test plans ensure that measurements of selected parameters are compared to calculated values to verify analytical methods and that meaningful acceptance criteria have been established from the calculational methods. The acceptance criteria ensure that safety-related SSCs are functioning within the bounds for which they were designed and that the license and technical specifications are satisfied. Acceptance criteria are developed using the information contained in design specifications, design documents, drawings, technical specifications, and other technical documents which define the functional requirements and performance objectives for the various SSCs.

### 12.11.1.2 Startup Test Report

SHINE will submit for NRC review a startup report that identifies the startup tests performed at the timeframe defined by technical specifications. The startup report will contain the following:

1. A description of the methods and objectives for each test;
2. A comparison of applicable test data with the related acceptance criteria;
3. Design and construction related deficiencies discovered during testing, system modifications and corrective actions required to correct those deficiencies, and the schedule for implementing these modifications and corrective actions unless previously reported to the NRC;
4. Justification for acceptance of systems or components that are not in conformance with design predictions or performance requirements; and
5. Results of test, including conclusions about system or component adequacy.

### 12.11.2 STARTUP TESTS

Startup tests are either designated as facility startup tests or IU startup tests. Facility startup tests are those tests required for the safe handling, storage, and processing of uranium and for operation of processing and facility systems, excluding those SSCs associated with individual IUs. IU startup tests are those tests required for the safe irradiation of target solution in the IU, including tests of the subcritical assembly system (SCAS) and SCAS support systems. Each startup test or group of tests includes the identification of key parameters which must be verified against predetermined acceptance criteria before the relevant process or SCC is considered operable.

#### 12.11.2.1 Facility Startup Tests

The following tests are required for the safe startup of the facility SSCs, excluding those SSCs associated with individual IUs.

##### 12.11.2.1.1 Preparation for Uranium Handling

Upon receipt and throughout processing, uranium and solutions containing uranium are tested against various acceptance criteria (e.g., enrichment, uranium concentration, etc.). Before the initial receipt of uranium, the availability and calibration of required testing equipment are verified. The acceptance criteria related to testing equipment are based on manufacturer instructions and are provided in test plans.

##### 12.11.2.1.2 Receipt, Unpacking, and Internal Transfer of Uranium

Uranium is received as either uranium oxide or uranium metal. Upon receipt, the uranium enrichment is tested to assure safety in downstream processes. The acceptance criteria related to the receipt, unpacking, and internal transfer of uranium are developed based on design details provided in [Section 4b.4](#) and are provided in test plans.

##### 12.11.2.1.3 Preparation of Uranyl Sulfate

Uranium oxide is converted into uranyl sulfate solution in the target solution preparation process. The conversion system is tested prior to use with uranium containing solution. Key parameters

include verifying target solution preparation process parameters (e.g., timing, temperatures, and concentrations). The acceptance criteria related to the preparation of uranyl sulfate are developed based on design details provided in [Section 4b.2](#) and are provided in test plans.

#### 12.11.2.1.4 Preparation for Reuse

Prior to each filling of the target solution vessel (TSV), solution is tested and compared to applicable acceptance criteria. Key parameters include uranium concentration, volume, temperature, and pH. The acceptance criteria related to the preparation of target solution for reuse are developed based on design details provided in [Section 4b.4](#) and are provided in test plans.

#### 12.11.2.1.5 Process Vessel Vent System

The process vessel vent system (PVVS) is tested prior to use with radioactive materials to ensure safety-related SSCs function adequately. The PVVS operational parameters are measured and compared against design parameters. Key parameters include temperatures, pressures, flow rates and the effective operation of the carbon guard and delay beds. The PVVS startup acceptance criteria are developed based on design details provided in [Section 9b.6](#) and are provided in test plans.

#### 12.11.2.1.6 Transfer of Target Solution

Solution is transferred within the facility using the vacuum transfer system (VTS). The VTS operation is confirmed by performing vacuum transfers using surrogate solutions prior to use with target solution. Operations involving initial transfers of target solution are conducted in accordance with test plans. The VTS startup acceptance criteria are developed based on design details provided in [Section 9b.2](#) and are provided in test plans.

#### 12.11.2.1.7 Packaging at End of Solution Life

At the end of solution life, the target solution is blended with other liquid wastes and solidified. During startup testing, the radioactive liquid waste immobilization (RLWI) system is tested with surrogate solution for parameters affecting waste acceptance at licensed disposal facilities. The RLWI startup acceptance criteria are developed based on design details provided in [Section 9b.7](#) and the waste criteria of licensed disposal facilities and are provided in test plans.

#### 12.11.2.1.8 Radiation Measurements

Installed radiation monitoring instruments are calibrated and tested during startup. Detector calibration acceptance criteria are developed based on manufacturer instructions and are provided in test plans.

Radiation measurements are taken throughout testing and compared to expected values. Measurements include the following:

- Measurements from continuous airborne monitors are compared against expected contamination level indications from the continuous airborne monitors.

- Measurements from the facility stack release monitor and carbon delay bed effluent monitor are compared against expected effluent releases during operations involving target solution.
- Area radiation measurements are taken in accordance with the SHINE Radiation Shield Test Program to confirm the adequacy of biological shielding.

The radiation measurement acceptance criteria are developed based on the expected values for the listed measurements and are provided in test plans.

#### 12.11.2.1.9 Ventilation Systems

Ventilation system parameters, particularly those used to control airborne contamination in the facility, are measured and compared to expected conditions. Key parameters include pressures, temperatures, and flow rates. The ventilation system startup acceptance criteria are developed based on design details provided in [Section 9a2.1](#) and are provided in test plans.

#### 12.11.2.1.10 Electrical Systems

The safety-related uninterruptible electrical power supply system (UPSS) is verified to be operable in accordance with technical specifications prior to being relied upon to perform its safety function. Startup testing verifies that the UPSS is capable of providing power to safety-related equipment long enough to prevent or mitigate the consequences of design basis accidents in the absence of power provided from off site or from the nonsafety-related standby generator. The electrical systems startup acceptance criteria are developed based on design details provided in [Chapter 8](#) and are provided in test plans.

#### 12.11.2.1.11 Instrumentation and Controls

Instrumentation and control (I&C) systems used to perform activities required by the Startup Testing Program are tested prior to or as part of those activities. Safety-related I&C systems are verified to be operable in accordance with technical specifications prior to being relied upon to perform their safety functions. Testing of safety-related I&C includes performing instrument calibration, establishing and verifying setpoints, and testing safety system actuations. Detectors are calibrated in accordance with manufacturer instructions or as described in [Subsection 12.11.2.2.1](#). Setpoints for safety-related instruments are established and calibrated in accordance with the methodology described in [Subsection 7.2.1](#). Trip determination is performed by the safety function module, which performs self-testing as described in [Subsection 7.4.5](#). The I&C startup acceptance criteria are developed based on design details provided in [Chapter 7](#) and are provided in test plans.

#### 12.11.2.1.12 Tritium Purification System

The tritium purification system (TPS) is tested prior to use with radioactive materials to ensure that safety-related SSCs function adequately. TPS leak rates are measured and compared to predetermined acceptance criteria, which are developed based on design details provided in [Section 9a2.7](#) and are provided in test plans.

#### 12.11.2.2 Irradiation Unit Startup Tests

The following tests are required for the safe startup of IUs.

#### 12.11.2.2.1 Detector Calibration

Detectors are calibrated using an isotopic method in accordance with implementing procedures. Detector calibration acceptance criteria are developed based on manufacturer instructions and are provided in test plans.

#### 12.11.2.2.2 Irradiation Unit Fill and Drain Systems

Before introducing target solution into an IU, the fill and drain mechanisms are tested using water in the place of target solution. The key parameters are the fill flow rate and the dump valve timing. Maximum flow rate of the fill system is designed to prevent excessive reactivity in the failure of all administrative controls during a fill. If necessary, the flow rate is adjusted. The ability for the safety and nonsafety-related control systems to stop the fill when limits have been exceeded is also confirmed.

The measured dump valve opening time and time to empty the TSV with one dump line are compared to the acceptance criteria. The time from signal initiation to valve opening is measured. The time to empty the TSV using each dump line individually and using both lines is measured.

The target solution fill flow rate and dump valve timing acceptance criteria are developed based on design details provided in [Section 4a2.6](#) and are provided in test plans.

#### 12.11.2.2.3 Subcritical Assembly System Nuclear Physics Parameters

Subcritical assembly system (SCAS) nuclear physics parameters are tested in order to develop appropriate operational parameters (uranium concentration, TSV fill height) and ensure the safe operability of each safety-related SSC. Key parameters include:

- Uranium concentration: Starting with low uranium concentration target solution and increasing until the optimum uranium concentration is reached, the TSV is filled multiple times using a 1/M approach. The optimum concentration is found between the highest uranium concentration limited by the maximum fill height (volume limited) and the lowest uranium concentration limited by the volume margin to critical (reactivity limited). The optimum uranium concentration is compared to calculations. The optimum concentration acceptance criteria are developed based on design details provided in [Section 4a2.6](#) and are provided in test plans.
- Critical height: The critical height is determined by a series of well-planned subcritical multiplication measurements to ensure the resulting calculated critical height is within reestablished acceptance criteria. After the optimum concentration is determined, the TSV is filled approximately four more times at up to 30 grams uranium per liter (gU/L) above optimum uranium concentration. These fill activities are ended when 95 percent of expected critical volume is reached. A curve of critical height versus concentration is created and compared to calculations. The critical height acceptance criteria are developed based on design details provided in [Section 4a2.6](#) and are provided in test plans.
- Calculational bias: TSV neutronic design has been performed using Monte Carlo N-Particle Transport Code (MCNP). The bias of MCNP in terms of uranium concentration and reactivity are both determined based on the optimum concentration and critical height

tests. The calculational bias acceptance criteria are developed based on design details provided in [Section 4a2.6](#) and are provided in test plans.

- Temperature coefficients: The solution temperature coefficients are determined by heating the solution. The temperature coefficient must be negative to be acceptable. The temperature coefficients acceptance criteria are developed based on design details provided in [Section 4a2.6](#) and are provided in test plans.
- Void coefficient: Qualitative measurement of the solution void coefficient is made by noting dips in power due to hydrogen and then oxygen coming out of solution. The void coefficient acceptance criteria are developed based on design details provided in [Section 4a2.6](#) and are provided in test plans.
- Flux distribution: Axial flux distribution is determined via foil activation in the sample tubes. The flux distribution acceptance criteria are developed based on design details provided in [Section 4a2.6](#) and are provided in test plans.

#### 12.11.2.2.4 Neutron Driver Assembly System (NDAS)

While functionality of the neutron driver is required for the successful completion of some of the startup testing, the neutron driver itself is not a safety-related component. The neutron driver is tested for operability, stability, and neutron yield prior to placement in the IU cell, in an off-site facility, or in the NDAS service 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.

#### 12.11.2.2.5 Target Solution Vessel Off-Gas System

TSV off-gas system (TOGS) parameters are tested in order to characterize operational parameters (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.

Additionally, the water holdup worth in TOGS during operation is determined. First, the volume of water held in TOGS is measured during startup tests to verify the extent of TOGS water holdup. Following the determination of holdup volume, the worth of TOGS holdup is determined. The change in reactivity due to water holdup is calculated from flux measurements.

The TOGS startup test acceptance criteria are developed based on design details provided in [Sections 4a2.6](#) and [4a2.8](#) and are provided in test plans.

#### 12.11.2.2.6 Primary Closed Loop Cooling System (PCLS)

Primary closed loop cooling system (PCLS) parameters are tested in order to characterize operational parameters (PCLS 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. The integrity of PCLS is tested periodically during

other startup testing activity by sampling the PCLS water for uranium or fission products as appropriate for the testing phase.

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 plans.

12.12 VACATED

This section has been vacated, per the Final Interim Staff Guidance Augmenting NUREG-1537.

### 12.13 MATERIAL CONTROL AND ACCOUNTING PLAN

The material control and accounting (MC&A) plan was developed to meet the requirements of Subpart D of 10 CFR 74. The MC&A plan addresses the following:

- Management structure,
- Measurements,
- Measurement control system,
- Statistics,
- Physical inventories,
- Item control,
- Receiving and shipping,
- Assessment and review of the MC&A plan,
- Tamper-safing,
- Designation of material balance areas, item control areas, and custodians,
- Resolving indications of loss, theft, diversion, or misuse of special nuclear material (SNM),
- Informational aid for assisting in the investigation and recovery of missing SNM, and
- Recordkeeping.

## 12.14 REFERENCES

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**USNRC, 1983a.** Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors, NUREG-0849, U.S. Nuclear Regulatory Commission, 1983.

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**USNRC, 2012a.** 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, Interim Staff Guidance Augmenting NUREG-1537, Part 1, U.S. Nuclear Regulatory Commission, 2012.

**USNRC, 2012b.** 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, Interim Staff Guidance Augmenting NUREG-1537, Part 2, U.S. Nuclear Regulatory Commission, 2012.

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