ENCLOSURE 7

SHINE TECHNOLOGIES, LLC

REVISION TO APPLICATION FOR ORDER APPROVING TRANSFERS OF CONSTRUCTION PERMIT AND CONFORMING ADMINISTRATIVE AMENDMENTS

QUALITY ASSURANCE PLAN DESCRIPTION

(CLEAN)

24 pages follow

2000-09-01 Rev. #

Quality Assurance Program Description (QAPD)

Responsible Department: Nuclear Quality Assurance

Responsible Manager Signature: _____

Responsible Manager Name: Jeff Bartelme

Effective Date:

REVISION LOG

Revision #	Description of Changes
0	Original Issue
1	Added the following definitions: boiling, gas management system barrier, neutron moderator, primary system boundary, primary cooling system, recombiner, radiolytic gas release, subcritical target, target solution vessel, target solution barrier, target solution. Modified the following definitions: basic component, finding, safety-related items Deleted the following definition: certificate of compliance Provided minor editorial changes.
2	Updates from the Final Interim Staff Guidance Augmenting NUREG-1537, part 1. Minor editorial and formatting changes.
3	Revision to address clarification and changes based on RAI responses. Removal of IROFS and modification of the QLs.
4	Additional clarifications on RAI responses and adding definitions.
5	Clarification for safety-related definition and minor edits
6	Revision to the definitions of QL-1 and QL-2, and additional clarification resulting from RAI responses.
7	Revised the management level for the Plant Manager and removed ANSI/ANS-15.1 management levels from those management positions outside of Plant Operations.
8	Revise reference section (6) to remove canceled document (2000-10-01, “Glossary of Terms”) and Glossary reference from section 1.3. Addition of safety-related activities definition to section 1.3. Update cover page document approval format to reflect current template.
9	Revised to reflect: changes in the organization; update to the Policy statement; added procedure implementing procedure table; consistency with FSAR submittal.
10	Revised definition of safety-related. Added position description of Chief Technology Officer (CTO). Moved/Modified language from The CEO, COO and the VPRA/QA duties and placed it in section 2.1. Revised definitions of QL-2 and 3.
11	Revised to reflect changes in: the organization in Section 2.1, the Organization Chart in Enclosure 2, and the number and title of the implementing procedure for Section 2.15 in Enclosure 3
12	Responsibility for the SHINE Document Control and Records Management program moved from VPRA/Q to COO and DoS. Update SHINE and Baker procedure references in Enclosure 3.
13	Change SHINE Medical Technologies, Inc. to SHINE Medical Technologies, LLC in the Executive Summary. Update and correct SHINE and Baker procedure references in Enclosure 3.

14	Remove QL-3 from the document, remove CTO role from and add Deputy to COO to Section 2.1, update organizational chart, and correct typographical errors. Added the following SHINE implementing procedures to Enclosure 3: 1200-01-01 Design Package, 1200-01-04 Technical Reports, 1200-09-04 Design Control Program; and changed 1200-01-10 Design Control to 1200-01-10 Design Criteria Documents, added Baker to follow 1200-01-06 to 2.3.6. Clarified Director of Construction description.
15	Remove Deputy COO from the body and organizational chart.
16	Engineering Support and Auxiliary Systems, and the Director of Engineering Support and Auxiliary Systems reporting to the VP of Engineering; modifying the programmatic responsibility for Document Control and Records Management from the Director of Engineering Support to the Chief Operating Officer. Editorial corrections throughout document.
17	1. Section 1.3 – Added NRC-approved definitions of commercial grade item, basic component, critical characteristics, dedication, and dedicating entity per exemption from 10 CFR 21.3 related to commercial grade dedication. 2. Section 2.1 – Removed CFO from body and organizational chart. Deleted DoS from body and added ESM in its place. 3. Enclosure 1 – Updated Org. Chart 4. Enclosure 3 – Added 2100-04-01 as an implementing procedure for section 2.5.
18	Section 2.1 – Changes include: 1. Deleted Chief Operating Officer (COO) 2. Added Diagnostics General Manager (DGM) 3. Deleted Plant Manager (PM) 4. Added Director of Plant Operations (DPO) 5. Added Director of Corporate Support (DCS) Enclosure 1 – Updated Org. Chart Enclosure 3 – Added or corrected the following implementing procedures: 1. 1600-01-07 added for section 2.7, 2. 1600-01-12 and 1600-01-19 added for section 2.8, 3. 2000-01-22 for section 2.10, 4. 1600-01-05 and SUT-01-01 added for section 2.11, a. 1200-01-13 title corrected for section 2.11, 5. MNT-01-04 added for section 2.12, 6. 1600-01-12 added for section 2.13, and 7. 1600-01-07 added for section 2.14

19	Section 2.1 – Organization – This section reflects changes to current SHINE organization and reporting relationships based on the following: 1. Replace Procurement Manager (PrM) with Supply Chain Director (SCD). 2. Replace Information Technology Manager (ITM) with VP Cybersecurity & Information Technology (VPCY/IT). Enclosure 1 – SHINE Functional Organizational Chart - Revised to reflect current SHINE organization. Enclosure 3 – Procedures That Implement the QAPD - Changes include: 1. Section 2.3 – Change Title of 1200-01-08 from Drawings to Drawings & 3D Models. 2. Section 2.3.6 – Change Title of 1200-01-06 from Design Change Control Process to Engineering Change Control. 3. Section 2.5 - Change Title of 1200-01-08 from Drawings to Drawings & 3D Models. 4. Section 2.7 - Add 2000-01-08, Assessments. 5. Section 2.7 - Add 2000-01-18, Commercial Grade Survey. 6. Section 2.8 - Remove 1600-01-12, Product Distribution, Warehousing, Stock Rotation and Traceability. 7. Section 2.8 – Update title of procedure 1600-01-19, Handling, Storage, Shipping, Identification and Control of Items. 8. Section 2.13 – Remove 1600-01-12, Product Distribution, Warehousing, Stock Rotation and Traceability. 9. Section 2.13 – Add 1600-01-19, Handling, Storage, Shipping, Identification and Control of Items.
20	Revised to reflect organizational changes in Section 2.1, “Organization,” and Enclosure 1, “SHINE Functional Organizational Chart.” Revised Enclosure 3, “Procedures that Implement the QAPD,” to update the procedure numbers and titles of the SHINE Implementing Procedures and to remove Baker Implementing Procedures.

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EXECUTIVE SUMMARY

This Quality Assurance Program Description (QAPD) provides the SHINE Chrysalis, LLC (SHINE) quality assurance program (QAP) for safe and reliable production of ^{99}Mo and other radioisotopes for medical use and is specific to SHINE. Title 10 of the Code of Federal Regulations (CFR), § 50.34(a)(7) requires each applicant for a construction permit to build a production or utilization facility to include, in its Final Safety Analysis Report (FSAR), a description of the QAP to be applied to the design, fabrication, construction, and testing of the structures, systems, and components (SSCs) of the facility. Furthermore, 10 CFR § 50.34(b)(6)(ii) requires that each applicant for a license to operate a facility include, in the FSAR, a description of the managerial and administrative controls to be used to assure safe operation.

NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”, Section 12.9, “Quality Assurance”, recommends the applicant consider the guidance in Regulatory Guide 2.5, “Quality Assurance Program Requirements for Research and Test Reactors”, and ANSI/ANS-15.8, “Quality Assurance Program Requirements for Research Reactors”. Regulatory Guide 2.5, Rev.1 states that ANSI/ANS-15.8-1995 provides an acceptable method of complying with the program requirements of 10 CFR § 50.34 and was used for developing this QAPD. SHINE has determined that ANSI/ANS-15.8-1995 is sufficient for use in the development of the SHINE QAPD, which is to be applied to the design, fabrication, construction, and operation of the SHINE facility.

POLICY STATEMENT

SHINE shall design, procure, operate and maintain the SHINE facility in a manner that will ensure the health and safety of the public and workers and protect the environment. SHINE commits to operating in a planned, prudent, efficient, safe and cost-effective manner that is in compliance with the CFR, the applicable Nuclear Regulatory Commission (NRC) Facility Operating License, and the applicable laws and regulations of the state and local governments.

In addition, the management of SHINE believes that sound quality, safety, security, and environmental programs are essential to SHINE's success and is personally engaged in their implementation. Quality is owned by every SHINE employee. Quality cannot be achieved solely through inspection. It is achieved by employees with the knowledge, skills, experience, training and motivation to do the job right. Persons who manage, perform and verify work all contribute to an integrated, cost effective and efficient quality management system to produce a quality product.

The SHINE QAP is the QAPD provided in this document and the associated implementing documents. They provide control over SHINE activities that affect the quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD is the top-level document that establishes the manner in which quality is to be achieved and presents the SHINE overall philosophy regarding the achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define organizational interfaces involved in conducting activities within the scope of the QAP. SHINE uses the guidance and best practices from various industry standards to develop implementing procedures. SHINE applies a graded approach consistent with importance to safety and reliability.

Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the SHINE QAPD.

1 INTRODUCTION

SHINE uses a new class of isotope generator that is compact and relatively inexpensive to generate a reliable supply of Mo-99 and other radioisotopes for medical applications. This technology does not use highly enriched uranium, nor does it require a nuclear reactor for production.

Although SHINE uses an accelerator for production, this technology requires licensing under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”. This QAPD addresses the requirements in 10 CFR § 50.34(b)(6)(ii) for a description of a QAP specific for SHINE. Regulatory Guide 2.5 and ANSI/ANS-15.8-1995 provide an acceptable method of complying with the quality assurance program requirements of 10 CFR § 50.34.

SHINE uses accelerator technology for neutron production and the sub-critical fission process and does not meet the definition of a nuclear reactor as identified in 10 CFR § 50.2, “Definitions”. Nonetheless, SHINE uses a definition of safety-related for systems, structures and components (SSCs) that is applied to the Quality Level 1 SSCs and uses a graded approach to quality for other SSCs. The graded approach to quality for this QAPD can be found in Enclosure 2.

1.1 Scope

SHINE addresses the requirements of 10 CFR § 50.34 for a description of the QAP in this controlled document. This QAPD and applicable implementing procedures apply specifically to SHINE. The procedures that implement the requirements in this document are found in the SHINE Information Management System.

The QAPD describes the administrative and engineered controls for ensuring compliance with requirements. It applies to the design, construction and operation of the SHINE facility.

1.2 Application

The quality assurance program applied by SHINE activities will be consistent with the importance of these activities to safety and reliability. Activities included in this quality assurance program are, as a minimum, those related to irradiation unit safety and protection system, material processing safety, criticality safety, engineered safety features, and applicable radiation monitoring systems, as identified in the Limiting Conditions for Operations sections of the Technical Specifications.

SHINE applies a graded approach to those items and activities that could affect the quality of safety-related structures, systems and components (SSCs) and other components not specifically designated as safety-related. A Quality Level (QL) matrix is used to ensure quality requirements are understood and specified for each SSC. Activities that could affect quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

SHINE developed and implemented the QAP beginning with the design, siting and construction phase of the facility. This QAP focuses on the development of appropriate controls to ensure the facility is properly designed and fabricated to meet SHINE requirements. The majority of these controls provide documentation that attests to the facility quality to support an operating license.

Following facility construction and commissioning, the focus of this quality program shifts to establishing those controls that ensure proper and reliable facility operation. All of the program provisions established during the design and construction phase will remain in place but will change in level of implementation appropriate to support facility operations; each portion of

Section 2, Design, Construction and Modifications, would be implemented only as necessary. The operating phase will impose additional requirements related to the conduct of operations. Additional program requirements are defined in Section 3.

1.3 Definitions

Definitions are listed to provide uniform interpretation of terms and phrases used.

Basic component – A basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee or activity subject to the regulations in 10 CFR Part 21 and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission would create a substantial safety hazard. In all cases, basic components include safety-related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

certified operator – an individual authorized by the chartering or licensing organization to carry out the duties and responsibilities associated with the position requiring the certification.

commercial grade item – A commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

commissioning – the process during which constructed irradiation facility structures, components, and systems are made operational and verified to meet design requirements.

corrective action – measures taken to rectify conditions adverse to quality, and where necessary, to prevent repetition.

critical characteristics – Critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

dedication – Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under an ANSI/ANS-15.8-1995 quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of ANSI/ANS-15.8-1995. The process is considered complete when the item is designated for use as a basic component.

dedicating entity – Dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to Section 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process. In cases where

the Licensee applies the commercial grade item procurement strategy and performs the dedication process, the Licensee would assume full responsibility as the dedicating entity.

document – any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

licensed operator – see “certified operator”.

maintenance – those activities necessary to maintain operability or restore systems to within specified design limits. Maintenance consists of repair, rework, replacement, adjustment, cleaning, or other actions necessary to maintain an item in or restore an item to an acceptable condition.

management – management means those persons within the SHINE organization whose responsibility and authority includes the quality assurance program. The levels of management are as described in ANSI/ANS-15.1-2007.

modification – a change in the physical design or functional characteristics of a system, structure, or component.

procedure – a document that specifies or describes how an activity is to be performed.

quality – the degree to which an item or process meets or exceeds the user’s requirements and expectations.

quality assurance – those planned and systematic actions necessary to provide adequate confidence that the structure, system, or component will perform satisfactorily in service.

safety-related activities – those activities affecting the safety-related functions of SSCs, including siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

safety-related Items - Those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents.

shall, should and may – the word "shall" is used to denote a requirement; the word "should" to denote a recommendation; and the word "may" to denote permission, neither a requirement nor a recommendation.

2 DESIGN, CONSTRUCTION, AND MODIFICATIONS

This section provides the requirements for establishing, managing, conducting, and assessing the program of controls over the design, construction, and modification of the SHINE facility. SHINE recognizes that the described controls are integral to the management of the licensed activity and do not necessitate the establishment of a separate program. This section will be implemented as applicable to the specific scope of work activities.

2.1 Organization

This section describes the SHINE organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes internal and external functions for SHINE including interface responsibilities for multiple organizations that perform quality-related functions. The organizational structure and assignment of responsibilities are defined and documented such that: (a) quality is achieved and maintained by those who have been assigned

responsibility for performing work; and (b) quality achievement is verified by those not directly performing the work. SHINE Senior Management ensures that those responsible for ensuring appropriate controls have been established, and for verifying that activities have been correctly performed, have sufficient authority, access to work areas, and freedom to: (a) identify problems; (b) initiate, recommend, or provide corrective action; and (c) ensure corrective action implementation. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes. The SHINE functional organization chart is provided in Enclosure 1.

Chief Executive Officer (CEO)

The CEO is responsible for the overall leadership of the company. The CEO reports to the Board of Directors with respect to all matters.

Chief Operating Officer (COO)

The COO is responsible for the design, management, and technical leadership of the company and is also responsible for all technical and administrative support activities provided by SHINE and suppliers. The COO provides direction to the Vice President of Projects and the Management Position Responsible for Information Technology to fulfill the organization's responsibilities. The COO reports to the CEO.

The COO has the overall responsibility for the SHINE QA Program.

Vice President of Projects (VPP)

The VPP reports to the COO and is responsible for technical and operational aspects of the division including engineering, procurement, construction, and operations. The VPP is also responsible for matters regarding regulatory affairs, quality, and environment, safety, and health.

Management Position Responsible for Engineering (EM)

The EM is responsible for the design of nuclear, instrumentation and control, auxiliary (mechanical, electrical and plumbing), and chemical process systems, structural design, and system testing. The EM is also responsible for facility design configuration control, engineering support, and maintaining the safety analysis, and is the design authority for the facility. The EM reports to the VPP.

Management Position Responsible for Regulatory Affairs (RAM)

The RAM reports to the VPP and is responsible for nuclear related licensing and quality activities. The RAM is responsible for the planning and execution of the licensing process for the design, construction, and operation of the facility. The RAM is also responsible for the implementation of the SHINE Corrective Action program. The RAM is responsible for ensuring clear lines of communication between SHINE and the NRC. The RAM is responsible for integrating the quality requirements as defined in the QAPD across the internal and external organizations and reports to the VPP on matters concerning quality. The RAM is also responsible for the development and implementation of the SHINE Document Control and Records Management programs compliance with all local, state and federal permits.

Management Position(s) Responsible for Quality (QM)

The QM is responsible for Quality Assurance (QA) and Quality Control (QC) processes and activities, including the development and verification of implementation of the QAPD described in this document. The QM is responsible for assuring compliance to regulatory requirements and procedures through assessments and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; for ensuring that contractors and suppliers providing quality services, equipment, parts, and materials to SHINE are meeting the requirements as defined in the QAPD. The QM has sufficient independence from other priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding SHINE's activities. The QM has the ability and responsibility to report to the COO any quality issues which cannot be resolved at the RAM level. The QM reports to the RAM. This management position may be fulfilled by separate QA and QC management positions.

Management Position Responsible for Licensing (LM)

The LM is responsible for implementing nuclear related licensing activities, including the planning and execution of the licensing process for the design, construction, and operation of the facility. The LM is responsible for communication between SHINE and the NRC. The LM reports to the RAM.

Management Position Responsible for Supply Chain (SCM)

The SCM reports to the VPP and is responsible for overall company policy regarding the procurement of material, equipment, and services; establishes specific procedures for the contracting of services and the purchase and control of materials and equipment. The SCM is also responsible for integrating and implementing applicable requirements from the QAPD into the procurement process to ensure that suppliers meet SHINE requirements. Additionally, the SCM is responsible for the oversight of suppliers and the management aspects associated with their execution of the design, fabrication, procurement, construction, and operation of the SHINE facility.

Supplier Organizations

Supplier organizations are responsible for their portion of the execution of the design, fabrication, procurement, construction, and testing of SSCs for the facility. Such supplier organizations are responsible for identifying, implementing, and verifying flow-down of quality requirements as applicable. They will participate in necessary assessments and inspections as specified in procurement documents.

Management Position Responsible for Engineering Construction (ECM)

The ECM is responsible for all aspects of facility construction, including work package development, modification activities, project management, and field engineering. The ECM reports to the VPP.

Management Position Responsible for Plant Operations (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 QAPD and other requirements. The OM reports to the VPP.

Management Position Responsible for Radiation Protection (RPM)

The RPM is responsible for establishing and implementing the Radiation Protection (RP) program, monitoring worker doses, and calibration and QA of all health physics instrumentation. The RPM reports to the OM.

Chief of Staff (COS)

The COS is responsible for establishing and managing the required training programs to support the organization. The COS reports to the CEO.

Management Position Responsible for Training (TM)

The TM is responsible for development, administration, and overall management of the implementation of the various training processes and activities, including as required by regulations and the training for site and facility personnel. The TM reports to the COS.

Management Position Responsible for Information Technology (ITM)

The ITM provides technical expertise regarding electronic data systems, computer networks, and telecommunications and ensuring the technology necessary for implementation of the QAPD and implementing procedures is available. The ITM reports to the COO.

2.1.1 Authority to Stop Work

All employees have the right and responsibility to stop work when they encounter an unsafe condition. Additionally, quality assurance and inspection personnel have the authority and the responsibility to stop work in progress which is not being done in accordance with approved procedures or where safety-related SSC quality may be jeopardized. This extends to off-site work performed by suppliers that furnish materials and services.

2.1.2 Quality Assurance Organizational Independence

Independence shall be maintained between the organizations performing the work or service and oversight performed by the quality organization (i.e., quality assurance and quality control).

2.2 Quality Assurance Program

This section describes the requirements for establishing, implementing, and managing the QAP for SHINE in accordance with the requirements in ANSI/ANS-15.8-1995, “Quality Assurance Program Requirements for Research Reactors”. This includes the managerial and administrative aspects of internal and external activities that affect quality of the SHINE facility and programs.

To achieve the goals of defining and effectively designing safety-related SSCs, SHINE implements the use of a graded approach to quality. The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. This approach to achieving levels of quality is described in this QAPD and related implementing documents.

The QAPD provides the basis for a planned and systematic approach to the cost-effective achievement of safety, quality and reliability. The primary method to ensure this is through the SHINE procedures. The SHINE procedures are delineated, managed and maintained by the RAM with support from all SHINE team members. See Enclosure 3 for a matrix of QAPD sections and their corresponding implementing procedures.

Delegated responsibilities may be performed under a contractor's or supplier's QAP, provided that they have been approved in accordance with the QAPD. Periodic assessments of their QAP are performed to ensure compliance with the SHINE QAPD and implementing procedures. In addition, routine interfaces with their personnel provide added assurance that quality expectations are met. Assessments may be planned and performed by SHINE qualified assessors or independent contractors or consultants as determined by the QM.

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. SHINE establishes and maintains formal and informal indoctrination and training programs for personnel performing, verifying or managing activities within the scope of the QAPD to ensure that suitable proficiency is achieved and maintained. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in applicable SHINE procedures. Indoctrination includes the administrative and technical objectives and requirements of the applicable codes and standards and the QAPD requirements as necessary. Records of personnel training and qualification are to be maintained.

2.3 Design Control

This section describes the requirements for establishing, developing, implementing and documenting a process to control the design, design changes, and temporary modifications subject to the provisions of the QAPD. Procedures identify the process and include provisions for the control of design, development, verification, approval, release, status, distribution, revisions, review of calculations and other design documents, control of software and implementation of required rules, regulations, codes and standards. As part of the design control, the design review program has been developed to meet the requirements of ANSI/ANS-15.8-1995.

2.3.1 Design Requirements

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards shall be identified and documented.

2.3.2 Design Process

Design interfaces shall be identified and controlled, and the design efforts shall be coordinated by the design organization among the participating organizations. Interface controls will include the assignment of responsibility and establishment of implementing documents among the interfacing design organizations for the review, approval, release, distribution and revision of documents involving design interfaces.

The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standardized or previously proven designs, and their effects on other features, shall be considered. Deviations from the established and documented design inputs, including the reasons for the changes, shall be documented and controlled.

The design organization is responsible to ensure that the final design shall:

1. be relatable to design input by documentation in sufficient detail to permit design traceability and verification, and
2. identify assemblies and/or components that are part of the item being designed.

When a computer design program is used to develop portions of the facility design or to analyze a design for acceptability, that program shall be fully documented, validated and controlled to ensure the correctness of its output. When a design program must be developed, the program shall be controlled to ensure that it is fully documented and validated. Where changes to previously valid computer programs are made, documented revalidation shall be required for the change. Verification of design-unique computer programs shall include appropriate benchmark testing.

2.3.3 Design Verification

Independent design reviews shall be used to verify the adequacy of design by one or more of the following:

1. performance of design reviews,
2. use of alternate calculations,
3. performance of qualification tests, or
4. comparison of similar proven systems.

The responsible design organization shall identify and document the particular design verification method or methods used. Design verification will be performed by competent individuals or groups other than those who performed the design, but whom may be from the same organization. In all cases the design verification shall be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations.

In the event that qualification testing is needed to verify design, the use of qualification tests will be defined in a formal test plan that shall include appropriate acceptance criteria and shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Test results will be documented and evaluated by the responsible design organization to ensure that test requirements have been met.

2.3.4 Design Documents and Records

Design documents and records, which provide evidence that the design and design verification process were performed, shall be collected, stored and maintained for the life of the safety-related unit.

2.3.5 Commercial Grade Items

The use of commercial-grade equipment in safety-related applications shall be reviewed to ensure that it can adequately perform its intended function. Procedures shall be implemented to provide guidance on how to review and evaluate commercial grade items for suitability in applications covered by the QAPD. When a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier’s published product description,

the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

2.3.6 Change Control

Procedures shall be established to ensure that modifications to safety-related structures, systems, and components, or computer codes shall be based on a defined “as-exists” design. Changes to verified designs shall be documented, justified, and subject to design control measures commensurate with those applied to the original design. The control measures shall include assurance that the design analyses for the structure, system, component, or computer code are still valid. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

2.4 Procurement Document Control

Procedures shall be established to ensure that procurement documents will contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of SHINE. Procurement documents at all procurement levels shall identify the documentation required to be submitted for information, review, or approval by SHINE. At each level of procurement, the procurement documents shall provide for access to the supplier’s plant facilities and records, for inspection or assessment by SHINE, a designated representative or other parties authorized by SHINE.

SHINE procurement documents shall include SHINE’s requirements for reporting and approving disposition of supplier‘s non-conformances associated with the items or services being procured. The procurement documents for safety-related items should prohibit the supply of sub-standard or counterfeit parts or materials.

2.5 Procedures, Instructions and Drawings

Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

These documents shall be prepared to prescribe performance expectations and define the proper sequence and detail to accomplish the work. Copies of applicable and necessary procedures, instructions and drawings shall be available to the appropriate SHINE internal and external organizations to accomplish work in an efficient and safe manner. See Enclosure 3 for a detailed listing of implementing procedures.

2.6 Document Control

The preparation, issue, and change of documents which specify requirements that affect quality or prescribe activities affecting quality, shall be controlled to ensure that correct documents are used. The document control system shall be documented, and provide for:

1. identification of documents to be controlled and their specified distribution;
2. identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents; and
3. review of documents for adequacy, completeness, and correctness prior to approval and issuance.

Major changes to controlled documents shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated.

2.7 Control of Purchased Items and Services

The procurement of items and services shall be controlled to ensure appropriate procurement planning, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, assessment and examination of items or services for acceptance upon delivery or completion.

2.7.1 Supplier Selection

The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with requirements of the procurement documents.

2.7.2 Work Control

SHINE shall establish measures to control the supplier's performance to ensure that purchased items and services meet quality requirements. Controls may include test plans, review of supplier's submitted documents, arrangements for source surveillance or inspection, and other technical and administrative interfaces with the supplier in accordance with procurement documents.

2.7.3 Verification Activities

The supplier shall be responsible for the quality of his product and shall verify and provide evidence of that quality. Supplier-generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to provide for the acquisition, processing, and recorded evaluation of technical, inspection and test data against acceptance criteria. Based on complexity of the product and importance to safety, SHINE shall consider independently verifying the quality of a supplier's product through source surveillances, inspections, assessments or review of the supplier's non-conformances, dispositions, waivers and corrective actions.

2.7.4 Item or Service Acceptance

Acceptance of items or services provided to SHINE shall require a system to provide assurances that purchased items and services conform to procurement specifications. Methods used to accept an item or related service from a supplier shall be a supplier Certificate of Conformance, source verification, receiving inspection, post-installation test or a combination thereof. Receiving inspection shall be performed in accordance with established procedures and instructions, to verify by objective evidence such features as proper configuration, identification and cleanliness, and to determine any shipping damage, fraud or counterfeit.

2.8 Identification and Control of Items

When specified by codes, standards, or specifications that include identification or traceability requirements, the item identification and control process shall be capable of providing identification and traceability control. Items' identification shall be maintained from the initial receipt or fabrication of the items up to and including installation and use. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied through the use of materials and methods which provide clear and legible identification and do

not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified item when the item is subdivided and shall not be obliterated or hidden by surface treatment or coatings unless substitute means are provided. Where specified, items having limited calendar or operating life shall be identified and controlled to preclude use of items whose shelf life or operating life is expired.

2.9 Control of Special Processes

Special processes include any in which the results are highly dependent on the control of the process or skill of the personnel. These are also those processes in which the specified quality cannot be readily determined by inspection or non-destructive testing of the product. Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers or other appropriate means. SHINE and its suppliers are responsible for adhering to the approved procedures and processes for performing the special process. The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions that control the process. Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment associated with special processes.

2.10 Inspections

Inspections to verify conformance of an item or activity to requirements shall be planned, documented and performed. The inspection program shall apply to procurement, construction, modification, and maintenance. Inspection of items in-process or under construction shall be performed for work activities where product quality cannot be determined by inspection of the completed product. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements. Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage or other characteristics as required to verify the quality and conformance of the item to specified requirements. Associated quality records shall be examined for adequacy and completeness. Only items that have passed the required inspections and tests shall be used, installed or operated. Measuring and Test Equipment (M&TE) used to perform inspections shall be identified in inspection documentation for traceability of inspection results.

Inspection results shall be documented. Acceptance of items shall be documented and approved by authorized personnel. Inspection shall be performed by persons other than those who performed the work being inspected, but may be from the same organization. Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task. The need for formal training shall be determined and training activities conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall be included, with emphasis on firsthand experience gained through actual performance of inspections. Records of inspection personnel’s qualification shall be established and maintained by their employer.

2.11 Test Control

Formal testing shall be required to verify conformance of designated structures, systems or components to specified requirements and demonstrate satisfactory performance for service or to collect data in support of design or fabrication. Testing shall include prototype qualification tests, proof tests prior to installation and functional tests. Test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Computer programs used for operational control shall be tested in accordance with an approved

verification and validation plan and shall demonstrate required performance over the range of operation of the controlled function or process.

2.12 Control of Measuring and Test Equipment

Tools, gauges, instruments and other M&TE used for activities affecting quality shall be controlled and calibrated or adjusted, at specified periods to maintain accuracy within specified limits. Out-of-calibration devices shall be tagged or segregated, and not used until they have been recalibrated. Records shall be maintained of calibration data traceable to the individual piece of M&TE. Calibration and control measures are not required when normal commercial equipment provides adequate accuracy.

2.13 Handling, Storage and Shipping

Handling, storage, and shipping of items shall be in accordance with work and inspection instructions, drawings, specifications, shipping instructions or other pertinent documents or procedures for conducting the activity.

2.14 Inspection, Test and Operating Status

The status of inspection and test activities shall be identified on the items or in documents traceable to the items, in order to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed or operated.

2.15 Control of Non-Conforming Items and Services

Items that do not conform to requirements shall be controlled to prevent inadvertent installation or use. Controls on non-conforming items shall provide for identification, documentation, evaluation, segregation from like conforming items when practical, and disposition of non-conforming items. Non-conforming conditions shall be evaluated for further reporting to appropriate regulatory agencies. Non-conforming characteristics shall be reviewed, and recommended dispositions of non-conforming items proposed and approved, in accordance with documented procedures.

The disposition (use-as-is, reject, repair, or rework) of non-conforming items shall be identified and documented. Technical justification for the acceptability of a non-conforming item disposition “repair” or “use-as-is” shall be documented. Non-conformance to design requirements of items dispositioned “use-as-is” or “repair” shall be subject to design control measures commensurate with those applied to the original design. The as-built records shall reflect the accepted deviation. Repaired or reworked items shall be re-examined in accordance with applicable procedures and with the original acceptance criteria, unless the non-conforming item disposition has established alternate acceptance criteria.

2.16 Corrective Actions

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. The corrective actions shall be in accordance with the design requirements unless those requirements were faulty. In the case of a significant condition adverse to quality, the cause of the condition shall be investigated, and corrective action taken to preclude recurrence.

2.17 Quality Records

A records system or systems shall be established at the earliest practical time consistent with the schedule for accomplishing work activities. The records system or systems shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other

documentation. The records shall include as a minimum: inspection and test results, results of quality assurance reviews, quality assurance procedures, and engineering reviews and analyses in support of designs or changes and modifications.

Some records shall be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use. Such records shall be classified in accordance with the following criteria:

1. those which would be of value in demonstrating capability for safe operation;
2. those which would be of value in maintaining, reworking, repairing, replacing, or modifying an item;
3. those which would be of value in determining the cause or results of an accident or malfunction of a safety-related item;
4. those which provide required baseline data for in-service inspections; or
5. those which would be of value in planning for facility decommissioning.

Other records shall be retained for a shorter period as determined by SHINE. The records shall be stored in a location or locations that prevent damage from moisture, temperature, and pestilence. Additional provisions shall be made for special processed records such as radiographs, photographs, negatives, microfilm and magnetic media, to prevent damage from excessive light, stacking, electromagnetic fields, temperature and humidity. Records maintained by a supplier shall be accessible to SHINE.

2.18 Assessments

SHINE will conduct periodic assessments of quality-affecting activities during design, construction, modification and operations to evaluate the effectiveness of the as-implemented quality program. Assessments shall be performed in accordance with written procedures or checklists. Assessment results shall be documented and should be reviewed by management personnel who have responsibility for the area assessed. Conditions requiring prompt corrective action shall be reported immediately to the appropriate management of the assessed organization.

Management of the assessed organization or activity shall investigate adverse findings, schedule corrective action (including measures to prevent recurrence) and notify the appropriate assessing organization in writing of action taken or planned. The adequacy of the responses shall be evaluated by the assessing organization. Assessment records include assessment plans, reports, written replies, and the record of completion of corrective action. Personnel selected for assessment assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be assessed. The assessor shall have the capability to communicate effectively, both in writing and orally.

3 FACILITY OPERATIONS

This section provides the elements of the QAP for conduct of operation at the SHINE facility. The requirements shall be applied to any equipment or operation as appropriate and consistent with its potential safety impact or program goals. Many of the program requirements are satisfied by existing documentation, or by procedures and activities required by other standards and requirements of the chartering or licensing agency. Some requirements of the QAP for operations may also be found in other documents, such as the Training Program, Emergency Plan, Security Plan, Technical Specifications (see ANSI/ANS-15.1-2007) and the Radiation Protection Program

(see American National Standard for Radiation Protection at Research Reactor Facilities, ANSI/ANS-15.11-2009). Such requirements do not need to be duplicated in the quality assurance program.

3.1 Organization

SHINE shall provide sufficient resources in personnel and materials to safely conduct operations. Planning should anticipate needs as appropriate for any task. The organization structure shall be defined as required by Technical Specifications.

3.2 Quality Assurance Program

SHINE shall establish a QAP by implementing a policy for the conduct of operations. The policy will assign personnel to implement the policy and identify the goals for operating the SHINE facility. Personnel assignments and progress toward achieving goals will be documented.

3.3 Performance Monitoring

SHINE shall monitor facility performance relative to the goals that will be used as performance indicators. SHINE shall document periodic observations of operations and identify and assess any deficiencies to ensure the execution of corrective actions that will prevent recurrence. If appropriate, trend analysis should be performed to indicate where improvements or lessons learned could be implemented. Violations of operating practices should be addressed and documented as appropriate.

3.4 Operator Experience

SHINE shall document the methods for maintaining operator experience. Operators should be responsible for maintaining experience in operating the SHINE facility. This may be achieved by routine operation of the SHINE facility and documentation of the activity. A method should be provided to make operators aware of important current information that is related to facility operations and individual job assignments. Operator training is addressed in American National Standard for the Selection and Training of Personnel for Research Reactors, ANSI/ANS-15.4-2016.

3.5 Operating Conditions

Pre-operations checklists shall be used to determine or verify required pre-operational conditions and readiness to operate. Operating equipment shall be periodically monitored to detect abnormal conditions or adverse trends. Operating conditions should be documented in an operations logbook or other record. The operator should notify the appropriate level of management of any abnormal situations.

3.6 Operational Authority

SHINE shall establish the method for conducting operations and the responsibility for each shift. Operating personnel shall conduct a comprehensive review of appropriate records and equipment before assuming responsibility for the facility. Operational authority may be transferred through a documented turnover briefing and facility walk-through procedures. These procedures should include checklists to record items important to facility status.

3.7 Control Area

Operators shall be alert and attentive to the control console's indications, alarms, and other activities within the control area. Only persons specifically authorized or certified to operate the SHINE facility shall operate control area equipment. Trainees may operate equipment only when

they are directly supervised by certified operators. Control area activities and access should be limited to ensure that the operators are attentive to control responsibilities. A procedure shall be in place for quick placement of the SHINE facility in a safe configuration if evacuation of the control area or site is necessary.

3.8 Ancillary Duties

Operators shall not be assigned ancillary duties to be performed during operations to the extent that these duties could interfere with the ability to monitor facility parameters and maintain control of the SHINE facility.

3.9 Emergency Communications

Operators shall be able to contact the appropriate level of management rapidly and shall have the means to notify all affected personnel promptly of operations or emergencies on-site.

3.10 Configuration Control

Equipment shall be identified that requires configuration control. SHINE is responsible for establishing and maintaining proper configuration and should authorize any changes to safety-related items. All configuration changes to safety-related items should be documented. Before placing equipment into operation, the system shall be properly calibrated or checked, as appropriate, and any deficiencies in the equipment or the current configuration of the system documented. This should also address methods for temporary modifications. SHINE facility maintenance that requires a change in the system shall be documented.

3.11 Lockouts and Tagouts

Locks and tags shall be placed on equipment when, for safety or other special administrative reasons, controls must be established. If there is potential for equipment damage or personnel injury during equipment operation, maintenance, inspection, or modification activities, or from inadvertent activation of equipment, a facility lockout/tagout procedure shall be implemented.

3.12 Test and Inspection

Tests shall be performed following system maintenance, design changes, or inspection that involves dismantlement of components or systems. A documented test plan shall be used to demonstrate that the component or system is capable of performing its intended function. The results of the test should be documented and retained in facility records as appropriate.

3.13 Operating Procedures

Operating procedures shall provide appropriate direction to ensure that the facility is operated normally within its design basis, and in compliance with technical specifications. Operating procedures shall be written, reviewed, approved by appropriate management, controlled, and monitored to ensure that the content is technically correct, and the wording and format are clear and concise. The facility policy on use of procedures should be documented and clearly understood by all operators. The extent of detail in a procedure should depend 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 should be documented. A controlled copy of all operations procedures should be maintained in the control room or equivalent area.

3.14 Operator Aid Postings

Any posted information that aids operators in performing their duties should be current and correct. Management should review operator aids to determine that they are necessary and correct before approving their postings. Postings should be checked periodically for continued applicability.

3.15 Equipment Labeling

Equipment shall be labeled to help facility personnel positively identify equipment they operate and maintain. Information on labels should be consistent with information found in facility procedures, valve lineup sheets, piping and instrument diagrams or other documents. Labels should be permanent, securely attached, readable and have appropriate information.

4 APPLICABILITY TO EXISTING FACILITIES

The SHINE facility will be a newly constructed facility and this section does not apply.

5 DECOMMISSIONING

This section of the QAPD will be updated at a later date.

6 REFERENCES

6.1 American National Standard for Quality Assurance Program Requirements for Research Reactors, ANSI/ANS-15.8-1995.

6.2 American National Standard for the Development of Technical Specifications for Research Reactors, ANSI/ANS-15.1-2007.

6.3 American National Standard for the Selection and Training of Personnel for Research Reactors, ANSI/ANS-15.4-2016.

6.4 Appendix B to 10 CFR Part 20—Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.

6.5 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, October 17, 2012.

6.6 NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content”.

6.7 Regulatory Guide 2.5, Rev.1, “Quality Assurance Requirements for Research and Test Reactors”.