CHAPTER 12

CONDUCT OF OPERATIONS

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Acronyms and Abbreviations

Acronym/Abbreviation	Definition
10 CFR	Title 10 of the Code of Federal Regulations
ALARA	as low as reasonably achievable
ANSI	American National Standards Institute
ANS	American Nuclear Society
CEO	Chief Executive Officer
ConOps	Conduct of Operations
COO	Chief Operating Officer
DC	Document Control
ES&H	Environment, Safety, and Health
FAM	Functional Area Manager
FSAR	Final Safety Analysis Report
NRC	U.S. Nuclear Regulatory Commission
OM	Operations Manager
PM	Plant Manager
POD	plan of the day
QA	quality assurance
QAPD	Quality Assurance Program Description
QL	Quality Level
QM	Quality Manager
RP	Radiation Protection
SHINE	SHINE Medical Technologies, Inc.
SSC	structure, system, and component
TL	Team Leader
TM	Training Manager

CHAPTER 12

CONDUCT OF OPERATIONS

12.1 ORGANIZATION

This section describes the SHINE Medical Technologies, Inc. (SHINE) organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure. The organizational structure includes internal and external functions for SHINE including interface responsibilities for multiple organizations. Management gives careful consideration to the timing, extent, and effects of organizational structure changes. The organizational structure facilitates the execution of the conduct of operations (ConOps) program. ConOps is a philosophy of working in a formalized, disciplined manner to achieve operational excellence. The ConOps program emphasizes safety in every aspect of plant operations. The organizational aspects of the radiation protection (RP) program, the production facility safety program, staffing, and selection and training of personnel will also be discussed in this section.

12.1.1 STRUCTURE

The SHINE functional organization is provided in Figure 12.1-1. The staff implementing the radiation safety function supports on-shift plant operations and interacts with Executive Management through the chain of command. The RP Manager reports directly to the Environment, Safety, and Health (ES&H) Manager. The ES&H Manager and the Quality Manager (QM) report to the Chief Operating Officer (COO) and, for independence, have a line of open communication directly to the Chief Executive Officer (CEO). The CEO reports directly to the SHINE Board of Directors. The Operations Manager (OM) and the Training Manager (TM) report to the Plant Manager (PM). The PM reports to the COO.

12.1.2 RESPONSIBILITY

12.1.2.1 SHINE MEDICAL TECHNOLOGIES, INC.

SHINE Medical Technologies, Inc. is the entity with legal responsibility for holding the Construction Permit and the facility Operating License.

12.1.2.2 CHIEF EXECUTIVE OFFICER

The CEO is responsible for the overall management and leadership of the company. The CEO provides direction to the COO and reports to the Board of Directors.

12.1.2.3 CHIEF OPERATING OFFICER

The COO reports to the CEO and is responsible for operational aspects of the company including safety, quality, environmental stewardship, regulatory affairs, and security.

12.1.2.4 PLANT MANAGER

The PM is responsible for all aspects of site operation, including the protection of personnel from radiation exposure resulting from site operations and materials, and for compliance with applicable U.S. Nuclear Regulatory Commission (NRC) regulations and the facility license. The PM is responsible for implementation of the ConOps program. The PM is also responsible for establishing and managing the required training programs to support the operations organization. The PM is the final certification authority for all individuals qualifying for Senior Operator or Operator status.

The PM (or designee) approves weekly site plans and plans of the day (PODs), designates Shift Supervisors (SSs) and other Senior Operators.

12.1.2.5 OPERATIONS MANAGER

The OM reports to the PM and is responsible for day-to-day operational activities.

12.1.2.6 SHIFT SUPERVISORS

The SS is responsible for the safe operation of the site. The SS authorizes all day-to-day site activities, including: control of access to the facility, work of any kind within the facility, all deliveries and shipments, decisions to start or shutdown equipment, and directing abnormal or emergency actions, including notifications. After facility commissioning, and until facility decommissioning, an SS is stationed at the site. Employees or vendors working at the site, regardless of functional area, will require the authorization of the SS. The SS reports to the OM or designated alternate. The SS keeps the OM and the PM informed as required and maintains a Senior Operator license.

The SS authorizes work in several ways, including: approving daily PODs, work permits, and execution of specific operations procedures. Once an approved POD is in place indicating the activities that are approved for the day, the SS must release each activity based on the evaluation of the site's readiness to safely execute the scheduled events.

12.1.2.7 SENIOR OPERATORS AND OPERATORS

Senior Operators and Operators are responsible for conforming to applicable rules, regulations, and procedures for operation of the facility. Senior Operators shall accept responsibility for safe and efficient operation of a portion of the facility when designated by the SS. Senior Operators and Operators are responsible for maintaining Senior Operator and Operator status, respectively.

12.1.2.8 QUALITY MANAGER

The QM reports to the COO and is responsible for overseeing review and audit of plant operations by review and audit teams, as described below. The QM is responsible for auditing for compliance with regulatory requirements and procedures through assessments and technical reviews, monitoring organizational processes to ensure conformance to commitments, and licensing document requirements. The QM has sufficient independence from other priorities to bring forward issues affecting safety and quality. The QM has the ability and responsibility to report to the CEO any quality issues that cannot be resolved at the COO level.

12.1.2.9 ENVIRONMENT, SAFETY, AND HEALTH MANAGER

The ES&H Manager reports to the COO and is responsible for all matters regarding environment, safety, and health, including radiation protection (RP). The ES&H Manager works closely with the QM on matters involving adherence to safety requirements defined in the Quality Assurance Program Description (QAPD) and other federal, state, and local regulatory requirements. The ES&H Manager works with other managers to ensure consistent interpretations of ES&H requirements, perform independent reviews, and support facility and operations change control reviews. The ES&H Manager has the ability and responsibility to report to the CEO any safety issues that cannot be resolved at the COO level.

12.1.2.10 RADIATION PROTECTION MANAGER

The RP Manager reports to the ES&H Manager and is responsible for establishing and implementing the RP program and the as low as reasonably achievable (ALARA) program, monitoring worker doses, and calibration and quality assurance of all health physics instrumentation.

12.1.3 STAFFING

SHINE provides sufficient resources in personnel and materials to safely conduct operations. Facility staffing considerations including minimum staffing levels, allocation of control functions, overtime restrictions, facility status updates during turnover between shifts, procedures, training, and availability of Senior Operators during routine operations will be defined in the FSAR.

12.1.4 SELECTION AND TRAINING OF PERSONNEL

SHINE establishes and maintains formal and informal indoctrination and training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. The Training Manager (TM) is responsible to the PM for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety. “American National Standard for the Selection and Training of Personnel for Research Reactors,” American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.4-2007 is used in the selection and training of personnel as applicable (ANSI/ANS, 2007). Records of personnel training and qualification are maintained.

Required minimum qualifications for facility staff will be provided in the FSAR.

Personnel who are likely to receive an occupational dose in excess of 100 mrem per year (in accordance with 10 CFR 19.12(b)) are kept informed, advised, and instructed per the requirements of 10 CFR 19.12(a)(1) through (6). Details of the training programs for facility personnel to meet the requirements of 10 CFR Part 19 will be provided in the FSAR.

The Senior Operator and Operator selection and licensing program will conform to 10 CFR 55 as appropriate for the SHINE facility.

12.1.5 RADIATION SAFETY

The RP program meets the requirements of 10 CFR 20, Standards for Protection Against Radiation and is consistent with the guidance provided in Regulatory Guide 8.2, Guide for Administrative Practice in Radiation Surveys and Monitoring. The facility develops, documents, and implements the RP program commensurate with the risks posed by a medical isotope production facility. The facility uses, to the extent practicable, procedures and engineering controls, based upon sound RP principles, to achieve occupational doses to facility personnel and doses to members of the public that are ALARA. The RP staff reports to the RP Manager, who in turn implements the RP program by supporting ongoing activities in the SHINE facility. The RP program content and implementation are reviewed at least annually, as required by 10 CFR 20.1101(c). Sufficient resources in terms of staffing and equipment are provided to implement an effective RP program. Further details related to the authority of the radiation safety staff with respect to facility operations will be provided in the FSAR.

The RP program is described in greater detail in Subsection 11.1.2.

12.1.6 PRODUCTION FACILITY SAFETY PROGRAM

The production facility safety program is developed and integrated with the radiological safety program and additional facility safety programs and utilizes the methods described in 10 CFR 70.61 and 10 CFR 70.62, per 10 CFR 50. Further details of the facility safety program and the Integrated Safety Analysis will be provided in the FSAR.

12.2 REVIEW AND AUDIT ACTIVITIES

The PM establishes review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. These activities are summarized and reported to Executive Management. Independent audits of the SHINE facility are conducted periodically.

12.2.1 COMPOSITION AND QUALIFICATIONS

Audit and review committees with the appropriate expertise and experience are established and members, designated by the PM, provide the SHINE Management an independent assessment of the operation. The minimum number of committee members, qualification of committee members, and the potential use of members from outside the organization will be discussed in the FSAR.

12.2.2 CHARTER AND RULES

The charter and rules of the review and audit committees will be developed for the FSAR. The charter for the committees will address the required meeting interval (at least one per year), quorum required for meetings (not less than one-half the committee membership), issuance of meeting minutes, and voting methods.

12.2.3 REVIEW FUNCTION

At a minimum, the following items shall be reviewed:

- Determinations that proposed changes in equipment, systems, test, experiments, or procedures are allowed without prior authorization by the responsible authority.
- All new procedures and major revisions thereto having safety significance, proposed changes in production facility equipment, or systems having safety significance.
- All new experiments or classes of experiments that could affect reactivity or result in the release of radioactivity.
- 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.
- Audit reports.

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

12.2.4 AUDIT FUNCTION

All aspects of facility operations, including the RP and laboratory program, the emergency, physical security, and operator requalification plans will be audited, at a minimum of every two years. These areas do not have to be audited at the same time, but all will be audited within the designated intervals. Each audit will have its own audit plan. Discussions with personnel and observation of operations will be used as appropriate. In no case shall 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 are examples of activities that will be audited:

- Facility operations for conformance to the technical specifications and applicable license conditions.
- The retraining and requalification program for the operating staff.
- The results of action taken to correct those deficiencies that may occur in the production facility equipment, systems, structures, or methods of operations that affect nuclear safety.
- The SHINE facility emergency plan and implementing procedures.

Deficiencies identified during the audit will be entered into the corrective action program.

12.3 PROCEDURES

Operating procedures provide appropriate direction to ensure that the facility is operated normally within its design basis, and in compliance with technical specifications. Operating procedures are written, reviewed, 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.

SHINE procedures are prepared, approved, revised, canceled, and implemented in accordance with the procedure program. Document Control (DC) maintains the Master Procedures List and ensures that revisions are documented appropriately, approved for release by authorized personnel, and distributed for use at the location where the prescribed activity is performed. DC also retains and distributes procedures in accordance with DC procedures for SHINE. The process required to make changes to procedures, including substantive and minor permanent changes, and temporary deviations to deal with special or unusual circumstances during operation is in compliance with ANSI/ANS 15.1-2007 (ANSI/ANS, 2007). A minimum list of procedural topics will be provided with the FSAR.

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

12.4 REQUIRED ACTIONS

Required actions to be taken in the event of a violation of a facility safety limit or the occurrence of a reportable event will be developed for the FSAR.

12.5 REPORTS

A detailed discussion of reports that will be submitted to the NRC will be provided in the FSAR.

12.6 RECORDS

The SHINE records management program defines the process for managing SHINE records. The records management program includes the identification, generation, authentication, maintenance, and disposition of records.

A detailed discussion of records management will be provided in the FSAR.

12.7 EMERGENCY PLANNING

The emergency plan will follow the guidance provided in ANSI/ANS 15.16-2008 (ANSI/ANS, 2008), “Emergency Planning for Research Reactors,” which is endorsed and amplified by Regulatory Guide 2.6, Revision 1. SHINE also will use NUREG-0849 for guidance on emergency planning.

Details about the production facility will be included in the FSAR, per the guidelines provided in NUREG-1520, Revision 1, Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility.

The emergency plan will be provided with FSAR.

12.8 SECURITY PLANNING

The security plan will be developed using the guidance provided in Regulatory Guide 5.59, Revision 1.

The security plan will be provided with the FSAR.

12.9 QUALITY ASSURANCE

SHINE QA-1, Quality Assurance Program Description (QAPD), is based on ANSI/ANS 15.8–1995 (R2005) (ANSI/ANS, 1995), “Quality Assurance Program Requirements for Research Reactors,” with guidance from Regulatory Guide 2.5, Revision 1.

The SHINE QAPD is provided in Appendix 12C.

12.10 OPERATOR TRAINING AND REQUALIFICATION

12.10.a REACTOR OPERATOR TRAINING AND REQUALIFICATION

This section is not applicable as the SHINE irradiation unit is not a reactor.

12.10b PRODUCTION FACILITY OPERATOR TRAINING AND REQUALIFICATION

The SHINE facility operator training and requalification program will be described in the FSAR.

12.11 STARTUP PLAN

The startup plan will be described in the FSAR.

12.12 VACATED

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

12.13 MATERIAL CONTROL AND ACCOUNTABILITY PROGRAM

The material, control, and accountability program will be provided with the FSAR.

12.14 REFERENCES

ANSI/ANS, 1995. Quality Assurance Program Requirements for Research Reactors, ANSI/ANS 15.8-1995 (R2005), American National Standards Institute/American Nuclear Society, 1995.

ANSI/ANS, 2007. The Development of Technical Specifications for Research Reactors, ANSI/ ANS 15.1-2007, American National Standards Institute/American Nuclear Society, 2007.

ANSI/ANS, 2008. Emergency Planning for Research Reactors, ANSI/ANS 15.16-2008, American National Standards Institute/American Nuclear Society, 2008.

ANSI/ANS,2007. Selection and Training of Personnel for Research Reactors, ANSI/ANS 15.4, American National Standards Institute/American Nuclear Society, 2007

APPENDIX 12A EMERGENCY PLAN

The emergency plan will be provided with the FSAR.

APPENDIX 12B SECURITY PLAN

The security plan will be provided with the FSAR.

APPENDIX 12C QUALITY ASSURANCE PROGRAM DESCRIPTION

SHINE Medical Technologies, Inc. (SHINE)

Quality Assurance Program Description (QAPD)

SHINE-QA-1

Revision: 2

Approved by: _____ Date 4/11/13

Vann Bynum, Ph.D.
Chief Operating Officer

Contents

Executive Summary

This QAPD provides the Shine Medical Technologies, Inc. (SHINE) quality assurance program 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, Section 50.34(a)(7) requires each applicant for a construction permit to build a production or utilization facility to include, in its preliminary safety analysis report, a description of the quality assurance program to be applied to the design, fabrication, construction and testing of the structures, systems, and components 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 final safety analysis report, a description of the managerial and administrative controls to be used to ensure 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, Rev.1, “Quality Assurance Requirements for Research and Test Reactors” and ANSI/ANS 15.8-1995;R2005 ”Quality Assurance Program Requirements for Research Reactors”. Regulatory Guide 2.5 states that ANSI/ANS 15.8-1995;R2005 provides an acceptable method of complying with the program requirements of 10 CFR 50.34 and was used for developing this QAPD.

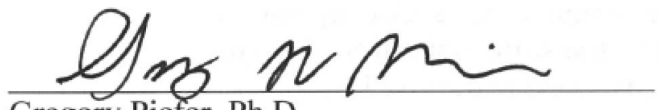
SHINE uses accelerator technology for neutron production and sub-critical fission process and does not meet the definition of a nuclear reactor as identified in 10 CFR 50.2, “Definitions”. Nonetheless, SHINE utilizes a definition of safety-related systems, structures and components (SSC) for the Quality Level 1 SSCs, where appropriate, and utilizes a portion of the definition of “Items Relied On For Safety” (IROFS), from 10 CFR 70.4, “Definitions”, for the Quality Level 2 SSCs, where appropriate.

Policy Statement

SHINE Medical Technologies, Inc., (SHINE) shall design, procure and 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. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating License, and 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 our business's success and is personally engaged in their implementation.

The SHINE Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. They provide for control over SHINE activities that affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not SSCs, but support safe and reliable plant operations.

The management of SHINE believes that quality is an integral part of everything we do. The QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents the SHINE overall philosophy regarding 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. Compliance with the QAPD and the implementing documents is mandatory for personnel directly or indirectly associated with implementation of the SHINE QAP.



Gregory Piefer, Ph.D.
Chief Executive Officer
SHINE Medical Technologies, Inc.

7-14-11
Date

1. Introduction

SHINE uses a new class of isotope generator that is compact and relatively inexpensive to generate a reliable supply of ^{99}Mo 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(a)(7) for a description of a Quality Assurance Program specific for SHINE. Regulatory Guide 2.5 and ANSI/ANS 15.8-1995;R2005 provide an acceptable method of complying with the quality assurance program requirements of 10 CFR 50.34(a)(7).

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 utilizes a definition of safety-related systems, structures and components (SSC) for the Quality Level 1 SSCs, where appropriate, and utilizes the definition of “Items Relied On For Safety” (IROFS), from 10 CFR 70.4, “Definitions”, for the Quality Level 2 SSCs, where appropriate. 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 Quality Assurance Program in this controlled document. This QAPD and applicable implementing procedures apply specifically to SHINE. This document meets the intent of the above documents and applicable SHINE policies and programs. 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, operation and decommissioning 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 shall be, as a minimum, those related to accelerator safety, 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 will apply 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. An Applicability Procedure for SHINE will ensure the effective designation and traceability of quality levels. Applicable activities will be performed in accordance with the Graded Approach until such time when it is determined that the SSC has changed to another

quality level. Activities that could affect quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, operating and decommissioning.

SHINE will develop and implement the quality assurance program beginning with the design, siting and construction phase of the facility. This quality assurance program will focus on the development of appropriate controls to ensure the facility is properly designed and fabricated to meet SHINE requirements. The majority of these controls will 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 Design, Construction and Modifications would be implemented only as necessary. The operating phase will impose additional requirements related to the conduct of operations.

1.3 Definitions

Definitions are listed to provide uniform interpretation of terms and phrases used. Definitions for use at SHINE are located in a stand-alone document and are under document control.

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. 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 management and leadership of the company. The CEO is also responsible for all technical and administrative support activities provided by SHINE and suppliers. The CEO provides direction to the COO, CFO, VP of Customer

Relations and Chief Technology Officer to fulfill the organization's responsibilities. The CEO reports to the Board of Directors with respect to all matters.
The CEO delegates the necessary responsibility and authority to his direct reports to ensure quality is achieved and maintained by those who have been assigned the responsibility for performing the work and quality achievement is verified by persons not directly performing the work.

Chief Operating Officer (COO)

The COO reports to the CEO and is responsible for all operational aspects of the company including safety, quality, environmental stewardship, regulatory affairs and security. The COO is responsible for all external operations of SHINE, including supplier organizations. The COO is responsible for integrating all quality requirements as defined in the QAPD across the internal and external organization and reports to the CEO on all matters concerning quality.

The COO delegates sufficient responsibility and authority to his direct reports to ensure that appropriate controls have been established and for verifying that activities have been correctly performed. Authority is also provided to access necessary work areas and encourages managers and employees to identify problems, initiate, recommend or provide corrective action and ensure corrective action implementation.

Chief Financial Officer (CFO)

The Chief Financial Officer (CFO) reports to the CEO and is responsible for all financial matters for SHINE. In addition the CFO will partner with senior leadership and the board of directors to develop and implement strategies across the organization. The CFO will oversee all compliance and recognition for government (federal and state) contracts and private grants. The CFO is also responsible for information technology, procurement, and financial accounting for the organization.

Vice President of Customer Relations

The Vice President (VP) of Customer Relations reports to the CEO and is responsible for sales and business development.

Chief Technology Officer (CTO)

The Chief Technology Officer (CTO) is responsible for leading the development of the technology necessary for the organization's success and periodically reviews cost, schedule, program development activities, technical adequacy of design development, progress reports, quality assessment results, and other program-related information. The CTO delegates the day-to-day performance of internal and external activities regarding both technical and administrative matters.

Environmental, Safety and Health Manager (ES&H)

The ES&H Manager reports to the COO and is responsible for all matters regarding environment, safety, and health. The ES&H Manager works closely with the Quality Manager (QM) on matters involving adherence to safety requirements defined in the QAPD and other regulatory, state and local requirements. The ES&H Manager is also

responsible for all environmental related licenses and permits. The ES&H Manager has the ability and responsibility to report to the CEO any safety issues which cannot be resolved at the COO level.

Quality Manager

The Quality Manager reports to the COO and is responsible for the development and verification of implementation of the QAPD described in this document. The Quality Manager 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 suppliers providing quality services, parts and materials to SHINE are meeting the requirements as defined in the QAPD. The Quality Manager 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 Quality Manager has the ability and responsibility to report to the CEO any quality issues which cannot be resolved at the COO level.

Plant Manager

The Plant Manager is responsible for the design, construction and management of the organization's facilities. Operational requirements and needs are factored into the design throughout the phases as required. The Plant Manager is also responsible for establishing and managing the required training programs to support the organization.

During the design, construction, or modification of the facility, most of the work may be performed by outside organizations or support contractors and suppliers. The Plant Manager will provide oversight of these organizations.

Licensing Manager

The Licensing Manager reports to the COO and is responsible for all nuclear related licensing. The Licensing Manager is responsible for the planning and execution of the licensing process for the design, construction and operation of the facility. The Licensing Manager is responsible for ensuring clear lines of communication between SHINE and the Nuclear Regulatory Commission (NRC).

Procurement Manager

The Procurement Manager is responsible for the administration of all goods and services in support of SHINE facility design and operations. The Procurement Manager is responsible for integrating and implementing all applicable requirements from the QAPD into the procurement process to ensure that all suppliers meet SHINE requirements. The Procurement Manager 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.

Project Controls Manager

The Project Controls Manager is responsible for developing and maintaining the project plan and the project scope, schedule, and budget. The Project Controls Manager also provides regular reports and analyses as required.

Physical Security Manager

The Physical Security Manager is responsible for establishing and maintaining the programs and systems to ensure protection of the company's assets and compliance with all security related licensing and permitting requirements. The Physical Security Manager will serve as the liaison to external response agencies.

Supplier Organizations

Supplier organizations are responsible for their portion of the execution of the design, fabrication, procurement, construction, and testing of quality-related SSC 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.

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 organization or organizations performing the checking (quality assurance and quality control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

2.2 Quality Assurance Program

This section describes the requirements for establishing, implementing, and managing the Quality Assurance Program (QAP) for SHINE in accordance with the requirements in ANSI/ANS-15.8-1995;R2005, "Quality Assurance Program Requirements for Research Reactors". The QAPD provides the requirements for establishing a QAP at the earliest time consistent with the project schedule for accomplishing quality affecting activities. 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 SSC, 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 Quality Manager with support from all SHINE team members.

Delegated responsibilities may be performed under a supplier's QAP, provided that they have been approved in accordance with the QAPD. Periodic assessments of their QA programs 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 Quality Manager.

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 will be maintained.

2.3 Design Control

This section describes the requirements for establishing and implementing a process to control the design, design changes, and temporary modifications subject to the provisions of the QAPD. Procedures will identify the process and include provisions for the control of design, development, verification, approval, release, status, distribution, revisions, review of calculations, 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;R2005.

2.3.1 Design Requirements

Applicable design inputs, such as, 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 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 safety-related SSCs.

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 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 item will 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.

Procedures for 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 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.

Procedures shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

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, audit 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 to adhere 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, maintenance, and experiment fabrication. 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 SHINE.

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.

2.19 Experimental Equipment

The quality assurance program shall provide controls over the design, fabrication, installation and modification of experimental equipment to the extent that these impact safety-related items.

3. Facility Operations

This section provides the elements of a quality assurance program 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 NRC and State of Wisconsin. Some requirements of the quality assurance program 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 quality assurance program 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 address or 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-15.4-2007.

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.

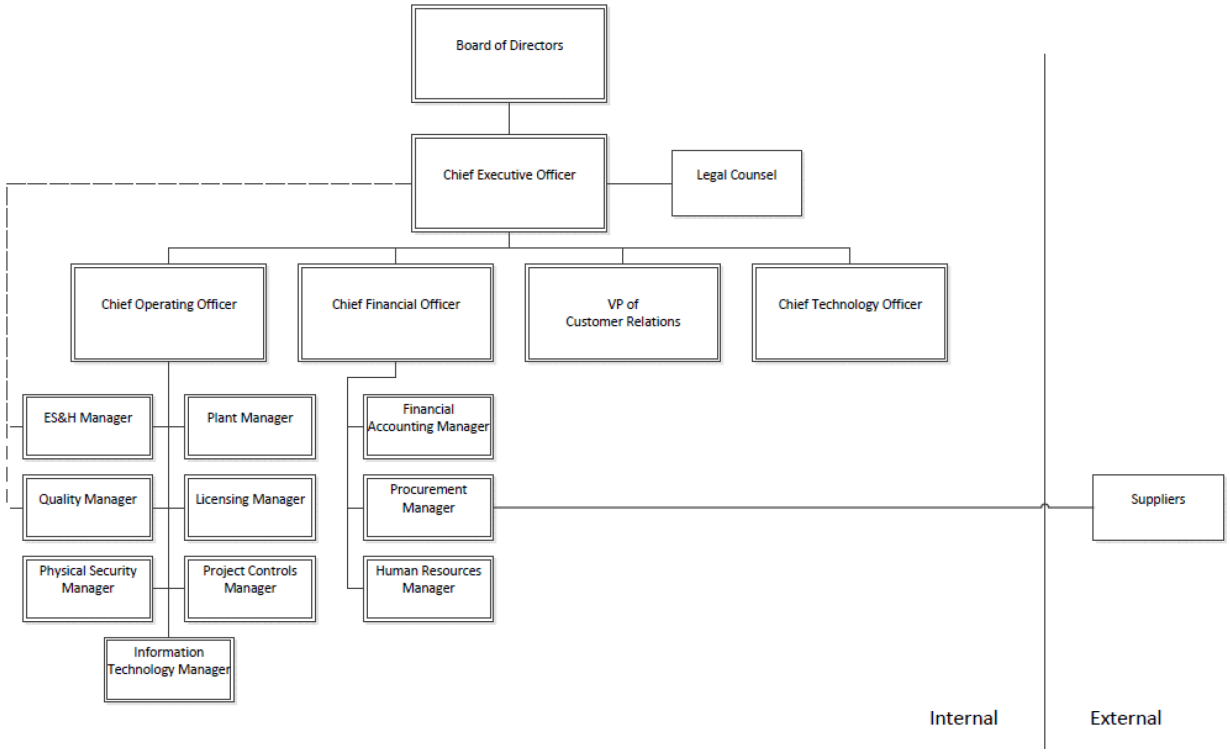
5. Decommissioning

The quality assurance requirements for the SHINE facility during the decommissioning phase are addressed by the appropriate sections of this QAPD and American National Standard for Decommissioning of Research Reactors, ANSI/ANS-15.1-1990;W2004 .

Enclosure 1

SHINE Functional Organizational Chart

SHINE Medical Technologies



Enclosure 2

Graded Approach to Quality

The graded approach to quality is a process by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance. The graded approach permits the implementing organization to focus resources on those activities that are deemed, by qualitative analysis, to reduce the associated risks and hazards.

The activities and tasks are performed in accordance with approved implementing procedures.

QL-1 shall implement the full measure of this QAPD and shall be applied to Safety-Related Structures, Systems and Components.

QL-2 will include the quality activities performed by the licensee, generally on a continuing basis, that are applied to ensure the items are available and reliable to perform their safety functions when needed. These quality activities include configuration management, maintenance, training and qualifications, procedures, assessments, incident investigations, records management and other quality assurance elements. These quality activities are embodied in this QAPD and will be further specified in the preliminary and/or final safety analysis report as appropriate. QL-2 shall be applied to the design of structures, systems and components that are relied upon to limit:

(1) the risk of nuclear criticality accidents with preventive controls and measures to ensure that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of sub-criticality for safety.
(2) the likelihood of occurrence of an event so that, upon implementation, the event is highly unlikely or its consequences are less than those listed below:
    - An acute worker dose of 1.0 Sv (100 rem) or greater total effective dose equivalent (highly unlikely)
    - An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to the public (highly unlikely)
    - An intake to the public of 30 mg or greater of uranium in soluble form (highly unlikely)
    - An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could endanger the life of a worker or lead to irreversible or other serious, long-lasting health effects to the public (highly unlikely)
(3) the likelihood of occurrence of an event so that, upon implementation, the event is unlikely or its consequences is less severe that those listed below:
    - An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent (unlikely)
    - An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to the public (unlikely)
    - An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could lead to irreversible or other serious, long-lasting health effects to a worker or mild transient health effect to the public (unlikely)

- A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values of Table 2 of Appendix B to Part 20 (unlikely)

QL-3 will include the non-safety related quality activities performed by the licensee, that are deemed necessary by SHINE to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements.

Enclosure 3

References

[1] American National Standard for Quality Assurance Program Requirements for Research Reactors, ANSI/ANS-15.8-1995;R2005.

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

[3] American National Standard for Radiation Protection at Research Reactor Facilities, ANSI/ANS-15.11-2009.

[4] American National Standard for the Selection and Training of Personnel for Research Reactors, ANSI/ANS-15.4-2007.

[5] American National Standard for Decommissioning of Research Reactors, ANSI/ANS-15.10-1994;W2004.

[6] 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.

[7] 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.

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

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

Enclosure 4

Revision Log

Revision	Effective Date	Description
0	7/14/2011	Initial issuance.
1	6/7/2012	**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	4/11/2013	Updates from the Final Interim Staff Guidance Augmenting NUREG-1537, part 1. Minor editorial and formatting changes.

APPENDIX 12D CONDUCT OF OPERATIONS PROGRAM DESCRIPTION

The ConOps program will be described in the FSAR.