July 27, 2021

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Subject: Response to the Abilene Christian University Quality Assurance Program Description Request for Additional Information

By letter dated March 18, 2021 (ADAMS Accession No. ML21099A109), Abilene Christian University (ACU) submitted, pursuant to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, Section 34(a)(7), the ACU Nuclear Energy eXperimental Testing Laboratory (NEXT Lab) Quality Assurance Program Description (QAPD) for its proposed ACU Molten Salt Research Reactor (MSRR) to the U.S. Nuclear Regulatory Commission (NRC) for review and approval. A Request for Additional Information (RAI) from NRC dated July 13, 2021 was received by NEXT Lab (ML21190A224).

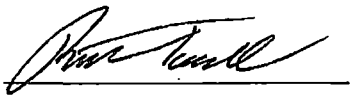
Enclosure 1 contains our replies to the RAI. Enclosure 2 is a revised copy (Revision B) of the QAPD showing changes made in addition/strikeout format. Enclosure 3 is a clean copy (Revision B) of the QAPD.

If there are any questions or a need for additional information, please contact Dr. Rusty Towell at the address above, by telephone at (325) 674-2034, or by email at Rusty.Towell@acu.edu.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 07/27/2021.

Very truly yours,



7-27-2021

Dr. Rusty Towell, Ph.D. Date

Director of NEXT Lab

Project Number: 99902088

Enclosure: As stated

cc: Edward Helvenston, NRC
Richard Rivera, NRC

Q004
YG01
NRR

Enclosure 1

Abilene Christian University
Quality Assurance Program Description
Response to Request for Additional Information

RAI - 1 : *Figure 1-1 in Section 2.1 of ACU's QAPD shows the Nuclear Projects Lead position, but this position does not appear to be described in the QAPD. Clarify where the Nuclear Projects Lead position is described or justify why no additional information is required.*

The "Nuclear Projects Lead" position in Figure 1-1 is described in the QAPD but is incorrectly referenced in the text as "Reactor Project Lead". To address this inconsistency, the five occurrences of "Reactor Project Lead" in Section 2.1 have been corrected to read, "Nuclear Projects Lead".

RAI – 2 : *ANSI/ANS-15.8-1995 defines the words 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. Section 1.2 of ACU's QAPD states that the definitions provided in ANSI/ANS-15.8-1995 apply to terms as used in the ACU QAPD.*

The word "shall" is removed in ACU's QAPD-001-A, Revision A, in the following sections that correspond to sections in ANSI/ANS-15.8-1995: twice in 1.2, once in 2.1, twice in 2.2, once in 2.3, once in 2.3.1, twice in 2.3.2, once in 2.5.1, once in 2.7.4, once in 2.8, four times in 2.10, twice in 2.15, three times in 2.17, and once in 2.19. The word "shall" is replaced with "will be" in 2.3.6 and "required" in 2.16. The word "shall" is used instead of "should" in 2.3.6 and 2.4.

Clarify the proper level of commitments in these sections or justify why no additional information is required.

The language in the QAPD (Revision A) was intended to be consistent with the definitions and level of commitments in ANSI/ANS-15.8-1995, specifically in the sections called out in this RAI. In Revision B of the QAPD, the complete RAI list of removed "shalls" has been addressed by revision to add "shall" consistent with ANSI/ANS-15.8-1995. (Note that the RAI refers to section 2.5.1. The QAPD does not contain a section 2.5.1. This was interpretated to mean section 2.5.) In addition, the replacement of "shall" with "will be" (section 2.3.6) and "required" (section 2.16) has been corrected by changing these to shall statements. In sections 2.3.6 and 2.4, "shall" has been replaced with "should" to be consistent with ANSI/ANS-15.8-1995.

Consistent with the scope of the RAI, further review of the QAPD revealed five other removed "shalls" in sections 2.10, 2.11, 2.15, 2.17 which have been revised to add "shall" as shown in Revision B of the QAPD. For further consistency with ANSI/ANS-15.8-1995, we have also added "in a graded approach" in section 1.2, changed "need" to "will have" in section 2.1, Replaced "QAPD the" with "QAPD, the" in section 2.2, added "appropriate to the circumstances" in section 2.5, changed "," to "upon", changed "to" to "through" in section 2.8, added "and" in section 2.17, and changed "are" to "and" in 2.7.4.

The details of the changes are as follows:

Section 1.2 – replaced "are" with "shall be, as a minimum", and "supports" with "shall support". Also added "in a graded manner".

Section 2.1 - Replaced "need" with "will have" and five instances of "Reactor Project Lead" to "Nuclear Projects Lead". Added missing "shall". Replaced five instances of "QAM" with "QA Manager". Removed "(QAM)".

Section 2.2 – Replaced "identifies" with "shall identify", "provides" with "shall provide", and "QAPD the" with "QAPD, the".

Section 2.3 – Replaced "prescribes, develops, documents, and preserves" with "shall prescribe, develop, document, and preserve".

Section 2.3.1 – Replaced "are" with "shall be".

Section 2.3.2 – Replaced "are" with "shall be" and "will" with "shall".

Section 2.3.6 – Replaced "shall" with "should" and two instances of "will" to "shall".

Section 2.4 – The word "shall" is replaced with "should". Replaced two instances of "QAM" with "QA Manager".

Section 2.5 – Replaced "have been" with "shall be". Added "appropriate to the circumstances".

Section 2.7 – Replaced "," with " upon".

Section 2.7.4 – Added "shall". Replaced "are" with "and".

Section 2.8 – Replaced "are" with "shall be" and "to" to "through".

Section 2.11 – Replaced "is" with "shall be".

Section 2.10 – Replaced "also applies" with "shall apply", two instances of "are" to "shall be", "will" to "shall", "is" to "shall be", and "are required to" to "shall". Replaced "QAM" with "QA Manager".

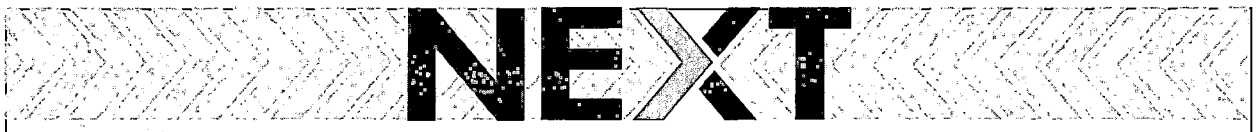
Section 2.15 – Replaced "includes" to "shall include", and two instances of "are" to "shall be".

Section 2.16 – Replaced "requires corrective action" with "corrective actions shall".

Section 2.17 – Added "shall". Replaced "inspection test results" to "inspection and test results" and three instances of "are" to "shall be".

Section 2.18 – Replaced two instances of "QAM" with "QA Manager".

Section 2.19 – Added "shall".



Quality Assurance Program Description

Title: Abilene Christian University Nuclear Energy eXperimental Testing Laboratory (NEXT Lab) Quality Assurance Program Description For Design, Licensing and Construction of the Abilene Christian University Molten Salt Research Reactor

Program Owner: Director of NEXT Lab

Safety-Related	Version Number Revision B	Effective Date 07-15-21

Revision Summary:

All revision markings updated from "A" to "B" throughout the document
Section 1.2 – replaced "are" with "shall be, as a minimum", and "supports" with "shall support". Also added "in a graded manner".
Section 2.1 - Replaced "need" with "will have" and five instances of "Reactor Project Lead" to "Nuclear Projects Lead". Added missing "shall". Replaced five instances of "QAM" with "QA Manager". Removed "(QAM)".
Section 2.2 – Replaced "identifies" with "shall identify", "provides" with "shall provide" and "QAPD the" with "QAPD, the".
Section 2.3 – Replaced "prescribes, develops, documents, and preserves" with "shall prescribe, develop, document, and preserve".
Section 2.3.1 – Replaced "are" with "shall be".
Section 2.3.2 – Replaced "are" with "shall be" and "will" with "shall".
Section 2.3.6 – Replaced "shall" with "should" and two instances of "will" to "shall".
Section 2.4 – The word "shall" is replaced with "should". Replaced two instances of "QAM" with "QA Manager".
Section 2.5 – Replaced "have been" with "shall be". Added "appropriate to the circumstances".
Section 2.7.4 – Added "shall". Replaced "are" with "and".
Section 2.8 – Replaced "are" with "shall be" and "to" to "through".
Section 2.10 – Replaced "also applies" with "shall apply", two instances of "are" to "shall be", "will" to "shall", "is" to "shall be", and "are required to" to "shall". Replaced "QAM" with "QA Manager".
Section 2.11 – Replaced "is" with "shall be".
Section 2.15 – Replaced "includes" to "shall include", and two instances of "are" to "shall be".
Section 2.16 – Replaced "requires corrective action" with "corrective actions shall".
Section 2.17 – Added "shall". Replaced "inspection test results" to "inspection and test results" and three instances of "are" to "shall be".
Section 2.18 – Replaced two instances of "QAM" with "QA Manager".
Section 2.19 – Added "shall".

Quality Assurance Program

Policy Statement

Abilene Christian University (ACU) and the Nuclear Energy eXperimental Testing Laboratory (NEXT Lab) shall design, procure, construct, and operate the ACU Molten Salt Research Reactor (MSRR) in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the U.S. Code of Federal Regulations, the applicable U.S. Nuclear Regulatory Commission Construction Permit and Facility Operating License, and applicable laws and regulations of the state of Texas and local governments.

The ACU NEXT Lab Project Quality Assurance Program (QAP) is comprised of the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. Together they provide for control of NEXT Lab activities that affect the quality of safety related structures, systems, and components 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 policy document that establishes the manner in which quality is to be achieved and presents the staff of NEXT Lab's overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP.

Next Lab personnel have authority commensurate with their responsibility, including the authority to stop work that does not conform to established requirements. This stop work authority may be exercised in accordance with established QAP as implemented in the NEXT Lab Quality Procedures.

3-18-21

Phil Schubert, Ed.D. Date

President

Abilene Christian University

3-18-21

Rusty Towell, Ph.D. Date

Director of NEXT Lab

Version Number Revision B Effective Date 07/15/21

Approved By:

7/15/2021

Rusty Towell, Ph.D. Date
Director of NEXT Lab

7/15/2021

Tony Hill, Ph.D. Date
Nuclear Projects Lead – Engineering, Construction and Technical Services
NEXT Lab

Table of Contents

1. Introduction

1.1 Scope

The Abilene Christian University (ACU) Nuclear Energy eXperimental Testing Laboratory (NEXT Lab) Quality Assurance Program Document (QAPD) is the top-level policy document that establishes the Quality Assurance Program (QAP) and assigns major functional responsibilities for all activities associated with the Molten Salt Research Reactor (MSRR) Project conducted by or for the NEXT Lab staff. The QAPD describes the methods and establishes Quality Assurance (QA) and administrative control requirements that meet Title 10 of the Code of Federal Regulations (CFR), Part 50, Section 50.34(a)(7) (10 CFR 50.34(a)(7)). ACU has determined that ANSI/ANS 15.8-1995 (R2005; R2013) "Quality Assurance Program Requirements for Research Reactors," (ANS-15.8) following the guidance in Regulatory Guide 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors" (RG 2.5) is sufficient for use in developing the QAPD for the MSRR.

1.2 Application

The QAP applied by ACU at the NEXT Lab to MSRR activities is consistent with the importance of activities affecting safety and reliability. Activities included in the QAP shall be, as a minimum, those affecting the quality and performance of safety-related Structures, Systems, and Components (SSCs). The QAP applies in a graded manner to those activities and items which could affect the quality of SSCs of the MSRR and its activities, including, but not limited to:

Designing	Receiving	Pre-Operational Activities
Siting	Storing	Maintaining
Procuring	Constructing	Repairing
Fabricating	Erecting	Modifying
Cleaning	Installing	Training
Handling	Inspecting	
Shipping	Testing	

The NEXT Lab QAP is implemented in a graded approach process to ensure that the level of analysis, documentation, and actions used to comply with a requirement, defined in ANS 15.8, are commensurate with: (1) the relative importance to safety, safeguards, and security; (2) the magnitude of any hazard involved; (3) the life cycle stage of the MSRR facility; (4) the programmatic mission of the MSRR facility; (5) the particular characteristics

of the MSRR facility; (6) the relative importance of radiological and non-radiological hazards; and (7) the quality levels defined in the NEXT Lab implementing procedures. The QAP implementation strategy shall support the graded approach by considering the tangible and intangible attributes of replacement costs, schedule delays and MSRR facility availability for research.

The development and implementation of the MSRR facility QAP for NEXT Lab began during the design phase and will continue through construction activities of the MSRR. The QAP focuses on the development of appropriate controls that ensure the MSRR is properly designed and fabricated to meet regulatory and university requirements. The majority of these controls provide documentation attesting to NEXT Lab quality to support the application for a construction permit. These design and construction program requirements are defined in Section 2 of this QAPD.

NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non- Power Reactors," Section 12.9, "Quality Assurance," recommends the applicant for licensure 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." As stated above, ACU's QAP follows Revision 1 of RG 2.5. RG 2.5 states that the 1995 version of ANS-15.8 reaffirmed in 2005 provides an acceptable method of complying with the program requirements of 10 CFR 50.34. ANS-15.8 was reaffirmed again in 2013. The NEXT Lab QAP is consistent with this guidance and meets or exceeds the requirements of ANSI/ANS 15.8-1995 (R2005; R2013).

Guidance contained in RG 2.5 does not limit research reactor licensees from including useful guidance in the regulatory information developed for power reactor licensees. As such, the NEXT Lab Quality Procedures (QPs) include additional layers of optional guidance in a manner consistent with ANS-15.8 and the relative importance of the item or activity. Any optional guidance will be reviewed during the development of QPs to confirm it meets the guidance of ANS-15.8 and the QAP.

The definitions provided in ANS-15.8-1995, Section 1.3, "Definitions," apply to terms as used in this document.

2. Design, Construction, and Modifications

This Section provides requirements for establishing, managing, conducting, and assessing the program of controls over the design, construction, and modification of the NEXT Lab MSRR. This QAPD recognizes that the described controls are integral to the management of a MSRR project or facility and do not cause the establishment of a separate program. The QAP is established administratively by this QAPD and implemented by a series of implementing QPs, that are applicable to the specific sections of the QAPD and the scope of work activities.

2.1 Organization

It is recognized that for most research reactor facilities, the owner/operator organization is small, with its personnel performing multiple functions. During the design, construction, or modification of a research reactor, most of the work may be performed by outside organizations or support contractors. The owner/operator's role is then primarily one of providing requirements and verifying compliance with those requirements. The following sections shall define and document the organizational structure and assignment of responsibilities of the NEXT Lab organization 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 persons not directly performing the work. NEXT Lab staff responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed, will 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.

The MSRR NEXT Lab quality organization is shown below (Figure 1-1).

1. President of ACU

The President of ACU is responsible for overall corporate policy of NEXT Lab and provides executive direction and guidance for the NEXT Lab activities as well as for the promulgation of ACU corporate policy through the Director of NEXT Lab. Staff responsibility for developing, implementing, and verifying execution of the NEXT Lab QAP is delegated to the Director of NEXT Lab.

2. Nuclear Research and Development Organization

- **ACU Vice President of Research**

This position reports to the President of ACU and is responsible for promulgating the university's vision and policies to promote and facilitate scholarship and research, strengthen external funding and strategic partnerships, and enhance the research infrastructure.

- **Director of NEXT Lab**

This position reports to the President of ACU and coordination of the NEXT Lab university research activities are managed with the ACU Vice President of Research. This organizational relationship is reflected in the NEXT Lab Organization Chart as an interdependent relationship. The Director of NEXT Lab has overall responsibility for the implementation of the NEXT Lab QAPD and for NEXT Lab activities including responsibility for overall MSRR nuclear safety. This responsibility includes setting and implementing policies, objectives, and priorities to ensure activities are performed in accordance with the NEXT Lab QAP. Responsibility for implementing the NEXT Lab QAP is delegated to the Director of NEXT Lab from the President of ACU.

3. Technical and Engineering Services Organization

The Technical and Engineering Services organization is responsible for support of NEXT Lab activities and the MSRR nuclear development by providing engineering, licensing, project, and document control support where applicable.

- **Nuclear Projects Lead**

The Nuclear Projects Lead reports to the President of ACU and the ACU Vice President of Research through the Director of NEXT Lab and is responsible for the administration and overall safe and efficient licensing, engineering, construction, and pre-operational testing of the MSRR Nuclear Project, and for the implementation of QA requirements in the areas specified by the QAP. This position is the interface between the MSRR project and the Director of NEXT Lab.

- **Project Manager**

The Project Manager reports to the Nuclear Projects Lead, is responsible for managing the overall licensing, engineering, construction, and pre-operational testing of the MSRR Nuclear Project, and for the implementation of QA requirements in the areas specified by the QAP.

- **Engineering Manager**

The Engineering Manager reports to the Nuclear Projects Lead and is responsible for the day-to-day oversight of the engineering effort as the MSRR is designed, constructed, and tested. This position is also responsible for the implementation of QA requirements in the areas specified by the QAP.

- **Procurement Manager**

The Procurement Manager reports to the Nuclear Projects Lead and is responsible to interface with engineering and design support staff on all activities related to quality item procurement. This position is responsible for the day-to-day oversight of purchased items and services, including procurement document control, and coordinating with QA and engineering staff for the selection and approval of vendors supporting NEXT Lab.

4. ACU University Services Organizations

The ACU Services organizations are responsible for supporting the NEXT Lab organization through performing activities related to procurement, safety and health and information technology where applicable.

5. Quality Assurance Organization

The NEXT Lab QA Organization is responsible for independently planning and performing activities to verify the development and effective implementation of the NEXT Lab QAP including but not limited to the development and verification of implementation of the QAP, oversight of engineering, licensing, document control, corrective action program and procurement activities that support MSRR activities and projects.

- **Quality Assurance Manager**

The NEXT Lab QA Manager reports to the President of ACU and the Director of NEXT Lab and is responsible for the development and verification of implementation of the QAPD described in this document. Authority for developing and verifying execution of the QAP is delegated to the NEXT Lab QA Manager by the NEXT Lab Director. The QA Manager is responsible for verifying compliance with regulatory requirements and QPs through audits and technical reviews; for monitoring organization processes to ensure conformance to commitments and licensing document requirements; and for verifying that vendors who provide services, parts, or materials to the MSRR project are meeting the requirements of the QAP. The QA Manager has sufficient independence from other NEXT Lab priorities to bring forward issues affecting safety and quality and make judgments regarding quality in all areas necessary regarding NEXT Lab's nuclear development activities.

- **Quality Assurance Authority**

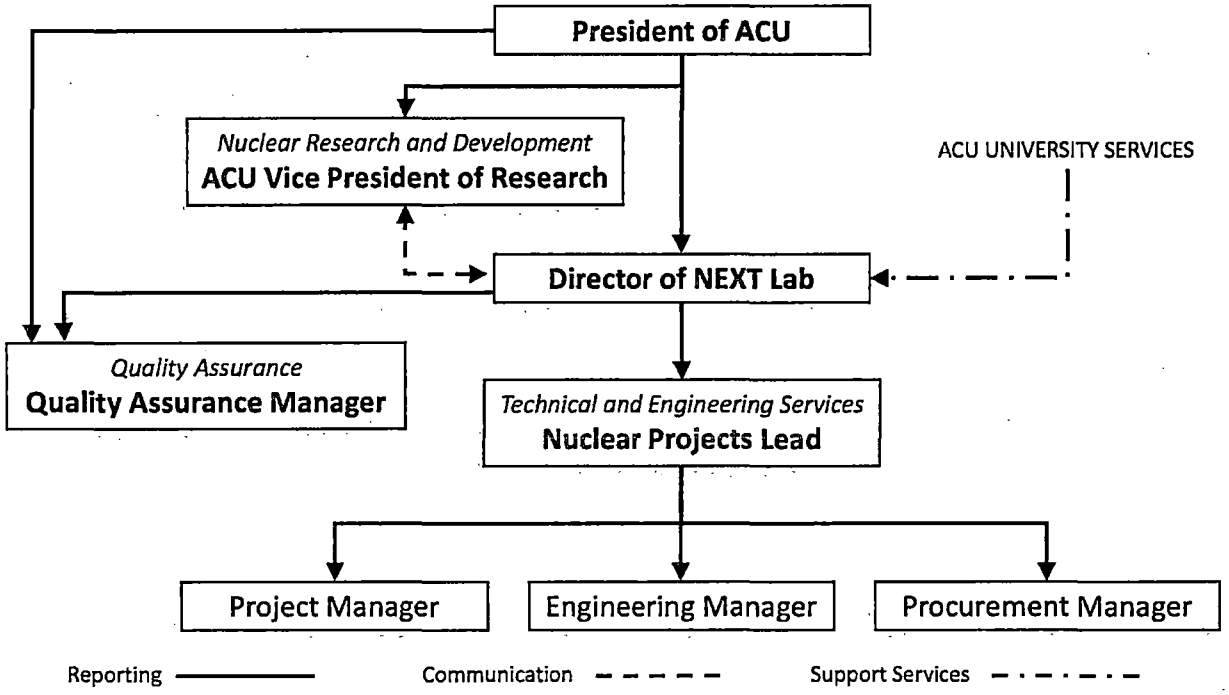
- **Stop Work**

All NEXT Lab personnel including QA and inspection personnel shall have the authority and the responsibility to stop work in progress which is not being done in accordance with approved NEXT Lab QPs or where safety-related SSC quality may be jeopardized. This extends to off-site work performed by suppliers that furnish materials and services to NEXT Lab.

- **Quality Assurance Organizational Independence**

For construction, independence shall be maintained between the organization or organizations performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

Figure 1-1 *ACU NEXT Lab Quality Organization for Design Licensing and Construction*



2.2 Quality Assurance Program

As documented in this QAPD, the NEXT Lab QAP shall be established in accordance with the requirements of this QAPD, or portions thereof, at the earliest time consistent with the schedule for accomplishing quality-affecting activities. This QAPD shall identify the items and activities to which it applies and the extent of program application for each item and activity. The program shall provide for the appropriate and necessary indoctrination and training of NEXT Lab staff who perform activities that affect quality, to ensure that suitable proficiency is achieved and maintained.

2.3 Design Control

NEXT Lab Design Engineering shall prescribe, develop, document, and preserve the design of the SSCs of the MSRR facility subject to the aspects of the QAP.

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 among the NEXT Lab participating organizations. 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 final design shall: (a) be relatable to the design input by documentation in sufficient detail to permit design traceability and verification; and (b) 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 assure 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: (a) the performance of design reviews, (b) the use of alternate calculations, (c) the performance of qualification tests, or (d) comparison to similar proven systems. NEXT Lab Engineering shall identify and document the design verification method or methods used. Design verification shall be performed by qualified NEXT Lab staff or groups other than those who performed the design, but who may be from the same organization. In all cases the design verification shall be completed prior to reliance upon the SSC or computer program to perform its function.

The need for or the use of a qualification test shall 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 shall be documented and evaluated by NEXT Lab Design Engineering to assure 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 are performed, shall be collected, stored, and kept for the life of the safety-related item.

2.3.5 Commercial Grade Items

The use of Commercial Grade Items (CGIs) in safety-related application shall be reviewed to assure that this equipment can adequately perform its intended function.

When a CGI, 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 CGI in a manner traceable to a documented definition of the difference.

2.3.6 Change Control

Modifications to MSRR facility SSCs or computer codes shall be based on 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. These measures shall include assurance that the design analyses for the SSCs or computer codes are still valid.

Where significant design changes are necessary because of an incorrect design, or MSRR facility change, the design process and verification procedure should be reviewed and modified as necessary.

2.4 Procurement Document Control

Procurement documents shall contain sufficient technical and quality requirements to ensure that all items or services satisfy the needs of the NEXT Lab procurement document or specification. The procurement documents at all procurement levels shall identify the documentation required to be submitted for information, review, or approval by the NEXT Lab QA Manager and Procurement Manager. At each level of a procurement, the procurement documents shall provide for access to the supplier's plant facilities and records, for inspection or audit by the NEXT Lab assigned Quality Assurance Lead Auditor, the designated representative, or other Lead Auditor qualified parties authorized and qualified by the NEXT Lab QA Manager. The procurement documents shall include NEXT Lab requirements for reporting and approving disposition of supplier nonconformances associated with the items or services being procured. The procurement documents for safety related items should prohibit the supply of substandard or counterfeit parts and materials.

2.5 Procedures, Instructions, and Drawings

Activities affecting quality shall be performed in accordance with NEXT Lab documented instructions, QPs, or drawings appropriate to the circumstances. These documents shall be developed, reviewed, and approved in accordance with this QAPD and include appropriate qualitative or qualitative acceptance criteria for determining that activities have been satisfactory accomplished.

2.6 Document Control

The preparation, issuance, and changes to documents which specify requirements that affect quality, or prescribe activities affecting quality, shall be controlled to assure that correct documents are used. The document control system shall be documented and provide for the following:

(a) identification of documents to be controlled and their specified distribution;

(b) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents; and

(c) 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 examinations of items and 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 the requirements of the procurement documents.

2.7.2 Work Control

The NEXT Lab QAP shall define and shall establish the necessary measures to control supplier's performance as appropriate.

2.7.3 Verification Activities

The suppliers shall be responsible for the quality of their products and shall verify and provide evidence of that quality. Supplier generated documents shall be controlled, handled, and approved in accordance with established methods described in this QAPD. Means shall be implemented to provide for the acquisition, processing, and record evaluation of technical, inspection, and test data against acceptance criteria. Based on the complexity of the product importance to safety, NEXT Lab staff shall consider independently verifying the quality of a supplier's product through source surveillances, inspections, audits, or review of the suppliers' nonconformances, dispositions, waivers, and corrective actions.

2.7.4 Item or Service Acceptance

NEXT Lab procurement QPs shall establish and implement measures to provide assurance that purchased items and services conform to NEXT Lab procurement specifications. The NEXT Lab methods used to accept items for safety-related service from a supplier shall be supplier Certificate of Conformance, source verification, receiving inspection, post-installation test, or a combination thereof.

NEXT Lab receiving inspections shall be performed in accordance with the established QPs, to verify by objective evidence such features as proper configuration, identification, marking, 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 specific identification of traceability requirements, NEXT Lab item identification and control process shall be capable of providing identification traceability control. The NEXT Lab QPs shall ensure that an item identification is maintained from the initial receipt or fabrication of the items up to and including installation and use. Where physical identification of items 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 the 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. It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes. 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 Inspection

Inspections to verify conformance of an item or activity to requirements shall be planned, documented, and performed. The NEXT Lab 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. In those cases, the final inspection requirements 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 performance of the item to specified requirements. Associated quality records shall be examined for adequacy and completeness. Only items that have passed 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 as described in this QAPD. Inspection shall be performed by persons other than those who perform the work being inspected, but they 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 NEXT Lab training and qualification process shall include identification of formal training needs and training activities shall be conducted as required to qualify NEXT Lab staff 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 qualifications shall be established and maintained by the NEXT Lab QA Manager.

2.11 Test Control

Formal testing shall be required to verify conformance of designated SSCs 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 NEXT Lab Design Engineering to assure test requirements have been satisfied. Computer programs used for operational controls 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 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 as implemented in the NEXT Lab QPs for conducting the activity.

2.14 Inspection, Test, and Operating Status

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

2.15 Control of Nonconforming Items

Items that do not conform to requirements shall be controlled to prevent inadvertent installation or use. Controls on nonconforming items shall provide for identification, documentation, evaluation, segregation from like conforming items when practical, and disposition of nonconforming items. Nonconforming conditions shall be evaluated in the Corrective Action Program (CAP) for further reporting to appropriate regulatory agencies. The evaluation of nonconformances shall include requirements to identify and resolve nonconforming characteristics and develop recommended dispositions for nonconforming items proposed and approved, in accordance with the evaluation requirements in the CAP as implemented in the NEXT Lab QPs.

The disposition (use as-is, reject, repair, or rework) of nonconforming items shall be identified and documented. Technical justification for the acceptability of a nonconforming item dispositioned "repair" or "use as-is" shall be documented. Nonconformance 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 reexamined in accordance with the evaluation requirements in the CAP as implemented in the NEXT Lab QPs.

2.16 Corrective Action

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. The NEXT Lab CAP corrective actions shall be in accordance with all design requirements unless those requirements were faulty and evaluated in the corrective action. 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 Assurance Records

A record system shall be established, through written requirements in the QPs, at the earliest practical time consistent with the schedule for accomplishing work activities. The NEXT Lab record system shall be defined, implemented and enforced in accordance with the NEXT Lab QPs. The records shall include as a minimum: inspection and test results, results of quality assurance reviews, quality assurance procedures, and engineering reviews and analysis in support of designs or changes and modifications.

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

(a) those which would be of value in demonstrating capability for safe operation;

(b) those which would be of value in maintaining, reworking, repairing, replacing, or modifying an item;

(c) those which would be of value in determining the cause or results of an accident or malfunction of a safety related item;

(d) those which provide required baseline data for in-service inspection; or

(e) those which would be of value in planning for facility decommissioning.

Other records shall be retained for a shorter period as defined in QPs for the record type and method of retention (i.e., electronic or hard copy). All NEXT Lab quality records shall be stored in location or locations that prevent damage from moisture, temperature, and pestilence. Additional provisions shall be included in the NEXT Lab implementing procedures for special process 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 suppliers shall be accessible to NEXT Lab staff.

2.18 Assessments/Audits

NEXT Lab staff, or its representative, or both, shall conduct periodic assessments of quality-affecting activities during design, construction, or modification to evaluate the effectiveness of the as-implemented QAP. Assessments shall be performed in accordance with the NEXT Lab QPs. Assessment results shall be documented, and should be reviewed by the NEXT Lab QA Manager. Conditions requiring prompt corrective action shall be entered into the NEXT Lab CAP and 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 NEXT Lab QA Manager and Design Engineering as appropriate.

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 NEXT Lab QAP and QPs shall include controls over the design, fabrication, installation, and modification of experimental equipment to the extent that these impact safety-related items.

Section 3. Facility Operations

The regulations in 10 CFR 50.34(b) require that the Final Safety Analysis Report (FSAR) include, among other things, the managerial and administrative controls to be used to assure safe operation, including a discussion of how the applicable quality requirements will be satisfied. How ACU intends to comply with this requirement will be described in the MSRR FSAR in the Operating License submittal.

Section 4. Applicability to Existing Facilities

Because the MSRR construction permit application will be an application for a new facility, there are no existing facilities that this QAPD applies to.

Section 5. Decommissioning

This QAPD contains reference to decommissioning activities where applicable (e.g., records retention). QA for decommissioning activities will be included as part of the decommissioning plan submission in accordance with 10 CFR 50.82(b)(4)(v).

Section 6. Reference Documents

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 Radiation Protection at Research Reactor Facilities, ANSI/ANS-15.11-2009.

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

6.5 10 CFR Part 20, "Standards for Protection Against Radiation," Code of Federal Regulations, Office of the Federal Register, as amended.

6.6 10 CFR Part 21, "Reporting of Defects and Noncompliance," Code of Federal Regulations, Office of the Federal Register, as amended.

6.7 10 CFR 50.34, "Contents of Applications; Technical Information," Code of Federal Regulations, Office of the Federal Register, as amended.

6.8 10 CFR 70.61, "Performance Requirements," Code of Federal Regulations, Office of the Federal Register, as amended.

6.9 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities," Code of Federal Regulations, Office of the Federal Register, as amended.

6.10 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.

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

6.12 Regulatory Guide 2.5 Rev.1, "Quality Assurance Requirements for Research and Test Reactors".