UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN

RESEARCH & TEST REACTOR

Quality Assurance Program Description for the University of Illinois Urbana-Champaign Research and Test Reactor

Topical Report

Issued by

The University of Illinois Urbana-Champaign

under

USNRC Project No. 99902094

Submitted: October 2022

Approved: May 23, 2023

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 23, 2023

Dr. Caleb S. Brooks
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University of Illinois at Urbana-Champaign
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104 South Wright Street
Urbana, IL 61801

SUBJECT: UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN – APPROVAL OF THE QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT (EPID NO.: L-2022-NFN-0004)

Dear Dr. Brooks:

By letter dated October 20, 2022 (Agencywide Documents Access and Management System (ADAMS) Package Accession No. ML22320A086), the University of Illinois at Urbana-Champaign (UIUC), submitted its topical report (TR) titled, "Quality Assurance Program Description for the University of Illinois at Urbana-Champaign Research and Test Reactor," for the U.S. Nuclear Regulatory Commission (NRC) staff's review. UIUC identified this version of the TR as Document Number IMRDD-MMR-22-03, Release 01. By letter dated February 20, 2023 (ADAMS Accession No. ML23053A092), UIUC responded to the NRC staff's request for additional information (RAI) pertaining to the review of UIUC's quality assurance program description (QAPD) TR. UIUC's response included proposed revisions to the QAPD TR.

The NRC staff's final safety evaluation (SE) for the UIUC's QAPD TR is enclosed. The NRC staff concluded that the QAPD is acceptable, subject to incorporation of changes communicated in the RAI response into the TR. The NRC staff requests that UIUC submit an accepted version of the QAPD TR within 3 months of receipt of this letter. The accepted version shall incorporate the proposed changes communicated in the RAI response. In addition, this version of the TR should incorporate this letter and the enclosed SE after the title page.

If you have any questions regarding this matter, please contact Adrian Muñiz at (301) 415-4093, or via email at Adrian.Muniz@nrc.gov.

Sincerely,

Signed by Wentzel, Michael
on 05/23/23

Michael J. Wentzel, Chief
Advanced Reactor Licensing Branch 2
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Project No.: 99902094

Enclosure:
As stated

cc: Distribution via University of Illinois HTGR GovDelivery
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SUBJECT: UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN – APPROVAL OF THE QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT (EPID NO.: L-2022-NFN-0004) DATED: MAY 23, 2023

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UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN – SAFETY EVALUATION OF TOPICAL REPORT, "QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN RESEARCH AND TEST REACTOR" (EPID L-2022-NFN-0004)

SPONSOR AND SUBMITTAL INFORMATION

Sponsor: University of Illinois at Urbana-Champaign

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Docket /Project No.: 99902094

Submittal Date: October 20, 2022

Submittal Agencywide Documents Access and Management System (ADAMS) Accession No.: ML22320A086

Supplement and request for additional information (RAI) response letter Date and ADAMS Accession No: February 20, 2023, (ML23053A092)

Brief Description of the Topical Report:

The University of Illinois at Urbana-Champaign's (UIUC's), Quality Assurance Program Description (QAPD), is the document that establishes the Quality Assurance Program (QAP) to be applied to the design, construction, and operation phase activities for the UIUC Research and Test Reactor (RTR). The NRC staff notes that in a letter dated December 9, 2022 (ML22343A282), UIUC submitted a topical report titled, "University of Illinois Urbana-Champaign High Temperature Gas-cooled Research Reactor: Applicability of Nuclear Regulatory Commission Regulations," stating that while its reactor is designed to operate at 15 MW(t), the maximum power will be set at that which is permitted under a research license. Therefore, while the topical report and this safety evaluation refers to the UIUC proposed reactor as an RTR, it is understood that UIUC plans to pursue licensing of its facility as a research reactor.

For additional details on the submittal, please refer to the documents located at the ADAMS Accession No(s). identified above.

REGULATORY EVALUATION

Regulatory Basis: Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34(a)(7), 10 CFR 50.34(b)(6)(ii), and 55.4.

The regulations in 10 CFR 50.34, “Contents of applications; technical information,” paragraph (a)(7), require that a preliminary safety analysis report (PSAR) include, “A description of the QAP to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.”

The regulations in 10 CFR 50.34, “Contents of applications; technical information, paragraph (b), “Final Safety Analysis Report,” subparagraph (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.

The regulation in 10 CFR 55.4, “Definitions,” defines operator as any individual licensed under 10 CFR 55 to manipulate a control of a facility.

The U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide (RG) 2.5, Revision 1, dated June 2010, “Quality Assurance Program Requirements for Research and Test Reactors” (Reference 3), states that the general recommendations for establishing and executing a QAP for the design, construction, testing, modification, and maintenance of research reactors in American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.8-1995, “Quality Assurance Program Requirements for Research Reactors” (Reference 4), provide an acceptable method for complying with the requirements of 10 CFR 50.34, “Contents of applications; technical information.” Therefore, the NRC staff used the recommendations in ANSI/ANS-15.8-1995 as the basis for evaluating the acceptability of the UIUC QAPD in conformance with the provisions of 10 CFR 50.34(a)(7) and 10 CFR 50.34(b)(6)(ii).

The NRC staff also used the guidance in Section 12.9, “Quality Assurance,” of NUREG-1537, Parts 1 and 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content” and “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria” respectively, dated February 1996 (References 5 and 6, respectively). Guidance in NUREG-1537, Part 1, Section 12.9, recommends that the applicant consider the guidance in RG 2.5 and ANSI/ANS 15.8 in developing QAPs for non-power reactors.

TECHNICAL EVALUATION

1.0 Introduction

QAPD Section 1.0, “Introduction,” provides a description of UIUC’s QAP for the site selection, design, construction, and operation of the UIUC Research and Test Reactor (RTR). This Section further states that the UIUC RTR is a non-power reactor as described in 10 CFR 50.21, “Class 104 licenses; for medical therapy and research and development facilities.” The QAPD is the top-level program document that establishes the quality assurance policy and assigns major functional responsibilities for all activities conducted by or for UIUC. The QAPD describes the methods and establishes quality assurance and administrative control requirements that meet 10 CFR 50.34 based on the criteria of ANSI/ANS-15.8-1995, “Quality Assurance Program Requirements for Research Reactors,” as endorsed in Regulatory Guide (RG) 2.5, “Quality Assurance Program Requirements for Research and Test Reactors”, Revision 1. As described

in QAPD Section 1.1, “Scope and Applicability”, the QAPD will be applied to design-phase, construction-phase, and operations-phase activities, including those in support of Construction Permit (CP) and Operating License (OL) applications affecting the quality and performance of safety-related structures, systems, and components (SSCs). Such activities will include, but are not limited to: designing, siting, procuring, fabricating, cleaning, handling, shipping, receiving, storing, constructing, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying.

Section 1.2 of the QAPD includes a set of definitions used throughout the document. In a RAI dated January 27, 2023 (ML23023A276), the NRC staff asked UIUC to describe the authorizations required to certify or license an operator for UIUC. In its response to this RAI, dated February 20, 2023 (ML23053A092), UIUC stated that the definitions of, “certified operator,” and “licensed operator,” listed in the UIUC QAPD, are consistent with the definitions stated in ANSI/ANS-15.8-1995, which UIUC says it implies that an operator – either licensed or certified – is authorized by license issued by the NRC under 10 CFR Part 55, “Operators’ Licenses,” to manipulate a control of a facility. UIUC clarified that the word “operator” in the UIUC QAPD means either an operator or a senior operator, as defined by 10 CFR 55.4. UIUC also stated that it will update QAPD Section 2.16, “Reactor Operations Staff,” to include the following sentence: “For the purposes of this document, an operator – either licensed or certified – is authorized by license issued by the NRC under 10 CFR Part 55, “Operators’ Licenses,” to manipulate a control of a facility.” The NRC staff finds this response acceptable since these definitions are consistent with ANSI/ANS 15.8-1995 and with the definition of “operator” in 10 CFR 55.4.

The NRC staff finds that the description provided in Section 1 of the UIUC QAPD meets the guidance provided in ANSI/ANS-15.8-1995, because it includes a description of the scope and application of the QAPD, and the definitions provided are consistent with those provided in ANSI/ANS 15.8 Section 1.3, “Definitions.” Therefore, the NRC staff finds that the description in QAPD Section 1, is acceptable.

2 Design, Construction and Modifications

2.1 Organization

QAPD Section 2.1 describes the UIUC organizational structure, functional responsibilities, levels of authority, and reporting relationships for establishing, executing, and verifying implementation of activities within the scope of the QAPD. The UIUC QAPD recognizes that for an RTR, the owner/operator organization is small and personnel may perform multiple functions. During the design, construction, or modification of the RTR, most of the work is anticipated to be performed by outside organizations or support contractors. UIUC’s role during these phases will be associated with the oversight of these outside organizations or support contractors.

The UIUC organizational structure and assignment of responsibilities are defined and documented such that quality is achieved and maintained by those who have been assigned the responsibility for performing work, and quality achievement is verified by persons not directly performing the work. The UIUC 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 the independence to identify problems; will initiate, recommend, or provide corrective actions; and will ensure corrective action implementation.

QAPD Section 2.1.1 states that the Head of the Department of Nuclear, Plasma, and Radiological Engineering (NPRE) is responsible for all aspects of design, construction and operations and has the overall responsibility of the QAP.

QAPD Section 2.1.2 states that the Reactor Advisory Committee, which reports to the Head of Department of NPRE, is responsible for the independent oversight of certain activities, including in some cases quality assurance, to ensure the safe operation of the facility.

QAPD Section 2.1.3 states that the Reactor Director, which reports to the Head of the Department of NPRE, is responsible for the execution of the QAP. In addition, the Reactor Director is responsible for the effective implementation of site-related construction and operation activities. The Reactor Director is also responsible for ensuring an effective transition from the design phase to construction and operations phases including ensuring that functions supporting quality-related activities retain their applicable responsibilities until the effective transition is complete.

QAPD Section 2.1.4 states that the Engineering Support and Operations Manager, which reports to the Reactor Director, is responsible for engineering activities, is the design authority for the facility, and is also responsible for maintaining the safety analysis. The Engineering Support and Operations Manager is also responsible for the implementation of the quality-related activities within the procurement process and is responsible for the oversight of support contractors and suppliers. During operations, the Engineering Support and Operations Manager's function is responsible plant operating activities, including operations, maintenance, and startup/preop testing.

QAPD Section 2.1.5 states that during the operations phase, the Reactor Health Physics Manager is responsible for Radiation Protection and the "as low as is reasonably achievable" programs, monitoring worker doses, and calibration of health physics instrumentation.

QAPD Section 2.1.6 states that During Operations, the Reactor Operations staff reports to the Engineering Support and Operations Manager and is responsible for the day-to-day operation of the facility, including license operations.

Section 2.1.7 states that the Quality Assurance (QA) Manager, which reports to the Reactor Director, is responsible for the establishment and implementation of the QAPD. Specific areas of responsibility include, but are not limited to, developing and maintaining the QAPD, evaluating conformance to the QAP requirements through assessments and technical reviews, independent oversight of the implementation of quality activities, ensuring that the suppliers which are providing quality services, parts, and materials for the RTR are conforming to the applicable QA requirements through UIUC supplier audits, and managing QA organization resources.

The QA Manager has sufficient independence from other UIUC priorities to bring forward issues affecting safety and quality and to make judgments regarding quality in all areas regarding the RTR design activities as appropriate. The QA Manager function maintains an indirect reporting relationship with the Head of the Department of NPRE to facilitate the escalation of topics requiring executive level disposition.

In an RAI dated January 27, 2023 (ML23023A276), the NRC staff asked UIUC to provide additional information on the roles and responsibilities of the engineering and QA organizations as it pertains to adequate supplier oversight responsibilities as described in ANSI/ANS-15.8,

Section 2.7, “Control of Purchased Items and Services.” In its response to this RAI, dated February 20, 2023 (ML23053A092), UIUC provided additional clarification on the roles and responsibilities of the organizations which are responsible for the oversight of the suppliers. Specifically, UIUC stated that the QA Manager has the overall responsibility for the control of purchased items and services, with the assistance of the Engineering Support and Operations Manager, to ensure that they are properly controlled. These individuals will also work closely with the UIUC Procurement Office to ensure that the rules and regulations regarding procurement are followed. The NRC staff finds this response acceptable since it more clearly describes the roles and responsibilities of those involved with supplier oversight activities and provides staff with information necessary to evaluate Section 2.1.

The NRC staff determined that UIUC’s organizational controls described in QAPD Section 2.1 are consistent with the guidance provided in Section 2.1 of ANSI/ANS-15.8-1995 because QAPD Section 2.1 provides an organizational structure and definitions of roles and responsibilities that help ensure the achievement and maintenance of quality by those assigned to perform work. Therefore, the NRC staff finds the description in QAPD Section 2.1 acceptable.

2.2 Quality Assurance Program

QAPD Section 2.2 states that the objective of the QAP is to assure that the RTR facility is designed, constructed, and operated in accordance with governing regulations and license requirements. UIUC will establish the necessary measures and governing procedures to implement the QAP as described in the QAPD at a time that is consistent with the schedule for accomplishing quality-affecting activities. The QAP applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design, fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations. A list or system that identifies SSCs and activities to which this program applies is maintained at the appropriate facility.

QAPD Section 2.2 states that the QAP provides for a graded approach to quality and that 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. The QAPD further states that this approach to achieving levels of quality is described in the QAPD and related implementing documents. In an RAI dated January 27, 2023 (ML23023A276), the NRC staff asked UIUC to clarify the statement above since no further details on this graded approach to quality were provided in the QAPD. The NRC staff also asked UIUC to describe the plans to assign quality levels to the SSCs and activities. In its response to the NRC staff’s RAI, dated February 20, 2023 (ML23053A092), UIUC stated that it will revise the QAPD to describe in greater detail UIUC’s graded approach to quality and how quality levels to the SSCs and activities are assigned. Specifically, UIUC stated that QAPD Section 2.2 will be revised to state that the “QAP will apply a graded approach to those items and activities that could affect the quality of safety-related 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. 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 graded approach to quality can be found in Enclosure 1 of the QAPD and related implementing documents and procedures.” In Enclosure 1, UIUC further described the quality levels in its graded approach to quality. These levels are Quality Level 1 (QL-1), QL-2 and QL-3. QL-1 will be applied to safety-related SSC and safety-related activities, QL-2 will be applied to selected SSCs and activities intended to support or protect the safety function of safety-related equipment, and QL-3 will be

applied non-safety--related SSCs and activities and does not support or protect the safety function of safety-related SSCs or activities. The NRC staff finds the response acceptable because the proposed additions to the QAPD adequately describe UIUC's graded approach to quality and provided information necessary for staff to evaluate Section 2.2.

QAPD Section 2.2 further states that personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. The QAPD states that UIUC establishes and maintains formal 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. Records of personnel training and qualification will be maintained.

The NRC staff determined that the programmatic controls described in QAPD Section 2.2 are consistent with the guidance provided in Section 2.2 of ANSI/ANS-15.8-1995 because QAPD Section 2.2 identifies the items and activities to which the QAP applies and the extent of its application. As recommended by the ANSI/ANS standard, QAPD Section 2.2 requires that the QAP be established at the earliest time consistent with the UIUC schedule for accomplishing quality-affecting activities. In addition, QAPD Section 2.2 states that the QAP provides for the training necessary for the UIUC staff to perform quality-affecting activities. Therefore, the NRC staff finds the description in QAPD Section 2.2 acceptable.

2.3 Design Control

The UIUC QAPD states that a process will be established and implemented to control design, design changes, and temporary modifications of items that are subject to the provisions of the QAP. The design process includes provisions for the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Specifically, the UIUC QAPD states the following as it pertains to design controls:

1. Design Requirements

   The UIUC QAPD states that applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards are to be identified and documented.

2. Design Process

   The UIUC QAPD states that design interfaces shall be identified and controlled and that design efforts shall be coordinated among the UIUC participating organizations. The applicability of standardized or previously proven designs with respect to meeting pertinent design inputs shall be verified for each application. Deviations from the established design inputs shall be documented and controlled.

   The QAPD also states that the final design will be relatable to the design input by documentation, in sufficient detail, to permit design traceability and verification and will identify assemblies and/or components that are part of the item being designed. Computer design programs used to develop portions of the facility design or to analyze the design will be fully documented, validated, and controlled. When a design program must be developed, the program will be controlled to ensure that it is fully documented and validated. Where changes to previously validated computer programs are made, documented revalidation shall be required for the change. Verification of design-unique computer programs shall include appropriate benchmark testing.

3. Design Verification

   The UIUC QAPD describes how the UIUC independent design reviews shall be performed to verify the adequacy of the design. The design verification will be performed by competent persons other than those who designed the item. The design verification will be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations. The qualification testing will be defined in formal test plans and will include appropriate acceptance criteria. Testing will demonstrate the adequacy of performance that simulates the most adverse design conditions. The test results will be documented and verified to have met the test requirements.

4. Design Documents and Records

   The QAPD states that design documents and records, which provide evidence that the design and design verification processes are performed, shall be collected, stored, and maintained for the life of the safety-related item.

5. Commercial Grade Items

   The UIUC QAPD states that the use of commercial grade items (CGIs) in safety-related applications shall be reviewed to ensure 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 or part shall be represented as different from the CGI in a manner traceable to a documented definition of the difference.

6. Change Control

   The UIUC QAPD states that modifications to safety-related SSCs, or computer codes shall be based on a defined "as-exists" design. The design changes will be documented, justified, and subject to control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for SSCs or computer codes are still valid. The QAPD requires that, when a significant design change is necessary because of an incorrect design, the design organization will review and modify the design process and verification procedure, as necessary.

The NRC staff finds that UIUC's design controls described above are consistent with the guidance provided in Section 2.3 of ANSI/ANS-15.8-1995 for design requirements, processes, verification, documents and records, verification of commercial grade items, and change control necessary to maintain design control. Therefore, the NRC staff finds the description in QAPD Section 2.3 acceptable.

2.4 Procurement Document Control

The UIUC QAPD describes a process required to ensure that procurement documents contain sufficient technical and quality requirements to ensure that the items and services satisfy the needs of UIUC. The UIUC QAPD stipulates that procurement documents at all procurement levels identify the documentation required to be submitted for information, review, or approval by UIUC. The procurement documents will provide access to the supplier's facilities and

records, for inspection or audit by UIUC, a designated representative, or other parties authorized by UIUC. Procurement documents will require the supplier to report 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.

The NRC staff determined that the UIUC procurement document controls in QAPD Section 2.4 are consistent with the guidance provided in Section 2.4 of ANSI/ANS-15.8-1995 because the controls described in QAPD Section 2.4 reflect the actions recommended to maintain sufficient technical and quality requirements throughout the procurement process, ensuring that the items and services satisfy the UIUC's needs as prescribed in its procurement processes or specifications. Therefore, the NRC staff finds the description in QAPD Section 2.4 acceptable.

2.5 Procedures, Instructions and Drawings

The UIUC QAPD describes the measures to ensure that quality activities are based on documented instructions, procedures, or drawings, as appropriate. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that the activities have been satisfactorily accomplished.

The NRC staff determined that the UIUC controls for instructions, procedures, and drawings in QAPD Section 2.5 are consistent with the guidance provided in Section 2.5 of ANSI/ANS-15.8-1995 because QAPD Section 2.5 contains the measures recommended to ensure that the activities affecting quality are based on the appropriate documented instructions, quality procedures, or drawings, and are, therefore, acceptable.

2.6 Document Control

The UIUC QAPD describes the required process to control the preparation, issuance and changes to documents which specify the requirements that affect quality or prescribe activities affecting quality. The document control system shall be documented and provide for identification, assignment of responsibilities, review and approval, and distribution of documents. Major changes to the controlled documents shall be reviewed and approved by the same organizations that performed the review of the original issue.

The NRC staff determined that the UIUC's document controls in QAPD Section 2.6 are consistent with the guidance provided in Section 2.6 of ANSI/ANS-15.8-1995 because they include processes to identify documents to be controlled and how they will be distributed; identify assignment of responsibilities for preparing, reviewing, approving and issuing documents; and require the review of documents for adequacy, completeness and correctness prior to issuance and approval. Therefore, the NRC staff finds the description in QAPD Section 2.6 acceptable.

2.7 Control of Purchased Items and Services

The UIUC QAPD describes the UIUC control measures required to ensure that purchased items and services conform to procurement documents. These measures include controls 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. Specifically, the UIUC QAPD states the following as it pertains to control of purchased items and services:

1. Supplier Selection

   The UIUC QAPD requires that the selection of suppliers be based on the evaluation of their capabilities to provide items or services that are consistent with the requirements of the procurement documents.

2. Work Control

   The UIUC QAPD requires that measures be established to control the supplier's performance to ensure that purchased items and services meet the UIUC quality requirements. Controls may include the review of test plans and suppliers' submitted documents, source surveillance or inspection, and other technical and administrative interfaces with the supplier, consistent with the procurement documents.

3. Verification Activities

   The UIUC QAPD states that the suppliers shall be responsible for the quality of their product and shall verify and provide evidence of that quality. Methods shall be established to control, handle, and approve supplier-generated documents. Means shall be implemented to provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against the acceptance criteria. Based on the complexity of the product and the importance to safety, UIUC will independently verify the quality of the supplier's product using source surveillances, inspections, audits, or the review of the supplier's non-conformances, dispositions, waivers, and corrective actions.

4. Item or Services Acceptance

   The UIUC QAPD requires that a system be established to ensure that the purchased items and services conform to procurement specifications. UIUC shall use one or more of the following methods to accept an item or service: supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test. Receiving inspections shall be performed in accordance with established procedures and instructions, to verify by objective evidence such features as proper configuration, identification and cleanliness, shipping damage, and to determine any shipping damage, fraud, or counterfeit.

The NRC staff determined that the UIUC controls for purchased items and services as described above, are consistent with the guidance provided in Section 2.7 of ANSI/ANS-15.8-1995 because QAPD Section 2.7 includes the information recommended to ensure that suppliers are selected based on the evaluation of their capabilities to provide the required items or services. Also, as recommended, QAPD Section 2.7 has measures to control the supplier's performance; establishes the responsibility of the supplier for the quality of their products and requires documented evidence of that quality is in accordance with established methods; and establishes a system to ensure that the purchased items and services conform to the procurement specifications. Therefore, the NRC staff finds the description in QAPD Section 2.7 acceptable.

2.8 Identification and Control of Items

The UIUC QAPD establishes measures for item identification and traceability controls. Items, including materials, will be identified by the appropriate means and the item identification shall be maintained from the initial receipt or fabrication of the items up to and including the installation and use. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be used. Identification markings shall be applied using materials and methods which provide clear and legible identification and do not detrimentally affect the function or service life of the item. Items having a limited calendar or operating life shall be identified and controlled to preclude its use.

The NRC staff determined that the UIUC's controls for identification and control of items in QAPD Section 2.8 are consistent with the guidance provided in Section 2.8 of ANSI/ANS-15.8-1995 because QAPD Section 2.8 provides the recommended measures for item identification and traceability control. Specifically, the QAPD provides for means to employ physical separation, procedural control, or other appropriate means, when physical identification of items is either impractical or insufficient. The QAPD also provides means to identify and control items that have limited calendar or operating life. Therefore, the NRC staff finds the description in QAPD Section 2.8 acceptable.

2.9 Control of Special Processes

The UIUC QAPD states that special processes include any in which the results are highly dependent on the control of the process or the skill of the personnel. Special processes also include activities in which the specified quality cannot be readily determined by inspection or non-destructive testing of the product. Special processes at UIUC will be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. The requirements of applicable codes and standards, including acceptance criteria for each process, shall be specified or referenced in the procedures or instructions that control the process. Records for qualified personnel, processes, and equipment associated with special processes will be maintained, as appropriate.

The NRC staff determined that the UIUC controls for special processes in QAPD Section 2.9 are consistent with the guidance provided in Section 2.9 of ANSI/ANS-15.8-1995 because QAPD Section 2.9 includes the recommended means to control these processes by instructions, drawings, checklists, travelers, or other appropriate means. QAPD Section 2.9 also states that responsibility for the special process will be assigned to the organization performing the special process, states that the procedures or instructions for the special process will include the requirements of applicable codes and standards and acceptance criteria, and specifies appropriate record maintenance. Therefore, the NRC staff finds the description in QAPD Section 2.9 acceptable.

2.10 Inspections

The UIUC QAPD describes the required inspection process implemented to verify the quality and conformance of the item or activity to specified requirements. The inspection process shall be planned, documented, and performed. The inspection process shall apply to procurement, construction, modification, and maintenance. Inspections shall be performed by persons other than those who performed the work being inspected but may be from the same organization. Completed items will 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. Measuring and Test Equipment (M&TE),

used to perform inspections will be identified in inspection documentation, for traceability of inspection results. Only items that have passed the required inspections and tests will be used, installed, or operated. Inspection results will be documented. The acceptance of items will be documented and approved by authorized personnel.

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 qualifications shall be established and maintained by their employer.

ANSI-ANS 15.8-1995, Section 2.10, "Inspection," states, in part, that, "The inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication." The NRC staff notes that the UIUC QAPD Section 2.10, does not address experiment fabrication activities as an area covered by the inspection program. In an RAI dated January 27, 2023 (ML23023A276), the NRC staff asked UIUC to clarify whether the QAPD will cover experiment fabrication activities or address why not. In its response to this RAI, dated February 20, 2023 (ML23053A092), UIUC stated that the QAPD will cover experiment fabrication activities and that it will revise QAPD Section 2.10, to specifically state that experiment fabrication activities will be covered by the QAPD.

The NRC staff determined that UIUC's controls for inspection in QAPD Section 2.10 are consistent with the guidance provided in Section 2.10 of ANSI/ANS-15.8-1995 because QAPD Section 2.10 describes the recommended requirements to plan, document and perform inspections required to verify conformance of quality affecting items or activities, including items in-process or under construction, to specified requirements. QAPD Section 2.10 also requires the recommended examination of the associated quality records for adequacy and completeness, requires that M&TE used to perform inspections be identified in the inspection documentation, and describes the qualification and training requirements, including on-the-job training, for the personnel performing the inspection activities. Therefore, the NRC staff finds the description in QAPD Section 2.10 acceptable.

2.11 Test Control

The UIUC QAPD describes the formal testing program to verify the conformance of designated SSCs to specified requirements and to 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. The test results shall be documented and evaluated by a responsible authority to ensure that the test requirements have been satisfied. Computer programs to be used for operational control shall be tested and be consistent with an approved verification and validation plan and will demonstrate required performance over the range of operation of the controlled function or process.

The NRC staff determined that the UIUC controls for testing in QAPD Section 2.11 are consistent with the guidance provided in Section 2.11 of ANSI/ANS-15.8-1995 because QAPD Section 2.11 describes the recommended formal testing requirements to verify conformance of designated SSCs to specified requirements and to demonstrate satisfactory performance for service, or to collect data to support the design or fabrication. QAPD Section 2.11 also requires the documentation and evaluation of test results by a responsible authority, and that verification and validation of computer programs be performed. Therefore, the NRC staff finds the description in QAPD Section 2.11 acceptable.

2.12 Control of Measuring and Test Equipment

The UIUC QAPD describes the measures to be implemented to ensure that tools, gauges, instruments, and other M&TE used for activities affecting quality are controlled, 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 of calibration traceable to an individual piece of M&TE will be maintained. Calibration and control measures are required when normal commercial equipment provides adequate accuracy.

The NRC staff determined that the UIUC's controls for M&TE in QAPD Section 2.12 are consistent with the guidance provided in Section 2.12 of ANSI/ANS-15.8-1995 because QAPD Section 2.12 includes recommended requirements for control, calibration, and adjustment that need to be performed for tools, gauges, instruments and other M&TE equipment used for activities affecting quality, as well as the measures that will be taken for out-of-calibration devices, and the requirements to maintain records of the calibration data for each M&TE. Therefore, the NRC staff finds QAPD Section 2.12 acceptable.

2.13 Handling, Storage, and Shipping

The UIUC QAPD requires that handling, storage, and shipping of items be performed consistent with work and inspection instructions, drawings, specifications, shipping instructions, or other pertinent documents for conducting the activity.

The NRC staff determined that UIUC QAPD Section 2.13 is consistent with the guidance provided in Section 2.13 of ANSI/ANS-15.8-1995 because QAPD Section 2.13 includes the controls for handling, storage, and shipping recommended in the ANSI/ANS standard, and is therefore, acceptable.

2.14 Inspection, Test, and Operating Status

The UIUC QAPD requires that the status of inspection and test activities 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.

The NRC staff determined that the UIUC's controls for inspection, test, and operating status in QAPD Section 2.14 are consistent with the guidance provided in ANSI/ANS-15.8-1995 because QAPD Section 2.14 includes actions that allow the traceability of the status of inspection and test activities of items and avoid the installation or operation of items that have not passed the required inspections and tests. Therefore, the NRC staff finds QAPD Section 2.14 acceptable.

2.15 Control of Non-Conforming Items and Services

The UIUC QAPD describes the required measures to control non-conforming items in order to prevent its inadvertent use or installation. These measures shall provide for identification, documentation, evaluation, segregation (as appropriate), and disposition of non-conforming

items. Recommended dispositions, such as, “use-as-is,” “reject,” “repair,” or “rework,” will be identified, documented, and approved.

Non-conformances to design requirements of items dispositioned as, “repair,” or “use-as-is,” will be subject to design control measures commensurate with those applied to the original design. The as-built records shall reflect the accepted deviation. Non-conforming items dispositioned as, “repair,” or “rework,” will be re-examined consistent with applicable procedures and appropriate acceptance criteria.

The NRC staff determined that the UIUC controls for non-conforming items and services in QAPD Section 2.15 are consistent with the guidance provided in Section 2.15 of ANSI/ANS-15.8-1995 because QAPD Section 2.15 includes the measures recommended to prevent inadvertent installation or the use of non-conforming items, and to allow identification, documentation, evaluation, and segregation of these items. In addition, as recommended, Section 2.15 includes requirements for documenting the technical justification for the acceptability of non-conforming items and includes the requirements for the re-examination of repaired or reworked items, consistent with the implemented corrective action program. Therefore, the NRC staff finds QAPD Section 2.15 acceptable.

2.16 Corrective Actions

The UIUC QAPD requires that conditions adverse to quality be identified promptly and corrected as soon as practical. The corrective actions shall be consistent with the design requirements unless those requirements were faulty. In the case of a significant condition adverse to quality, the cause of the condition will be investigated and corrective action to prevent recurrence will be taken.

The NRC staff determined that the UIUC’s controls for corrective actions in QAPD Section 2.16 are consistent with the guidance provided in Section 2.16 of ANSI/ANS-15.8-1995 because QAPD Section 2.16 requires the prompt identification and correction of conditions adverse to quality in accordance with UIUC’s corrective action plan and requires that investigation and corrective actions be performed for conditions that are significantly adverse to quality to preclude recurrence. Therefore, the NRC staff finds QAPD Section 2.16 acceptable.

2.17 Quality Records

The UIUC QAPD describes the record system required to ensure that the records that are applicable to quality are maintained and appropriately stored. 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 will be maintained by or for the plant owner for the life of the item while it is installed in the plant or stored for future use. Such records will be classified consistent with the applicable documented classification criteria. Other records will be retained for a shorter period, as determined by UIUC.

Records shall be stored in a location that provides damage prevention from moisture, temperature, and pestilence. Provisions shall be made for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage. The UIUC QAPD requires that records maintained by a supplier be accessible to UIUC.

The NRC staff determined that UIUC's controls for quality records in QAPD Section 2.17 are consistent with the guidance provided in Section 2.17 of ANSI/ANS-15.8-1995 because QAPD Section 2.17 includes requirements to store records that are applicable to quality, for specified periods and under appropriate conditions. Therefore, the NRC staff finds QAPD Section 2.17 acceptable.

2.18 Assessments

The UIUC QAPD describes the necessary measures for conducting periodic assessments of quality-affecting activities during design, construction, modification, and operations, to evaluate the effectiveness of the quality assurance program implementation. Assessments shall be performed consistent with written procedures or checklists. Assessment results shall be documented and reviewed by the management personnel responsible for the area assessed. Management of the assessed organization shall investigate adverse findings, schedule corrective actions (including measures to prevent recurrence) and notify the appropriate assessing organization in writing of any action(s) taken or planned. The adequacy of the responses will be evaluated by the assessing organization. Assessment records will include plans, reports, written replies, and records of completion of corrective actions.

The UIUC QAPD requires that personnel conducting assessments have the requisite training and experience 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.

As stated above, the UIUC will conduct periodic assessments of quality-affecting activities during the design, construction, modification, and operation. QAPD Section 2.7 states, in part, that, "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." In a request for confirmation of information, dated January 27, 2023 (ML23023A276), the NRC staff asked UIUC to confirm that the terms, "assessment," and "audit," can be used interchangeably within the UIUC QAPD. In its response to the request for confirmation of information, dated February 20, 2023 (ML23053A092), UIUC confirmed that the terms, "assessment," and "audit," are identical and are used interchangeably in the UIUC QAPD.

The NRC staff determined that UIUC's controls for assessments in QAPD Section 2.18 are consistent with the guidance provided in Section 2.18 of ANSI/ANS-15.8-1995 because QAPD Section 2.18 requires the UIUC staff, representatives, or both to conduct and document periodic assessments of quality-affecting activities during design, construction, modification and operations to evaluate the effectiveness of the as-implemented QAP; requires the review of such documents by the management personnel; and requires the prompt implementation of corrective actions. QAPD Section 2.18, also requires the UIUC management to investigate adverse findings, schedule corrective actions, and notify the appropriate assessing organization of any actions taken or planned. QAPD Section 2.18, further requires the maintenance of assessment records, and requires that the personnel selected for assessment assignments

have the requisite experience and training. Therefore, the NRC staff finds QAPD Section 2.18 acceptable.

2.19 Experimental Equipment

The UIUC QAPD states that the QAP will provide controls over the design, fabrication, installation, and modification of experimental equipment to the extent that these impact safety-related items.

The NRC staff determined that the UIUC controls for experimental equipment in QAPD Section 2.19 are consistent with the guidance provided in ANSI/ANS-15.8-1995 because QAPD Section 2.19 requires controls of experimental equipment to the extent that it impacts safety-related items. Therefore, the NRC staff finds QAPD Section 2.19 acceptable.

3. Facility Operations

The UIUC QAPD describes the elements of a QAP for conduct of operations at the UIUC RTR. The UIUC QAPD establishes that some requirements of the QAP for operations may be found in other documents, such as the Training Program, Emergency Plan, Security Plan, Technical Specifications, and the Radiation Protection Program, and would not be duplicated in the QAP. The NRC staff noted that there is no specific requirement to place these programs, plans or technical specifications in the QAP. UIUC has established its facility operations QAP based on ANSI/ANSI-15.8-1995. Specifically, the UIUC QAPD states the following as it pertains to facility operations:

1. Organization

   The UIUC QAPD requires UIUC to provide sufficient resources in personnel and materials to safely conduct operations at the RTR. The organization structure shall be defined as required by Technical Specifications.

2. Quality Assurance Program

   The UIUC QAPD requires UIUC to establish a QAP for the RTR by implementing a policy for the conduct of operations. This policy should assign personnel to implement and identify the goals for operating the RTR. Personnel assignments and progress toward achieving the goals should be documented.

3. Performance Monitoring

   The UIUC QAPD states that UIUC shall monitor facility performance relative to the goals used as performance indicators for the RTR. UIUC shall also document periodic observations of operations and identify any deficiencies and, these deficiencies should be assessed to ensure the execution of corrective actions that 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.

4. Operator Experience

   The UIUC QAPD states that the UIUC shall document the methods for maintaining operator experience for the RTR. Operators should be responsible for maintaining experience in operating the RTR. A method should be provided to make operators aware of important current information that is related to facility operations and individual job assignments. The QAPD references ANSI/ANS-15.4-2016, “Selection and Training of Personnel for Research Reactors,” which addresses operator training.

5. Operating Conditions

   The UIUC QAPD states that pre-operations checklists shall be used to determine or verify required pre-operational conditions and readiness to operate. UIUC shall periodically monitor the operating equipment to detect abnormal conditions or adverse trends. Operating conditions should be documented in an operations logbook or other record.

6. Operational Authority

   The UIUC QAPD states that UIUC shall establish the method for conducting operations and the responsibility for each shift for the RTR. 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 that are important to the facility status.

7. Control Area

   The UIUC QAPD states that 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 RTR shall operate the 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 the quick placement of the RTR in a safe configuration if an evacuation of the control area or site is necessary.

8. Ancillary Duties

   The UIUC QAPD states that 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 the facility parameters and maintain control of the RTR.

9. Emergency Communications

   The UIUC QAPD states that 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.

10. Configuration Control

The UIUC QAPD states that UIUC is responsible for identifying, establishing, and maintaining the proper configuration for the RTR and should authorize any changes to safety-related items. Configuration changes to safety-related items should be documented. UIUC shall ensure that, 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 shall be documented. This should also address methods for temporary modifications. Reactor maintenance that requires a change in the system shall be documented.

11. Lockouts and Tagouts

The UIUC QAPD states that locks and tags shall be placed on equipment when, for safety or other special administrative reasons, controls must be established. A facility lockout/tagout procedure shall be implemented if there is potential for equipment damage or personnel injury during the equipment operation, maintenance, inspection, or modification activities, or from inadvertent activation of equipment.

12. Test and Inspection

The UIUC QAPD establishes the requirements for tests to 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 can perform its intended function. The results of the test should be documented and retained in the facility records as appropriate.

13. Operating Procedures

The UIUC QAPD states that the 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.

14. Operator and Postings

The UIUC QAPD states that 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 posting. Postings should be checked periodically for continued applicability.

15. Equipment Labeling

The UIUC QAPD establishes the requirements for labeling equipment. The QAPD states that equipment shall be labeled to help facility personnel positively identify equipment

that they operate and maintain. Information on the labels should be consistent with the information found in the facility procedures, valve lineup sheets, piping and instrument diagrams, or other documents. Labels should be permanent, securely attached, readable, and have appropriate information.

The NRC staff finds that the UIUC's QAP controls for the conduct of operations described above, are consistent with Section 3.0 of ANSI/ANS-15.8-1995. Therefore, the NRC staff finds that the UIUC's QAP controls to develop and conduct quality assurance activities provide reasonable assurance that the UIUC QAP for the conduct of facility operations will comply with applicable requirements.

4. Applicability to Existing Facilities

UIUC QAPD Section 4 states that the UIUC RTR facility will be a newly constructed facility and this section does not apply. The NRC staff finds that this section of the QAPD does not apply to the UIUC RTR facility.

5. Decommissioning

UIUC QAPD Section 5 indicates that this section of the QAPD will be updated later and that a QAPD for decommissioning activities will be included as part of a decommissioning plan submission in accordance with 10 CFR 50.82(b)(4)(v).

Because the submission of a decommissioning plan and associated QA provisions are not required until a licensee applies for a license termination after the permanent cessation of operations, the NRC staff finds that a detailed evaluation of QA for decommissioning is not required at this time. The NRC staff will review QA for decommissioning upon receipt of a proposed decommissioning plan in accordance with 10 CFR 50.82(b)(4)(v).

LIMITATIONS AND CONDITIONS

The NRC staff did not identify any areas in the QAPD that would require the use of limitations or conditions on the application of the QAPD for the design, fabrication, construction, and operation of UIUC's RTR facility or for referencing the QAPD in a future UIUC license application.

CONCLUSION

Based on its evaluation of the UIUC QAPD topical report, the NRC staff finds, subject to the implementation of changes communicated in the RAI responses described above, that the QAPD is consistent with the guidance contained within Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS-15.8-1995, which the NRC endorsed in RG 2.5, Revision 1. Therefore, the NRC staff concludes that the UIUC QAPD, subject to the incorporation of the changes communicated in the RAI responses described above, into the topical report, complies with the applicable requirements of 10 CFR 50.34(a)(7) and 10 CFR 50.34(b)(6)(ii), and is approved for use by the UIUC for the QAP implemented for the design, fabrication, construction, and operation of the UIUC RTR facility.

REFERENCES

1. Letter from the UIUC to the NRC, “Submittal of the University of Illinois at Urbana-Champaign Quality Assurance Program Description,” dated October 20, 2022 (ML22320A086).
2. Letter from the NRC to UIUC, “Request for Additional Information Regarding Quality Assurance Description,” dated January 27, 2023 (ML23023A276).

3. Letter from the UIUC to the NRC, “Response to the UIUC Quality Assurance Program Description Request for Additional Information,” dated February 20, 2023 (ML23053A092).

3. Regulatory Guide 2.5, “Quality Assurance Requirements for Research and Test Reactors,” Revision 1, dated June 2010 (ML093520099).

4. ANSI/ANS-15.8-1995, “American National Standard for Quality Assurance Program Requirements for Research Reactors,” dated May 10, 2013.

5. NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” dated February 1996 (ML042430055).

6. NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” dated February 1996 (ML042430048).

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 27, 2023

Dr. Caleb S. Brooks, Associate Professor
University of Illinois at
Urbana-Champaign
Department of Nuclear, Plasma,
and Radiological Engineering
Talbot Laboratory,
Room 111C, MC-234
104 South Wright St.
Urbana, IL 61801

SUBJECT: UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN - REQUEST FOR ADDITIONAL INFORMATION REGARDING QUALITY ASSURANCE PROGRAM DESCRIPTION (EPID NO. L-2022-NFN-0004)

Dear Dr. Brooks:

By letter dated October 20, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22320A086), the University of Illinois at Urbana-Champaign (UIUC) submitted; pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 50.34(a)(7) and 50.34(b)(6)(ii); its Quality Assurance Program Description (QAPD) for its proposed non-power reactor to the U.S. Nuclear Regulatory Commission (NRC) staff for its review and approval.

The NRC staff identified additional information needed to continue its review of the QAPD, as described in the enclosure to this letter. As discussed, provide a response to the request for additional information (RAI) within 30 days of the date of this letter. Following receipt of the complete response to the RAI, the NRC staff will continue its review of the QAPD.

The response to the RAI must be submitted in accordance with 10 CFR 50.4, “Written communications,” and pursuant to 10 CFR 50.30(b), “Oath or affirmation,” and be executed in a signed original document under oath or affirmation. Information included in the response that you consider sensitive or proprietary, and seek to have withheld from public disclosure, must be marked in accordance with 10 CFR 2.390, “Public inspections, exemptions, requests for withholding.” Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, “Protection of Safeguards Information: Performance Requirements.”

If you have any questions regarding the NRC staff's review or if you intend to request additional time to respond, please contact me at (301) 415-4093 or via e-mail at Adrian.Muniz@nrc.gov.

Sincerely,

Adrian Muñiz Signed by Muniz Gonzalez, Adrian on 01/27/23

Adrian Muñiz, Senior Project Manager
Advanced Reactor Licensing Branch 2
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Project No. 99902094

Enclosure:
As stated

SUBJECT: UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN - REQUEST FOR ADDITIONAL INFORMATION REGARDING QUALITY ASSURANCE PROGRAM DESCRIPTION (EPID NO. L-2022-NFN-0004) DATED: JANUARY 27, 2023

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ADAMS Accession No. ML23023A276 **NRR-088**

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DATE	1/23/2023	1/25/2023	1/25/2023	1/26/2023	1/27/2023

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REQUEST FOR ADDITIONAL INFORMATION
QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE
UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN NON-POWER REACTOR
DOCKET NO. 99902094
EPID NO. L-2022-NFN-0004

Background:

By letter dated October 20, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22320A086), the University of Illinois-Champaign (UIUC) submitted its Quality Assurance Program Description (QAPD) topical report for its proposed non-power reactor for approval. UIUC submitted the topical report pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 50.34(a)(7) and 50.34(b)(6)(ii). The NRC staff has reviewed the topical report and has identified that additional information is needed to complete its review as discussed in the requests for additional information (RAIs) and request for confirmation of information (RCI) below.

RAI and RCI Regulatory Basis:

The regulation in 10 CFR 50.34(a)(7), requires that a preliminary safety analysis report include "[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." In addition, the regulation in 10 CFR 50.34(b)(6)(ii) requires a final safety analysis report to include managerial and administrative controls to be used to assure safe operation of the facility. Guidance in NRC Regulatory Guide (RG) 2.5, "Quality Assurance Program Requirements for Research and Test Reactors," Revision 1, dated June 2010 (ADAMS Accession No. ML093520099), which states that the general requirements for establishing and executing a quality assurance program for the design, construction, testing, modification, and maintenance of research and test reactors in American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.8-1995, "Quality Assurance Program Requirements for Research," provide an acceptable method for complying with the program requirements of 10 CFR 50.34, "Contents of Applications; Technical Information." UIUC states in the topical report that the QAPD describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50.34, based on the criteria of ANSI/ANS-15.8 as endorsed by RG 2.5, Revision 1. Therefore, the NRC staff used ANSI/ANS-15.8-1995 (Reaffirmed 2013) as the basis for evaluating the acceptability of the UIUC QAPD in conformance with the provisions of 10 CFR 50.34(a)(7) and 50.34(b)(6)(ii).

RAIs and RCI:

RAI-1: Section 2.2, "Quality Assurance Programs" of the QAPD states, in part, that "This QAP provides for 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 the QAPD and related implementing documents". However, the QAPD topical report does not seem to discuss this graded approach to quality. Therefore, the NRC staff is requesting that UIUC provide additional information on this approach and how it plans to assign quality levels to the SSCs and activities.

RAI-2: Section 2.1.4, “Engineering Support and Operations Manager” of the QAPD states, in part, that the Engineering support and operations manager is responsible for providing oversight of outside organizations or support contractors and suppliers. Section 2.1.7, “Quality Assurance Manager” of the QAPD states, in part, that the QA manager is responsible for ensuring that the suppliers provide quality services, parts and materials that conform with applicable QA requirements.

Provide additional information on the roles and responsibilities of the engineering and QA organizations as it pertains to adequate supplier oversight responsibilities as described in ANSI/ANS-15.8 Section 2.7, “Control of Purchased Items and Services.”

RAI-3: Section 55.4 to 10 CFR, provides a definition of “operator.” QAPD Section 1.2, “Definitions” include the following definitions:

a. Certified operator - An individual authorized by the chartering or licensing organization to carry out the duties and responsibilities associated with the position requiring the certification.

b. Licensed operator – see certified operator

Describe the authorizations required to certify or license an operator for UIUC.

RAI-4: ANSI-ANS 15.8, Section 2.10, “Inspection” states, in part, that “The inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication. The NRC staff notes that the UIUC QAPD does not address experiment fabrication activities.

Please clarify whether the QAPD will cover experiment fabrication activities or address why not.

RCI-1: Section 2.7 of ANSI/ANS-15.8, “Control of Purchased Items and Services,” as reflected in QAPD 2.7 states, in part, that “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.”

QAPD Section 2.18, “Assessments,” consistent with Section 2.18 of ANSI/ANS-15.8, states, in part, that “UIUC conducts 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.

Please confirm that the terms “assessment” and “audit” can be used interchangeably within the UIUC QAPD.

UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN

The Grainger College of Engineering
Department of Nuclear, Plasma, & Radiological Engineering
Suite 100 Talbot Laboratory, MC-234
104 S. Wright St.
Urbana, IL 61801

February 20, 2023

Docket No.: 99902094

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

Subject: Written communication as specified by 10 CFR 50.4 regarding the responses to the "University of Illinois at Urbana-Champaign – Request for Additional Information Regarding Quality Assurance Program Description (EPID No. L-2022-NFN-0004)," dated January 27, 2023

By letter dated October 20, 2022 (ML22320A086), the University of Illinois at Urbana-Champaign (UIUC) submitted its Quality Assurance Program Description (QAPD) for its proposed non-power reactor to the U.S. Nuclear Regulatory Commission (NRC) staff for its review and approval.

By letter dated January 27, 2023, the NRC staff requested additional information and clarification regarding the QAPD in the form of four (4) requests for additional information (RAIs) and one (1) request for confirmation of information (RCI). Those questions, and UIUC's responses to those questions, are enclosed as Attachments 1 and 2.

The responses to the RAIs and RCI do not contain any commercially sensitive information and can be posted for unrestricted access by the public. Questions or other requests related to these responses should be directed to Caleb Brooks at csbrooks@illinois.edu or (217) 265-0519.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 20, 2023.

Sincerely,

Caleb S. Brooks, Ph.D.
Associate Professor
University of Illinois at Urbana-Champaign
Department of Nuclear, Plasma, and Radiological Engineering
Talbot Laboratory, Room 111C, MC-234
104 South Wright St, Urbana, IL 61801
TEL 217-265-0519 | FAX 217-333-2906
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Attachments:
1. Responses to the "University of Illinois at Urbana-Champaign – Request for Additional Information Regarding Quality Assurance Program Description (EPID No. L-2022-NFN-0004)," dated January 27, 2023
2. University of Illinois at Urbana-Champaign Quality Assurance Program Description, Enclosure 1 – Graded Approach to Quality

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ATTACHMENT 1

RAI-1*: Section 2.2, "Quality Assurance Programs" of the QAPD states, in part, that "This QAP provides for 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 the QAPD and related implementing documents". However, the QAPD topical report does not seem to discuss this graded approach to quality. Therefore, the NRC staff is requesting that UIUC provide additional information on this approach and how it plans to assign quality levels to the SSCs and activities.*

The UIUC QAPD will be revised accordingly to describe in greater detail UIUC's graded approach to quality and how quality levels to the SSCs and activities are assigned.

The third paragraph under Section 2.2., "Quality Assurance Program," will be revised to read:

"This QAP will apply a graded approach to those items and activities that could affect the quality of safety-related 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. 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 graded approach to quality can be found in Enclosure 1 of the QAPD and related implementing documents and procedures."

Enclosure 1 (Attachment 2 to these responses) will be added to the UIUC QAPD, which describes the Quality Level matrix in detail – the level of analysis, documentation, and actions necessary to comply with a requirement commensurate with the safety significance.

RAI-2*: Section 2.1.4, "Engineering Support and Operations Manager" of the QAPD states, in part, that the Engineering support and operations manager is responsible for providing oversight of outside organizations or support contractors and suppliers. Section 2.1.7, "Quality Assurance Manager" of the QAPD states, in part, that the QA manager is responsible for ensuring that the suppliers provide quality services, parts and materials that conform with applicable QA requirements.*

Provide additional information on the roles and responsibilities of the engineering and QA organizations as it pertains to adequate supplier oversight responsibilities as described in ANSI/ANS-15.8 Section 2.7, "Control of Purchased Items and Services."

As discussed in Section 2.1.7. of the UIUC QAPD, the Quality Assurance (QA) Manager is responsible for the establishment and implementation of the UIUC QAPD, which includes responsibility for planning and performing activities to verify development and effective implementation. Effective implementation includes, but is not limited to, developing, and maintaining the QAPD, evaluating conformance to QAP requirements through assessments and technical reviews, independent oversight of the implementation of quality activities, and ensuring that suppliers providing quality services, parts, and materials for the facility are conforming with the applicable QA requirements through UIUC supplier audits, and managing QA organization resources.

As discussed in Section 2.1.4. of the UIUC QAPD, the Engineering Support and Operations Manager has areas of responsibilities that include authority for day-to-day engineering support activities, design engineering, engineering configuration management, engineering administration, modifications and their implementation, facility design configuration control, document control/records management, facility engineering, system engineering, system testing, and technical support. This individual is the design authority for the facility and is responsible for maintaining the safety analysis. Additionally, the Engineering Support and Operations Manager is responsible for the implementation of the quality-related

activities within the procurement process to ensure that all suppliers meet UIUC requirements and 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 facility.

As such, the QA Manager has overall responsibility for the control of purchased items and services, with the assistance of the Engineering Support and Operations Manager, to ensure they are properly controlled as discussed below. These individuals will also work closely with the UIUC Procurement Office to ensure that all University rules and regulations regarding procurement are followed.

Supplier Selection – The QA Manager, Engineering Support and Operations Manager, and UIUC Procurement Office will work collectively regarding supplier selection based on evaluation of their capability to provide items or services in accordance with requirements of the procurement documents.

Work Control – The QA Manager shall establish measures to control the supplier's performance to ensure that purchased items and services meet UIUC 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. The QA Manager will seek technical input from the Engineering Support and Operations Manager, when required.

Verification Activities – The supplier shall be responsible for the quality of its product and shall verify and provide evidence of that quality. The QA Manager shall ensure that supplier-generated documents are 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. The QA Manager will seek technical input from the Engineering Support and Operations Manager, when required.

Based on complexity of the product and importance to safety, UIUC shall consider independently verifying the quality of a supplier's product through source surveillances, inspections, audits, or review of the supplier's non-conformances, dispositions, waivers, and corrective actions. These activities will be performed by both the QA and Engineering Support and Operations Managers.

Item or Service Acceptance – The Engineering Support and Operations Manager, with the assistance of the QA Manager, shall establish 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 inspections 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.

RAI-3*: Section 55.4 to 10 CFR, provides a definition of "operator." QAPD Section 1.2, "Definitions" include the following definitions:*

a. *Certified operator - An individual authorized by the chartering or licensing organization to carry out the duties and responsibilities associated with the position requiring the certification.*

b. *Licensed operator – see certified operator*

Describe the authorizations required to certify or license an operator for UIUC.

ATTACHMENT 1

The definitions of "certified operator" and "licensed operator" listed in the UIUC QAPD follow the definitions stated in American National Standard ANSI/ANS-15.8-1995 (2018), "Quality Assurance Program Requirements for Research Reactors," which is to imply an operator – either licensed or certified – is authorized by license issued by the U.S. Nuclear Regulatory Commission under 10 CFR 55, "Operators' Licenses," to manipulate a control of a facility. Anywhere the word "operator" appears in the UIUC QAPD means either an operator or a senior operator, as defined by 10 CFR 55.4.

The following sentence will be added to the end of Section 2.1.6., "Reactor Operations Staff," to ensure that the authorization required for an operator – either licensed or certified – is clearly defined:

"For the purposes of this document, an operator – either licensed or certified – is authorized by license issued by the NRC under 10 CFR 55, "Operators' Licenses," to manipulate a control of a facility."

RAI-4*: ANSI-ANS 15.8, Section 2.10, "Inspection" states, in part, that "The inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication. The NRC staff notes that the UIUC QAPD does not address experiment fabrication activities.*

Please clarify whether the QAPD will cover experiment fabrication activities or address why not.

Yes, the UIUC QAPD will cover experiment fabrication activities. This was inadvertently omitted from Section 2.10. "Inspections," of the QAPD. The second sentence of the first paragraph in Section 2.10. will be revised to read:

"The inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication."

RCI-1*: Section 2.7 of ANSI/ANS-15.8, "Control of Purchased Items and Services," as reflected in QAPD 2.7 states, in part, that "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."*

QAPD Section 2.18, "Assessments," consistent with Section 2.18 of ANSI/ANS-15.8, states, in part, that "UIUC conducts 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.*

Please confirm that the terms "assessment" and "audit" can be used interchangeably within the UIUC QAPD.

Yes, the terms "assessment" and "audit" are identical and are used interchangeably in the UIUC QAPD. Both "assessment" and "audit" are defined as: a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation.

ATTACHMENT 2

ENCLOSURE 1 – 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. This 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. The following describes each quality level of UIUC's graded approach to quality:

Quality Level 1 (QL-1) shall implement the full measure of this QAPD and shall be applied to safety-related SSCs and safety-related activities.

Quality Level 2 (QL-2) is applied to selected SSCs and activities intended to support or protect the safety function of safety-related equipment. QAP elements are applied to an extent that is commensurate with the item's importance to safety. Implementing documents establish program element applicability.

Quality Level 3 (QL-3) is applied to non-safety-related SSCs and activities and does not support or protect the safety function of safety-related SSCs or activities. However, the performance of QL-3 SSCs and activities may be important to ensuring requirements are met, or operational or mission-related goals are achieved. Controls, appropriate for the application, are applied to SSCs and activities using the UIUC QAP for efficiency to avoid the creation and use of a separate or redundant management system. The controls on these SSCs and activities do not impact QL-1 or QL-2 SSCs and activities or the regulatory basis of the facility.

Quality Assurance Program Description
for the
University of Illinois Urbana-Champaign
Research and Test Reactor

Topical Report

Prepared by

The University of Illinois Urbana-Champaign

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CONFIGURATION CONTROL SUMMARY

Document Revision History

Document No.	Rel.	Date	Prepared By	Revision Description
IMRDD-MMR-22-03	01	10/20/2022	University of Illinois	Initial issue for NRC review.
IMRDD-MMR-22-03	02	06/16/2023	University of Illinois	Added document control table. Incorporated changes based on RAIs from NRC (dated January 27, 2023) per Revision Summary below. NRC approval May 23, 2023.

Revision Summary for Release 02:	
RAI-1	Section 2.2 – The third paragraph was revised to read: "This QAP will apply a graded approach to those items and activities that could affect the quality of safety-related 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. 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 graded approach to quality can be found in Enclosure 1 of the QAPD and related implementing documents and procedures." Enclosure 1 was added, which describes the Quality Level matrix in detail – the level of analysis, documentation, and actions necessary to comply with a requirement commensurate with the safety significance.
RAI-2	No change required.
RAI-3	Section 2.1.6. – The following sentence was added to the end of the section: "For the purposes of this document, an operator – either licensed or certified – is authorized by license issued by the NRC under 10 CFR 55, "Operators' Licenses," to manipulate a control of a facility."
RAI-4	Section 2.10 – The second sentence of the first paragraph was revised to read: "The inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication."

EXECUTIVE SUMMARY

This topical report provides a description of the Quality Assurance Program (QAP) for the University of Illinois at Urbana-Champaign (University of Illinois, University or UIUC) Research and Test Reactor (RTR, also referred to as a "non-power" reactor) as described in 10 CFR 50.21, "Class 104 licenses; for medical therapy and research and development facilities." NRC NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," refers applicants to ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," (ANSI/ANS-15.8) for the preparation of applications for non-power reactors. This standard is endorsed by the NRC in NRC Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research and Test Reactors" (RG 2.5).

The UIUC Quality Assurance Program Description (QAPD) provides the methods and establishes quality assurance and administrative control requirements that meet 10 CFR 50.34 based on the criteria of ANSI/ANS-15.8-1995 as endorsed by RG 2.5, Revision 1.

The scope of this QAP includes design, construction, and operation phase activities for the UIUC non-power reactor. Consistent with common licensing practice, text is written in the present tense, active voice, including discussions of activities and processes associated with a phased implementation of design, construction, and operation.

UIUC requests NRC review and approval of this topical report to be used to satisfy quality assurance requirements for use in the non-power reactor application submitted in accordance with 10 CFR 50 (as applicable), i.e.,

- Construction Permit (CP) Application pursuant to 10 CFR 50.34(a)(7),
- Operating License (OL) Application pursuant to 10 CFR 50.34(b)(6)(ii).

Abbreviations

Term	Abbreviation
ANS	American Nuclear Society
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
CP	Construction Permit
FSAR	Final Safety Analysis Report
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
M&TE	Measurement & Test Equipment
NPRE	Nuclear, Plasma & Radiological Engineering
NRC	Nuclear Regulatory Commission
OL	Operating License
QA/QC	Quality Assurance/Quality Control
QAP	Quality Assurance Program
RG	Regulatory Guide
RTR	Research and Test Reactor
SAR	Safety Analysis Report
SSC	Structures, Systems, and Components
UIUC	University of Illinois Urbana-Champaign

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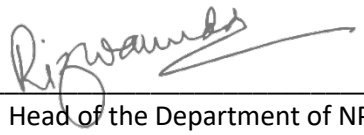
POLICY STATEMENT

University of Illinois at Urbana-Champaign (UIUC) shall design, procure, deliver, construct, and operate the UIUC Research and Test Reactor (RTR) in a manner that ensures the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations and applicable laws and regulations of the state and local governments.

The Quality Assurance Program (QAP) is described in this document. Together they provide for control of UIUC activities that affect the quality of safety-related structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs perform satisfactorily in service. This Quality Assurance Program Description (QAPD) may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The QAPD is the top-level program document that establishes the manner in which quality is to be achieved and presents UIUC's overall philosophy regarding achievement and assurance of quality for the RTR. Implementing documents will come later that assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. The Head of the Department of Nuclear, Plasma, and Radiological Engineering (NPRE) establishes overall expectations for effective implementation of the QAP and is responsible for obtaining the desired end result. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the QAP.



Head of the Department of NPRE

10/20/2022

Date

1. INTRODUCTION

This document provides the description of the University of Illinois at Urbana-Champaign (UIUC) Quality Assurance Program (QAP) for the site selection, design, construction, and operation of the UIUC Research and Test Reactor (RTR).

The Quality Assurance Program Description (QAPD) is the top-level program document that establishes the quality assurance policy and assigns major functional responsibilities for all quality-related activities conducted by or for UIUC.

The RTR is a non-power reactor as described in 10 CFR 50.21, “Class 104 licenses; for medical therapy and research and development facilities.” NRC NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," refers applicants to ANSI/ANS-15.8-1995, “Quality Assurance Program Requirements for Research Reactors,” (ANSI/ANS-15.8) when preparing an application for non-power reactors. This standard is endorsed by NRC Regulatory Guide 2.5, “Quality Assurance Program Requirements for Research and Test Reactors” (RG 2.5).

The QAPD describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50.34 based on the criteria of ANSI/ANS-15.8 as endorsed by RG 2.5, Revision 1.

The QAP comprises the NRC-approved regulatory document that describes the QA elements (i.e., the QAPD), along with the associated implementing documents. Procedures and instructions that prescribe quality-related activities are developed prior to commencement of those activities. Policies that establish high-level responsibilities and authority for carrying out important administrative functions are outside the scope of the QAPD.

1.1. SCOPE AND APPLICABILITY

The QAPD applies to design-phase, construction-phase, and operations-phase activities, including those in support of Construction Permit (CP) and Operating License (OL) applications affecting the quality and performance of safety-related structures, systems, and components (SSCs), including, but not limited to:

Designing	Shipping	Inspecting
Siting	Receiving	Testing
Procuring	Storing	Operating
Fabricating	Constructing	Maintaining
Cleaning	Erecting	Repairing
Handling	Installing	Modifying

Safety-related SSCs within the scope of the QAPD are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 establish QA requirements for activities within their scope.

1.2. DEFINITIONS

Term	Definition
Certified Operator	An individual authorized by the chartering or licensing organization to carry out the duties and responsibilities associated with the position requiring the certification.
Commissioning	The process during which constructed reactor structures, components, and systems are made operational and verified to meet design requirements.
Corrective Action	Measures taken to rectify conditions adverse to quality and, where necessary, to prevent repetition.
Document	Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.
Experiment	Any operation, hardware, or target (excluding devices such as detectors, foils, etc.), that is designed to investigate non-routine reactor characteristics or that is intended for irradiation within the pool, on or in a beamport or irradiation facility, and that is not rigidly secured to a core or shield structure so as to be a part of their design.
Licensed Operator	See certified operator.
Maintenance	Those activities necessary to maintain operability or restore systems to within specified design limits. Maintenance consists of repair, rework, replacement, adjustment, cleaning, or other actions necessary to maintain an item in or restore an item to acceptable condition.
Management	Management means those persons within the research reactor organization whose responsibility and authority includes the quality assurance program. The levels of management are as described in American National Standard for Development of Technical Specifications for Research Reactors, ANSI/ ANS-15.1-2013.
Modification	A change in the physical design or functional characteristic of a system, structure, or component.
Non-Power Reactor	A research or test reactor licensed under 10 CFR 50.21(c) or 10 CFR 50.22.
Procedure	A document that specifies or describes how an activity is to be performed
Quality	The degree to which an item or process meets or exceeds the user's requirements and expectations.

Term	Definition
Quality Assurance	Those planned and systematic actions necessary to provide adequate confidence that the structure, system, or component will perform satisfactorily in service.
Safety-Related Items	Those physical structures, systems, and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents.
Shall, Should, and May	The word "shall" is used to denote a requirement; the word "should" to denote a recommendation; and the word "may" to denote permission, neither a requirement nor a recommendation.

2. DESIGN, CONSTRUCTION, AND MODIFICATIONS

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

2.1. ORGANIZATION

This section describes the UIUC organizational structure supporting the RTR including functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation during design, construction, and operations phases. The organizational structure includes internal and external functions that perform quality-related functions.

The organizational structure and assignment of responsibilities is defined and documented such that: (a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and (b) quality achievement is verified by persons not directly performing the work. Persons responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed, have sufficient authority, access to work areas, and independence to: (a) identify problems; (b) initiate, recommend, or provide corrective action; and (c) ensure corrective action implementation.

It is recognized that for the RTR, the organization is small, and personnel may perform multiple functions. During the design, construction, or modification of the RTR, most of the work is anticipated to be performed by outside organizations or support contractors. It is anticipated that the primary activities to be performed directly by UIUC during this phase will be associated with the oversight of these outside organizations or support contractors.

The organizational structure comprises functions for the RTR 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 considers the timing, extent, and effects of organizational structure changes.

UIUC is responsible to size the Quality Assurance staff commensurate with the duties and responsibilities assigned.

Design, engineering, environmental, and construction services may be provided to UIUC for the RTR by contractors in accordance with their quality programs.

The following sections describe the reporting relationships and functional responsibilities implementing and supporting the RTR QA Program. The organization for UIUC is shown in Figure 2.1-1.

2.1.1. Head of the Department of Nuclear, Plasma, and Radiological Engineering

The Head of the Department of Nuclear, Plasma, and Radiological Engineering (NPRE) is responsible for all aspects of design, construction, and operations. The Head of the Department of NPRE is also responsible for all technical and administrative support activities performed by UIUC and contractors. The Head of the Department of NPRE directs Engineering, Supply Chain, and Quality Assurance in the fulfillment of their responsibilities

The Head of the Department of NPRE has overall responsibility for QAP and 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.

2.1.2. Reactor Advisory Committee

During Operations, the Reactor Advisory Committee reports to the Head of the Department of NPRE and maintains an indirect reporting relationship with the Reactor Director function to facilitate routine activities. The Reactor Advisory Committee is responsible for independent oversight of certain activities, including in some cases quality assurance, to ensure the safe operation of the facility.

2.1.3. Reactor Director

The Reactor Director function reports to the Head of the Department of NPRE and is responsible for the execution of the QAP. During construction and operations phases, the Reactor Director function is responsible for the effective implementation of site-related construction and operation activities. The Reactor Director function is responsible for ensuring effective transition from the design phase to construction and operations phases including ensuring that functions supporting quality-related activities retain their applicable responsibilities until effective transition is complete.

2.1.4. Engineering Support and Operations Manager

The Engineering Support and Operations Manager function reports to the Reactor Director function and has areas of responsibilities that include authority for day-to-day engineering support activities, design engineering, engineering configuration management, engineering administration, modifications and their implementation, facility design configuration control, document control/records management, facility engineering, system engineering, system testing, and technical support. The Engineering Support and Operations Manager function is the design authority for the facility and is also responsible for maintaining the safety analysis.

The Engineering Support and Operations Manager function is responsible for the implementation of the quality-related activities within the procurement process to ensure that all suppliers meet UIUC requirements. The Engineering Support and Operations Manager function 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 RTR.

During operations, the Engineering Support and Operations Manager function is responsible plant operating activities, including operations, maintenance, and startup/preop testing.

The Engineering Support and Operations Manager function is also responsible for establishing and managing the required training and support programs (e.g., Corrective Action Program) to support the organization during all phases.

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 Engineering Support and Operations Manager function provides oversight of these organizations.

2.1.5. Reactor Health Physics Manager

During Operations, the Reactor Health Physics Manager function reports to the Reactor Director function and is responsible for the implementation of the Radiation Protection Program and the "as low as is reasonably achievable" (ALARA) program, monitoring worker doses, and calibration of health physics instrumentation. The Reactor Health Physics Manager function maintains a line of communication with the Head of the Department of NPRE to facilitate the escalation of topics requiring executive level disposition. The Reactor Health Physics Manager function has the responsibility and ability to interdict or terminate licensed activities that it believes are unsafe. The Reactor Health Physics Manager function maintains a line of communication with the University Division of Research Safety that is independent of the QAP.

2.1.6. Reactor Operations Staff

During Operations, the Reactor Operations staff reports to the Engineering Support and Operations Manager function and is responsible for the day-to-day operation of the facility, including license operations. For the purposes of this document, an operator – either licensed or certified – is authorized by license issued by the NRC under 10 CFR 55, "Operators' Licenses," to manipulate a control of a facility.

2.1.7. Quality Assurance Manager

The Quality Assurance (QA) Manger function Reports to the Reactor Director and is responsible for the establishment and implementation of the QAPD.

The QA Manager function and is responsible for planning and performing activities to verify development and effective implementation. Effective implementation includes, but is not limited to, developing, and maintaining the QAPD, evaluating conformance to QAP requirements through assessments and technical reviews, independent oversight of the implementation of quality activities, and ensuring that suppliers providing quality services, parts, and materials for the RTR are conforming with the applicable QA requirements through UIUC supplier audits, and managing QA organization resources.

The QA Manager function has sufficient independence from other UIUC priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding the RTR design activities as appropriate. The QA Manager function maintains an indirect reporting relationship with the Head of the Department of NPRE to facilitate the escalation of topics requiring executive level disposition.

2.1.7.1. Authority to Stop Work

Quality Assurance and Quality Control 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 or SSC integrity may be jeopardized. This authority extends to off-site work performed by suppliers that furnish safety-related materials and services UIUC for the RTR.

2.1.7.2. Quality Assurance Organizational Independence

Independence shall be maintained between the organization(s) performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

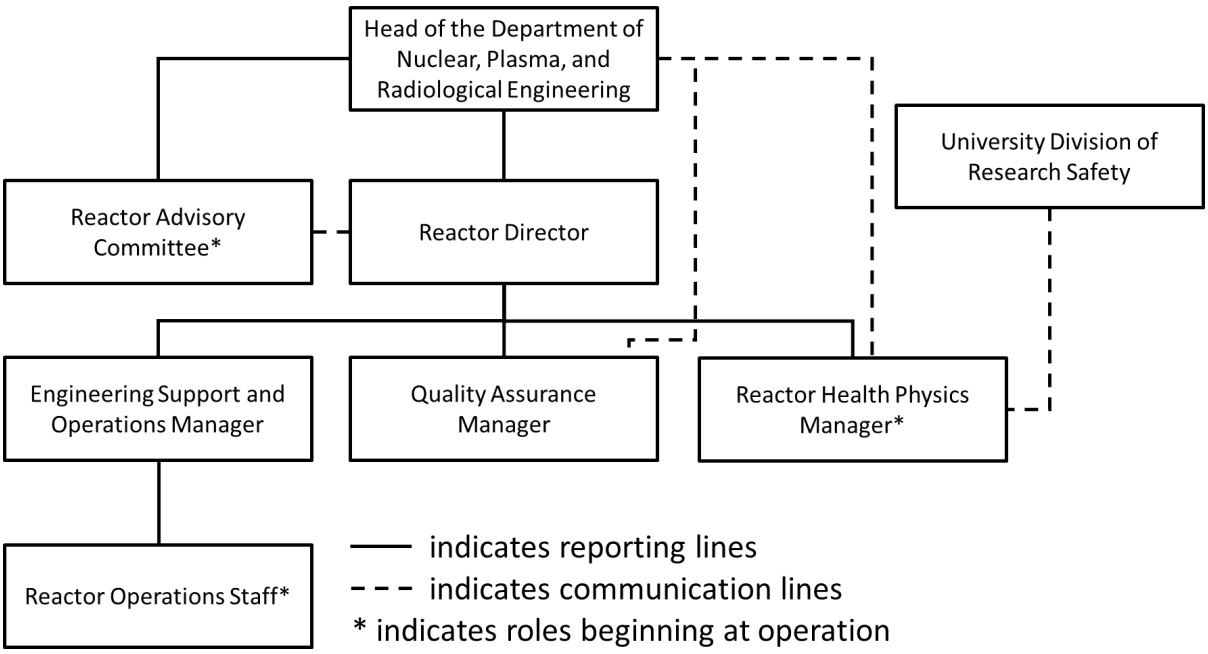


Figure 2.11 UIUC Organization for the UIUC RTR

2.2. QUALITY ASSURANCE PROGRAM

UIUC establishes the necessary measures and governing procedures to implement the QAP as described in the QAPD at a time consistent with the schedule for accomplishing quality-affecting activities. UIUC is committed to implementing this QAP in all aspects of work that are safety-related as described, and to the extent delineated, in the QAPD. This QAP shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, UIUC ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet applicable quality requirements. Senior management is regularly apprised of the adequacy of implementation of the QAP through the assessment functions described in Section 2.18.

The objective of the QAP is to assure that Reactor Facility is designed, constructed, and operated in accordance with governing regulations and license requirements. The program is based on the criteria of ANSI/ANS-15.8, as further described in this document. This QAP applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design, fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations. Examples of CP/OL program safety-related activities include, but are not limited to, engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis. A list or system that identifies SSCs and activities to which this program applies is maintained at the appropriate facility. Design documents are used as the basis for this list. This includes the managerial and administrative aspects of internal and external activities that affect quality.

This QAP will apply a graded approach to those items and activities that could affect the quality of safety-related 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. 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 graded approach to quality can be found in Enclosure 1 of the QAPD and related implementing documents and procedures.

In general, the program requirements specified herein are detailed in implementing procedures that are either UIUC implementing procedures, or supplier implementing procedures governed by a supplier QAP.

Delegated responsibilities may be performed under a supplier’s quality program, provided that it has been approved in accordance with the QAPD. Periodic assessments are conducted to assure compliance with the supplier's or principal contractor's quality program 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 UIUC qualified assessors or independent contractors, or consultants as determined by the QA Manager.

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. UIUC establishes and maintains formal 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 UIUC procedures. Indoctrination includes the administrative and technical objectives and requirements of the

applicable codes and standards and QAP requirements as necessary. Records of personnel training and qualification are maintained.

2.3. DESIGN CONTROL

UIUC establishes and implements a process to control the design, design changes, and temporary modifications of items that are subject to the provisions of the QAP. The design process includes provisions for the development, verification, approval, release, status, distribution, and revision of design inputs and outputs.

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

1. performance of design reviews,

2. use of alternate calculations,

3. performance of qualification tests, or

4. comparison of similar proven systems.

The responsible design organization shall identify and document the design verification method or methods used. Design verification is performed by competent individuals 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 component, system, structure, or computer program to perform its function in operations.

In the event that qualification testing is needed to verify design, the use of qualification tests is 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 are 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 item.

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. When a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

2.3.6. Change Control

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 should be reviewed and modified as necessary.

2.4. PROCUREMENT DOCUMENT CONTROL

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

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

2.5. PROCEDURES, INSTRUCTIONS, AND DRAWINGS

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

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

UIUC shall establish measures to control the supplier's performance to ensure that purchased items and services meet UIUC 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 its 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, UIUC shall consider independently verifying the quality of a supplier's product through source surveillances, inspections, audits, or review of the supplier's non-conformances, dispositions, waivers, and corrective actions.

2.7.4. Item or Service Acceptance

UIUC shall establish 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 inspections 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 using 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 those 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. These processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. UIUC and its suppliers are responsible to adhere to the approved procedures and processes when performing special processes. The requirements of applicable codes and standards, including acceptance criteria for each 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 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 need for formal training shall be determined and training activities conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall be included, with emphasis on firsthand experience gained through actual performance of inspections. Records of inspection personnel's qualification shall be established and maintained by their employer.

2.11. TEST CONTROL

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

Computer programs used for operational control shall be tested in accordance with an approved verification and validation plan and shall demonstrate required performance over the range of operation of the controlled function or process.

2.12. CONTROL OF MEASURING AND TEST EQUIPMENT

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

2.13. HANDLING, STORAGE, AND SHIPPING

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

2.14. INSPECTION, TEST, AND OPERATING STATUS

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

2.15. CONTROL OF NON-CONFORMING ITEMS AND SERVICES

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

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

2.16. CORRECTIVE ACTIONS

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

2.17. QUALITY RECORDS

A records system or systems shall be established at the earliest practical time consistent with the schedule for accomplishing work activities. The records system or systems shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. The records shall include as a minimum: inspection and test results, results of quality assurance reviews, quality assurance procedures, and engineering reviews and analyses in support of designs or changes and modifications.

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

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

Other records shall be retained for a shorter period as determined by UIUC. 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 UIUC.

2.18. ASSESSMENTS

UIUC conducts 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 QAP shall include 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 UIUC RTR. The requirements shall be applied to any equipment or operation as appropriate and consistent with its potential safety impact or program goals. Many of the program requirements are satisfied by existing documentation, or by procedures and activities required by other standards and requirements of the chartering or licensing agency. Some requirements of the 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-15.1-2013, and the Radiation Protection Program (see American National Standard for Radiation Protection at Research Reactor Facilities, ANSI/ANS-15.11-2016. Such requirements do not need to be duplicated in the quality assurance program.

3.1. ORGANIZATION

UIUC shall provide sufficient resources in personnel and materials to safely conduct operations at the RTR. Planning should anticipate needs as appropriate for associated tasks. The organization structure shall be defined as required by Technical Specifications.

3.2. QUALITY ASSURANCE PROGRAM

UIUC shall establish a quality assurance program for the RTR by implementing a policy for the conduct of operations. The policy should assign personnel to implement and identify the goals for operating the RTR. Personnel assignments and progress toward achieving goals should be documented.

3.3. PERFORMANCE MONITORING

UIUC shall monitor facility performance relative to the goals used as performance indicators for the RTR. UIUC shall document periodic observations of operations and identify any deficiencies. UIUC should assess deficiencies to ensure the execution of corrective actions that 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

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

3.5. OPERATING CONDITIONS

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

3.6. OPERATIONAL AUTHORITY

UIUC shall establish the method for conducting operations and the responsibility for each shift for the RTR. 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 RTR 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 RTR 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 RTR.

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. UIUC is responsible for establishing and maintaining proper configuration for the RTR and should authorize any changes to safety- related items. 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. Reactor 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

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 posting. 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 UIUC RTR will be a newly constructed facility and this section does not apply.

5. DECOMMISSIONING

This section of the QAPD will be updated at a later date. A QAPD for decommissioning activities will be included as part of the decommissioning plan submission in accordance with 10 CFR 50.82(b)(4)(v).

6. REFERENCES

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

ANSI/ANS-15.1-2013, “American National Standard for The Development of Technical Specifications for Research Reactors.”

ANSI/ANS-15.11-2016, “American National Standard for Radiation Protection at Research Reactor Facilities.”

ANSI/ANS-15.4-2016, “American National Standard for The Selection and Training of Personnel for Research Reactors.”

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

NUREG 1537, Part 2 “Guidelines for Preparing and Reviewing Applications for The Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria.”

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

ENCLOSURE 1 – 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. This 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. The following describes each quality level of UIUC's graded approach to quality:

Quality Level 1 (QL-1) shall implement the full measure of this QAPD and shall be applied to safety-related SSCs and safety-related activities.

Quality Level 2 (QL-2) is applied to selected SSCs and activities intended to support or protect the safety function of safety-related equipment. QAP elements are applied to an extent that is commensurate with the item's importance to safety. Implementing documents establish program element applicability.

Quality Level 3 (QL-3) is applied to non-safety-related SSCs and activities and does not support or protect the safety function of safety-related SSCs or activities. However, the performance of QL-3 SSCs and activities may be important to ensuring requirements are met, or operational or mission-related goals are achieved. Controls, appropriate for the application, are applied to SSCs and activities using the UIUC QAP for efficiency to avoid the creation and use of a separate or redundant management system. The controls on these SSCs and activities do not impact QL-1 or QL-2 SSCs and activities or the regulatory basis of the facility.