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

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)

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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).