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.