

REQUEST FOR ADDITIONAL INFORMATION
BY THE OFFICE OF NUCLEAR REACTOR REGULATION
BWXT BANR QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD)
BWXT TECHNOLOGIES, INC.
DOCKET NO. 99901469
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Question 1

The BANR QAPD addresses the activities associated with the technology development and design activities conducted by or for BWXT AT. However, since BWXT AT is not presently an applicant for a construction permit, operating license (OL), design certification, early site permit, combined license (COL), standard design approval, or manufacturing license activities as described in 10 CFR Part 50 and 10 CFR Part 52, the NRC staff will limit its review to the QA activities associated only with technology development and high-level design activities.

For example, the BANR QAPD did not establish quality requirements for nonsafety-related SSCs that are credited for regulated events, which the NRC staff reviews for OLs and COLs per the guidance in NUREG-0800, Section 17.5, Paragraph II.U.2. The NRC staff will not review the QAPD for this topic. Any BWXT AT activities outside of technology development and high level design activities will not be covered by NRC approval of the BANR QAPD without additional supplements or submittals.

Please confirm BWXT AT's desired scope of review and if it aligns with the NRC staff's proposed scope of review.

Response

BWXT AT's desired scope of review is limited to the QA activities associated only with technology development and high-level design activities. This aligns with the NRC staff's proposed scope of review.

Question 2

Section 7.2 of the BANR QAPD states, "BWXT AT will implement the NRC endorsed guidance from NEI 14-05A, Rev. 1-A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys in Procurement of Laboratory Calibration and Test Services" [ADAMS Accession No. ML21069A347] when procuring commercial grade calibration and testing services." In addition, Section 12 of the BANR QAPD states, "The suppliers of commercial-grade calibration services are controlled as described in Part II, Section 7,"

The NRC safety evaluation for NEI 14-05A, Revision 1, (ML20322A019) contains the following conditions in Section 3.4,

"2) The method the licensee and/or supplier of basic components needs to follow, and document in their QA program, consists of:

1. A documented review of the laboratory's accreditation is performed and includes a verification of the following:

- The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
- For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
- For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
- The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments."

Please confirm if these conditions are applicable to BWXT AT's proposed scope of review for the QAPD and/or applicable to the approach to supplier accreditation within the BANR QAPD. If they are applicable, discuss where these conditions will be listed to demonstrate how commercial-grade calibration services are controlled.

Response

Yes, the conditions of NRC safety evaluation for NEI 14-05A, Revision 1, are applicable to BWXT AT's proposed scope of review for the QAPD and applicable to the approach to supplier accreditation within the BANR QAPD.

These conditions are listed in the BWXT AT implementing procedures that control commercial-grade calibration services and the conditions will be added to the QAPD.

Question 3

Section 10.2 of the BANR QAPD states that "[inspection] qualification program requirements are described in [QAPD] Part II, Section 2," and Section 18.1 of the BANR QAPD references "a qualified lead auditor."

Part II, Section 2.6, of the BANR QAPD commits to implement the quality standards described in NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," Requirement 2, however, the BANR QAPD does not specifically address the qualification program requirements for Inspection and Test, Lead Auditor, Auditors, and Technical Specialists. NQA-1-2015, Requirement 2, Section 302 through 305, provides Qualification Requirements (Section 300) for Inspection and Test (Section 302), Lead Auditor (Section 303), Auditors (Section 304), and Technical Specialists (Section 305). Additionally, RG. 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, (ML17207A293) Regulatory Position C.1.a, contains a clarification regarding the qualifications of lead auditors.

Please provide additional information regarding the qualification program requirements for Inspection and Test, Lead Auditor, Auditors, and Technical Specialists.

Response

The following provides additional information regarding the qualification program requirements for Inspection and Test Personnel, Lead Auditor, Auditors, and Technical Specialists and will be added to Section 2 of the BANR QAPD:

2.6 Qualification of Inspection and Test Personnel

Personnel performing inspections or test activities shall be qualified in accordance with NQA-1-2015 Requirement 2, Section 302. Specific requirements for the qualification of inspection and test personnel are provided in implementing procedures.

2.7 Qualification of Quality Assurance Audit Personnel

Lead Auditors organize and direct audits, report audit findings, and evaluate corrective action. Lead Auditors shall be qualified in accordance with the requirements of NQA-1-2015, Requirement 2, Section 303. Orientation, training and qualification processes for Auditors and Technical Specialists are described in an implementing procedure and shall meet the requirements specified in NQA-1-2015 Requirement 2, Sections 304 and 305.

2.8 Records of Qualification

The qualification of inspection and test personnel, and Lead Auditors shall be certified in writing and shall include the information required by NQA-1-2015 Requirement 2, Section 400. These requirements are described in implementing procedures.

Question 4

The NRC staff observed a possible typographical error to the third bullet in Section 7.2, "NQA-1 Commitment / Exceptions" of the BANR QAPD. The NRC staff assumes that "2015" refers to NQA-1-2015.

Please confirm if this assumption is correct.

Response

Yes, "2015" refers to NQA-1-2015. The bullet should read "In establishing commercial grade item requirements, BWXT AT commits to compliance with NQA-1-2015, Section 700 and Subpart 2.14, with the following clarification:"

Question 5

Section 7.1 of the BANR QAPD states, "BWXT AT may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet

BWXT AT requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by the American Society of Mechanical Engineers (ASME), Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.”

The NRC staff understands that BWXT AT does not currently have access to supplier information from ASME (non-public), NUPIC (not a member), or other established utility groups. Please describe how BWXT AT intends to obtain input for the basis for supplier qualification, or edit Section 7.1 to remove reference to such industry programs.

BWXT Response

ASME and utility groups are not used as the basis for supplier qualification by BWXT AT at this time.

Section 7.1 of the BANR QAPD will be revised as follows:

BWXT AT may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet BWXT AT requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.