

Blue Energy - QAPD LTR - BE-QAPD-001, Revision 1, "Quality Assurance Program Description" Review

NRC Staff Information needs

Note: On March 28, 2025, Blue Energy Global Inc. (Blue Energy) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Topical Report (TR) BE-QAPD-001, "Quality Assurance Program Description, Revision 0 (ML25087A131). By letter dated May 8, 2025 (ML25128A357), Blue Energy submitted Revision 1 of its QAPD. Revision 1 of the QAPD was determined by the NRC staff to be acceptable for review by letter dated June 3, 2025 (ML25142A248). The NRC staff has formally reviewed Revision 1 of the Blue Energy's QAPD and has determined that the following information is needed:

1. 10 CFR 50.4(b)(7)(ii), states, "A change to an NRC-accepted quality assurance topical report from nonlicensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent."

Issue: The QAPD does not mention that Blue Energy commits to the applicable requirements included in 10 CFR 50.4(b)(7)(ii) when making changes to the QAPD.

Information need: As a non-licensee, please demonstrate compliance with the applicable requirements included in 10 CFR 50.4(b) (7)(ii) when making changes to the QAPD.

2. QAPD Section 2.6 "QA Program exceptions" states that "The following exception to NQA-1-2022, Requirement 7, *Control of Purchased Items and Services* is being taken:
 - Blue Energy considers other 10 CFR Part 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, and other state and Federal agencies that provide items and services to Blue Energy, to be **exempt** from audits or evaluations (**exemption** endorsed by NRC Safety Evaluation Report (SER) ML23254A050). This exemption does not include procurements from manufacturing licensees for which quality can only be verified during the fabrication or manufacturing process."

The TVA SER referenced above states that "TVA New Nuclear considers that other 10 CFR Part 50 and 52 licensees, Authorized Nuclear Inspection (ANI) Agencies, National Institute of Standards and Technology (NIST), or other State and Federal agencies which may provide items or services to the TVA New Nuclear plants **are not required** to be evaluated or audited. The NRC staff's evaluation of these exceptions is provided in Section 3.1.7.1 of this safety evaluation."

Issue- In the referenced SER, the NRC staff authorized an exception, not an exemption to Appendix B requirements.

Information need – Please used the language approved in the referenced SER when referencing the exception in Section 2.6 of the QAPD.

3. QAPD Section 2.6.2 states that “Under exigent conditions, the audit and / or survey interval may be extended up to 25 percent by the CQAM”. This section also states: “Exercising this extension is described in the implementing procedure and is allowed by NRC SER (ML20132A017). This extension may be applied to domestic or international suppliers.”

This extension is allowed by SE dated August 6, 2020 (ML20216A681), the NRC staff approved a 25% extension of audit or survey frequency during extenuating circumstances. The 25% extension of audit or survey frequency is allowed if several conditions included in the SE are met.

Information need- Please clarify if you intend to meet all the conditions included in the SE when implementing the extended audit or survey frequency during extenuating circumstances. If so, please state so and include all the conditions in the QAPD.

4. QAPD Section 7.9 “NQA-1 Commitment” states that, “When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, Blue Energy will implement the requirements of Revision 1 of NEI 14-05A as endorsed by NRC Final Safety Evaluation (ML20322A019).“

Information need –Please include all the conditions referenced in Section 3.4 of the SE in the QAPD or describe where these conditions are controlled and implemented.

Information need #2 - Revision 1 of NEI 14-05A recognizes the 2017 edition of ISO/IEC 17025 as the basis for the ILAC accreditation process. The Blue Energy QAPD does not state the edition of the referenced ISO/IEC 17025. Please clarify if it is Blue Energy intention to reference the 2017 edition of ISO/IEC 17025 and update the QAPD accordingly.

5. Criterion XV of Appendix B to 10 CFR Part 50, states, in part, “Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation.”

10 CFR Part 21.2(a)(3) and (a)(4) identify applicability of 10 CFR Part 21 for each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule 10 CFR Part 52, and applying for or holding a standard design approval under 10 CFR Part 52, respectively.

Issue: QAPD is not clear whether there will be appropriate interfaces between the QAP for the identification of nonconforming materials, parts, or components and corrective action programs and the non-QA Reporting Program to identify, evaluate, and report defects and noncompliances to satisfy the applicable requirements of 10 CFR Part 52, 10 CFR Part 50.55 and /or 10 CFR Part 21.

Information need: Include a statement in sections 15 & 16 of the QAPD to ensure that the necessary interfaces between the control of nonconforming items and corrective action programs and the non-QA reporting program satisfy applicable regulatory requirements.

6. The content in QAPD Section 3.5.4 “Configuration Management of Operating Facilities” is typically associated with operational phase activities which, according to the Introduction section of the QAPD, fall outside the scope of this QAPD.

Issue – QAPD Section 3.5.4 appears to be outside of the QAPD scope.

Information need: Clarify if the content in this section would support design and pre-construction activities associated with a construction permit application.

7. QAPD Section 10.6 “Inspection During Operations” states that, “The process to perform periodic and / or in-service inspection or surveillance of structures, systems, or components shall be planned and executed to ensure the continued performance of their required functions.

Issue – this section appears to be outside of the scope of the QAPD.

Information need: Clarify if the content in this section would support design and pre-construction activities associated with a construction permit application.

8. The staff notes that in Section 21 of the QAPD “Regulatory Commitments” Blue Energy commits to the following RG:
 - a. Regulatory Guide 1.164, Rev. 0, June 2017, Dedication of Commercial-Grade Items for Use in Nuclear Power Plants
 - b. Regulatory Guide 1.234, Rev. 0, April 2018, Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21
 - c. Regulatory Guide 1.26, Quality Group Classifications and Standards for Water-, Steam-, And Radioactive-Waste-Containing Components of Nuclear Power Plants, Rev 5, February 2017.
 - d. Regulatory Guide 1.29, Seismic Design Classifications for Nuclear Power Plants, Rev 5, July 2016.

Issue #1 - The most recent revisions of RG 1.164 and RG 1.234 are Revision 1, dated April 2024 and March 2024, respectively. The most updated revision for RG 1.26 is Revision 6, dated December 2021 and for RG 1.29 is Revision 6, dated July 2021.

Information need- Please explain the rationale for not committing to meeting the latest revisions of RGs. 1.164, 1.234, 1.26 and 1.29.

9. Section 20 of the QAPD references RG 1.189, “Fire Protection for Operating Nuclear Power Plants” and RG 1.155 “Station Blackout.”

Issue #1 – No revision number/date associated with RG 1.189 and RG 1.155 was provided.

Information need – please update the QAPD to include the revision # and date associated with these RGs. If you don't intend to commit to the latest revisions of these RGs, please explain the rationale for not committing to meeting the latest revision.

10. Headers in all pages should reference QAPD Rev 1, not Rev 0.

11. QAPD Section 7.7 “Commercial Grade Items and Services” states “The requirements of NQA-1-2022, Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, shall apply.”

Information need - Please clarify if Blue Energy will assume 10 CFR 21 reporting responsibility for all items that Blue Energy dedicates as safety-related.

12. SRP 17.5.A.11 “Organization” states that “Management ensures that the size of the QA organization is commensurate with its duties and responsibilities. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(F)).”

Issue – QAPD Section 1 “Organization” does not provide a requirement to ensure the adequate sizing of the QA organization.

Information need – Consistent with SRP 17.5 and the TMI related requirements in 10 CFR 50.34(f)(3)(iii)(F), please clarify how Blue Energy will implement measures to ensure that the size of the QA organization is commensurate with its duties and responsibilities in order to meet the TMI-related requirement.

13. SRP 17.5.B.5 “Quality Assurance Program” states “The QAPD includes the criteria used to identify the items and activities to which the QA program applies. A list of the SSCs and/or activities under the control of the QA program is required to be established and maintained at the applicant’s or holder’s facility.”

Issue 1 - QAPD Section 2 “Quality Assurance Program” does not identify specific activities to which the QA program applies to.

Issue 2 – The QAPD does not include a statement committing to establishing and maintaining a list of SSCs and/or activities under control of the QA program at the applicant’s or holder’s facility.

Information need – Please reference these requirements in Section 2 of the QAPD.

14. QAPD Section 3.0 “General” states “applicable regulatory requirements, codes and standards, and design **based** for safety-related structures, systems, and components are correctly translated into specification, drawings, procedure, and instructions.

Issue – Statement should reference design basis, not design based.

Information need – Please make this correction in the QAPD.

15. QAPD Section 3.9 “NQA-1 Commitment” states, “In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 3, Design Control and Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.

NQA-1-2022 Subpart 2.20 “Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities” provides amplified requirements related to subsurface investigations.

Issue: Activities described in NQA-1-2022 Subpart 2.20 would be part of a construction permit application.

Information need: please clarify if you intend to meet the requirements of NQA-1-2022 Subpart 2.20.

16. SRP 17.5.D.3 “Procurement Document Control” states “Applicable technical, regulatory, administrative, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, “Reporting of Defects and Noncompliance,” are invoked for the procurement of items and services.”

Issue – QAPD Section 4.1 “Content of Procurement Documents” doesn’t include requirements to include applicable regulatory requirements such as 10 CFR Part 50 Appendix B and Part 21 as part of procurement documents.

Information need – Consistent with SRP 17.5.D.3, please update Section 4.1 of the QAPD to include a reference to applicable regulatory requirements (Appendix B and Part 21) to be invoked in procurement documents.

17. QAPD Section 10.8 states that “In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 10, Inspection.”

NQA-1-2022 Subpart 2.5 “Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities” include amplified requirements for installation, inspection, and testing of structural concrete, structural steel, soils, and foundations.

Information need: please clarify if you intend to meet the requirements of NQA-1-2022 Subpart 2.5.

18. SRP 17.5.P.4 states that “The program requires all personnel to identify conditions that are adverse to quality.”

SRP 17.5.P.5 states that “Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions and trends adverse to quality are reported to the appropriate level of management.”

Issue – QAPD Section 16 doesn’t include a description of these requirements.

Information need – These requirements should be included as part of Section 16 “Corrective Actions” of the QAPD.

19. SRP 17.5.Q “Quality Assurance Records” states:

- Training is provided for individuals or organizations in charge of electronic records generation, data/media storage, implementation of security measures, migration/regeneration, and recovery (RIS 2000-18).
- Transfer of authentication authority is documented and controlled in accordance with written procedures (RIS 2000-18).
- For electronic records, in addition to the minimum indexing information requirements, the software name, version, and equipment (hardware) used to produce and maintain the electronic media must be provided (Appendix B/RIS 2000-18).
- Retention requirements for electronic records also identify and maintain the information system (software/hardware), the documentation that describes the information system operation and use, and the record standard it produces (RIS 2000-18).

Issue – RIS 2000-18 provides guidance the NRC considers acceptable for managing quality assurance (QA) records in electronic media.

Information need – Clarify if Blue Energy intends to manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated Nuclear Information and Records Management Association (NIRMA) technical guides TG 11-2011, TG 15-2011, TG 16-2011, and TG 21-2011.

20. QAPD Section 18.1.3.3 “Suppliers and Other Nuclear Support Organizations” states that “All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. This interval may be extended to 2 years based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements.”

QAPD Section 18.4.4 “External (Supplier) audits” “External or supplier audits shall be performed on a triennial basis and supplemented by annual evaluation of the Supplier’s performance to determine if the regular schedule audit frequency shall be maintained or decreased if other corrective action is required.

Issue – it appears there is a discrepancy in supplier audit frequency requirements in sections 18.1.3.3 and 18.4.4 of the QAPD.

Information need – please clarify the audit frequency requirements for suppliers.