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BWXT ADVANCED TECHNOLOGIES LLC – DRAFT SAFETY EVALUATION OF TOPICAL REPORT, BANR-QAPD-001, "BWXT ADVANCED NUCLEAR REACTOR QUALITY ASSURANCE PROGRAM DESCRIPTION," REVISION 000 (EPID NO. L-2022-TOP-0022)

SPONSOR AND SUBMITTAL INFORMATION

Sponsor: BWXT Advanced Technologies, LLC

Address: 109 Ramsey Place
Lynchburg, VA 24501

Project No.: 99901469

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Brief Description of the Topical Report: By letter dated November 30, 2022, BWXT Advanced Technologies LLC (BWXT AT) submitted for NRC review and approval BWXT AT's Quality Assurance Program Description (QAPD) topical report (TR) for the BWXT Advanced Nuclear Reactor (BANR) project. The introduction section to the QAPD Part I states:

> The QAPD describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements and guidance of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II as identified in [the QAPD].

The NRC staff limited the scope of the review to the quality assurance (QA) activities associated with technology development and high-level design. Any BWXT AT activities outside of those for technology development and high-level design will not be covered by the NRC staff approval of the BANR QAPD without additional supplements or submittals.

REGULATORY EVALUATION

Regulatory Bases: Appendix B to 10 CFR Part 50

The NRC's regulatory requirements related to QA programs are set forth in Appendix B to 10 CFR Part 50. Appendix B to 10 CFR Part 50 establishes QA requirements for the design, fabrication, construction, and testing of structures, systems, and components (SSCs) for the facility. The pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing,

fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, (Reference 3) endorses, with certain clarifications and regulatory positions, various versions of the American Society of Mechanical Engineers (ASME) NQA-1 standard; the standards included are the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015 (Reference 4). This endorsement means, as applicable to this safety evaluation (SE), that the NRC staff views the application of NQA-1-2015 as one acceptable way to meet the regulations in Appendix B to 10 CFR Part 50.

TECHNICAL EVALUATION

In evaluating the adequacy of the BANR QAPD, the NRC staff utilized the guidance contained in Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," of NUREG-0800, "Standard Review Plan [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Revision 1, dated August 2015 (Reference 5), which provides guidance to the NRC staff for the review of a QAPD for design certification, early site permit, combined license, construction permit, and operating license applicants. Section 17.5 of the SRP is based on Appendix B to 10 CFR Part 50 and describes regulatory and industry guidance determined to be acceptable methods for meeting the requirements of Appendix B to 10 CFR Part 50. Although the SRP is written for NRC reviews of light water reactors (LWRs), QA criteria associated with technology development and high-level design activities of BANR and LWRs are similar; therefore, the guidance in Section 17.5 of the SRP is applicable to the BANR QAPD.

1.0 Introduction

TR BANR-QAPD-001, Revision 000, provides for the control of BWXT AT activities affecting the quality and performance of SSCs including, but not limited to designing, procuring, inspecting, and fuel performance testing. The following sections correspond to QA criteria in Appendix B to 10 CFR Part 50 and parallel sections in the BANR QAPD. The BANR QAPD is based on NQA-1-2015 and evaluated with Section 17.5 of the SRP.

1.1 Organization

The NRC staff reviewed Part II, Section 1, "Organization," of the BANR QAPD. During the review, the staff found that the BANR QAPD provides an organizational description that includes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the implementation of BWXT AT's QA program. For the organizations performing QA functions, the BANR QAPD establishes organizations with sufficient authority and organizational freedom where independence is maintained between the organization performing the checking (QA and control) functions and the organization performing the functions.

The NRC staff found that the BWXT AT organization is responsible for technology development, engineering, and testing activities. The BANR QAPD provides for applicable management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. The BANR QAPD provides the authority and responsibility to stop work in progress not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. Finally, responsibility and authority for planning, establishing, and implementing

an effective overall QA program are clearly described and defined. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.A.

Additionally, the NRC staff found that the BANR QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 1, without further clarifications or exceptions.

Because BWXT AT's organization controls, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.A, and BWXT also commits to comply with NQA-1-2015, Requirement 1, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT's organizational controls are acceptable.

1.2 Quality Assurance Program

The NRC staff reviewed Part II, Section 2, "Quality Assurance Program," of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures to implement a QA program in order to ensure that the technology development and high-level design activities of the BWXT AT is in accordance with governing regulations and license requirements. The QA program applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design and testing of the facility. Managerial and administrative controls to be used to assure safe operation will be applied conceptually to the technology development and high-level design activities of BWXT AT's BANR since BWXT AT is not presently an applicant for either an OL or COL.

The NRC staff found that the BANR QAPD specifies that a list or system be maintained that identifies SSCs and activities to which the QA program applies. BWXT AT may delegate all or part of the activities for which they are responsible to others but retains overall responsibility for QA program effectiveness. The BANR QAPD provides measures to assess the adequacy of the QA program and to ensure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. In addition, consistent with SRP Section 17.5, Paragraph II.B.10, the BANR QAPD applies a grace period of 90 days to activities that must be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backwards by performing the activity early. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.B.

Additionally, the NRC staff found that the BANR QAPD describes the necessary measures to establish and maintain formal indoctrination, training, and qualification for personnel performing, verifying, or managing activities within the scope of the QAPD to achieve initial proficiency, maintain proficiency, and adapt to technology changes, method, or job responsibilities. The BANR QAPD provides measures to provide qualification programs for: (1) inspection and test personnel; (2) audit personnel; (3) and personnel performing, verifying, or maintaining activities within the scope of the QAPD to assure that proficiency is achieved and maintained. Inspection and test personnel are required to be trained and qualified in accordance with Section 302, "Inspection and Test," of Requirement 2, "Quality Assurance Program," of NQA-1-2015. Audit personnel are required to be trained and qualified in accordance with Sections 303, "Lead Auditors," of Requirement 2 of NQA-1-2015, as modified by the regulatory positions in Revision 5 of RG 1.28. The BANR QAPD provides the minimum training requirements for orientation, training and qualification processes for Auditors and Technical Specialists to meet the requirements specified in NQA-1-2015 Requirement 2, Sections 304 and 305. The NRC

staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraphs II.S and II.T.

Finally, the NRC staff found that the BANR QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 2, without further clarifications or exceptions.

Because BWXT AT's QA program, as described above, meets the guidance contained in SRP Section 17.5, Paragraphs II.B, II.S, and II.T and BWXT also commits to comply with NQA-1-2015, Requirement 2, as endorsed by RG 1.28, the NRC staff determined that it comply with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT's QA program is acceptable.

1.3 Design Control

The NRC staff reviewed Part II, Section 3, "Design Control," of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary design control measures to ensure design inputs are correctly translated into design outputs. In addition, the BANR QAPD provides for design documents to specify appropriate quality standards and for deviations from those standards to be controlled. These design documents are to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary QA requirements. BWXT AT design processes ensure that items and activities are selected and independently verified to be suitable for their intended application. Design changes are subject to these controls, which include verification measures commensurate with those applied to original plant design. Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing. Where design adequacy is verified by qualification tests, the tests are performed under conditions that simulate the most adverse design conditions.

The NRC staff found that the BANR QAPD governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. The BANR QAPD contains measures to ensure computer programs used for design analysis are verified to be acceptable and changes are documented and controlled by authorized personnel. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.C.

Additionally, the NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 3, "Design Control," Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications," and Subpart 2.14, "Quality Assurance Requirements for Commercial-Grade Items and Services," without further clarifications or exceptions.

Because BWXT AT's design controls as described above meet the guidance contained in SRP Section 17.5, Paragraph II.C, and BWXT also commits to comply with NQA-1-2015, Requirement 3, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT's design controls are acceptable.

1.4 Procurement Document Control

The NRC staff reviewed Part II, Section 4, “Procurement Document Control,” of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QA program requirements are included or referenced in procurement documents. The applicable technical, regulatory, administrative, quality, 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. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of Appendix B to 10 CFR Part 50, as appropriate to the circumstances of procurements (or the supplier may work under BWXT AT’s approved QA program). The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.D.

The NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 4, “Procurement Document Control,” with the following clarifications to NQA-1-2014, Requirement 4:

- With regard to service performed by a supplier, BWXT AT procurement documents may allow the supplier to work under the BWXT AT QA program, including implementing procedures, in lieu of the supplier having its own QA program.

The NRC staff evaluated this proposed clarification and determined that it provides adequate control for establishing and executing the responsibilities for the QA program. Criterion IV, “Procurement Document Control,” of Appendix B to 10 CFR Part 50, requires suppliers to have a QA program consistent with the regulations. In Section 3.2.4 of the “Final Safety Evaluation for Technical Report NEI 06-14, ‘Quality Assurance Program Description,’ Revision 7,” dated November 3, 2009 (Reference 6), the NRC staff determined this clarification to be acceptable. The bases of the BANR QAPD are applicable to the QAPD described in NEI 06-14, and therefore, the NRC staff finds that this clarification is acceptable.

- Sections 300 and 400 of NQA-1-2015, Requirement 4, require the review of technical and QA program requirements of procurement documents prior to award of a contract and for procurement document changes. BWXT AT may satisfy this requirement through the review of the procurement specification when the specification contains the technical and QA requirements of the procurement.

Also, in the Final Safety Evaluation for Technical Report NEI 06-14, the NRC staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change, and therefore, the NRC staff finds that this alternative is acceptable.

- Procurement documents for Commercial Grade Items that will be procured by BWXT AT for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with the BANR QAPD, Section 7, “Control of Purchased Material, Equipment and Services.”

The NRC staff evaluated this proposed clarification and determined that it meets the NRC staff guidance provided in Generic Letter (GL) 89-02, “Actions to Improve the detection of Counterfeit and Fraudulently Marked Products,” dated March 21, 1989 (Reference 7), and GL 91-05,

"Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (Reference 8), as delineated in SRP Section 17.5, paragraphs II.V.1.d and II.V.1.e.

Because BWXT AT's procurement document controls, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.D, and BWXT also commits to comply with NQA-1-2015, Requirement 4, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT's procurement document controls are acceptable.

1.5 Instructions, Procedures, and Drawings

The NRC staff reviewed Part II, Section 5, "Instructions, Procedures, and Drawings," of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with instructions, procedures, or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QA program as described in the BANR QAPD. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.E.

The NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 5, "Instructions, Procedures, and Drawings," without further clarifications or exceptions.

Because BWXT AT's controls for instructions, procedures, and drawings, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.E, and BWXT also commits to comply with NQA-1-2015, Requirement 5, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT's controls for instructions, procedures, and drawings are acceptable.

1.6 Document Control

The NRC staff reviewed Part II, Section 6, "Document Control," of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe affecting quality, including organizational interfaces, to ensure that correct documents are employed. The QAPD provides measures to assure that documents, including revisions or changes (other than those defined in implementing procedures as minor changes), are reviewed and approved by the same organization that performed the original review and approval, unless other organizations are specifically designated. A list of all controlled documents that identifies the current approved revision or date is maintained so personnel can determine the appropriate document for use. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.F.

The NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 6, "Document Control," without further clarifications or exceptions.

Because BWXT AT's document controls, as described above, and BWXT also commits to comply with NQA-1-2015, Requirement 6, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT's document controls are acceptable.

1.7 Control of Purchased Material, Equipment, and Services

The NRC staff reviewed Part II, Section 7, "Control of Purchased Material, Equipment, and Services," of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to control purchased items and services to ensure conformance with specified requirements. These measures provide for source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services.

The NRC staff found that the BANR QAPD establishes and implements measures to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. The BANR QAPD provides measures for evaluating prospective suppliers to assess their effectiveness of quality controls at intervals consistent with the importance, complexity, and quantity of the product or services. The BANR QAPD includes provisions for ensuring that qualified suppliers continue to provide acceptable products and services. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.G.

Additionally, the NRC staff found that the BANR QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 7, "Control of Purchased Items and Services," with the following clarifications and exceptions to NQA-1-2015, Requirement 7:

- BWXT AT considers that 10 CFR Part 50 and 10 CFR Part 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 BWXT AT's plants, are not required to be evaluated or audited.

The staff's current regulatory position regarding this exception is documented in Section 3.1.7.1 of the SE dated December 12, 2023 (Reference 6) for the Tennessee Valley Authority (TVA) New Nuclear QAPD. The NRC staff verified that the TVA New Nuclear QAPD commitments associated with supplier oversight activities are the same as those provided by BWXT AT in its QAPD. Therefore, the NRC staff's position associated with this exception, as documented in the TVA QAPD SE, would apply to the BANR QAPD. The NRC staff concludes that the requested exception regarding audit and evaluation, as described above, is acceptable subject to the limitations described in the TVA New Nuclear QAPD SE, and as identified in Section 5.0 of this SE, for control of purchased material, equipment, and services.

- BWXT AT will implement the guidance from Nuclear Energy Institute (NEI) 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1-A (Reference 9), for using the International Laboratory Accreditation (ILAC) accreditation process in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process.

The NRC staff evaluated this proposed alternative and determined that it is consistent with the NRC's regulatory position regarding the acceptability of procuring commercial-grade calibration

and testing services from laboratories accredited by ILAC. The document, “Final Safety Evaluation for Technical Report NEI 14-05A, ‘Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,’” Revision 1, dated November 23, 2020, (Reference 10) provides an evaluation of this alternative. The conditions of NRC safety evaluation for NEI 14-05A, Revision 1, are addressed in, “BWXT Advanced Technologies LLC’s Response to Request for Additional Information by the Office of Nuclear Reactor Regulation, BWXT BANR Quality Assurance Program Description,” dated June 1, 2023 (Reference 2). The bases are applicable to the conditions described in NEI 14-05A, Revision 1, and therefore, the NRC staff finds that this alternative is acceptable.

- 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:

    - For commercial grade items, quality verification requirements are established and described in BWXT AT documents to provide the necessary assurance an item will perform satisfactorily in service. The BWXT AT documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

Establishment of quality verification requirements and processes for identification of critical characteristics of BWXT AT documents as part of the commercial grade dedication process is acceptable because this is consistent with the guidance in SRP Section 17.5, Subsection II, Item G, and is therefore acceptable.

    - BWXT AT will assume 10 CFR 21 reporting responsibility for all services that BWXT AT dedicates as safety-related.

In Section 3.1.7, “Control of Purchased Material, Equipment, and Services,” of the document, “U.S. Nuclear Regulatory Commission Final Safety Evaluation for X-Energy’s Topical Report XEQAPD-NP, ‘Quality Assurance Program Description,’ Revision 3,” (Reference 11) the NRC staff evaluated this clarification and determined that it ensures that 10 CFR Part 21 reportability requirements encompass all items that are dedicated as safety-related and does not remove the supplier’s responsibilities under 10 CFR Part 21. The regulations in 10 CFR Part 21 are applicable to the BANR QAPD, and therefore, the NRC staff finds that this clarification is acceptable.

Because BWXT AT’s controls for purchased material, equipment, and services, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.G, and BWXT also commits to comply with NQA-1-2015, Requirement 7, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion VII, of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT’s controls for purchased material, equipment, and services are acceptable.

1.8 Identification and Control of Materials, Parts, and Components

This element is not applicable to the BWXT AT’s technology development and high-level design activities and has not been reviewed or approved by the NRC staff.

1.9 Control of Special Processes

This element is not applicable to the BWXT AT's technology development and high-level design activities and has not been reviewed or approved by the NRC staff.

1.10 Inspection

The NRC staff reviewed Part II, Section 10, "Inspection," of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to implement inspections of activities affecting quality to verify conformance with the documented instructions, procedures, and drawings. These activities include source, in-process, final, and receipt inspections. These inspections are performed by individuals other than those who performed the activity being inspected and who are appropriately qualified.

The NRC staff found that the inspection program establishes measures for examinations, measurements, or tests of material or products processed for each work operation where necessary to ensure quality. Measures are established to ensure that inspection procedures and instructions are made available with necessary drawings and specifications for use prior to performing the inspections. Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.J.

Additionally, the NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 10, "Inspection," without further clarifications or exceptions.

Because BWXT AT's inspection controls, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.J, and BWXT also commits to comply with NQA-1-2015, Requirement 10, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT's inspection controls are acceptable.

1.11 Test Control

The NRC staff reviewed Part II, Section 11, "Test Control," of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to ensure that testing is required to demonstrate that SSCs will perform satisfactorily in service. The test program is performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents and are executed by qualified personnel. Test procedures include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and performed under suitable environmental conditions. Test results will be documented and evaluated to ensure that test requirements have been satisfied. Test records contain results and actions taken in connection with any deviations.

The NRC staff found that the BANR QAPD establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained, and configuration control maintained. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.K.

Additionally, the NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 11, “Test Control,” and Subpart 2.7, “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications,” without further clarifications or exceptions.

Because BWXT AT’s testing controls, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.K, and BWXT also commits to comply with NQA-1-2015, Requirement 11, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion XI, “Test Control,” of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT’s test controls are acceptable.

1.12 Control of Measuring and Test Equipment

The NRC staff reviewed Part II, Section 12, “Control of Measuring and Test Equipment,” of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met or information important to safe plant operation. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.L.

The NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 12, “Control of Measuring and Test Equipment,” without further clarifications or exceptions.

Because BWXT AT’s controls for M&TE, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.L, and BWXT also commits to comply with NQA-1-2015, Requirement 12, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50.Therefore, the NRC staff concludes that BWXT AT’s controls for M&TE are acceptable.

1.13 Handling, Storage, and Shipping

This element is not applicable to the BWXT AT’s technology development and high-level design activities and has not been reviewed or approved by the NRC staff.

1.14 Inspection, Test, and Operating Status

This element is not applicable to the BWXT AT’s technology development and high-level design activities and has not been reviewed or approved by the NRC staff.

1.15 Nonconforming Materials, Parts, or Components

The NRC staff reviewed Part II, Section 15, “Nonconforming Materials, Parts, or Components,” of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to control materials, parts, or components which do not conform to requirements in order to prevent inadvertent use.

The NRC staff found that controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to

affected organizations. Nonconforming items are reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. Nonconformances to design requirements which are dispositioned “repair” or “use-as-is” are subject to design control measures commensurate with those applied to the original design.

In addition, the NRC staff found that the BANR QAPD provides for establishing the appropriate interfaces between the QA program for identification and control of nonconforming materials, parts, or components, and the non-QA reporting program in order to satisfy the requirements of 10 CFR Part 21. Non-QA reporting program refers to notification requirements of 10 CFR Part 21, whereas QA reporting program is mentioned in paragraph above for “notification to affected organizations.” The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.O.

The NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 15, “Control of Nonconforming Items,” without further clarifications or exceptions.

Because BWXT AT’s controls for nonconforming materials, parts, or components, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.O, and BWXT also commits to comply with NQA-1-2015, Requirement 15, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT’s controls for nonconforming materials, parts, or components are acceptable.

1.16 Corrective Action

The NRC staff reviewed Part II, Section 16, “Corrective Action,” of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality.

The NRC staff found that for significant conditions adverse to quality, the cause of the condition is determined and corrective actions to preclude recurrence are taken. In the case of suppliers working on safety-related activities or other similar situations, BWXT AT may delegate specific responsibilities for corrective actions, but maintains responsibility for the effectiveness of corrective action measures. Reports of conditions that are averse 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. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.P.

The NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 16, “Corrective Action,” without further clarifications or exceptions.

Because BWXT AT’s corrective action controls, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.P, and BWXT also commits to comply with NQA-1-2015, Requirement 16, as endorsed by RG 1.28, the NRC staff determined that they comply with the requirements of Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT’s corrective action controls are acceptable.

1.17 Quality Assurance Records

The NRC staff reviewed Part II, Section 17, “Quality Assurance Records,” of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to ensure that sufficient records of completed items and activities affecting quality are appropriately stored and maintained to furnish evidence of activities affecting quality.

The NRC staff found that the BANR QAPD establishes measures to ensure that sufficient records of completed items and activities affecting quality are appropriately stored. The records and retention times are based on Regulatory Position C.3.a.(1) and C.3.a(2) of RG 1.28, Revision 5, for design. In all cases where state, local, or other agencies have more restrictive requirements for record retention, the BANR QAPD provides that those requirements will be met.

The NRC staff found that when using electronic records storage and retrieval systems, the BANR QAPD provides for compliance with the NRC guidance contained in NRC Generic Letter 88-18, “Plant Record Storage on Optical Disks” (Reference 12), Regulatory Issue Summary (RIS) 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media” (Reference 13), and the associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG), including TG 11-1998, “Authentication of Records and Media,” TG 15-1998, “Management of Electronic Records” (Reference 14), TG 16-1998, “Software Configuration Management and Quality Assurance” (Reference 15), and TG 21-1998, “Electronic Records Protection and Restoration” (Reference 16). The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.Q.

The NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 17, “Quality Assurance Records,” and the regulatory positions described in RG 1.28, Revision 5, without further clarifications or exceptions.

Because BWXT AT’s controls for QA records, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.Q, and BWXT also commits to comply with NQA-1-2015, Requirement 17, and the regulatory positions described in RG 1.28, Revision 5, the NRC staff determined that they comply with the requirements of Criterion XVII, “Quality Assurance Records,” of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT’s controls for QA records are acceptable.

1.18 Audits

The NRC staff reviewed Part II, Section 18, “Audits,” of the BANR QAPD. During the review, the staff found that the BANR QAPD establishes the necessary measures and governing procedures to implement audits to verify compliance with activities covered by the BANR QAPD and to determine the effectiveness of the program. Audits of suppliers of safety-related components and/or services are conducted as described in section 1.7 of this SE.

The NRC staff found that the BANR QAPD provides for conducting periodic internal audits. Internal audits are conducted to determine the adequacy of program and procedures, as well as to determine if they are meaningful and comply with the overall QAPD. Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is

completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. These audits are performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results are documented and reviewed by management having responsibility in the area audited, and follow-up action, including re-audit of deficient areas, shall be taken where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.R.

The NRC staff found that the BANR QAPD commits to the quality standards described in NQA-1-2015, Requirement 18, “Audits,” and the regulatory positions described in RG 1.28, Revision 5, without further clarifications or exceptions.

Because BWXT AT’s QA controls for audits, as described above, meet the guidance contained in SRP Section 17.5, Paragraph II.R, and BWXT also commits to comply with NQA-1-2015, Requirement 18, and the regulatory positions described in RG 1.28, Revision 5, the NRC staff determined that they comply with the requirements of Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50. Therefore, the NRC staff concludes that BWXT AT’s QA controls for audit are acceptable.

2.0 Nonsafety-Related SSCs - Significant Contributors to Plant Safety

The NRC staff reviewed Part III, Section 1, “Nonsafety-Related SSCs – Significant Contributors to Plant Safety,” of the BANR QAPD. The NRC staff found that the BANR QAPD establishes specific program controls to be applied to nonsafety-related SSCs that are significant contributors to plant safety, but for which Appendix B to 10 CFR Part 50 is not applicable. The BANR QAPD applies specific program controls consistent with applicable sections of those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety. The NRC staff review determined that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.U.1.

Because BWXT AT’s controls for nonsafety-related SSCs that are significant contributors to plant safety meet the guidance contained in Section 17.5, Paragraph II.U.1 of the SRP, the NRC staff concludes that they are acceptable.

3.0 Non-Safety-Related SSCs Credited for Regulatory Events

This element is not applicable to the QA activities associated with technology development and high-level design activities for the BANR project, and has therefore, not been reviewed or approved by the NRC staff.

4.0 Regulatory Commitments

The NRC staff reviewed Part IV, “Regulatory Commitments,” of the BANR QAPD. The NRC staff found that the BANR QAPD follows the guidance of SRP Section 17.5, Paragraph II.V, for establishing QA program commitments. Because of the potential differences between BANR and a LWR design, the BANR QAPD commitments and exceptions to the RGs were not assessed by the NRC staff as part of this review; however, they will be addressed by the NRC staff as part of a future application review.

5.0 Limitations and Conditions

The approval of this topical report is only for activities associated with technology development and high-level design. Any BWXT AT activities outside of those for technology development and high-level design will not be covered by the NRC staff approval of the BANR QAPD without additional supplements or submittals.

As referenced in Section 1.7 of this SE, the limitations on the use of this QAPD are:

- The exception to not perform audit or evaluation for procurements from other Parts 50 and 52 licensees only applies when BWXT AT procures from other Parts 50 and 52 *power reactor* licensees.

- When BWXT AT procures from manufacturing licensees where inspections during the fabrication or manufacturing process is required to assure quality, BWXT AT must establish measures for source verification for these procurements, as required by Criterion VII of Appendix B to 10 CFR Part 50.

CONCLUSION

The BANR QAPD delineates the policies, processes, and controls established by BWXT AT and associated implementing documents relative to U.S. domestic licensing requirements for QA at nuclear power plants. Together, the QA program documents defined in the BANR QAPD provide for control of BWXT AT's activities that affect the quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The BANR QAPD may also be applied to certain equipment and activities that are not safety-related where other NRC guidance establishes program requirements.

The BANR QAPD conforms to the format of SRP Section 17.5. The NRC staff used the acceptance criteria of SRP Section 17.5 as the basis for evaluating the compliance of the BANR QAPD with Appendix B to 10 CFR Part 50. On the basis of its review of the BANR QAPD, the NRC staff concludes that:

- The BANR QAPD adequately describes the authority and responsibility of management and supervisory personnel, performance and verification personnel, and self-assessment personnel, in relation to activities to which the BWXT AT's QA program is applicable.

- The BANR QAPD adequately provides for organizations and personnel to perform verification and self-assessment functions related to BWXT AT activities that affect the quality of safety-related nuclear plant SSCs, as well as select nonsafety-related SSCs, with these organizations and personnel having the authority and independence to conduct activities without undue influence from those directly responsible for costs and schedules.

- The BANR QAPD adequately applies to activities and items that are important to safety.

- The BANR QAPD adequately establishes controls that, when properly implemented, comply with the requirements of Appendix B to 10 CFR Part 50, and 10 CFR Part 21,

consistent with the criteria contained in SRP Section 17.5, as well as the relevant regulatory guidance.

On the basis of its review, the NRC staff determined that the BANR QAPD adequately describes the BWXT AT's QA program. Accordingly, the NRC staff concludes that the BWXT AT's QA program complies with the applicable NRC regulations and industry standards and can be used by BWXT AT for technology development and high-level design activities associated with the BANR.

REFERENCES

1. Letter from Steve W. Schilthelm, BWXT Advanced Technologies LLC, to the NRC Document Control Desk, "Quality Assurance Program Description Topical Report for BWXT BANR Project," dated November 30, 2022 (ADAMS Accession No. ML22335A417)

2. Letter from Steve W. Schilthelm, BWXT Advanced Technologies LLC, to the NRC Document Control Desk, "BWXT Advanced Technologies LLC's Response to Request for Additional Information by the Office of Nuclear Reactor Regulation, BWXT BANR Quality Assurance Program Description," dated June 1, 2023 (ADAMS Accession No. ML23152A260)

3. Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, dated October 31, 2017 (ADAMS Accession No. ML17207A293)

4. American Society of Mechanical Engineers NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facility Applications," New York, NY, dated February 20, 2015

5. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," Revision 1, dated August 28, 2015 (ADAMS Accession No. ML15037A441)

6. Final Safety Evaluation by the Office of Nuclear Reactor Regulation Regarding the Topical Report on the Quality Assurance Program Description for the Tennessee Valley Authority New Nuclear Program," dated December 12, 2023 (ADAMS Accession No. ML23254A050)

7. Generic Letter 89-02, "Actions to Improve the detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989 (ADAMS Accession No. ML031140060)

8. Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (ADAMS Accession No.ML031140508)

9. Revision 1-A of NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated September 30, 2020 (ADAMS Accession No. ML21069A347)

10. Final Safety Evaluation for Technical Report NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory

Calibration and Test Services," Revision 1, dated November 23, 2020 (ADAMS Accession No. ML20322A019)

11. U.S. Nuclear Regulatory Commission Final Safety Evaluation for X-Energy's Topical Report XEQAPD-NP, "Quality Assurance Program Description," Revision 3, dated September 4, 2020 (ADAMS Accession No. ML20233A910)

12. Generic Letter 88-18, "Plant Record Storage on Optical Disks," dated October 20, 1988 (ADAMS Accession No. ML031130450)

13. Regulatory Issue Summary (RIS) 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000 (ADAMS Accession No. ML003739359)

14. Nuclear Information and Records Management Association, Inc. TG 111998, "Authentication of Records and Media"

15. Nuclear Information and Records Management Association, Inc. TG 16-1998, "Software Configuration Management and Quality Assurance"

16. Nuclear Information and Records Management Association, Inc. TG 21-1998, "Electronic Records Protection and Restoration"

Principal Contributor(s): Dong H. Park, NRR/DRO

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