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

December 23, 2025

Ms. Lisa Williams
Energy Northwest Nuclear Development
P.O. Box 968, MD 1035
Richland, WA 99352-0968

SUBJECT: FINAL SAFETY EVALUATION FOR TOPICAL REPORT REGARDING THE QUALITY ASSURANCE PROGRAM FOR ENERGY NORTHWEST NEW NUCLEAR REVISION 2 (EPID: L-2024-TOP-0037)

Dear Ms. Williams:

By letter dated December 17, 2024 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML24352A486), Energy Northwest New Nuclear (ENNN) submitted the Energy Northwest New Nuclear Quality Assurance Topical Report (TR) Revision 0 for the U.S. Nuclear Regulatory Commission (NRC or Commission) staff's review. Subsequently, ENNN submitted Revision 1 of this TR (ML25132A315) on May 12, 2025, and Revision 2 (ML25196A303) on July 15, 2025. This TR describes the activities covered by ENNN's Quality Assurance Program (QAP) and is applicable to ENNN's design, procurement, construction, and pre-operational testing activities.

The NRC staff's final safety evaluation (SE) for the QAPD for ENNN is enclosed. The NRC staff reviewed ENNN's revised QAPD, Revision 2 and finds that it complies with the criteria of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and is therefore, acceptable. The NRC staff requests that ENNN submit an accepted version of the TR within 3 months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE.

If you have any questions, please contact Denise McGovern at (301) 415-0681 or via email at Denise.McGovern@nrc.gov.

Sincerely,

Signed by Neuhausen, Alissa
on 12/23/25

Alissa Neuhausen, Chief
Advanced Reactor Licensing Branch 2
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Project No.: 99902130

Enclosure:
As stated

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SAFETY EVALUATION FOR THE TOPICAL REPORT ON THE QUALITY ASSURANCE PROGRAM FOR ENERGY NORTHWEST NEW NUCLEAR REVISION 2 (EPID: L-2024-TOP-0037)

Sponsor: Energy Northwest New Nuclear

Sponsor Address: P.O. Box 968, MD 1035
Richland, WA 99352-0968

Project No.: 99902130

Submittal Date: July 15, 2025

Submittal Agencywide Documents Access and Management System (ADAMS) Accession No.: ML25196A303

Supplement and Request for Additional Information response letter Date(s) and ADAMS Accession No(s): N/A

1.0 INTRODUCTION

By letter dated December 17, 2024 (Agencywide Document Access and Management Systems (ADAMS) Accession No. ML24352A486), Energy Northwest New Nuclear (ENNN) submitted Quality Assurance Topical Report (TR) No. EN-NN-QAPD-01, "Quality Assurance Program Description (QAPD)," Revision 0 to the U.S. Nuclear Regulatory Commission (NRC) for the staff's review and approval. This TR describes the activities covered by ENNN's Quality Assurance Program (QAP) and is applicable to ENNN's design, procurement, construction, and pre-operational testing activities.

The NRC staff held a public meeting with ENNN on April 4, 2025 (ML25100A121) to discuss the NRC staff's initial review. The NRC staff discussed a draft request for additional information (RAI) (ML25091A131) needed to complete its review. By letter dated May 12, 2025 (ML25132A315), ENNN submitted Revision 1 of the EN-NN-QAPD-01 QAPD for the NRC staff's review.

The NRC staff held clarification calls with ENNN on June 5, 2025 (ML25156A345) with a follow-up discussion on June 18, 2025 to clarify any remaining open items. By letter dated July 15, 2025 (ML25196A303), ENNN submitted Revision 2 of the EN-NN-QAPD-01 for the NRC staff's review. The NRC staff's review is based on Revision 2 of the EN-NN-QAPD-01.

The QAPD for plant design and construction identifies the basis of the ENNN QAP and its application to the development of projects that ENNN may engage in. The QAPD describes methods and establishes quality assurance (QA) and administrative control requirements that

meet the requirements of Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” and of the American Society of Mechanical Engineers (ASME) NQA-1-2022, “Quality Assurance Requirements for Nuclear Facility Applications.”

The NRC staff notes that ENNN clarified that the ENNN QAPD is only used for a Construction Permit (CP).

2.0 REGULATORY EVALUATION

The Commission’s regulatory requirements related to QAPs are set forth in the following regulations:

- Appendix B to 10 CFR Part 50, which establishes QA requirements for the design, manufacture, construction, and operation of structures, systems, and components (SSCs) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those SSCs; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying for nuclear power plants and fuel reprocessing plants.

- Paragraph 50.34(a)(7) of 10 CFR, which requires an application for a CP to include a description of the QAP to be applied to the design, fabrication, construction, and testing of SSCs of the facility. The description of the QAP for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

3.0 EVALUATION

In evaluating the adequacy of the ENNN QAPD, Revision 2, the NRC staff utilized the guidance contained in NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” section 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants,” Revision 1 dated August 2015. Standard Review Plan (SRP) section 17.5 provides guidance to the NRC staff for the review of a QAPD for Design Certification (DC), Early Site Permit, Combined License (COL), Construction Permit (CP), and Operating License applications. Section 17.5 of the SRP describes regulatory and industry guidance determined to be acceptable methods for meeting the requirements of Appendix B to 10 CFR Part 50. The ASME standard NQA-1-2022 edition, upon which the ENNN QAPD is based, is endorsed (with certain exceptions and clarifications) by the NRC in Regulatory Guide (RG) 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 6.

3.1 Quality Assurance Program Overview

The ENNN QAPD and the associated implementing documents control ENNN activities that affect 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 ENNN QAPD is the top-level policy document that establishes the QA policy and assigns major functional responsibilities for all quality-related activities conducted by or for ENNN. The ENNN QAPD describes the methods and establishes QA and administrative control requirements that meet Appendix B to 10 CFR Part 50. The ENNN QAPD is based on the requirements and guidance from Parts I and II of ASME NQA-1-2022. The ENNN QAPD also includes selected sections from ASME NQA-1-2022 Parts III and IV.

Sections of the ENNN QAPD that are not yet utilized for active work are in conformance with applicable sections of ASME NQA-1-2022 though implementation may not be complete. Procedures and instructions that control quality-related activities will be developed prior to the commencement of those activities.

The ENNN QAPD applies to plant design and construction activities affecting the quality and performance of safety-related SSCs, including, but not limited to, designing, siting, procuring, fabricating, cleaning, handling, shipping, receiving, storing, constructing, erecting, installing, inspecting, testing, maintaining, repairing, modifying, and training.

Contractors, suppliers, or other organizations supporting ENNN are required to comply with the ENNN QAPD, or with their own programs as determined to include sufficient controls to meet the applicable requirements of Appendix B to 10 CFR Part 50.

3.1.1 Organization

Part II, section 1, “Organization,” of the ENNN QAPD, describes the ENNN organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation. The ENNN organizational structure includes corporate, support, off-site, and on-site functions that include interface responsibilities for multiple organizations that perform quality-related functions. Figure 1 of the ENNN QAPD depicts the organizational structure. Descriptions and documentation of interfacing organizations, including interface responsibilities for multiple organizations that perform quality-related functions, are provided in applicable implementing procedures. The QA Manager is responsible for determining the size of the QA staff commensurate with the duties and responsibilities assigned.

Part II, section 1.2, “Responsibilities and Authorities,” of the ENNN QAPD, describes the key upper management personnel of the ENNN organization, including: (1) the Manager, ENNN, LLC., who provides top-level leadership for ENNN and is responsible for implementation and execution of the ENNN QAPD; (2) the Vice President, Energy Services and Development (VP-ES&D), who is responsible for providing technical and administrative support activities to ENNN; and (3) the General Manager, who reports to the VP-ES&D and is responsible for the establishment and effective implementation of all activities controlled by the ENNN QAPD.

Part II, section 1.3, “Management Responsibility for Quality,” of the ENNN QAPD, states that managers responsible for executing any part of the ENNN QAPD may delegate any or all of the work to others but shall retain responsibility. Quality is administered as a line organization function, such that all personnel are responsible for meeting QA requirements. A line organization is defined as any department or organization that implements any portion of the QAP and includes, but is not limited to, procurement, engineering, laboratory/testing, and records management and document control.

Part II, section 1.4, “Quality Assurance,” of the ENNN QAPD, states that the QA Manager is

assigned primary responsibility for verifying that the ENNN QAPD is implemented effectively. The VP-ES&D and the QA Manager ensure that adequate QA resources are applied to oversight functions. The QA Manager may delegate QAP administration and verification to a senior QA person assigned to an ENNN project but shall maintain overall responsibility for those delegated duties. Regardless of the organizational structure, the person(s) assigned the responsibility for assuring effective execution of any portion of the ENNN QAPD, at any location where it's important to safety, including safety-related activities, are being performed, shall have direct access to the levels of management necessary to perform the required functions without hindrance.

QA personnel have sufficient authority, are independent from cost and schedule personnel, and have access to work areas and organizational freedom to: 1) review item characteristics, process implementation, and other quality-related information, and to identify items, services, and processes to confirm compliance with requirements and effectiveness; 2) identify quality problems; 3) initiate, recommend or provide solutions to quality problems; 4) verify implementation of solutions to problems; and 5) ensure that further processing, delivery, installation or use is controlled for non-conformance items.

The QA Manager is responsible for: (1) overall implementation of the QAP; (2) ensuring that the ENNN QAPD and implementing procedures adequately address all customer requirements; (3) approval of QA manuals; (4) preparation and issuance of QA procedures; (5) review of procurement documents to suppliers and subcontractors to ensure specification of appropriate quality requirements; (6) performance of audits and surveillance of supplier and subcontractor activities; (7) scheduling and participating in annual management review of the QAP to ensure its suitability and effectiveness; (8) representing ENNN for quality evaluations conducted by external assessors and/or customers on ENNN's quality system; 9) providing adequate resources and/or trained personnel to satisfy the contractual requirements of projects executed by ENNN; (10) verifying that the quality system is adequately and effectively implemented and maintained through the performance of annual audits, surveillance, and reviews of engineering, design, procurement, and fabrication documents; and (12) coordinating project responses to external audits and/or reviews.

The QA Manager reports directly to the VP-ES&D, who ensures that required authority and organizational freedom are provided to meet the responsibilities of the QA Manager. QA is at the same organizational level as the highest line organization directly responsible for performing activities affecting quality. QA is sufficiently free from cost and schedule considerations associated with fulfilling the assigned responsibilities. QA is the owner of this ENNN QAPD.

If QA disagrees with any actions by the organization and is unable to obtain resolution, QA shall bring the matter to the attention of the ENNN Manager, who will determine the final disposition. QA has stop-work authority to curtail work at ENNN facilities or at supplier locations, as deemed necessary in response to quality problems. Resumption of work after the quality problems have been appropriately addressed will be authorized by the VP-ES&D and may be delegated to QA.

Part II, section 1.5, "Engineering and Technical Authority," of the ENNN QAPD, describes the individual who has responsibility for ensuring that the equipment and facilities are engineered and designed in compliance with the project and customer requirements and are in accordance with the requirements in the ENNN QAPD. Engineering provides design support and/or engineering personnel to individual projects. This organization is responsible for ensuring the adequacy and consistency of qualification and the training of engineers and other technical personnel; staffing projects as necessary with engineering and/or technical personnel; analytical

software control; and for the technical adequacy of design for all projects.

Part II, section 1.7, “Contracts and Supply Management,” of the ENNN QAPD, states that this function is responsible for contracting and procurement functions. This function is responsible for activities and interfaces related to external contracts and agreements, supplier management and procurement, and assists line organizations to implement contracts, including flow down to client QA requirements. This function is responsible for assuring that subcontracted services are in full compliance with project, customer, and procurement document requirements by: (1) coordinating development of approved bidders’ lists; (2) commercial evaluation/validation of the bid/pricing data received; (3) coordination of bid reviews and subcontractor selection with QA and engineering; (4) participation in subcontractor qualification; and (5) review of procurement documents with engineering and QA to establish the necessary level of supplier surveillance and to identify supplier quality control and document submittal requirements.

Part II, section 1.8, “Line Organization Managers,” of the ENNN QAPD, describes the various responsibilities of the different managers, including: (1) establishing, maintaining, and controlling department work instructions/procedures to satisfy the ENNN QAPD requirements; (2) ensuring that personnel are qualified in accordance with written procedures and only perform activities for which they are qualified; (3) interfacing the QA Management in implementing changes affecting QA; and (4) providing support to QA for internal audits and external audits.

Part II, section 1.10, “Quality Assurance Organizational Independence,” of the ENNN QAPD, states that quality is achieved and maintained by those assigned responsibility for performing work while quality verification is achieved by those not directly responsible for performing the work.

Part II, section 1.11, “NQA-1 Commitment,” of the ENNN QAPD, states that ENNN commits to compliance with NQA-1-2022, Part 1, Requirement 1 without further clarifications or exceptions.

The NRC staff reviewed the descriptions of the roles and responsibilities of the various positions described in Part II, section 1.0 of the ENNN QAPD, and concludes that the ENNN QAPD adequately describes: (1) the QA functions performed by these roles; (2) the positions that are responsible for the establishment and effective implementation of the ENNN QAP; and (3) the authority, including the ability to stop work, and responsibilities of the positions that perform the verification of activities affecting safety-related functions have been correctly performed. The NRC staff also evaluated the authority and organizational independence of persons and organizations performing QA functions and concludes that these persons and organizations have access to and report to an appropriate level of management and have the requisite authority and independence.

The NRC staff determined that this description conforms to the guidance of SRP section 17.5, subsection II, item A, “Organization (Criterion I).”

Based on this evaluation and ENNN’s commitment to ASME NQA-1-2022, part I, requirement 1, the NRC staff determined that part II, section 1.0 of the ENNN QAPD complies with the requirements of Criterion I, “Organization,” of Appendix B to 10 CFR Part 50.

3.1.2 Quality Assurance Program

Part II, section 2.1, “General,” of the ENNN QAPD, states that ENNN has established the necessary measures and governing procedures to plan, implement and maintain the QAP. The

QAP shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, the systematic process ensures that suppliers of safety-related equipment or services meet the applicable requirements of Appendix B to 10 CFR Part 50. Senior management is regularly apprised of the adequacy of implementation of the QAP through the audits.

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, and to managerial and administrative controls that are important to public health and safety. A list of systems that identifies SSCs and activities to which the ENNN QAPD applies is maintained at ENNN facilities.

Prospective lead auditors shall receive training to the extent necessary to ensure auditing competence and maintain suitable proficiency. Formal training and qualification program documentation shall include the objective, content of the program, attendees, and date of attendance.

Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided that the supplier or principal contractor has been approved as a supplier. Periodic audits and assessments of supplier QAPs are performed to ensure compliance with the supplier's or principal contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier’s personnel provide added assurance that quality expectations are met.

For audits, a grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis, unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90-day general period could be applied. The grace period does not allow the “clock” for a particular activity to be reset forward. The “clock” for an activity is reset backwards by performing the activity early. Audit schedules are based on the month in which the audit starts. This is consistent with the NRC’s SE for approving a grace period of 90 days for performing audits (ML101820108).

Part II, section 2.2, “Responsibilities,” of the ENNN QAPD, states that personnel who work directly or indirectly for ENNN are responsible for achieving acceptable quality in the work covered by the ENNN QAPD. Personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the ENNN QAPD are performed as directed by documented instructions, procedures, and drawings that are of detail that is appropriate for the activity's complexity and effect on safety. Instructions, procedures, and drawings specify quantitative or qualitative acceptance criteria appropriate for the activity, and the verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used.

Part II, section 2.3, “Delegation of Work,” of the ENNN QAPD, states that the roles identified in part II, section 1.0, of the ENNN QAPD, may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the appropriate level based upon their nature and effect, with technical advice or review as appropriate.

Part II, section 2.5, “Periodic Review of the Quality Assurance Program (Management

Reviews),” of the ENNN QAPD, states that management of those organizations implementing the ENNN QAP, or portions thereof, shall assess the adequacy of that part of the program for which they are responsible to ensure its effective implementation at least once each year, or at least once during the life of the activity, whichever is shorter.

Part II, section 2.7, “Personnel Training and Qualifications,” of the ENNN QAPD, states that formal indoctrination, training, certification, and qualification, as necessary, are established and maintained for personnel performing, verifying, or managing activities within the scope of the ENNN QAPD to achieve initial proficiency, maintain proficiency, and adapt to technological changes, methods, or job responsibilities. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance of the activities; and include: (1) education, experience, and proficiency of the personnel receiving training; (2) general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and QAP requirements; and (3) on-the-job training, if direct hands-on applications or experience is needed to achieve and maintain proficiency.

Records of personnel training and qualification are maintained. Records for inspection and test personnel, non-destructive examination personnel and lead auditors meet the specific record content requirements of ASME NQA-1-2022, part I, requirement 2.

Requirements for the qualification of QA lead auditors, QA auditors, and technical specialists are prescribed in written procedures. The ENNN QAPD also details the minimum qualification of the QA Manager and the individuals responsible for supervising QA personnel.

Part II, section 2.8, “NQA-1 Commitment/Exceptions” of the ENNN QAPD, states that ENNN commits to compliance with ASME NQA-1-2022, part 1, requirement 2, and RG 1.28, Revision 6, with the following clarifications and exceptions:

- Section 300, “Qualification Requirements” of ASME NQA-1-2022, part I, requirement 2, requires any person who has not performed inspection or testing activities in the qualified area for a period of 1 year shall be reevaluated. A 90-day grace period can be applied to this activity.

  The NRC staff evaluated this exception and determined that it is acceptable on the basis that it is approved in an NRC SE (ML101820108), in which a 90-day grace period can be applied to any person who has not performed inspection, examination, or testing activities in the qualified area for a period of 1 year. This is also consistent with SRP section 17.5, position II.B.10.

- Sections 300 and 400, “Records of Qualification” of ASME NQA-1-2022, part I, requirement 2, require that an annual assessment be performed of each lead auditor's qualification. A 90-day grace period can be applied to this activity.

  The NRC staff evaluated this exception and determined that it is acceptable on the basis that it is consistent with SRP 17.5, position II.B.10, which was approved by NRC SE (ML101820108), in which a 90-day grace period can be applied to lead auditor’s qualification.

- Under section 303.3, “Audit Participation” of ASME NQA-1-2022, part I, requirement 2, prospective lead auditors, with comparable industry experience, may satisfy the lead auditor qualification requirement of participating in a minimum of five QA audits within a period of 3 years prior to the date of qualification by alternatively demonstrating the ability to properly implement the audit process, effectively organize and report results, and participate in at least one nuclear audit within the year preceding the date of qualification, subject to review and acceptance by the responsible QA organization.

  The NRC staff evaluated this exception and determined that it is acceptable on the basis that it is consistent with SRP section 17.5, position II.S.4.c and RG 1.28, Revision 6, position C.1.a.

- Section 401, “Inspection and Test Personnel: (g)” of ASME NQA-1-2022, part I, requirement 2, requires the date of certification expiration be included on the qualification record. ENNN considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.

  The NRC staff evaluated this exception and determined that the date of certification establishes the expiration date when combined with the certification interval. The certification interval is normally a function of a code or standard and is identified in the organization’s procedure and having both dates on the form is redundant. The use of this exception was previously approved in the NRC SE for Kairos Power, LLC. (ML21308A597). The exception proposed by ENNN is consistent with that previously approved; therefore, the NRC staff determined this exception to be acceptable.

The NRC staff evaluated the description of measures that are established in the QAP for: (1) ensuring that activities affecting quality are accomplished under suitably controlled conditions; (2) developing and maintaining a list of SSCs and activities under the control of the ENNN QAPD in accordance with design documents; (3) identifying the scope of activities the ENNN QAPD is applicable to; (4) verifying the effective implementation of the QAP; and (5) establishing a training and qualification program for those personnel implementing elements of the ENNN QAPD. The NRC staff evaluated ENNN’s clarifications and exceptions to its commitment to compliance with ASME NQA-1-2022, part 1, requirement 2, and determined that they are acceptable.

The NRC staff determined that this description conforms to the guidance of SRP section 17.5, subsection II, item B, “Quality Assurance Program (Criterion II),” and item S, “Training and Qualification Criteria (Criterion II),” and item T, “Training and Qualification – Inspection and Test (Criterion II).”

Based on this evaluation and ENNN’s commitment to ASME NQA-1-2022, part I, requirement 2 and RG 1.28, Revision 6, including the evaluation of the clarifications and exceptions, the NRC staff determined that part II, section 2.0 of the ENNN QAPD complies with the requirements of Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50.

3.1.3 Design Control

Part II, section 3.0, “Design Control,” of the ENNN QAPD, states that ENNN has established and implemented a process to control the design, design changes, and temporary modifications of items that are subject to the provisions of the ENNN QAPD. The design process includes

provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces. Use of existing data will be performed in accordance with ASME NQA-1-2022, part IV, subpart 4.2.3, “Guidance on Qualification of Existing Data.” These provisions ensure that design inputs are correctly translated into design outputs so that the final design output contains or references appropriate acceptance criteria that can be related to the design input in sufficient detail to permit verification by inspection and test, as required. Deviations from the acceptance criteria are controlled. Applicable design inputs shall be identified and documented. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

Design change processes are detailed in procedures. Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design. Design changes and disposition of nonconforming items as “use as is” or “repair” are reviewed and approved by the design organization or by other organizations authorized by ENNN.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements.

Design analysis shall be sufficiently detailed such that a technically competent person in the subject matter can review and understand the analysis and verify the adequacy of the results without recourse to the originator.

Part II, section 3.2, “Design Verification,” of the ENNN QAPD, states that design processes provide for documented design verification to ensure that items, computer programs, and activities subject to the provisions of the ENNN QAPD are suitable for their intended application, consistent with their effect on safety. Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management. Design verification methods may include, but are not limited to, design reviews, alternate calculations, and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the item's intended use.

Part II, section 3.3, “Design Records,” of the ENNN QAPD, states that design records sufficient to provide evidence that the design was properly accomplished are maintained. These records include the final design output and any revisions thereto, as well as record the important design steps and the sources of input that support the final output. Design records shall be sufficiently detailed such that a technically qualified individual in the subject area can review and understand the analysis and verify the adequacy of the results without recourse to the analysis preparer.

In establishing its program for design control and verification, ENNN commits to comply with ASME NQA-1-2022, part I, requirement 3, “Design Control,” and part II, subpart 2.7, “Quality Assurance Requirements for Computer Software for Nuclear Facilities Applications,” part II, subpart 2.14, “Quality Assurance Requirements for Commercial Grade Items and Services,” and part II, subpart 2.20, “Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities,” without further clarifications or exceptions.

The NRC staff evaluated the description of design control measures that are established and determined that this description conforms to the guidance within SRP section 17.5, subsection II, item C, “Design Control and Verification (Criterion III).”

Based on this evaluation and ENNN’s commitment to comply with the requirements of ASME NQA-1-2022, part I, requirement 3, part II, subparts 2.7, 2.14, and 2.20, the NRC staff determined that part II, section 3.0 of the ENNN QAPD complies with the requirements of Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50.

3.1.4 Procurement Document Control

Part II, section 4.0, “Procurement Document Control,” of the ENNN QAPD states that ENNN has established the necessary measures and governing procedures to ensure that purchased items, computer programs, and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.

Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21) are invoked for procurement of items and services. Part 21 of 10 CFR requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to ensure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QAP that is determined to meet the applicable requirements of Appendix B to 10 CFR Part 50, or the supplier may work under the ENNN QAP.

Reviews of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

Part II, section 4.2 “NQA-1 Commitment/Exceptions,” of the ENNN QAPD states that ENNN commits to comply with ASME NQA-1-2022, part 1, requirement 4 with the following clarifications and exceptions:

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

The NRC staff evaluated this proposed clarification and determined that it provides adequate control for establishing and executing the responsibilities for the QAP. Criterion IV, “Procurement Document Control,” of Appendix B to 10 CFR Part 50, requires suppliers to have a QAP 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 (ML092650695), the NRC staff determined this clarification to be acceptable. Therefore, the NRC staff determined that this clarification is acceptable.

- Sections 300, "Procurement Document Review" and 400, "Procurement Document Changes" of ASME NQA-1-2022, part I, of requirement 4 require the review of procurement documents and changes thereto to ensure the inclusion of the appropriate technical and QA requirements prior to a contract award. ENNN may satisfy this requirement through the review of the procurement specification, when the specification contains the technical and QA requirements of the procurement.

The NRC staff evaluated this proposed clarification and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change to the contract, consistent with the SE described above. Therefore, the NRC staff determined that this clarification is acceptable.

- Procurement documents for commercial-grade items that will be procured for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with section 7.0, "Control of Purchased Material, Equipment and Services," of the ENNN QAPD.

The NRC staff evaluated this proposed clarification and determined that it is consistent with 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, and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, as delineated in the NRC staff's review guidance in SRP section 17.5, paragraphs II.V.1.d and II.V.1.e. Therefore, the NRC staff determined that this clarification is acceptable.

The NRC staff evaluated the descriptions of measures that are established to ensure that applicable regulatory requirements, design bases, and other requirements are included in procurement documents. The NRC staff evaluated ENNN's clarifications and exceptions to its commitment to comply with ASME NQA-1-2022, part 1, requirement 4, and determined that they are acceptable. The NRC staff determined that this description conforms to the guidance of SRP section 17.5, subsection II, item D, "Procurement Document Control (Criterion IV)."

Based on this evaluation and ENNN's commitment with ASME NQA-1-2022, part I, requirement 4, the NRC staff determined that part II, section 4.0 of the ENNN QAPD complies with the requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50.

3.1.5 Instructions, Procedures, and Drawings

Part II, section 5.0, "Instructions, Procedures, and Drawings," of the ENNN QAPD, states that the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures, or drawings, including, where applicable, quantitative or qualitative acceptance criteria to implement the QAP, are established. Provisions are included for reviewing, updating, and canceling such procedures.

This section also establishes the policies that procedures are followed, and in cases when a procedure cannot be followed as written, provisions are established for making changes in

accordance with part II, section 6.0, “Document Control,” of the ENNN QAPD. In addition, provisions are established for when personnel are authorized to depart from approved procedures in cases of emergency, when necessary to prevent injury to personnel or damage to the plant. Procedures governing tests, inspections, operational activities, and maintenance will include, as applicable, initial conditions and prerequisites for the performance of the activity.

Section 5.2, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to comply with NQA-1-2022, requirement 5 without further clarifications or exceptions.

The NRC staff evaluated the description of measures established for ensuring that activities affecting quality are prescribed by and performed in accordance with written procedures in part II, section 5.0 of the ENNN QAPD, and determined that this description conforms to the guidance of SRP section 17.5, subsection II, item E, “Instructions, Procedures, and Drawings (Criterion V).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, requirement 5, the NRC staff determined that part II, section 5.0 of the ENNN QAPD complies with the requirements of Criterion V, “Instructions, Procedures, and Drawings,” of Appendix B to 10 CFR Part 50.

3.1.6 Document Control

Part II, section 6.0, “Document Control,” of the ENNN QAPD, states that the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are established. This section specifies the controls that are applied to documents and the types of documents to which these controls apply. Part II, section 6.2, “Review and Approval of Documents,” of the ENNN QAPD specifies criteria for document review and approval. Part II, section 6.3, “Changes to Documents,” of the ENNN QAPD specifies criteria for revisions to documents, including the approval authority for changes. Changes to documents are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.

Section 6.4, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to comply with NQA-1-2022, requirement 6 for document control without further clarifications or exceptions.

The NRC staff evaluated the descriptions of measures and controls that are applied to the issuance and revisions to documents and determined that this description conforms to the guidance within SRP section 17.5, subsection II, item F, “Document Control (Criterion VI).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, requirement 6, the NRC staff determined that part II, section 6.0 of the ENNN QAPD complies with the requirements of Criterion VI, “Document Control,” of Appendix B to 10 CFR Part 50.

3.1.7 Control of Purchased Material, Equipment, and Services

Part II, section 7.0, “Control of Purchased Material, Equipment, and Services,” of the ENNN QAPD, states that the necessary measures and governing procedures to control purchased items and services to ensure conformance with specified requirements are established. Control includes source evaluation prior to a contract award and selection, the evaluation of objective

evidence of quality furnished by the supplier, source inspection, an audit, and the examination of items or services.

Measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item or service's importance to safety, complexity, quantity, and the frequency of procurement are established. Verification actions include testing, as appropriate, during design, fabrication, and construction activities.

Measures to ensure the quality of purchased items and services include:

- Inspections, identification, and storage of items to protect against damage, deterioration, or misuse.

- Evaluations of prospective safety-related items and service suppliers to ensure only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly changes the scope, methods, or controls performed by a supplier, an audit of the changes is performed, thus starting a new triennial period.

- Use of audits conducted by outside organizations for supplier qualifications provided that the scope and adequacy of the audits meet ENNN requirements.

- Use of documented annual evaluations for qualified suppliers to ensure they continue to provide acceptable products and services. Industry programs, such as those applied by Nuclear Procurement Issues Corporation (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 are 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.

- Provisions are used for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions should be established by the purchaser with the appropriate input from the supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to ensure that they will perform satisfactorily in service in safety-related applications.

- If there is insufficient evidence of implementation of a QAP, the initial evaluation is of the existence of a QAP addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QAP.

Section 7.3, “NQA-1 Commitment / Exceptions,” of the ENNN QAPD states that ENNN commits to compliance with ASME NQA-1-2022, part I, requirement 7 and RG 1.28, Revision 6 with the following clarifications and exceptions:

- Other 10 CFR Part 50 and 52 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to the ENNN plants are not required to be evaluated or audited.

The NRC staff’s current regulatory position regarding this exception is documented in a Tennessee Valley Authority’s (TVA) SE dated December 12, 2023 (ML23254A050). The NRC staff verified that the ENNN QAPD provided the same commitments associated with supplier oversight activities as those provided in the TVA New Nuclear QAPD. Therefore, the NRC staff’s position associated with this exception, as documented in the TVA New Nuclear QAPD SE, would apply to the ENNN QAPD. As discussed in the TVA SE pertaining to Part 50 and Part 52 power reactor licensees, each of these licensees’ QAPDs is approved by the NRC staff and subsequent changes to the QAPD can be made consistent with the requirements in 10 CFR 50.54(a) and 10 CFR 50.55(f), as applicable. Since this reasoning pertains to power reactor licensees, the NRC staff is limiting the proposed exception to other Part 50 and Part 52 power reactor licenses. This is identified as Limitation and Condition 1. The NRC staff concludes that the requested exception regarding the audit and evaluation is acceptable subject to the applicable limitations described in the TVA New Nuclear QAPD SE, which are included in the Limitations and Conditions section of this SE, for the control of purchased material, equipment, and services.

- 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 (MRA), ENNN will implement the guidance from Nuclear Energy Institute (NEI) 14-05 A, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1, dated September 2020.

In an NRC SE dated November 23, 2020 (ML20322A019), the NRC staff concluded that NEI 14- 05 A, Revision 1, provides an acceptable approach for licensees and suppliers of basic components for using the ILAC accreditation process in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process, provided certain conditions are met. The NRC staff evaluated this proposed clarification and determined that it is consistent with the NRC SE and the NRC staff’s endorsement of NEI 14-05 A, Revision 1 in RG 1.28, Revision 6, which is the NRC staff’s current regulatory position regarding the acceptability of procuring commercial-grade calibration and testing services from laboratories accredited by ILAC. Therefore, the NRC staff concluded that this clarification is acceptable.

- For section 501 of ASME NQA-1-2022, part I, requirement 7, documents may be stored in approved electronic media under ENNN or vendor control, not physically located on the plant site, but accessible from the prospective nuclear facility site. Following completion of the construction period, sufficient as-built documentation will be turned over to support operations. The records management system will provide for timely retrieval of necessary records.

The NRC staff evaluated this exception and determined that it meets Criterion VII, “Control of Purchased Material, Equipment, and Services” of Appendix B to 10 CFR Part 50. Criterion VII

requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. This provision would allow for accessing and reviewing the necessary procurement documents at the site before installation and use. The NRC staff's evaluation of ENNN's use of electronic records is documented in section 3.1.17 of this SE. Therefore, the NRC staff concluded that this exception is acceptable.

- In establishing commercial-grade item requirements, ENNN commits to comply with ASME NQA-1-2022 part II, subpart 2.14 with the clarification that:

    - 1) quality verification requirements are established and described in ENNN documents to provide the necessary assurance that an item will perform satisfactorily in service. These documents address determination of 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;

    - 2) ENNN will assume 10 CFR Part 21 reporting responsibility for all items that are dedicated as safety-related.

The purpose of 10 CFR Part 21 states that any individual director or responsible officer of a firm constructing, owning, operating, or supplying the components of any licensed or regulated facility or activity, who obtains information reasonably indicating: (a) that the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards; or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, must immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply."

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. Therefore, the NRC staff concluded that this clarification is acceptable.

- Remote vendor surveillance for source verification is allowed as an adequate dedication or acceptance process when a pandemic or similar state of emergency has been declared restricting access or travel to and/or from vendor locations affected by the declaration. The remote vendor surveillance will be in accordance with the Electric Power Research Institute (EPRI)'s April 2020 Final Report 3002019436, "Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance" to screen for eligibility, planning, performance using real time video, and documentation.

The ENNN QAPD provides for performing fully remote source verifications during exigent conditions in accordance with the guidance in EPRI Technical Report No. 3002019436, Revision 0, dated April 2020. The use of EPRI Technical Report No. 3002019436 was previously approved in an NRC SE for Columbia Generating Station (ML20203K876).

The NRC staff evaluated this clarification/exception and determined that it is acceptable on the basis that it is consistent with EPRI Technical Report No. 3002019436, which explains that the current available technologies can be effectively applied to sufficiently and successfully verify

certain activities. The NRC staff notes that the COVID-19 public health emergency (PHE) expired on May 11, 2023; therefore, the provisions for remote source verification under exigent conditions, as described above, can no longer be used unless new exigent conditions exist. The NRC staff evaluated the description of measures that are established to ensure control of purchased materials, equipment and services, and determined that this description conforms to the guidance in SRP section 17.5, subsection II, item G, “Control of Purchased Material, Equipment, and Services (Criterion VII).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, part I, requirement 7, and RG 1.28, Revision 6, including the evaluation of the clarifications and exceptions, the NRC staff determined that part II, section 7.0 of the ENNN QAPD complies with the requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50.

3.1.8 Identification and Control of Materials, Parts, and Components

Part II, section 8.0, “Identification and Control of Items,” of the ENNN QAPD, states that the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items are established. This includes controls for consumable materials and items with limited shelf-life. The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation, consistent with the item’s effect on safety. Identification locations and methods are selected so as not to affect the function or quality of the item. If at any time an item cannot be physically identified, that item shall be considered nonconforming requiring the preparation of a nonconformance report.

Section 8.2, “NQA-1 Commitment,” of the ENNN QAPD, states that ENNN commits to compliance with ASME NQA-1-2022, part I, requirement 8, without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to ensure identification and control of items to prevent the use of incorrect or defective items and determined that this description conforms to the guidance in SRP section 17.5, subsection II, item H, “Identification and Control of Materials, Parts, and Components (Criterion VIII).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, part I, requirement 8, the NRC staff determined that part II, section 8.0 of the ENNN QAPD complies with the requirements of Criterion VIII, “Identification and Control of Materials, Parts, and Components” of Appendix B to 10 CFR Part 50.

3.1.9 Control of Special Processes

Part II, section 9.0, “Control of Special Processes,” of the ENNN QAPD, states that the necessary measures and governing procedures to ensure that special processes that require interim process controls to ensure quality, such as welding, heat treating, and nondestructive examination, are established. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Processes are controlled by instructions, procedures, drawings, checklists, travelers, or other process control documentation. Records are to be maintained to document the qualified personnel, methods, and equipment for each special process.

Section 9.2, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to comply with ASME NQA-2022, part 1, requirement 9 without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to ensure special processes are controlled in accordance with procedures and instructions by qualified personnel and determined that this description conforms to the guidance in SRP section 17.5, subsection II, item I, “Control of Special Processes (Criterion IX).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, part 1, requirement 9, the NRC staff determined that part II, section 9.0 of the ENNN QAPD complies with the requirements of Criterion IX, “Control of Special Processes” of Appendix B to 10 CFR Part 50.

3.1.10 Inspection

Part II, section 10.0, “Inspection,” of the ENNN QAPD, states that the necessary measures and governing procedures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents are established. Inspection may also be applied to items, services, and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction, installation, maintenance, and modification activities. Inspections are carried out by qualified persons independent of those who performed or directly supervised the work.

The inspection program establishes inspections as necessary to verify quality: (1) at the source of supplied items or services; (2) in-process during fabrication at a supplier’s facility or at a ENNN facility; (3) for final acceptance of fabricated and/or installed items during construction; (4) upon receipt of items for a facility; and 5) during maintenance and modification activities.

The inspection program establishes requirements for: (1) planning inspections; (2) where inspection hold points are to be applied; (3) determining applicable acceptance criteria; (4) the frequency of inspection; and (5) the identification of special tools needed to perform the inspection.

Inspection records identify the item inspected, the date of inspection, the inspector’s identity, the type of observation, the inspection results and acceptability, and reference information on actions taken in connection with nonconformances. Inspection results are reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results.

Modifications, repairs, rework, or replacements to items that have already been inspected shall require a re-inspection to the extent necessary based on the modification, repair, rework, or replacement. If the inspection of items is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both.

Qualification programs for personnel performing quality inspections are established. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

Section 10.4, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to

compliance with ASME NQA-1-2022, part I, requirement 10 and part II, subparts 2.5, “Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities,” and 2.8, “Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Items for Nuclear Facilities,” without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to verify that inspection activities affecting quality conform with documented instructions, procedures, and drawings, and determined that this description conforms to the guidance in SRP section 17.5, subsection II, item J, “Inspection (Criterion X).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, part 1, requirement 10 and part II, subparts 2.5 and 2.8, the NRC staff determined that part II, section 10.0 of the ENNN QAPD complies with the requirements of Criterion X, “Inspection” of Appendix B to 10 CFR Part 50.

3.1.11 Test Control

Part II, section 11.0, “Test Control,” of the ENNN QAPD states that the necessary measures and governing procedures to demonstrate that items subject to the provisions of the ENNN QAPD will perform satisfactorily in service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant is satisfactory, are established. These programs include criteria for determining when testing is required, such as proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, in-service tests, and operational tests, to demonstrate that the performance of plant systems is in accordance with the design.

Tests are performed in accordance with applicable procedures that include: 1) instructions and prerequisites to perform the test, 2) use of proper test equipment, 3) acceptance criteria, 4) mandatory verification points as necessary to confirm satisfactory test completion, 5) any special qualification requirements for personnel, and 6) any special environmental conditions. Test results are documented, maintained, and evaluated by the organization performing the test and reviewed by a responsible authority to ensure that the test requirements have been satisfied. If acceptance criteria are not met, retesting is performed as needed to confirm acceptability following the correction of the system or equipment deficiencies that caused the failure. Test programs ensure the appropriate retention of test data in accordance with the records requirements of the ENNN QAPD.

Section 11.2, “NQA-1 Commitment for Computer Program Testing,” of the ENNN QAPD states that provisions to ensure that computer software used in applications affecting safety is prepared, documented, verified, tested, and used such that the expected output is obtained, and configuration control is maintained, are established.

Section 11.2 and section 11.3, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to compliance with ASME NQA-1-2022, part 1, requirement 11 for test control. In addition, ENNN commits to comply with applicable provisions in ASME NQA-1-2022, part II, subpart 2.7, “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications,” for establishing provisions for computer program testing, without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to ensure that all

testing required to demonstrate SSCs will perform satisfactorily and determined that this description conforms to the guidance in SRP section 17.5, subsection II, item K, “Test Control (Criterion XI).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, part I, requirement 11, and applicable provisions of part II, subpart 2.7, the NRC staff determined that part II, section 11.0 of the ENNN QAPD complies with the requirements of Criterion XI, “Test Control,” of Appendix B to 10 CFR Part 50.

3.1.12 Control of Measuring and Test Equipment

Part II, section 12.0, “Control of Measuring and Test Equipment,” of the ENNN QAPD states that 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 that acceptance criteria are met or the information that is important to safe plant operation are established. The provisions of such procedures cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and nondestructive examination equipment.

M&TE are calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards if such standards exists or to a documented basis otherwise.

Section 12.2, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to comply with NQA-1-2022, requirement 12, without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to control M&TE used in activities affecting quality and determined that this description conforms to the guidance in SRP section 17.5, subsection II, item L, “Control of Measuring and Test Equipment (Criterion XII).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, requirement 12, the NRC staff determined that part II, section 12.0 of the ENNN QAPD complies with the requirements of Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50.

3.1.13 Handling, Storage, and Shipping

Part II, section 13.0, “Handling, Storage, and Shipping,” of the ENNN QAPD states that the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration are established. These provisions include specific procedures when required to maintain acceptable quality of the items that are important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item’s integrity and indicate the need for special controls. Special controls are provided when required to maintain acceptable quality.

This section also describes controls for special handling tools and equipment, and hoisting, rigging, and transportation activities. Section 13.2, “Housekeeping,” describes the housekeeping practices that are established to account for conditions or environments that could affect the quality of SSCs within the plant, including controls for the cleanliness of facilities and materials,

fire prevention and protection, disposal of combustible material and debris, control of access to work areas, and protection of equipment.

Section 13.3, “NQA-1 Commitment/Exceptions,” of the ENNN QAPD states that ENNN commits to comply with ASME NQA-1-2022, requirement 13. During the construction of the plant, ENNN also commits to comply with ASME NQA-1-2022, part II, subpart 2.1, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Facilities,” subpart 2.2, “Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities,” subpart 2.3, “Quality Assurance Requirements for Housekeeping at Nuclear Facilities,” and part III, subpart 3.2-2.1, “Implementing Guidance for Part II, Requirement 2.1: Cleaning of Fluid Systems,” with the following clarifications and exceptions:

- ASME NQA-1-2022, part II, subpart 2.1, section 301, “Cleanness Classification” and section 302, “Cleanness Criteria” establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of subpart 2.1, cleanness requirements may be established on a case-by-case basis, consistent with the other provisions of subpart 2.1. Appropriate cleanliness controls for work on safety-related equipment are established to minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of the absence of foreign material prior to system closure.

The NRC staff evaluated this proposed exception and determined that it is consistent with the NRC staff’s review guidance provided in SRP section 17.5. In addition, this exception was previously approved in an NRC SE for Nuclear Management Company (NMC) (ML050700416). Therefore, the NRC staff concluded that this exception is acceptable.

- For ASME NQA-1-2022, part II, subpart 2.2, section 309, “Marking”, ENNN commits to RG 1.28, Revision 6.

The NRC staff evaluated this clarification and determined that it is acceptable on the basis that it is consistent with RG 1.28, Revision 6. The specific condition in RG 1.28, Revision 6 states that “Etching should not be used on nickel alloys, weld areas, or sensitized areas of stainless steel.”

- ASME NQA-1-2022, part II, subpart 2.2, section 606, “Storage Records,” requires written records to be prepared to contain information on personnel access. As an alternative to this requirement, controls are established for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. These records of access are not considered quality records and will be retained in accordance with administrative controls of the applicable plants.

In an NRC SE (ML13164A017) for Technical Report NEI 06-14, the NRC staff evaluated this proposed exception and determined that these records of access are not considered quality records. The NRC staff evaluated this exception and determined that these records do not meet the classification of a quality record as defined in NQA-1-2022, requirement 17, “Quality Assurance Records.” Therefore, the NRC staff concluded that this exception is acceptable.

- ASME NQA-1-2022, part II, subpart 2.3, section 202, “Classification of Cleanness,” requires the establishment of five zone designations for housekeeping cleanliness

> controls. Instead of the five-level zone designation, control over housekeeping activities is based on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions which, in the case of maintenance or modification work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible.

The NRC staff evaluated this exception and determined that it is consistent with the NRC staff's review guidance in SRP section 17.5. In addition, this exception was previously approved in the NRC staff's SE for NMC (ML050700416). Therefore, the NRC staff concluded that this exception is acceptable.

The NRC staff evaluated the description of measures that are established to control the handling, storage, package, shipping, cleaning, and preservation of material and equipment to prevent damage or deterioration. The NRC staff evaluated ENNN's clarifications and exceptions to its commitment to comply with NQA-1-2022, part II, subparts 2.1, 2.2, 2.3, and Part III, subpart 3.2-2.1, and determined that they are acceptable. The NRC staff determined that this description conforms to the guidance of SRP section 17.5, Subsection II, Item M, "Handling, Storage and Shipping (Criterion XIII)."

Based on this evaluation and ENNN's commitment to comply with ASME NQA-1-2022, part I, requirement 13, part II, subpart 2.1, subpart 2.2 and subpart 2.3, and part III, subpart 3.2-2.1, including the evaluation of the clarifications and exceptions, the NRC staff determined that part II, section 13.0 of the ENNN QAPD complies with the requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50.

3.1.14 Inspection, Test, and Operating Status

Part II, section 14.0, "Inspection, Test, and Operating Status," of the ENNN QAPD, states that the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the ENNN QAPD in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment, are established. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test, or operating status to be verified before release, fabrication, receipt, installation, test, or use. This section also describes the controls for temporary design changes or modifications, as well as controls for altering the sequence of required tests, inspections, and other operations.

Section 14.2, "NQA-1 Commitment," of the ENNN QAPD states that ENNN commits to comply with ASME NQA-1-2022, part I, requirement 14 without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to: 1) indicate the status of inspections and tests performed of items and components, 2) preclude inadvertent bypassing of inspections or tests, or inadvertent operation of items and components, and 3) control temporary changes or modifications. The NRC staff determined that this description conforms to the guidance of SRP section 17.5, subsection II, item N, "Inspection, Test, and Operating Status (Criterion XIV)."

Based on this evaluation and ENNN's commitment to comply with ASME NQA-1-2022, part I,

requirement 14, the NRC staff determined that part II, section 14.0 of the ENNN QAPD complies with the requirements of Criterion XIV, “Inspection, Test, and Operating Status,” of Appendix B to 10 CFR Part 50.

3.1.15 Nonconforming Materials, Parts, or Components

Part II, section 15.0, “Control of Nonconforming Items,” of the ENNN QAPD states that the necessary measures and governing procedures to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use, are established. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of part II, section 16.0, “Corrective Action,” of the ENNN QAPD. Controls are established to identify, document, evaluate, segregate, and dispose of nonconforming items. Controls are provided for the conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition, with requirements for documenting the basis for such conditional release.

Nonconformances dispositioned as repair or use-as-is, are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy and analysis of quality trends, and are reported to the designated management. Significant trends are reported to management in accordance with procedures, regulatory requirements, and industry standards.

Section 15.2, “Interface with the Reporting Program,” of the ENNN QAPD states that appropriate interfaces for the identification and control of nonconforming materials, parts, or components to satisfy the requirements of 10 CFR 50.55, and 10 CFR Part 21 are established during design and construction.

Section 15.3, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to comply with ASME NQA-1-2022, part I, requirement 15 without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to control materials, parts, or components that do not conform to requirements in order to prevent their inadvertent use. The NRC staff determined that this description conforms to the guidance of SRP section 17.5, subsection II, item O, “Nonconforming Materials, Parts, or Components (Criterion XV).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, part I, requirement 15, the NRC staff determined that part II, section 15.0 of the ENNN QAPD complies with the requirements of Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50.

3.1.16 Corrective Action

Part II, section 16.0, “Corrective Action,” of the ENNN QAPD states that the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality are established. Procedures ensure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. Procedures require personnel to identify known conditions adverse to quality. Conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant

condition adverse to quality, the cause is determined and actions to preclude recurrence are taken. In the case of suppliers working on safety-related activities, or other similar situations, ENNN may delegate specific responsibilities for corrective actions, but ENNN maintains responsibility for the effectiveness of corrective action measures.

Section 16.2, “Interface with the Reporting Program,” of the ENNN QAPD states that appropriate interfaces for corrective actions to satisfy the requirements of 10 CFR 50.55, and 10 CFR Part 21, are established.

Section 16.3, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to comply with ASME NQA-1-2022, part I, requirement 16 without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to ensure that: 1) conditions adverse to quality are promptly identified and corrected, and 2) the cause of significant conditions adverse to quality is determined and corrective actions to preclude repetition are implemented. The NRC staff determined that this description conforms to the guidance of SRP section 17.5, subsection II, item P, “Corrective Action (Criterion XVI).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, part I, requirement 16, the NRC staff determined that part II, section 16.0 of the ENNN QAPD complies with the requirements of Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50.

3.1.17 Quality Assurance Records

Part II, section 17.0, “Quality Assurance Records,” of the ENNN QAPD, states that the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, revised, and maintained to reflect that completed work are established. The provisions of such procedures establish the scope of the records retention program and include requirements for record administration, receipt preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

Measures are established to ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, manufacturing, construction, installation, inspection and test, and audits and their retention times are defined in appropriate procedures. Records and retention times are based on regulatory position C.3 of RG 1.28, Revision 6, for design and construction.

Records are stored in a manner that minimizes the risk of loss, damage, or destruction from natural disasters, environmental conditions, infestation of insects, mold or rodents, and dust or airborne particles. In general, records are maintained electronically. Where paper records are maintained, they are stored in an appropriate storage facility. Storage of final records are also established for single storage facilities and dual storage facilities.

Section 17.3, “Electronics Records,” of the ENNN QAPD states that the provisions are applied to electronic records. The storage of electronic records is managed in accordance with the Nuclear Information and Records Management Association, Inc. (NIRMA) guidelines, as approved by RG 1.28, Revision 6.

Section 17.4, “NQA-1 Commitment,” of the ENNN QAPD states that ENNN commits to comply with ASME NQA-1-2022, part I, requirement 17 and Staff Regulatory Guidance in RG 1.28,

Revision 6, without further clarifications or exceptions.

The NRC staff evaluated the description of measures that are established to ensure that sufficient records are maintained to furnish evidence of activities affecting quality. The NRC staff determined that this description conforms to the guidance of SRP section 17.5, subsection II, item Q, “Quality Assurance Records (Criterion XVII).”

Based on this evaluation and ENNN’s commitment to comply with ASME NQA-1-2022, part I, requirement 17 and RG 1.28, Revision 6, the NRC staff determined that part II, section 17.0 of the ENNN QAPD complies with the requirements of Criterion XVII, “Quality Assurance Records,” of Appendix B to 10 CFR Part 50.

3.1.18 Audits

Part II, section 18.0, “Audits,” of the ENNN QAPD states that the necessary measures and governing procedures to implement audits to verify that activities covered by the ENNN QAPD are performed in conformance with the established requirements and performance criteria are met, are established.

Internal audits of selected aspects of licensing, design, and construction activities are performed with a frequency commensurate with safety significance and in a manner which ensures that audits of safety-related activities are completed. During the early portions of site characterization and construction activities, audits will focus on areas including, but not limited to, site investigation, procurement, and corrective action. The audits are scheduled on a formal preplanned audit schedule and in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the QA Manager.

ENNN is responsible for conducting periodic internal audits to determine the adequacy of programs and procedures, and to determine if they are meaningful and comply with the overall ENNN QAPD. The results of each audit are reported in writing to the QA Manager or designee as appropriate. Additional internal distribution is made to other concerned management levels and to the management of the internal audited organizations or activities in accordance with the approved procedures. Audit reports shall include a summary of the audit results, including a statement on the effectiveness of the elements audited, as well as a description of each reported adverse audit finding.

Internal audits of activities conducted prior to placing the facility in operation are performed in such a manner as to ensure that an audit of all applicable QAP elements occurs at least once each year or at least once during the life of the activity, whichever is shorter.

Section 18.4, “NQA-1 Commitment/Exceptions,” states that in establishing the independent audit program, ENNN commits to comply with ASME NQA-1-2022, part I, requirement 18 and the regulatory Positions stated in RG 1.28, Revision 6, with the following exception:

- Under exigent conditions such as a severe local or national public health concern, a natural disaster, or a declaration of a national emergency, the audit or survey internal

may be extended up to 25 percent. Under these exigent conditions, the audit performed within this extension resets the triennial clock. The 25 percent grace period extension is applicable to domestic and international suppliers. During the use of the 25 percent extension, an evaluation of the supplier's program shall be performed, and the documented results are used to determine any necessary adjustments to their qualification status. Suppliers on the Approved Supplier List may be maintained during the 25 percent extension period provided that the following steps are taken:

1) Verification that:

   a) The supplier is still implementing a QAP that meets 10 CFR 50, Appendix B or

   b) Commercial suppliers surveyed are still maintaining adequate controls for activities affecting quality.

2) On-going and previous supplier performance is promptly monitored considering the impact of the following types of information:

   a) Results of receipt inspection activities or other operating experience.

   b) Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.

   c) Results of audits and inspections from other sources (e.g., customer, NUPIC, Nuclear Industry Assessment Corporation audits or NRC inspections).

3) In the event of a new procurement activity or change to existing procurements that significantly extends the scope or changes the method/controls for activities performed by the supplier, the evaluation shall document the justification that the change(s) are adequately addressed by the supplier's QAP or mitigating actions are taken by ENNN.

4) Evaluation of any significant open issues with the NRC, 10 CFR Part 21 Notifications, and any open findings since the previous triennial audits describing impact on the items/services being procured from that supplier.

5) Review of the procurement history since the last triennial audit/survey including the receipt inspection results to identify any potential issues. The results of the performance history must be included in the evaluation.

6) The degree of standardization of the items being procured. For instance, suppliers of catalog items which are used across multiple industries with widely accepted good performance histories would be considered good candidates for a 25 percent (9-month) grace period.

The NRC staff evaluated this exception to its commitment to comply with ASME NQA-1-2022, part I, requirement 18 and determined that it is acceptable on the basis that it is consistent with an approved NRC SE (ML20216A681) for audits under exigent conditions.

The NRC staff notes that the COVID-19 PHE expired on May 11, 2023; therefore, the provisions

for an audit extension under exigent conditions, as described above, can no longer be used unless new exigent conditions exist.

The NRC staff evaluated the description of measures that are established to ensure that planned and periodic audits are carried out to verify compliance with all aspects of the QAP and to determine the effectiveness of the audit program. The NRC staff determined that this description conforms to the guidance in SRP section 17.5, subsection II, item R, "Audits (Criterion XVIII)."

Based on this evaluation and ENNN's commitment to comply with ASME NQA-1-2022, part I, requirement 18, including the evaluation of the clarifications and exceptions, the NRC staff determined that part II, section 18.0 of the ENNN QAPD complies with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

3.2 Quality Control for SSCs that are Not Safety-Related

The ENNN QAPD does not include a section to address non-safety-related SSCs that are significant contributors to plant safety. As stated in SRP section 17.5, Item U, "Non-Safety-Related SSCs that are significant contributors to plant safety," the review of quality controls for these SSCs is applicable to design certifications and combined licenses. The NRC staff finds the ENNN approach acceptable because ENNN intends to only use the ENNN QAPD for a CP.

Part III, "Non-Safety-Related SSC Quality Control", section 1.0, "Non-safety-related SSCs – Credited for Regulatory Events," of the ENNN QAPD states that for those SSCs that are not safety-related but are credited to meet the regulations in, the following criteria apply:

- Under 10 CFR 50.48 for fire protection equipment, quality requirements are implemented in accordance with Staff Regulatory Position 1.7, "Quality Assurance," of RG 1.189, "Fire Protection for Nuclear Power Plants," Revision 5, dated October 2023.

- Under 10 CFR 50.62 for anticipated transients without scram (ATWS) equipment, quality requirements are implemented in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment that is Non Safety Related," dated April 1985.

- Under 10 CFR 50.63 for the station blackout (SBO) equipment, quality requirements are implemented in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment that is not Safety-Related," and appendix A, "Quality Assurance Guidance for Nonsafety Systems and Equipment," in RG 1.155, "Station Blackout," Revision 0, dated August 1988.

The NRC staff evaluated the descriptions in part III, section 1.0 of the ENNN QAPD for equipment that are not safety-related but are credited for certain regulatory events, as listed above, and determined that these descriptions conform to the guidance in SRP section 17.5, subsection II, item U.

3.3 Regulatory Commitments

Part IV, "Regulatory Commitments" of the ENNN QAPD states that ENNN identifies the extent of conformance with the following NRC RGs and QA standards or within applicable license application documents, with certain clarifications and exceptions, as described below:

- RG 1.8, “Qualification and Training of Personnel for Nuclear Power Plants,” Revision 4, dated June 2019.

  The ENNN QAPD states that conformance and exceptions for the applicable regulatory position guidance in this RG are identified in applicable license applications such as safety analysis reports (SARs).

- RG 1.26, “Quality Group Classifications and Standards for Water, Steam, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” Revision 6, dated December 2021.

  The ENNN QAPD states that conformance and exceptions for the applicable regulatory position guidance in this RG are identified in applicable license applications such as SARs.

- RG 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 6, dated September 2023.

  The ENNN QAPD states that conformance and exceptions for the applicable regulatory position guidance in this RG are identified in the QAPD.

- RG 1.29, “Seismic Design Classification,” Revision 6, dated July 2021.

  The ENNN QAPD states that conformance and exceptions for the applicable staff regulatory guidance in this RG are identified in applicable license applications such as SARs.

- RG 1.54, “Service Level I, II, III, and In-Scope License Renewal Protective Coatings Applied to Nuclear Power Plants,” Revision 3, dated April 2017.

  The ENNN QAPD states that conformance and exceptions for the applicable staff regulatory guidance in this RG are identified in applicable license applications such as SARs.

- RG 1.87, “Acceptability of ASME Code, Section III, Division 5, “High Temperature Reactors,”” Revision 2, dated January 2023.

  The ENNN QAPD states that RG 1.87, appendix A provides guidance on establishing quality group assignments of mechanical systems and components of non-light-water reactors acceptable to the NRC staff for all the safety classification methods. ENNN follows the risk-informed classification method described in RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.”

  The ENNN QAPD states that conformance and exceptions for the applicable staff regulatory guidance in this RG are identified in applicable license applications such as SARs.

- RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plant,” Revision 1, dated April 2024.

  The ENNN QAPD states that conformance and exceptions for the applicable staff regulatory guidance in this RG are identified in applicable license applications such as SARs.

- RG 1.231, “Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants,” Revision 0, dated January 2017.

  The ENNN QAPD states that conformance and exceptions for the applicable staff regulatory guidance in this RG are identified in applicable license applications such as SARs.

- RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.”

  The ENNN QAPD states that conformance and exceptions for the applicable staff regulatory guidance in this RG are identified in applicable license applications such as SARs.

- RG 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21,” Revision 1, dated March 2024.

  The ENNN QAPD states that conformance and exceptions for the applicable staff regulatory guidance in this RG are identified in applicable license applications such as SARs.

- ASME NQA-1-2022 - Quality Assurance Requirements for Nuclear Facility Applications.

  ENNN commits to ASME NQA-1-2022 as described in the ENNN QAPD.

- Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs).

  ENNN commits to NIRMA TGs as described in part II, section 17.0 of the ENNN QAPD.

- NEI 14-05 A, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1.

  ENNN commits to NEI 14-05 A, Revision 1, as described in section 7.0 of the ENNN QAPD.

The NRC staff evaluated the RGs and standards described in part IV of the QAPD and determined that they conform to the guidance of SRP section 17.5, subsection II, item V, “Quality Assurance Program Commitments,” and are consistent with NRC endorsed standards.

4.0 CONCLUSION

The ENNN QAPD delineates the policies, processes, and controls for QA requirements established by ENNN. The ENNN QAPD provides for the control of activities that affect the quality of safety-related SSCs and includes all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service.

The NRC staff used the acceptance criteria set forth in SRP section 17.5 as the basis for evaluating the compliance of the ENNN QAPD, with the provisions of Appendix B to 10 CFR Part 50 and concludes that the ENNN QAPD satisfies the acceptance criteria in SRP section 17.5. The NRC staff concludes the ENNN QAPD meets the requirements in Appendix B to 10 CFR Part 50, and is therefore acceptable.

5.0 LIMITATIONS AND CONDITIONS

The approval of this TR is only for the activities associated with the design, construction, and fabrication activities. As referenced in section 3.1 of this SE, the NRC has identified the following limitations associated with ENNN's QAPD:

1) The exception to not perform an audit or evaluation for procurements from other Part 50 and Part 52 licensees only applies when ENNN procures from other 10 CFR Part 50 and 52 power reactor licensees.

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

6.0 REFERENCES

1. Energy Northwest Letter to the US NRC, "Energy Northwest New Nuclear Quality Assurance Topical Report Rev. 0 (Project #99902130)," dated December 17, 2024 (ML24352A486).

2. US NRC Letter to the Energy Northwest, "Draft Request for Additional Information by the Office of Nuclear Reactor Regulation, EN Quality Assurance Program Description (Topical Report)" Energy Northwest Docket No. 99902130) (ML25091A131).

3. Energy Northwest Letter to the US NRC, "Energy Northwest New Nuclear LLC Quality Assurance Topical Report Rev. 1 (Project #99902130)," dated May 12, 2025 (ML25132A315).

4. Energy Northwest Letter to the US NRC, "Energy Northwest New Nuclear LLC Quality Assurance Topical Report Rev. 2 (Project #99902130)," dated July 15, 2025 (ML25196A303).

5. NUREG-0800, Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," Revision 1, dated August 2015 (ML15037A441).

6. RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 6, dated October 2017 (ML17207A293).

7. ASME NQA-1-2022, “Quality Assurance Program Requirements for Nuclear Facilities.”

8. NEI 11-04 A, “Nuclear Generation Quality Assurance Program Description,” Revision 0, dated May 2011 (ML13164A017).

9. NEI 14-05 A, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1, dated September 2020 (ADAMS Accession No. ML20259B731).

10. EPRI 3002019436-A, “Remote Source Verification During a Pandemic or Similar State of Emergency, Screening Criteria and Process Guidance,” dated October 2020 (ML20300A386).

11. US NRC SE, “Final Safety Evaluation for Technical Report NEI 11-04, “Quality Assurance Program Description,” Revision 0,” dated May 9, 2013 (ML13023A051).

12. US NRC SE, “Final Safety Evaluation by the Office of Nuclear Reactor Regulation for the Nuclear Energy Institute Technical Report 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 2020 (ML20322A019).

13. US NRC SE, “Safety Evaluation by the Office of Nuclear Reactor Regulation Proposed Revision 25 to the Rochester Gas and Electric Corporation Quality Assurance Program for Station Operation R.E. Ginna Nuclear Power Plant,” dated July 22, 1998 (ML101820108).

14. US NRC SE, “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, (ML23254A050).

15. US NRC SE, “Columbia Generating Station – Correction to Reduction in Commitment to the Operational Quality Assurance Program Description [Covid-19]),” dated July 22, 2020 (ML20203K876).

16. US NRC SE, “Approval of Nuclear Management Company Quality Assurance Topical Report,” dated March 24, 2005 (ML050700416).

17. US NRC SE, “Final Safety Evaluation for Technical Report NEI 06-14, “Quality Assurance Program Description,” dated April 25, 2007 (ML13311C594).

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