DRAFT REQUEST FOR ADDITIONAL INFORMATION
BY THE OFFICE OF NUCLEAR REACTOR REGULATION
EN QUALITY ASSURANCE PROGRAM DESCRIPTION (TOPICAL REPORT)
ENERGY NORTHWEST
DOCKET NO. 99902130
ISSUE DATE: N/A

Background

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

The Quality Assurance Program Description (QAPD) submitted by New Nuclear describes methods 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 American Society of Mechanical Engineers (ASME) NQA-1 2022, "Quality Assurance Program Requirements for Nuclear Facility Applications."

It also states that the QAPD was prepared using the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," ASME NQA-1-2022, Parts I and II, with specific reference to selected Parts III and IV appendices, and Regulatory Guide (RG) 1.28, Revision 6, "Quality Assurance Program Criteria (Design and Construction)."

Regulatory Basis

The NRC staff reviewed the information provided in the QAPD against the quality assurance (QA) requirements in Appendix B to 10 CFR Part 50, and in accordance with the review guidance in Standard Review Plan (SRP) Section 17.5, Revision 1. Based on this review, the NRC staff requests additional information, as documented in the questions below, to complete its review.

Question 1

Part I, Executive Summary of the QAPD states that:

"This Quality Assurance Program Description (QAPD) for plant design and construction identifies the basis of the Energy Northwest (EN) New Nuclear (New Nuclear) Quality Assurance Program (QAP) and its application to the development of projects that EN may engage in."

Part I, Section 2.1 of the QAPD states that:

"The QAPD applies to nuclear-related construction permit, construction, and pre-operational activities affecting the quality and performance of safety-related structures, systems, and components…"

The two sections above include different information. The NRC staff requests New Nuclear to clarify what application(s) New Nuclear intends to apply and use this QAPD for.

In addition, the NRC staff would like to discuss which entity will be the applicant for the construction permit as it is unclear in the QAPD.

Question 2

Part II, Section 2.0 “Quality Assurance Program,” of the QAPD, Subsection 2.1.2 states that:

“A list or system that identifies SSCs and activities to which this program applies is maintained at New Nuclear facilities or by the Reactor Technology Provider.” The staff notes that this information needs to be maintained at the facility by the applicant not the Reactor Technology Provider. 10 CFR 50.34(f)(3)(ii) requires that "the quality assurance (QA) list required by Criterion II... includes all structures, systems, and components important to safety."

Appendix B to 10 CFR Part 50, Criterion II, “Quality Assurance Program,” states “The applicant shall identify the structures, systems, and components to be covered by the quality assurance program ...”

A list of system that identifies SSCs to which the QAPD is applicable should be maintained and controlled at a facility by New Nuclear (the applicant). The NRC staff requests New Nuclear to address who is responsible for maintenance of the list or system that identifies SSCs in the QAPD.

Question 3

Part II, Section 7.3, “NQA-1 Commitment/Exceptions” of the QAPD provides a list of exceptions to NQA-1 commitments, specifically, bullet 2) states:

> “Subpart 2.19 of NQA-1-2022 will not be implemented. Instead, the requirements of revision 1 of NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” as endorsed by the NRC, for the use of accreditation in lieu of commercial grade surveys in procuring laboratory calibration and test services is implemented.”

NRC Safety Evaluation (ADAMS Accession No. ML20322A019) endorses the use of NEI 14-05A, Revision 1, dated September 2020, with additional provisions the licensee shall follow. The provisions state:

> “The method to use accreditation by an ILAC MRA signatory in lieu of a commercial-grade survey (alternative method) is documented in the licensee and/or supplier of basic components’ QA program.”

Specifically, the following information needs to be in the QAPD or to implementing procedures:

> 1) The method to use accreditation by an ILAC MRA signatory in lieu of a commercial grade survey (alternative method) is documented in the purchaser’s QA program.1) The method to use accreditation by an ILAC MRA signatory in lieu of a commercial grade survey (alternative method) is documented in the purchaser’s QA program.

2) The method the purchaser needs to follow, and document in their QA program, consists of:

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

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

2. The purchase documents require that:

a. The service must be provided in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.
b. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance. (for calibration services only)
c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration. (for calibration services only)
d. Subcontracting of these accredited services is prohibited.
e. The customer must be notified of any condition that adversely impacts the laboratory’s ability to maintain the scope of accreditation.
f. Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the Accreditation Body within the past 48 months.
g. Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

3. It is validated, at receipt inspection, that the laboratory’s documentation certifies that:3. It is validated, at receipt inspection, that the laboratory’s documentation certifies that:

a. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and
b. The purchase order’s requirements are met.

The NRC staff requests New Nuclear to add the conditions above in the QAPD, or in New Nuclear's implementing procedures. If the implementing procedures are used, the QAPD shall

indicate that the conditions from the NRC safety evaluation are included in the implementing procedures.

In addition, the NRC staff notes that there are two versions of NEI 14-05A, Revision 1, the initial version is dated May 2020, and a second version is dated September 2020. The NRC staff requests New Nuclear to specifically state in the QAPD that NEI 14-05A, Revision 1, dated September 2020 is committed to and referenced in the QAPD.

Question 4

Part II, Section 10.4 “NQA-1 Commitment” of the QAPD states that

“In establishing inspection requirements, New Nuclear commits to compliance with NQA 1-2022, Part I Requirement 10, and NQA-1-2022 Part II Subparts 2.5 and 2.8 for establishing appropriate inspection requirements.”

RG 1.28, Revision 6, Position C.6 states that:

“Codes and standards are referenced or invoked throughout Subpart 2.5. When the referenced or invoked code or standard becomes superseded or canceled, licensees or applicants should submit their proposed alternative for NRC review and approval, as appropriate, for continued use of the code or standard or a proposed alternative.”

The NRC staff requests New Nuclear to address if New Nuclear intends to follow this provision in RG 1.28, Revision 6. If so, please add the commitment to RG 1.28 Revision 6 to Section10.4 similar to Section 2.8, NQA-1 Commitments / Exceptions.

Question 5

Part II, Section 13.0 “Handling, Storage, and Shipping” of the QAPD provides the requirements for handling, storage, packaging, shipping, cleaning, and preservation of items. In Part II, Section 13.3, “NQA-1 Commitment/Exceptions,” New Nuclear also states that

“In establishing provisions for handling, storage, and shipping, New Nuclear commits to compliance with NQA-1-2022, Part I Requirement 13. New Nuclear also commits, during the construction phase of the plant, to compliance with the requirements of NQA-1-2022, Part II Subpart 2.1, Subpart 2.2, and Subpart 2.3, and NQA-1-2022 Part III Subpart 3.2-2.1, with the following clarifications and exceptions.

Paragraph 309, “Marking” under NQA-1, Part II, Subpart 2.2, “Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities” specifically states that

“Etching, including electrochemical etching on nickel alloys, weld areas, or sensitized areas of stainless steel, may only be used, provided appropriate cleaning is performed of etching solutions.”

RG 1.28, Revision 6, Position C.5 provides the following condition:

“Etching should not be used on nickel alloys, weld areas, or sensitized areas of stainless steel.”

The NRC staff requests New Nuclear to address if etching of items on nickel alloys, weld areas, or sensitized areas of stainless steel will be used. If etching is prohibited consistent with the RG, please add a commitment to RG 1.28 Revision 6 in section 13.3.

Question 6

Part II, Section 18.4 of the QAPD describes NQA-1 commitments and exceptions under Appendix B to 10 CFR Part 50 Criterion XVIII, "Audits." Subsection 18.4.1 specifically details the commitment/exceptions to extend audit or survey interval up to 25% under exigent conditions.

The third bullet states that:

During the use of the 25% extension, an evaluation of the supplier's program shall be performed, and the documented results used to determine any necessary adjustments to their qualification status. Suppliers on the Approved Supplier List (ASL) may be maintained during the 25% extension period provided the following actions (1 – 3) are taken and the results satisfactory:

1) Verification that:

a. The supplier is still implementing a quality assurance program that meets 10 CFR 50 Appendix B or
b. Commercial suppliers surveyed are still maintaining adequate controls for activities affecting quality.

2) Monitor on-going and previous supplier performance promptly 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, Nuclear Procurement Issues Corporation (NUPIC), Nuclear Industry Assessment Corporation (NIAC) 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 quality assurance program or mitigating actions are taken by New Nuclear.

The NRC staff approved such audit extension during exigent conditions in an NRC Safety Evaluation (ADAMS Accession No. ML20216A681). In this Safety Evaluation, there are other conditions imposed in order to use this 25% audit extension that are not in Section 18.4, such as:

1) 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.

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

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

The NRC staff requests New Nuclear to address these conditions from the Safety Evaluation in order to properly incorporate the NRC approved alternative.

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