SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION REGARDING APPALACHIAN POWER COMPANY TOPICAL REPORT, "APCo ESP QAPD, NUCLEAR QUALITY ASSURANCE PROGRAM QUALITY ASSURANCE PROGRAM DESCRIPTION", REVISION 1

1.0 INTRODUCTION

By letter dated January 28, 2025 (Reference 1), Appalachian Power Company, (APCo), submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Topical Report (TR), "Quality Assurance Program Description for the Appalachian Power Small Modular Reactor Early Site Permit Activities" (QAPD), Revision 0. In this letter, APCo requested the NRC staff's review and approval of the APCo QAPD for the early site permit (ESP) activities affecting the quality and performance of safety-related structures, systems, and components (SSCs), including, but not limited to siting and licensing.

The NRC staff held a public meeting with APCo on June 11, 2025 (Reference 2) to discuss clarification items identified as part of its review of QAPD TR, Revision 0. APCo submitted Revision 1 of the QAPD by letter dated June 25, 2025 (Reference 3). This safety evaluation (SE) is based on the staff's review of the APCo QAPD Revision 1.

APCo's QAPD addresses ESP activities affecting the quality and performance of safety-related SSCs. The APCo QAPD is based on the applicable portions 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." Additionally, APCo's QAPD commits to the applicable requirements of the American Society of Mechanical Engineers (ASME) NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facilities," (Reference 4), as endorsed by NRC Regulatory Guide (RG) 1.28, Revision 5, "Quality Assurance Program Criteria (Design and Construction)" (Reference 5).

2.0 REGULATORY EVALUATION

The regulatory requirements related to quality assurance (QA) programs are, in part, set forth in 10 CFR 52.17(a)(1)(xi), Specifically, 10 CFR 52.17(a)(1)(xi) requires an application for an ESP to include a description of the quality assurance program (QAP) applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site. The description of the QAP for a nuclear power plant site shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

Appendix B to 10 CFR Part 50 sets forth the requirements for QA programs for nuclear power plants, and establishes QA requirements for the design, fabrication, construction, and testing of SSCs for the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs, including designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

3.0 TECHNICAL EVALUATION

In evaluating the compliance of APCo's QAPD with applicable requirements, 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" (SRP), Section 17.5, Revision 1, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants" (Reference 6). SRP Section 17.5, Revision 1, outlines an acceptable QA program template for design certification, early site permit, combined license, construction permit, and operating license applicants. SRP Section 17.5, Revision 1, describes regulatory and industry guidance determined to be acceptable methods for satisfying the requirements of Appendix B to 10 CFR Part 50.

3.1 Quality Assurance Program Description Details

3.1.1 Organization

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.A, for providing an organizational description that includes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying APCo's QA program implementation. Based on its review, the NRC staff finds that APCo's QAPD establishes independence between the organization that performs oversight functions related to the QA program and the organization responsible for performing the functions to be evaluated. In addition, the APCo QAPD provides for applicable management to be responsible for sizing the QA organization commensurate with the duties and responsibilities assigned. The APCo QAPD clearly describes and defines the responsibility and authority for planning, establishing, and implementing an effective overall QA program.

The APCo QAPD provides the authority and responsibility to stop work immediately in accordance with approved procedures whenever personnel safety or SSC integrity may be jeopardized. This authority extends to offsite work performed by suppliers that furnish safety-related materials and services to APCo.

The APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 1, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's Organization, as detailed above, complies with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.2 Quality Assurance Program

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.B, for establishing the necessary measures to implement a QA program to ensure that ESP activities affecting the quality and performance of safety-related SSCs are in accordance with the governing regulations and license requirements. Examples of ESP program safety-related activities include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis.

APCo may delegate all or part of the activities for which they are responsible to others but retains overall responsibility for the QA program effectiveness. The APCo QAPD provides for measures to assess the adequacy of the QAP and to ensure its effective implementation, at least once each year or at least once during the life of the activity, whichever is shorter.

In addition, consistent with SRP Section 17.5, Paragraph II.B.10, the APCo QAPD allows for the application of a grace period of 90 days to activities that must be performed on a periodic basis.

The administrative control of the APCo QAPD will be in accordance with 10 CFR 50.55(f) once those regulations apply. Until then, 50.4(b)(7)(ii) applies.

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraphs II.S and II.T, by providing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the APCo QAPD to ensure that suitable proficiency is achieved and maintained. The APCo QAPD provides the minimum training qualification for all personnel responsible for implementation of APCo's QA program.

The APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 2, and the regulatory position stated in RG 1.28, Revision 5, with the following clarifications and exceptions:

- NQA-1-2015, Part I, Requirement 2, Section 302, Inspection and Test

  - NQA-1-2015, Requirement 2 includes use of Part III, Subpart 3.1-2.3, guidance as if it were part of the Requirement.

  (1) In lieu of being certified as Level I, II, or III in accordance with NQA-1- 2015, personnel that perform independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.

The NRC staff evaluated this proposed clarification and determined that the guidance in NQA-1-2015, Part III, Subpart 3.1-2.3 can be used to meet the requirements of Appendix B to 10 CFR Part 50 and is equivalent to the guidance in SRP Section 17.5, paragraph II.T.5. Therefore, the NRC staff finds the use of Subpart 3.1-2.3 of NQA-1-2015 for qualification of inspection and test personnel acceptable.

(2) A qualified engineer may be used to plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purpose of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, civil) and has a minimum of five years engineering work experience with at least two years of this experience related to nuclear facilities.

The NRC staff reviewed this clarification and determined that there is no conflict with regulatory guidance, NQA-1-2015, or other industry guidance in this subject area. Therefore, the NRC staff finds this clarification acceptable.

- APCo conforms to NQA-1-2015, Part I, Requirement 2, Section 301, Nondestructive Examination, for qualification of nondestructive examination personnel, except that APCo will follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME Boiler and Pressure Vessel Code approved by the NRC for use at APCo sites for the scope of activities governed by these cited standards.

The regulations in 10 CFR 50.55a, "Codes and Standards," endorses versions of ASME B&PV Code Sections III and XI for activities within the scope of these sections. Therefore, the NRC staff finds the alternative proposed for the use of Sections III and XI of the ASME B&PV Code for qualification of nondestructive examination personnel to be acceptable.

- As an alternative to NQA-1-2015, Part I, Requirement 2, Section 303.3, Audit Participation, that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years, the guidance in RG 1.28, Revision 5, Section C.1.a, "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 notes that this clarification has been documented as a regulatory position in RG 1.28, Revision 5, issued October 2017 (Reference 5), and, therefore, is considered acceptable.

- NQA-1-2015, Part I, Requirement 2, Section 401 (g) requires the date of certification expiration to be included on the qualification record. APCo 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; therefore, because having both dates on the form is redundant, the NRC staff determined the exception to be acceptable.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's QA program, as detailed above, complies with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.3 Design Control

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.C, for establishing the necessary measures to control the design, design changes, and temporary modifications of

safety-related items and services that are subject to the provisions of the QAPD. The APCo QAPD design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within APCo and with suppliers. These provisions ensure that the design inputs (such as design bases and the performance, regulatory, quality and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification.

Consistent with SRP Section 17.5, Paragraph II.C, the APCo QAPD design processes provide for design verification to ensure that items and activities subject to the provisions of the QA program are suitable for their intended application and are consistent with their effect on safety. Design changes are subject to these controls, which include verification measures commensurate with those applied to the original plant design. The extent of the design verification required is a function of the importance to safety of the item under consideration or computer program under consideration, the complexity of the design, the degree of standardization, the state-of-the art, and the similarity with previously proven designs. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing. 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 APCo QAPD governs the development, procurement, testing, maintenance, and use of computer applications when used in safety-related applications and designated non-safety-related applications. APCo and its suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer applications. The APCo QAPD states that procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification.

The APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 3, as well as the standards in NQA-1-2015, Part II, Subpart 2.7 “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications,” Subpart 2.14 “Quality Assurance Requirements for Commercial Grade Items and Services,” and Subpart 2.20, “Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities,” without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo’s Design Control, as detailed above, complies with the requirements of Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.4 Procurement Document Control

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.D, for establishing the necessary measures and governing procedures for preparing and reviewing procurement documents to ensure that the documents include or reference applicable regulatory, technical, and QA program requirements. The APCo QAPD ensures that relevant personnel develop and review the procurement documents and that changes are subject to the same degree of control as those used in preparing the original documents.

The APCo QAPD states that applicable technical, regulatory, administrative, quality, and reporting requirements (such as those in specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, "Reporting of Defects and Noncompliance,") are invoked for the procurement of items and services.

To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR Part 50, Appendix B. Alternatively, the APCo QAPD allows the supplier to work under APCo's approved QA program.

The APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 4, with the following clarifications and exceptions.

- NQA-1-2015, Part I, Requirement 4, Section 203, Quality Assurance Program Requirements, requires the purchaser to specify the quality assurance requirements in the procurement documents. To meet this requirement, APCo may require suppliers to have a documented QAP that meets the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of the procurement.

The NRC staff evaluated this proposed alternative and determined that it provides adequate control for establishing and executing the responsibilities for the QA program. In addition, Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50, requires suppliers to have a QA program consistent with said Appendix. Therefore, the NRC staff concluded that this alternative is acceptable.

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

The NRC staff evaluated this proposed exception and determined that it provides adequate control for establishing and executing the responsibilities for the QA program because it is consistent with SRP Section 17.5, Paragraph II.D.1. In addition, Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50, requires suppliers to have a QA program consistent with the regulations. Therefore, the NRC staff determined that the exception is acceptable.

- Section 300 and 400 of NQA-1-2015, Part I, Requirement 4, requires the review of technical and QAP requirements of procurement documents prior to award of a contract and for procurement document changes. APCo may satisfy this requirement through the review of the procurement specification when the specification contains the technical and quality assurance 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 because it is consistent with SRP Section 17.5, Paragraph II.D.3. Therefore, the NRC staff determined that the clarification is acceptable.

- Procurement documents for commercial grade items that will be procured by APCo for use as safety-related items shall contain technical and quality requirements such that the

procured item can be appropriately dedicated in accordance with this QAPD, Section 7, "Control of Purchased Material, Equipment, and Services."

The NRC staff evaluated this proposed clarification and determined that it is consistent with NRC staff guidance provided in RG 1.164, Revision 1, "Dedication of Commercial Grade Items for use in Nuclear Power Plants," issued April 2024 (Reference 7). The proposed clarification is also consistent with Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989 (Reference 8), and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (Reference 9), as delineated in SRP Section 17.5, Paragraphs II.V.1.d and II.V.1.e. Therefore, the NRC staff determined that the clarification is acceptable.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's Procurement Document Control, as detailed above, complies with the requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.5 Instructions, Procedures, and Drawings

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate to the circumstances and that, where applicable, include quantitative or qualitative acceptance criteria to implement the APCo QA program. The APCo QAPD 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 of the APCo QAPD. In addition, means shall be provided to disseminate to the staff instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions shall be included for reviewing, updating, and canceling such procedures. Furthermore, 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.

The APCo QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 5, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's Instructions, Procedures, and Drawings, as detailed above, complies with the requirements of Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.6 Document Control

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.F, for establishing the necessary measures and governing procedures to control the preparation, review,

approval, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled. Measures are provided to assure that documents, including revisions or changes (other than those defined in implementing procedures as minor changes), are reviewed and approved by the same organization that performed the original review and approval, unless other organizations are specifically designated. A list of all controlled documents, identifying the current approved revision or date, is maintained so personnel can determine the appropriate document for use.

The APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 6, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's Document Control, as detailed above, complies with the requirements of Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.7 Control of Purchased Material, Equipment, and Services

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The APCo QAPD provides measures for source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services. The APCo QAPD establishes and implements 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's or service's importance to safety, complexity, quantity, and frequency of procurement.

The APCo QAPD provides measures for evaluating prospective suppliers and selecting only qualified suppliers, as well as auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services. Qualified suppliers are audited on a triennial basis.

The APCo QAPD also outlines acceptance actions, such as source verification, receipt inspection, certificates of conformance, and review of documentation (e.g., Certified Material Test Reports/Certificates) to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. In addition, the QAPD establishes controls for the selection, determination of suitability for intended use (i.e., critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

The APCo QAPD allows for the extension of audit or survey intervals up to 25 percent under exigent conditions. This unique grace period can be applied if exigent conditions exist including, but not limited to the following:

a. a severe local or national public health concern,
b. severe localized or national weather conditions, or
c. a declaration of a national emergency.

The APCo QAPD requires that, under these exigent conditions, APCo will evaluate the supplier's program to provide reasonable assurance that the quality of items and services will continue to be maintained during this extension period. Under the 25 percent extension, APCo would not have to reset the audit or survey "clock" backwards to the original expiration date for which the audit/survey should have been performed. The end of the audit or survey would determine the date of the next triennial audit or survey. The use of the 25 percent frequency extension for audits and commercial-grade surveys during extenuating circumstances was previously approved in the NRC staff's SE for a change to Callaway Plant's Operating Quality Assurance Manual, dated August 6, 2020 (Reference 10)

The NRC staff notes that the Coronavirus Disease 2019 (COVID-19) related public health emergency expired on May 11, 2023; therefore, the provisions for audit extension under exigent conditions, as described above, can no longer be used unless new exigent conditions exist.

In establishing procurement verification controls and commercial grade item requirements, the APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 7, and Part II, Subpart 2.14 with the following clarifications and exceptions:

- APCo considers that 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 APCo plants(s), are not required to be evaluated or audited.

The NRC staff has documented its current regulatory position regarding this exception SE Section 3.1.7.1 of the Tennessee Valley Authority (TVA) New Nuclear QAPD, dated December 12, 2023 (Reference 11). The NRC staff verified that the APCo 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 APCo QAPD. The NRC staff concludes that the requested exception regarding audit and evaluation, as described above, is acceptable subject to the limitations described in the TVA New Nuclear QAPD SE, as identified in Section 5.0 of this SE, for control of purchased material, equipment, and services.

- When purchasing commercial grade calibration or testing services from a calibration or test laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

    1. A documented review of the supplier's accreditation will be performed and will include a verification of the following:

        a. The calibration or test laboratory holds a domestic (United States) accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA): (1) National Voluntary Laboratory Accreditation Program (NVLAP), (2) American Association for Laboratory Accreditation (A2LA), (3) ACLASS Accreditation Services (ACLASS), (4) International Accreditation Service (IAS), (5) Laboratory Accreditation Bureau (L-A-B).

        b. The accreditation encompasses ANS/ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."

c. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, range, and uncertainties.

d. The published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.

e. The laboratory has achieved accreditation based on an onsite accreditation assessment by the selected accrediting body 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 onsite accreditation assessment by the accrediting 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:

   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 evaluated this proposed clarification and determined that it is consistent with the NRC staff's current regulatory position, documented in RG 1.28, Revision 6, issued September 2023 (Reference 12). In this RG, the NRC staff concluded that Nuclear Energy Institute 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated September 2020, Revision 1 (Reference 13), provides an acceptable approach for licensees and suppliers subject to the QA

requirements of Appendix B to 10 CFR Part 50. This Nuclear Energy Institute (NEI) document relates to using laboratory accreditation by Accreditation Bodies that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procuring calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA. Therefore, the NRC staff concluded that this clarification is acceptable.

- For NQA-1-2015, Part I, Requirement 7, Section 501, Acceptance of Item or Service-General, APCo considers documents that may be stored in approved electronic media under the Nuclear QA Program or vendor control, not physically located on the plant site, but accessible from the respective nuclear facility site, as meeting the NQA-1 requirement for documents to be available at the site.

The NRC staff concludes that APCo's position that documents stored in approved electronic media under APCo or vendor control is an acceptable alternative to Section 501 of NQA-1-2015, Requirement 7 based on the NRC staff's evaluation of APCo's use of electronic records as documented in Section 3.1.17 of this SE.

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

The NRC staff considers that the establishment of quality verification requirements and processes for identification of critical characteristics of APCo's documents as part of the commercial grade dedication process is acceptable because this is consistent with the guidance in SRP Section 17.5, Subsection II, Item G, and is therefore acceptable.

- APCo will assume 10 CFR Part 21 reporting responsibility for all items that APCo dedicates as safety-related.

Under 10 CFR Part 21, 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 that could create a substantial safety hazard, must immediately notify the Commission of such failure to comply or such defect, unless they have 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.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's controls for

purchased material, equipment, and services, as detailed above, complies with the requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.8 Identification and Control of Materials, Parts, and Components

The APCo QAPD follows the guidance of SRP Section 17.5, Subsection II.H, for establishing the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. Identification of items is maintained throughout fabrication, erection, installation, and use so that the materials, parts, or components can be traced back to their documentation, consistent with the item’s effect on safety. The location and identification methods are selected so the function or quality of the item being identified is not affected.

The APCo QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 8, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that APCo’s description of identification and control of materials, parts, and components, as detailed above, complies with the requirements of Criterion VIII, “Identification and Control of Materials, Parts, and Components,” of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.9 Control of Special Processes

The APCo QAPD follows the guidance of SRP Section 17.5, Subsection II.I, for establishing the necessary measures and governing procedures to provide assurance that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination are controlled. Special processes are accomplished by qualified personnel using qualified procedures and equipment, and in accordance with applicable codes, standards, specifications, criteria, or other special requirements. Records are maintained as appropriate for currently qualified personnel, processes and equipment for each special process.

The APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 9, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo’s control of special processes, as detailed above, complies with the requirements of Criterion IX “Control of Special Processes” of Appendix B to 10 CFR Part 50, and therefore, is acceptable.

3.1.10 Inspection

The APCo QAPD follows the guidance of SRP Section 17.5, Subsection II.J, for establishing the necessary measures and governing procedures to implement inspections that provide assurance that items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Types of inspections may include the following verifications: (1) at the source of supplied items or services, (2) in-process during fabrication at a supplier's facility or at an APCo

facility, (3) for final acceptance of fabricated and/or installed items during construction, and (4) upon receipt of items for a facility. These types of inspections will be performed by properly qualified personnel independent of those who performed or directly supervised the work, and the inspection results will be documented.

APCo's inspection program establishes requirements for planning the inspections, such as measures for (1) the identification of the group or discipline responsible for performing the inspection, (2) the application of hold points, (3) the acceptance criteria for inspection, and (4) the frequency of inspections. Inspection plans are based on, as appropriate, (1) the importance of the item to safety, (2) the complexity of the item, (3) the technical requirements to be met, and (4) the design specifications. Inspection information and results, such as rejection, acceptance criteria, reinspection results, and the person(s) performing the inspection, are documented. 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 to information on action taken in connection with nonconformances. Inspection results are reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results.

APCo will establish requirements for qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2 of the QAPD and APCo commits to the requirements of NQA-1-2015, Part I, Requirement 2, Section 302, Inspection and Test. These qualification programs are applied to individuals performing quality inspections regardless of the functional group to which they are assigned.

The APCo QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 10, and Part II, Subpart 2.5, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that APCo's description of inspection controls, with the included clarification, as detailed above, complies with the requirements of Criterion X, "Inspection" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.11 Test Control

The APCo QAPD follows the guidance of SRP Section 17.5, Subsection II.K, for establishing the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service. Test programs include criteria for determining when testing is required to demonstrate that performance of plant systems is in accordance with design. Tests are performed according to applicable procedures that include, consistent with the effect on safety, (1) instructions and prerequisites to perform the tests, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented 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, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure. Personnel who perform or evaluate tests are qualified in accordance with the requirements established in Part II, Section 2 of the APCo QAPD and APCo commits to the requirements of NQA-1-2015, Part I, Requirement 2, Section 302, Inspection and Test.

For non-computer program testing, APCo's QAPD commits to implementing the quality standards described in NQA-1-2015, Part 1, Requirement 11 without further clarifications or exceptions.

For computer program testing, APCo's QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 11 and Part II, Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2015, Requirement 3, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that APCo's description of testing controls, as detailed above, complies with the requirements of Criterion XI, "Test Control" of Appendix B to 10 CFR Part 50, and therefore, is acceptable.

3.1.12 Control of Measuring and Test Equipment

The APCo QAPD follows the guidance of SRP Section 17.5, Subsection II.L, for establishing the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met for information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and nondestructive examination equipment.

APCo's QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 12, with the following clarification and exception.

- The out of calibration conditions described in NQA-1-2015, Part I, Requirement 12, Section 303.2, Corrective Action, refers to when the M&TE is found out of the required accuracy limits (i.e., out of tolerance) during calibration and not overdue for calibration.

The NRC staff finds that the clarification for out of calibration conditions is consistent with the overall objective of NQA-1-2015, Requirement 12, Section 303.2, and Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, which require that M&TE used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Therefore, the NRC staff concluded that this clarification is acceptable.

- M&TE are not required to be marked with the calibration status, as described in NQA-1-2015, Part I, Requirement 12, Section 303.6, Status Indication, where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device.

The NRC staff finds this exception consistent with the overall objective of NQA-1-2015, Requirement 12, Section 303.6, and Criterion XII of Appendix B to 10 CFR Part 50, which require that M&TE used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Therefore, the NRC staff determined that the exception is acceptable.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that APCo's description of M&TE controls, as detailed above, complies with the requirements of Criterion XII, of Appendix B to 10 CFR Part 50, and therefore, is acceptable.

3.1.13 Handling, Storage, and Shipping

The APCo QAPD follows the guidance of SRP Section 17.5, Subsection II.M, for establishing 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. Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and provide indication of the needs for special controls. Any special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required. In addition, the procurement documents identify any special or additional handling, storage, shipping, cleaning, and preservation requirements. Special handling tools and equipment are controlled to ensure safe and adequate handling. These special tools and handling equipment are inspected and tested in accordance with procedures at specified time intervals or before use. Operators of special handling and lifting equipment are experienced or trained in the use of the equipment. Where required, APCo complies with applicable hoisting, rigging, and transportation regulations and codes.

The APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 13 without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that APCo's description of handling, storage, and shipping controls, as detailed above, complies with the requirements of Criterion XIII, "Handling, Storage and Shipping" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.14 Inspection, Test, and Operating Status

The APCo QAPD follows the guidance of SRP Section 17.5, Subsection II.N, for establishing the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Measures are provided for the verification of inspections, tests, and operating status to preclude the 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. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

The APCo QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 14, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that APCo's description of inspection, test,

and operating status controls, as detailed above, complies with the requirements of Criterion XIV, “Inspection, Test, and Operating Status” of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.15 Nonconforming Materials, Parts, or Components

The APCo QAPD follows the guidance of SRP Section 17.5, Subsection II.O, for establishing the necessary measures and governing procedures to control items, including services, that do not conform to specified requirements in order to prevent inadvertent installation or use. Controls provide for the identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming items, and notification to affected organizations. Controls are also provided to address the conditional release of nonconforming items for use on an at-risk basis before resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release.

Nonconforming items are evaluated for impact on the operability of quality SSCs to provide assurance that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements that are dispositioned “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, analysis of quality trends, and reported to designated management. Significant trends are reported to management in accordance with APCo’s procedures, regulatory requirements, and industry standards.

The APCo QAPD Revision 1 provides for establishing the appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55 and/or 10 CFR Part 21 during the ESP.

The APCo QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 15, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that APCo’s description of controls for nonconforming materials, parts, or components, as detailed above, complies with the requirements of Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.16 Corrective Action

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.P, for establishing the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. The APCo QAPD provides for procedures to 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.

The APCo QAPD requires personnel to identify known conditions adverse to quality. Reports of 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 or contractors working on safety-related activities, or other similar situations, APCo may delegate specific responsibilities for corrective actions, but APCo maintains overall responsibility for the effectiveness of corrective action measures and the corrective action program.

The APCo QAPD Revision 1 provides for establishing the appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR Part 52, 10 CFR 50.55 and/or 10 CFR Part 21 during the ESP.

The APCo QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 16, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's Corrective Action program complies with the requirements of Criterion XVI, "Corrective Action" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.17 Quality Assurance Records

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.Q, for establishing the necessary measures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for APCo and include requirements for records administration including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

The APCo QAPD establishes measures to ensure that records of activities for design, engineering, procurement, inspection and test, and audits and their retention times are defined in appropriate procedures. The records include operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. Records and retention are identifiable and retrievable. Records and retention times are based on RG 1.28, Revision 5, Regulatory Positions C.3.a.(1) for "Lifetime Records" and C.3.a (2) for "Nonpermanent Records." In all cases in which state, local, or other agencies have more restrictive requirements for record retention, the APCo QAPD provides that those more restrictive requirements will be met.

When using optical disks for electronic records storage and retrieval systems, the APCo QAPD complies with the NRC guidance contained in NRC GL 88-18, "Plant Record Storage on Optical Disks dated October 20, 1988 (Reference 14)." In addition, APCo will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," and the associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG), including TG 11-2011, "Authentication of Records and Media," (Reference 15), TG 15-2011, "Management of Electronic Records," (Reference 16), TG 16-2011, "Software Configuration Management and Quality Assurance," (Reference 17), and TG 21-2011, "Electronic Records Protection and Restoration" (Reference 18).

The APCo QAPD commits to implementing the quality standards described in NQA-1-2015, Part I, Requirement 17 and regulatory positions stated in RG 1.28, Revision 5, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's QA Records complies with the requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50 and, therefore, is acceptable.

3.1.18 Audits

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.R, for establishing the necessary measures and governing procedures to implement audits to verify that activities covered by the QA program are performed in conformance with the established requirements and performance criteria are met. APCo also reviews the audit programs for effectiveness as part of the overall audit process. Internal audits of selected aspects of licensing and design activities are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. During the initial portions of APCo activities, audits will focus on areas including but not limited to, site investigation, procurement, and corrective action. 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 APCo's QA management.

The APCo QAPD provides for all audit results to be documented and reviewed by responsible management. Management responds to all audit findings and initiates corrective actions when determined necessary. In addition, if corrective action measures are determined necessary, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means, is conducted to verify the implementation and effectiveness of the assigned corrective actions.

The APCo QAPD provides for conducting periodic internal and external audits. Internal audits of organization and facility activities, conducted prior to placing the facility in operation, shall be performed in such a manner as to assure that an audit of applicable QA program elements is completed at least once each year or at least once during the life of the activity, whichever is shorter.

The scope of the internal include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by the QAPD; corrective actions taken following abnormal occurrences; and activities including associated record keeping.

External audits determine the adequacy of supplier and contractor QA programs, and APCo QAPD Section 7.1 describes additional controls for external audits.

The APCo QAPD commits to implement the quality standards described in NQA-1-2015, Part I, Requirement 18 with the following clarification:

- APCo annual evaluation of the supplier in RG 1.28, Revision 5, Position C. 4.b. (4). (a), (b), and (c) shall only be required to consider activities related to APCo procurement activities.

The intent of NRC Positions C. 4. b. (4). (a), (b), and (c) are for applicants or licensees to assess supplier performance on an annual basis. Activities referenced in C. 4. b. (4). (a), (b), and (c) are performed as part of procurement activities in order to ensure suppliers are qualified and have performed sufficient work to demonstrate that its organization is implementing a QA program that has the required scope for purchases. Therefore, since this clarification is consistent with the intent of the staff's position document in RG 1.28, Revision 5, the NRC staff considers this clarification acceptable.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered to be acceptable to the NRC staff and provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of APCo's audits complies with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.2 Regulatory Commitments

The APCo QAPD follows the guidance of SRP Section 17.5, Paragraph II.V, for establishing QA program commitments. Furthermore, APCo commits to comply with the following NRC RGs and other QA standards to supplement and support the QA program:

- RG 1.26, Revision 6, December 2021, "Quality Group Classifications and Standards for Water, Steam, and Radioactive-Waste Containing Components of Nuclear Power Plants." RG 1.26 defines classification of systems and components containing water, steam, or radioactive material in light-water-cooled nuclear power plants. APCo identifies conformance and exceptions for the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., safety analysis reports). (Reference 19)

- RG 1.28, Revision 5, October 2017, "Quality Assurance Program Criteria (Design and Construction)." RG 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite QAP for the design and construction of nuclear power plants. APCo identifies conformance and exceptions for the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., safety analysis reports). (Reference 5)

- RG 1.29, Revision 6, July 2021, "Seismic Design Classification for Nuclear Power Plants." RG 1.29 defines systems required to withstand a safe shutdown earthquake (SSE). APCo identifies conformance and exceptions for the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., safety analysis reports). (Reference 20)

- RG 1.164, Revision 1, April 2024, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants." RG 1.164 provides guidance for dedication of commercial-grade items and services used in nuclear power plants. APCo identifies conformance and exceptions for the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., safety analysis reports). (Reference 7)

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

Plants." RG 1.231 describes methods acceptable to the NRC staff for complying with the Commission's regulations with regard to acceptance and dedication of commercial-grade design and analysis computer programs used in safety-related applications for nuclear power plants. APCo identifies conformance and exceptions for the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., safety analysis reports). (Reference 21)

- RG 1.234, Revision 1, March 2024, "Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21." RG 1.234 describes methods acceptable to the NRC staff for complying with the Commission's regulations with regard to 10 CFR Part 21, "Reporting of Defects and Noncompliance." APCo identifies conformance and exceptions for the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., safety analysis reports). (Reference 22)

- ASME NQA-1-2015, Part I and Part II (as described in Parts 1 and II of the APCo QAPD). (Reference 4)

- NIRMA TGs, (as described in Part II, Section 17 of the APCo QAPD). (References 15-18).

- NEI 14-05A, Guidelines for the Use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services, Revision 1 (As described in Part II, Section 7.2 of the APCo QAPD). (Reference 13)

Based on its review, the NRC staff has determined that this approach, as described in the APCo QAPD, is consistent with SRP Section 17.5, Paragraph II.V, and, therefore, is acceptable.

4.0 CONCLUSION

The NRC staff concludes that the APCo QAPD delineates the policies, processes, and controls and implementing documents associated with APCo's activities that affect the quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service.

The APCo QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or for which other NRC guidance establishes program requirements.

The NRC staff finds that the APCo QAPD follows the NRC guidance contained within, and conforms to the format of, SRP Section 17.5. The NRC staff used the acceptance criteria of SRP Section 17.5 as the basis for evaluating the acceptability of the APCo QAPD in conformance with the provisions of 10 CFR 52.17(a)(1)(xi) and Appendix B to 10 CFR Part 50. Based on its review of the APCo QAPD, the NRC staff concludes the following:

- The APCo QAPD adequately describes the authority and responsibility of management and supervisory personnel, performance and verification personnel, and self-assessment personnel, in relation to activities to which the APCo QAP is applicable.

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

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

- The APCo QAPD adequately establishes controls that, when properly implemented, and subject to the limitations in Section 5.0 of this SE, comply with the requirements of 10 CFR Part 52, Appendix B to 10 CFR Part 50, and 10 CFR Part 21, consistent with the criteria contained in SRP Section 17.5, as well as the relevant regulatory guidance.

Based on its review, the NRC staff has determined that the APCo QAPD, Revision 1, adequately describes the APCo QA program for a potential ESP application. Further, the staff concludes that the APCo QA program complies with applicable NRC regulations and industry standards and can be used by APCo for ESP activities affecting the quality and performance of safety-related SSCs.

5.0 LIMITATIONS AND CONDITIONS

This APCo QAPD is specific to ESP activities affecting the quality and performance of safety-related SSCs. Any application referencing the approved revision of the APCo QAPD Revision 1 shall provide a description that the APCo QAPD meets Appendix B to 10 CFR Part 50 and associated regulatory requirements.

As referenced in Section 3.1.7 of this SE, the following limitations on the use of this QAPD apply:

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

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

6.0 REFERENCES

1. Letter from Shane Lies, American Electric Power Company, Inc., to the NRC, “Quality Assurance Program Description for the Appalachian Power Small Modular Reactor Early Site Permit Activities, Revision 0,” dated January 28, 2025 (ML25028A159).

2. NRC, “U.S. Nuclear Regulatory Commission Summary of the June 11, 2025, Public Meeting to Discuss Nuclear Regulatory Commission Staff Information

Needs for Appalachian Power Company's Early Site Permit Small Modular Reactor Quality Assurance Program Description Topical Report," dated July 23, 2025 (ML25190A638).

3. Letter from Shane Lies, American Electric Power Company, Inc., to the NRC, "Quality Assurance Program Description for the Appalachian Power Small Modular Reactor Early Site Permit Activities, Revision 1," dated June 25, 2025 (ML25176A216).

4. American Society of Mechanical Engineers (ASME) NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facilities Applications," dated February 20, 2015.

5. RG 1.28, Revision 5 "Quality Assurance Program Criteria (Design and Construction)," dated October 2017 (ML17207A293).

6. 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," dated August 2015(ML15037A441).

7. RG 1.164, Revision 1, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," April 2024 (ML24038A310).

8. NRC, Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," dated March 21, 1989 (ML031140060).

9. NRC, Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (ML031140508).

10. Letter to Mr. Fadi Diya, Senior Vice President and Chief Nuclear Officer, Ameren Missouri, "Callaway Plant, Unit No. 1 - Operating Quality Assurance Manual Change Revision 34b, dated August 6, 2020 (ML20216A681).

11. SE 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).

12. RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 6, dated September 2023 (ML23177A002).

13. 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," dated September 2020 (ML20259B731).

14. NRC, Generic Letter 88-18, "Plant Record Storage on Optical Disks", dated October 20, 1988.

15. Nuclear Information and Records Management Association (NIRMA), "Authentication of Records and Media," TG 11-2011, New York, NY.

16. NIRMA, “Management of Electronic Records,” TG 15-2011, Windham, NH.

17. NIRMA, “Software Configuration Management and Quality Assurance,” TG 16-2011, Windham, NH.

18. NIRMA, “Electronic Records Protection and Restoration,” TG 21-2011, Windham, NH.

19. RG 1.26, Revision 6, "Quality Group Classification and Standards for Water, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” dated December 2021 (ML21232A142).

20. RG 1.29, Revision 6, "Seismic Design Classification," dated July 2021 (ML21155A003).

21. RG 1.231, Revision 0, “Acceptance of Commercial-Grade Design and Analysis Computer Programs used in Safety-Related Applications for Nuclear Power Plants,” dated January 2017 (ML16126A183).

22. RG 1.234, Revision 1, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21,” dated March 2024 (ML240038A311).