May 9, 2013

Mr. Russell J. Bell, Director
New Plant Licensing
Nuclear Generation Division
Nuclear Energy Institute
1201 F Street, NW, Suite 1100
Washington, DC 20004

SUBJECT: FINAL SAFETY EVALUATION FOR TECHNICAL REPORT NEI 11-04, "QUALITY ASSURANCE PROGRAM DESCRIPTION," REVISION 0

Dear Mr. Bell:

By letter dated May 27, 2011, the Nuclear Energy Institute (NEI) submitted Draft Revision 0 of NEI 11-04, "Quality Assurance Program Description. NEI 11-04 provides a Quality Assurance Program Description (QAPD) template for applicants of Part 52 permits or licenses to use in meeting the requirements in Title 10 of the *Code of Federal Regulation* (10 CFR) Parts 50 and 52. In a safety evaluation report dated July 13, 2010, the U.S. Nuclear Regulatory Commission (NRC) previously endorsed NEI 06-14 "Quality Assurance Program Description, Revision 9," which is based on American Society of Mechanical Engineers NQA-1-1994. NEI 11-04 updates the NEI generic QAPD template to reflect the requirements of NQA-1-2008 and the NQA-1a-2009 Addenda, which the NRC endorsed in Regulatory Guide (RG) 1.28, Revision 4.

By letter dated February 8, 2012, the NRC requested additional information to complete its review of NEI 11-04. A teleconference was held September 5, 2012, to promote a better understanding of the NEI responses to the NRC's request for addition information (RAI). By a letter dated September 13, 2012, NEI submitted NEI 11-04, Revision 0, which incorporates NEI responses to NRC staff comments on NEI 11-04.

The NRC staff has reviewed the NEI submittal and supporting documentation. On the basis of its review, the staff concludes that the QAPD template can be used by applicants of 10 CFR Part 52 permits or licenses, as applicable, for establishing a quality assurance program that complies with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Parts 50 and 52.

CONTACT: Wesley Held, NRO/DARR
301-415-1583

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 11-04 to determine if the applicant adequately followed the guidance provided in the QAPD template and has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in Standard Review Plan Section 17.5. Key areas that an applicant is required to address include:

- The organizational description addressed in Part II, Section 1 of NEI 11-04, Revision 0.
- Record retention criteria addressed in Part II, Section 17.1 of NEI 11-04, Revision 0.
- Regulatory commitments addressed in Part IV of NEI 11-04, Revision 0.

To ensure all quality assurance requirements for the operating phase are addressed, an applicant must either demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-2008 and the NQA-1a-2009 Addenda by explicitly addressing the provisions in NEI 11-04, Revision 0, Part V and Appendix 1, or otherwise by including a commitment to RG 1.33, “Quality Assurance Program Requirements (Operation),” Revision 2 in Part IV of the QAPD.

Enclosed is the NRC staff’s SER which defines the basis for acceptance of NEI 11-04, Revision 0. The NRC staff finds that for combined license applications (COLAs), NEI 11-04, Revision 0, provides an acceptable template for describing a quality assurance program.

Our acceptance applies only to material provided in NEI 11-04, Revision 0. We do not intend to repeat our review of the acceptable material described in NEI 11-04, Revision 0, when referenced in a COLA. Licensing requests that deviate from NEI 11-04, Revision 0, will be subject to a plant-specific or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC Web site, we request that NEI publish the accepted version of NEI 11-04, Revision 0 within 3 months of receipt of this letter. The accepted version should incorporate this letter and the enclosed SER. The accepted version should also contain historical review information, including NRC RAIs and your responses. The accepted versions shall include a “-A” (designating accepted) following the report identification symbol.

If future changes to the NRC’s regulatory requirements affect the acceptability of NEI 11-04A, NEI will be expected to revise NEI 11-04A appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact Wesley W. Held at (301) 415-1583 or via email at Wesley.Held@nrc.gov.

Sincerely,

/RA/

Joseph Colaccino, Branch Chief
Policy Branch
Division of Advanced Reactors and Rulemaking
Office of New Reactors

Project No.: 689

Enclosure:
Safety Evaluation Report

cc w/encl: See next page

If you have any questions, please contact Wesley W. Held at (301) 415-1583 or via email at Wesley.Held@nrc.gov.

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SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS
TECHNICAL REPORT NEI 11-04,
"QUALITY ASSURANCE PROGRAM DESCRIPTION" REVISION 0

1.0 Introduction

By letter dated October 19, 2006 (Ref. 1), the Nuclear Energy Institute (NEI) submitted an industry quality assurance program description (QAPD) template for review and approval by the U.S. Nuclear Regulatory Commission (NRC) staff. In its letter dated January 7, 2007, NEI revised the QAPD template in technical report NEI 06-14, "Quality Assurance Program Description," that provides a generic template for use by early site permit (ESP) and combined license (COL) applicants to implement NRC regulatory requirements related to quality assurance (QA) programs. NEI 06-14 is based on American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as supplemented by quality assurance and administrative control requirements specific to the operations phase. NEI 06-14 provides a common format for applicants when making commitments to comply with Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," (Appendix B), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

The QAPD template was initially released in May 2008, as NEI 06-14A, Revision 0, the 'A' denoting NRC staff approval as documented by NRC safety evaluation (SE) dated April 25, 2007 (Ref. 2). Its most recent Revision, NEI 06-14A, Revision 7, received NRC staff approval as documented by NRC SE dated July 13, 2010 (Ref. 3).

In June 2010, the NRC issued Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 4. This RG described methods that the NRC staff considered acceptable for complying with the provisions of 10 CFR Part 50, 10 CFR Part 52 which refer to 10 CFR Part 50, Appendix B for establishing and implementing a QA program for the design and construction of nuclear power plants and fuel reprocessing plants.

RG 1.28, Revision 4, endorsed the Part I and Part II requirements included in NQA-1-2008 and the NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants as acceptable to the NRC staff. The NEI template provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to specific additions and modifications of NQA-1-2008 and the NQA-1a-2009 Addenda and the regulatory position in RG 1.28, Revision 4.

By letter dated May 27, 2011, the NEI submitted Draft Revision 0, (Ref. 4) to NEI 11-04 for staff review and approval. NEI 11-04 updated the NEI generic QAPD template to reflect the requirements of NQA-1-2008 and the NQA-1a-2009 Addenda.

By letter dated February 8, 2012 (Ref. 5), the NRC requested additional information to complete its review of NEI 11-04. A teleconference was held September 5, 2012 to promote understanding of the NEI responses to the NRC requests for additional information (RAIs). By letter dated September 13, 2012 (Ref. 6), NEI submitted NEI 11-04, Revision 0, which incorporates NEI responses to NRC staff comments on NEI 11-04. This safety evaluation report (SER) documents the basis for the NRC staff's acceptance of NEI 11-04, Revision 0, as an acceptable basis for developing a QAPD that meets Appendix B to 10 CFR Part 50 requirements.

2.0 Background

The QAPD template provides guidance for establishing a top-level policy document that defines QA policy and assigns major QA program functional responsibilities. This QAPD template can be used for ESP, COL, construction, preoperational, and/or operation activities, as applicable, that affect the quality and performance of safety-related structures, systems, and components (SSCs).

The QAPD template includes brackets throughout the document to allow for user-specific text for statements that are scope dependent, are not applicable to combined license applications (COLAs) with an approved ESP, or are applicable only to ESP applications. In addition, the QAPD template uses brackets to provide guidance to users on how to address areas that are specific to the application. Brackets are also used to provide the user with different alternatives that satisfy the requirements of Appendix B to 10 CFR Part 50.

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 11-04 to determine if the applicant adequately followed the guidance provided in the QAPD template and has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in Standard Review Plan (SRP), Section 17.5, "Quality Assurance Program Description, Design Certification, Early Site Permit, and New License Applicants."

3.0 Discussion and Evaluation

3.1 Regulatory Evaluation

The Commission's regulatory requirements related to QA programs are set forth in 10 CFR Part 50, Appendix B. Appendix B establishes QA requirements for the design, fabrication, construction, and testing of the SSCs of the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

10 CFR 52.17 establishes the technical information requirements for ESP applications. Section 52.17(a)(1)(xi) requires that ESP applications provide a description of the QA program 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.

10 CFR 52.79 establishes the technical information requirements for COLAs. Section 52.79(a)(25) requires that COLAs provide a description of the QA program applied to the design, and to be applied to the fabrication, construction, and testing of the SSCs of the facility. Further, 10 CFR 52.79(a)(25) requires that the description of the QA program include a discussion of how the applicable requirements of Appendix B have been and will be satisfied, and also include a discussion of how the QA program will be implemented. Finally, 10 CFR 52.79(a)(27) requires that the application contain information on the managerial and administrative controls to be used to assure safe operation consistent with the requirements of Appendix B to 10 CFR Part 50 and a discussion of how such requirements will be satisfied.

3.2 Evaluation

In evaluating the adequacy of the QAPD template, the staff followed SRP Section 17.5 (Ref. 7), that provides guidance to NRC staff for evaluating QA program descriptions submitted under 10 CFR Part 52. SRP Section 17.5 is based on ASME standard NQA-1, 1994 Edition; RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 3; RG 1.28; and RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2. An evaluation of the applicant's conformance with these RGs is included in Part IV of the QAPD template.

3.2.1 Organizational Description

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.A, by providing an example of an organizational description for a new plant license, independence of working and checking organizations, and providing interrelationships of new plant and existing utility organizations. The template provides adequate guidance for ESP and COL applicants to describe an organizational structure that clearly delineates those management positions responsible for establishing, maintaining, and implementing regulatory requirements from corporate through operating plant positions. The QAPD template provides guidance for applicants to describe functional responsibilities and position descriptions during the construction, preoperational, and operations phases, as well as characterizing control and transitions between phases. It allows management to size the QA organization commensurate with its assigned duties and responsibilities. Information in Part II, Section 1 of NEI 11-04, Revision 0, is applicant-specific and will be reviewed and approved by the staff on a case-by-case basis.

In addition, the QAPD template commits the applicant to the QA standards described in NQA-1-2008, Requirement 1.

3.2.2 Quality Assurance Program

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.B for establishing the necessary measures to implement a QA program to ensure that the design, construction, and operation of nuclear power plants are in accordance with governing regulations and license requirements. The QA program comprises those planned and systematic actions necessary to provide confidence that SSCs will perform their intended safety function, including certain

nonsafety-related SSCs and activities that are significant contributors to plant safety, as described in the ESP site safety analysis report or the COL final safety analysis report. A listing or system identifying SSCs and activities within the scope of the QA program is maintained by the applicant at an appropriate facility.

The QAPD template provides measures to assess the adequacy of the QAPD and to ensure its effective implementation at least once each year or at least once during the life of a quality related activity, whichever is shorter. The period for assessing the QAPD during the operations phase may be extended to once every 2 years. In addition, consistent with SRP Section 17.5, paragraph II.B.8, a grace period of 90 days is applied to activities that must be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity may be reset backwards when an activity is performed early.

The QAPD template follows the guidance of SRP Section 17.5, paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD to ensure task-related proficiency is maintained. Plant technical specifications delineate the minimum qualifications for plant and support staff. The QAPD has personnel completing training for positions identified in 10 CFR 50.120, "Training and Qualification of Nuclear Plant Personnel," according to programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training. The QAPD template provides the minimum training requirements for managers responsible for QAPD implementation and for the manager responsible for planning, implementing, and maintaining the QAPD.

The QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 2 with the following clarifications and exceptions:

- *Section 302, Inspection and Test [NOTE: The applicant may either adopt nonmandatory Appendix 2A-1 as if it were part of the requirement by following Option 1 below or taking exception to Appendix 2A-1 by following Option 2.]*

  - [*Option 1; NQA-1-2008, Requirement 2 includes use of Appendix 2A-1 guidance as if it were part of the Requirement.] [NOTE: When applying Option 1, either or both of the following two alternatives may be applied to the implementation of this Requirement and Appendix:]*

  (1) *[In lieu of being certified as Level I, II, or III in accordance with NQA-1-2008, 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.]* This alternative is consistent with SRP Section 17.5, paragraph II.T.5.

(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 staff's review determined that there is no conflict with regulatory guidance, NQA-1-2008, or other industry guidance in this subject area.

- *[Option 2 is based on the SER under Agencywide Documents Access and Management System (ADAMS) Accession No. ML050700416 and may only be applied during the Operational phase. The post-Three Mile Island (TMI) regulations at 10 CFR 50.34(f)(3)(iii) apply during construction phase.]*

a) *[In lieu of Nonmandatory Appendix 2A-1, [CA] does not establish levels of qualification/certification for inspection personnel. Instead, [CA] establishes initial qualification requirements and determines individual qualification through evaluation of education, training and experience, and through demonstration of capability in performing the type of inspections expected on the job.]* The staff determined that this exception is acceptable as documented in a previous SE under ADAMS Accession No. ML050700416 and is only applicable during operations, because the TMI regulations at 10 CFR 50.34(f)(3)(iii) apply during the construction phase.

b) *[NOTE: When selecting Option 2, the following alternative may be applied to the implementation of Requirement 2.] [Inspections, examinations or tests may be performed by individuals in the same organization as that which performed the work, provided that (a) the qualifications of the inspector for an activity are equal to or better than the minimum qualifications for persons performing the activity, (b) the work is within the skills of personnel and/or is addressed by procedures, and (c) if work involves breaching a pressure-retaining item, the quality of the work can be demonstrated through a functional test. When a, b and c are not met, inspections, examinations, or tests are carried out by individuals certified in accordance with Section 300. Individuals performing visual inspections required by the ASME Boiler & Pressure Vessel (BPV) Code are qualified and certified according to Code requirements.]* This alternative is consistent with SRP Section 17.5, paragraph II.T.5 and 6.

- *[CA] follows Section 301 for qualification of nondestructive examination personnel, except that [CA] will follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME BPV Code approved by the NRC for use at [CA] sites for the scope of activities governed by these cited standards.* The regulation in 10 CFR 50.55a, "Codes and Standards," requires use of the latest edition and addenda of Sections III and XI endorsed in 10 CFR 50.55a. Therefore, the staff finds the use of Sections III and XI of the ASME BPV Code for qualification of nondestructive examination personnel acceptable.

- *Section 400(a)(8) requires the date of certification expiration be included on the qualification record. [CA] 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 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 staff determined that this exception is acceptable.

3.2.3 Design Control

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.C, for establishing the necessary measures to control design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items within the scope of the QAPD. The QAPD template includes measures to control design inputs, outputs, changes, interfaces, records, and organizational interfaces among the applicant and its 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). In addition, the QAPD template provides for individuals knowledgeable in QA principles to review design documents to ensure that they contain the necessary QA requirements.

The QAPD template commits the applicant to the quality standards for its program in design control and verification described in NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3, Subpart 2.7 for computer software, Subpart 2.14 for QA requirements for commercial-grade items and services and Subpart 2.20 for subsurface investigation requirements. [NOTE: Subpart 2.20 does not apply to an Operations-only QAP].

3.2.4 Procurement Document Control

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.D, for establishing the necessary administrative controls and processes to ensure that procurement documents include or reference applicable regulatory, technical, and QA program requirements. Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and the regulation at 10 CFR Part 21, "Reporting of Defects and Noncompliance") are invoked for procurement of items and services.

The QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 4, with the following clarifications and exceptions:

- *With regard to service performed by a supplier, [CA] procurement documents may allow the supplier to work under the [CA] QAP, including implementing procedures, in lieu of the supplier having its own QAP.* Criterion IV of Appendix B requires suppliers to have a QA program consistent with Appendix B. Therefore, the staff determined this clarification to be acceptable, because it is consistent with SRP Section 17.5, paragraph II.D.2.d..

- *Sections 300 and 400 of Requirement 4 require the review of technical and QA program requirements of procurement documents prior to award of a contract and for procurement document changes. [CA] may satisfy this requirement through the review of the procurement specification, when the specification contains the technical and QA requirements of the procurement.* The staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change, which is consistent with SRP Section 17.5, paragraph II.D.3. Therefore, the staff concluded that this alternative is acceptable.

- *Procurement documents for commercial-grade items that will be procured by [CA] for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with the [CA] QAPD, Section 7, "Control of Purchased Material, Equipment and Services.*" This alternative is consistent with staff guidance 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 SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d.

3.2.5 Instructions, Procedures, and Drawings

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.E, for establishing necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, and drawings.

The QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 5, for establishing procedural controls.

3.2.6 Document Control

The QAPD template 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, and changes of documents that specify quality requirements or prescribe measures for controlling activities affecting quality, including organizational interfaces. The template provides measures to ensure that the same organization that performed the original review and approval also reviews and approves revisions or changes to documents, unless other organizations are specifically designated. A listing of all controlled documents identifying the current approved revision or date is maintained so that personnel can readily determine and access current and applicable documents for specific applications.

To ensure effective and accurate procedures during the operational phase, procedures are reviewed and updated as necessary, consistent with the guidance provided in SRP Section 17.5, paragraph II.F.8. During the operational phase, temporary changes to a procedure that clearly do not alter the intent of the procedure may be implemented, provided that two members of the operations staff knowledgeable in the areas affected by the procedure approve the changes.

These temporary changes include a specific period of time during which the revised procedure may be used.

In establishing provisions for document control, the QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 6.

3.2.7 Control of Purchased Material, Equipment, and Services

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.G, for establishing necessary measures and governing procedures that control procurement of items and services to ensure conformance with specified requirements. The controls include measures for evaluating prospective suppliers and selecting only those that are qualified. In addition, controls include auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides for acceptance actions, such as source verification, receipt inspection, pre- and post-installation tests and review of documentation, such as certificates of conformance, to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. Purchased items (components, spares, and replacement parts necessary for plant operation, refueling, maintenance, and modifications) and services are subject to quality and technical requirements at least equivalent to those specified for original equipment, or specified by properly reviewed and approved revisions to design documentation, to ensure that the items are suitable for their intended service and are of acceptable quality, consistent with their effect on safety.

In establishing procurement verification control, the QAPD template commits the applicant to the quality standards described in NQA-1-2008 and NQA-1a-2009, Requirement 7, with the following clarifications and exceptions:

- *[CA] considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection (ANI) Agencies, National Institute of Standards and Technology(NIST), or other State and Federal agencies which may provide items or services to the [CA] plant[s] are not required to be evaluated or audited.*

  The staff acknowledges that 10 CFR Part 50 and Part 52 licensees, ANI agencies, the NIST, and other State and Federal agencies perform work under acceptable quality programs, and no additional audit or evaluation is required. The staff determined that this exception is acceptable as documented in a previous SE under ADAMS Accession No. ML052710224. The applicant or holder is still responsible for ensuring that the items or services conform to its Appendix B program, applicable ASME BPV Code requirements, and other regulatory requirements and commitments. The applicant or holder is also responsible for ensuring that the items or services are suitable for the intended application and for documenting this evaluation. The proposed exception is acceptable on the basis that it provides an appropriate level of quality and safety.

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

  - *The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the [CA] QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.*

  - *The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.*

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

    - *The calibration laboratory holds a domestic (United States) accreditation by an NRC approved domestic (United States) accrediting bodies, recognized by the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.*

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

    - *The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.*

  The staff determined that the provisions of this exception are consistent with the regulatory guidance provided in SRP Section 17.5, paragraph II.L.8, for the procurement of commercial-grade calibration services for safety-related applications and as documented in a previous SE under ADAMS Accession No. ML052710224. The staff expects full conformance to the guidance in SRP Section 17.5, paragraph II.L.8, and subparagraph h, that "The alternative method is limited to the domestic calibration service suppliers."

- *For Section 501, [CA] considers documents that may be stored in approved electronic media under [CA] 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. Following completion of the construction period, sufficient as-built documentation will be turned over to [CA] to support operations. The [CA] records management system will provide for timely retrieval of necessary records.*

  The staff determined that this alternative meets the requirements of Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services." Criterion VII requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. Therefore, this provision, which would allow for accessing and reviewing the necessary procurement documents at the site before installation and use, would meet this requirement.

- *In establishing commercial-grade item requirements, QAPD template commits to compliance with NQA-1a-2009, Section 700 and Subpart 2.14, with the following clarification:*

  - *For commercial-grade items, quality verification requirements are established and described in [CA] documents to provide the necessary assurance an item will perform satisfactorily in service. The [CA] 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.*

  - *[CA] will assume 10 CFR Part 21 reporting responsibility for all items that [CA] dedicates as safety-related.*

  The staff determined that the provisions of this exception are consistent with the regulatory requirements of 10 CFR Part 21 and regulatory guidance provided in SRP Section 17.5, paragraphs II.U.1.d and II.U.1.e.

3.2.8 Identification and Control of Materials, Parts, and Components

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.H, for establishing necessary measures for identification and control of items such as materials, including consumables, and items with limited shelf life, parts, components, and partially fabricated subassemblies. Identification of items is maintained throughout fabrication, erection, installation, and use so that the item is traceable to its documentation.

In establishing provisions for identification and control of items, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 8.

3.2.9 Control of Special Processes

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.I, for establishing and implementing programs, procedures, and processes to ensure that special processes requiring interim process controls to ensure quality, such as welding, heat treating, chemical cleaning, and nondestructive examinations, are controlled in accordance with applicable codes, specifications, and standards for the specific application.

In establishing measures for the control of special processes, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 9.

3.2.10 Inspection

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.J, for establishing necessary measures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to documented specifications, instructions, procedures, and design documents. The inspection program establishes requirements for planning inspections, determining applicable acceptance criteria, setting the

frequency of inspection, and identifying special tools needed to perform the inspection. Qualified personnel perform the inspections and are independent of those who performed or directly supervised the work

In establishing inspection requirements, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 10, and Subparts 2.4, 2.5 and 2.8 for establishing appropriate inspection requirements with the following clarifications;

- *Subpart 2.4 commits [CA] to Institute of Electrical and Electronics Engineers (IEEE) Std 336-1985, which refers to IEEE Std 498-1985. Both IEEE Std 336-1985 and IEEE Std 498-1985 use the definition of "Safety Systems" from IEEE Std 603-1980. [CA] commits to the definition of Safety Systems in IEEE Std 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.* The clarification is to reinforce the fact that the QAPD is not committing to the entirety of IEEE Std 603-1980. The staff determined that the use of the definition of safety systems equipment in the context of Subpart 2.4 is acceptable because it is an accurate clarification of the definition.

3.2.11 Test Control

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.K, for establishing necessary measures and governing provisions to demonstrate that items within the scope of the QAPD will perform satisfactorily in service, that the plant can be operated safely as designed, and that the operation of the plant, as a whole, is satisfactory.

[CA] establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained and configuration control maintained. To this end [CA] commits to compliance with the requirements of NQA-1a-2009, Requirement 11 and Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2008, Requirement 3.

In establishing provisions for testing, QAPD template commits the applicant to the quality standards described in NQA-1a-2009, Requirement 11.

3.2.12 Control of Measuring and Test Equipment

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.L, for establishing necessary measures to control the calibration, maintenance, and use of measuring and test equipment that provides information important to safe plant operation. In establishing provisions for control of measuring and test equipment, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 12 with the following clarification and exception:

NQA-1-2008, Subpart 2.4 refers to American National Standards Institute (ANSI)/IEEE Std 336-1985 for the installation, inspection, and testing requirements for power,

instrumentation, and control equipment at nuclear facilities. Where ANSI/IEEE Std 336-1985 makes reference to the use of IEEE Std 498-1985 for measuring and test equipment control, [CA] will implement the QA requirements of NQA-1-2008, Requirement 12. The staff finds that this alternative is consistent with the staff guidance provided in SRP Section 17.5, paragraph II.L.3.

3.2.13 Handling, Storage, and Shipping

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.M, for establishing necessary measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration.

In establishing provisions for handling, storage, and shipping, the QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 13. *[CA] also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-2008 and NQA-1a-2009, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions: [NOTE: This commitment and the following clarifications and exceptions do not apply to an ESP-only QAPD.]*

[NQA-1a-2009, Subpart 2.1

- *Subpart 2.1, Sections 301 and 302 establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, [CA] may establish cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. [CA] establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference under ADAMS Accession No. ML050700416.]]* The staff finds that this alternative is consistent with the staff guidance provided in SRP Section 17.5, and was approved previously in *ADAMS Accession No. ML050700416.*

NQA-1a-2009, Subpart 2.2

- *[Subpart 2.2, Section 202 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, [CA] may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference under ADAMS Accession No. ML050700416.]]* The

staff finds that this alternative is consistent with the staff guidance provided in SRP Section 17.5, and was approved previously in *ADAMS Accession No. ML050700416.*

- *Subpart 2.2, Section 606, "Storage Records." This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, [CA] documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.* The staff determined that this proposed alternative is acceptable, on the basis that these records do not meet the classification of a quality record as defined in NQA-1-2008, Requirement 17.

[NQA-1-2008, Subpart 2.3

- *Subpart 2.3, Section 202 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, [CA] bases its control over housekeeping activities 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, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference under ADAMS Accession No. ML050700416.]* The staff finds that this alternative is consistent with the staff guidance provided in SRP Section 17.5, and was approved previously in *ADAMS Accession No. ML050700416.*

NQA-1-2008, Part III, Subpart 3.2

- *Subpart 3.2, Appendix 2.1: only Section 300, "Cleaning Recommendations and Precautions" are being committed to in accordance with RG 1.37 "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," Revision 1. In addition, a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels.* The staff determined that this proposed clarification is acceptable, on the basis that these precautions are consistent with the regulatory positions of RG 1.37, Revision 1.

3.2.14 Inspection, Test, and Operating Status

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.N, for establishing necessary measures to identify the inspection, test, and operating status of items and components within the scope of the QAPD to maintain personnel and reactor safety and avert inadvertent operation of equipment.

In establishing measures for control of inspection, test, and operating status, the QAPD template commits the applicant to compliance with NQA-1-2008, Requirement 14.

3.2.15 Nonconforming Materials, Parts, or Components

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.O, for establishing necessary measures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Nonconformances are evaluated for their impact on operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation or maintenance of the item or service. Results of evaluations of conditions adverse to quality are analyzed to identify quality trends, documented, and reported to upper management in accordance with applicable procedures.

In addition, the QAPD template provides for establishing the necessary interfaces between the QA program for identification and control of nonconforming material, parts, and components and the non-QA reporting program that satisfy the applicable requirements of 10 CFR 50.55(e), and/or 10 CFR Part 21 during design, construction and operations.

In establishing measures for nonconforming materials, parts, or components, the QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 15.

3.2.16 Corrective Action

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.P, for establishing necessary measures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD template 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 are documented and reported to responsible management. In the case of suppliers working on safety-related activities or similar situations, the applicant or holder, as applicable, may delegate specific responsibility for the corrective action program, but the applicant or holder maintains responsibility for the program's effectiveness.

In addition, the QAPD template provides for establishing the necessary interfaces between the QA corrective actions program and the non-QA reporting program to identify, evaluate, and report defects and noncompliances to satisfy the applicable requirements of 10 CFR 50.55(e) and/or 10 CFR Part 21.

In establishing provisions for corrective action, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 16.

3.2.17 Quality Assurance Records

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.Q, for establishing necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable.

Regulatory position C.1.a of RG 1.28, Revision 4 provides record retention times for lifetime and nonpermanent records. In establishing the retention time for records, the QAPD template provides ESP and COL applicants the guidance to base the retention on regulatory position C.1.a of RG 1.28, Revision 4 or by including their specific table in the QAPD. The NRC staff will evaluate the adequacy of records retention times as site-specific information when an ESP or COL applicant submits their application.

Concerning the use of electronic records storage and retrieval systems, the QAPD template provides for compliance with NRC guidance given in GL 88-18, "Proposed Final NRC Generic Letter 88-18, Supplement 1," "Guidance on Managing Quality Assurance Records in Electronic Media," dated September 13, 1999; Regulatory Issue Summary 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000; and associated Nuclear Information and Records Management Association (NIRMA) guidelines TG 11-1998, TG 15-1998, and TG 21-1998.

In establishing provisions for records, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 17, and regulatory positions stated in RG 1.28, Revision 4.

3.2.18 Audits

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.R, for establishing necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the established requirements. The effectiveness of the audit program is reviewed as part of the overall audit process. The QAPD provides for the applicant or holder, as applicable, to conduct periodic internal and external audits. Internal audits are conducted to determine the adequacy of the program and its procedures and to determine if they are meaningful and comply with the QAPD requirements. Internal audits are performed with a frequency commensurate with safety significance and in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area within a period of 2 years after the initial determination that the audit program has been soundly established. External audits determine the adequacy of a supplier's or contractor's QA program. Responsible management reviews audit results; these reviews are documented. Management responds to all audit findings and initiates corrective action where indicated. Where corrective actions are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify that corrective action have been adequately implemented.

In establishing the independent audit program, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 18 and the regulatory positions stated in RG 1.28, Revision 4.

3.3 Nonsafety-Related SSC Quality Assurance Control

3.3.1 Nonsafety-Related SSCs—Significant Contributors to Plant Safety

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.V.1, for establishing specific program controls applied to nonsafety-related SSCs that are significant

contributors to plant safety and to which Appendix B does not specifically apply. Specific applicable QAPD controls are used in a prescribed manner, targeting those characteristics or critical attributes that make the SSC a significant contributor to plant safety consistent.

3.3.2 Nonsafety-Related SSCs Credited for Regulatory Events

In establishing quality requirements for nonsafety-related SSCs credited for regulatory events, the QAPD template follows the guidance of SRP Section 17.5, paragraph II.V.2, and commits the applicant to comply with the following regulatory guidance:

- The applicant or holder shall implement quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants," issued April 2001.

- The applicant or holder shall implement quality requirements for anticipated transient without scram (ATWS) equipment in accordance with GL 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," issued January 1985.

- The applicant or holder shall implement quality requirements for station blackout (SBO) equipment 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 Non-Safety Systems and Equipment," in RG1.155, Station Blackout," issued August 1988.

3.4 Regulatory Commitments

Commitments to NRC RGs identified in COL and ESP applications are listed in Chapter 1 of the Final Safety Analysis Report (FSAR). An applicant must make a specific statement for evaluation of conformance to the following RGs related to an applicant's QA program. These RGs are typically identified in Chapter 1 of the FSAR and their inclusion is consistent with RG 1.206, Section C.I.1.9.

- RG 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants," issued May 2000.

- RG 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," issued March 2007.

- RG 1.28, Revision 4, "Quality Assurance Program Requirements (Design and Construction)," issued June 2010.

- RG 1.29, Revision 4, "Seismic Design Classification," issued March 2007.

- RG 1.33, Revision 2, "Quality Assurance Program Requirements (Operations)," issued February 1978. (Exception to RG 1.33 see Section 3.4.1 of SER)

- RG 1.37, Revision 1, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants,” issued March 2007.

- RG 1.54, Revision 2, “Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants,” issued October 2010.

Applicants must provide an evaluation for conformance to the RGs identified in Part IV of the QAPD template, in the bracketed text, by either including a commitment to the RGs or by providing an alternative or exception to be reviewed for adequacy by the NRC staff. The NRC staff will review the adequacy of commitments to these RGs on an applicant-specific basis.

The QAPD template includes regulatory commitments to the following industry guidance related to QA:

- ASME NQA-1-2008 Edition with NQA-1a-2009 Addenda, “Quality Assurance Requirements for Nuclear Facility Applications.” The QAPD template commits to NQA-1-2008 with NQA-1a-2009 Addenda, Parts I and II, as described in Part[s] II [and V] of the QAPD template with specific identification of exceptions or clarification and commits to NQA-1-2008 with NQA-1a-2009 Addenda, and Part III only as specifically noted in Part[s] II [and V] of the QAPD template.

- NIRMA technical guides, as described in Section 3.2.17 of this SER.

3.4.1 Alternative for Commitment to RG 1.33

RG 1.33, Revision 2, describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants. The requirements for administrative controls of ANSI N18.7-1976 are incorporated into the text of the NEI 11-04, Revision 0, QAPD template in Part V. The principal difference between ANSI N18.7-1976 and NQA-1-2008 with NQA-1a-2009 Addenda is that administrative controls, required during the operational phase of a nuclear power plant, were not incorporated into NQA-1-2008 with NQA-1a-2009 Addenda. Therefore, in order to satisfy Appendix B to Part 50 requirements during the operations phase, an applicant must either demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-2008 with NQA-1a-2009 Addenda by explicitly addressing the provisions in NEI 11-04, Revision 0, Appendix 1, while also completing Part V of the QAPD template or, otherwise, by including an explicit commitment to RG 1.33 in Part IV of the QAPD. A commitment to RG 1.33 indicates the applicant will comply with the provisions of ANSI N18.7-1976, as supplemented or modified by the regulatory positions in RG 1.33. The NRC staff will review the adequacy of alternatives for commitment to RG 1.33 on an applicant-specific basis.

4.0 Conclusion

Based on its review of NEI 11-04, Revision 0, in accordance with the guidance of SRP Section 17.5, the NRC staff concludes that the QAPD template provides an acceptable format

and adequate guidance for establishing a QA program that complies with Appendix B to 10 CFR Part 50. The QAPD template is based on ASME NQA standard NQA-1-2008 with NQA-1a-2009 Addenda, as supplemented by additional regulatory guidance and industry guidance applicable to administrative and quality controls during nuclear power plant operation. Accordingly, the staff concludes that the QAPD template can be used, by applicants for 10 CFR Part 52 permits or licenses, as applicable, for establishing a QA program description required by the provisions of 10 CFR 52.17(a)(1)(xi) for an ESP application and 10 CFR 52.79(a)(25) for a COL application.

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 11-04 to determine if the applicant adequately followed the guidance provided in the QAPD template and has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in SRP Section 17.5. Key areas that an applicant is required to address include:

- The organizational description addressed in Part II, Section 1 of NEI 11-04.
- Record retention criteria addressed in Part II, Section 17.1 of NEI 11-04.
- Regulatory commitments addressed in Part IV of NEI 11-04.

To ensure all quality assurance requirements for the operating phase are addressed, an applicant must either demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-2008 with NQA-1a-2009 Addenda by explicitly addressing the provisions in NEI 11-04, Revision 0, Appendix 1, or otherwise by including a commitment to RG 1.33 in Part IV of the QAPD.

5.0 REFERENCES

1. Heymer, A. P., Nuclear Energy Institute, to the U.S. NRC, “NEI Technical Report on Template for an Industry Quality Program Description,” October 19, 2006. (ADAMS Accession No. ML062990149.)

2. U.S. NRC, Office of New Reactors, Final Safety Evaluation for Technical Report NEI 06-14, “Quality Assurance Program Description,” April 25, 2007. (ADAMS Accession No. ML070510300.)

3. U.S. NRC, Office of New Reactors, Final Safety Evaluation for Technical Report NEI 06-14, “Quality Assurance Program Description,” Revision9, July 13, 2010. (ADAMS Accession No. ML101800497.)

4. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, “NEI Technical Report 11-04, *Quality Assurance Program Description*, Draft Revision 0,” May 27, 2011. (ADAMS Accession No. ML111940285.)

5. U.S. NRC, Office of New Reactors, to the NEI, “Request for Additional Information

Regarding Nuclear Energy Institute Technical Report 11-04, Quality Assurance Program Description, Draft Revision 0," dated February 8, 2012, (ADAMS Accession No. ML12026A803.)

6. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "NEI Technical Report 11-04, *Quality Assurance Program Description*, Revision 0," September 13, 2012. (ADAMS Accession No. ML 12258A358.)

7. NUREG-0800, "Standard Review Plan," Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," March 2007. (ADAMS Accession No. ML06310019.)

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