April 25, 2007

Adrian P. Heymer, Senior Director
New Plant Deployment
Nuclear Generation Division
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington, DC 20006-3708

SUBJECT: FINAL SAFETY EVALUATION FOR TECHNICAL REPORT NEI 06-14, "QUALITY ASSURANCE PROGRAM DESCRIPTION" (PROJECT NO. 689; TAC NO. MD3406)

Dear Mr. Heymer:

By letter dated October 19, 2006, the Nuclear Energy Institute (NEI) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review, its proposed Quality Assurance Program Description (QAPD), Revision 0. By letter dated October 27, 2006, NEI designated this program as NEI 06-14.

Enclosed is the staff's safety evaluation (SE) which defines the basis for acceptance of NEI 06-14. On the basis of its review, the NRC staff finds that the NEI template for a QAPD complies with the applicable NRC regulations and industry standards and can be used for early site permits, combined licenses, construction, pre-operation and/or operation activities.

Our acceptance applies only to material provided in NEI 06-14. We do not intend to repeat our review of the acceptable material described in the NEI 06-14. When the NEI 06-14 appears as a reference in regulatory applications, our review will ensure that the material presented applies to the specific application involved. Licensing requests that deviate from NEI 06-14 will be subject to a plant- or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that NEI publish the accepted version of NEI 06-14 within three months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE after the title page. Also, the accepted version must contain historical review information, including NRC requests for additional information 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 06-14, NEI will be expected to revise NEI 06-14 appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact Joelle Starefos at (301) 415-8488, or JLS1@nrc.gov.

Sincerely,

/RA/

Stephanie M. Coffin, Chief
AP1000 Projects Branch
Division of New Reactor Licensing
Office of New Reactors

Project No. 689

Enclosure:
Safety Evaluation

cc w/encl: See next page

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FINAL SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS

TECHNICAL REPORT NEI-06-14

"TEMPLATE FOR A QUALITY ASSURANCE PROGRAM DESCRIPTION"

NUCLEAR ENERGY INSTITUTE (NEI)

PROJECT NO. 689

1. INTRODUCTION

By letter dated October 19, 2006 (Ref. 1), the Nuclear Energy Institute (NEI), submitted a technical report on an industry quality assurance program description (QAPD) template for review and approval by the U.S. Nuclear Regulatory Commission (NRC) staff. The NEI New Plant Quality Assurance Task Force developed the technical report for use by early site permit (ESP) applicants and combined license (COL) applicants and holders for new plant construction and operation. Letters dated January 4, 2007 (Ref. 2), and February 13, 2007 (Ref. 3), provided additional information in support of and revisions to the original QAPD template submitted on October 19, 2006.

The quality assurance program described in the QAPD template commits to the guidance in American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications." NEI used the guidance of the draft Standard Review Plan (NUREG-0800, referred to as the SRP), Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," to determine the appropriate regulatory guidance that applies to the proposed QAPD template.

The QAPD template contains bracketed text that the applicants will modify with specific information as necessary for the ESP or COL application. The staff will review and approve the bracketed text included in the QAPD template with the ESP and COL application to determine the acceptability of the QAPD submitted by the applicant.

2. REGULATORY EVALUATION

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," sets forth the Commission's regulatory requirements related to quality assurance programs.

Appendix B establishes quality assurance requirements for the design, fabrication, construction, and testing of the structures, systems and components (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.

3. EVALUATION

In evaluating the adequacy of the format and level of detail of the QAPD template, the staff followed draft SRP Section 17.5 for guidance (Ref.4). Draft SRP Section 17.5 outlines a quality assurance program for design certification, ESP, COL, construction permit, and operating license applicants. The staff developed draft SRP Section 17.5 using ASME NQA Standard NQA-1-1994, as supplemented by additional regulatory and industry guidance for nuclear operating facilities.

3.1 Quality Assurance Program Description Template Overview

The QAPD template provides guidance for establishing a top-level policy document that defines the quality policy and assigns major functional responsibilities. This QAPD template can be used for ESP, COL, construction, preoperation and/or operation activities, as applicable, affecting the quality and performance of safety-related SSCs. In addition, the QAPD template applies selected elements of the QAPD to nonsafety-related SSCs that are significant contributors to plant safety. It will be incumbent upon the applicant to identify the specific quality assurance requirements that need to be met for its specific scope of activities.

3.2 QAPD Template Details

3.2.1 Organization

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.A, for providing an organizational description that includes an organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation. The QAPD template establishes independence between the organization responsible for checking a function and the organization that performs the function. In addition, the QAPD template allows management to size the quality assurance organization commensurate with the duties and responsibilities assigned. The information in this section will be specific to the applicant and will require additional review and approval by the staff.

The template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

3.2.2 Quality Assurance Program

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.B for establishing the necessary measures to implement a quality assurance program to ensure that the design, construction, and operation of nuclear power plants are in accordance with governing regulations and license requirements. The quality assurance 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 COL final safety analysis report, as applicable. A list or system identifying SSCs and activities to which the QAPD applies is maintained at the 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 the 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 draft SRP Section 17.5, paragraph II.B.8, the QAPD applies a grace period of 90 days to activities that must be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backwards by performing the activity early.

The QAPD template follows the guidance of draft 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 that they achieve and maintain suitable proficiency. The plant technical specifications delineate the minimum qualifications for plant and support staff. Personnel complete the 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 also provides the minimum training requirements for managers responsible for QAPD implementation, in addition to the minimum training requirements for the individual responsible for planning, implementing, and maintaining the QAPD.

The QAPD template follows draft SRP Section 17.5, paragraph II.W for providing guidance to the applicant to establish an independent review program for activities occurring during the operational phase.

The QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 2S-1, includes use of the guidance provided in Appendix 2A-1 to NQA-1-1994 . The following alternatives may be applied to the implementation of this supplement and appendix:

  – As an alternative to the requirement in Appendix 2A-1 to be certified as Level I, II, or III; personnel performing independent quality verification inspections, examinations, measurements, or tests will be required to possess qualifications equal to or better than those required for performing the task being verified. In addition, the verification performed must be within the skills of these personnel and/or addressed by procedures. These personnel will not be responsible for planning quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspection), evaluating inspection training programs, or certifying inspection personnel. This alternative is consistent with draft SRP Section 17.5, paragraph II.T.5.

  – A qualified engineer may plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purposes of these functions, a qualified engineer is one who has a baccalaureate degree in engineering in a discipline related to the inspection activity (such as electrical, mechanical, or civil engineering) and has at least 5 years of engineering work experience, with at least 2 years of this experience related to nuclear facilities. In accordance with Supplement 2S-1 to

NQA-1-1994, the organization must designate those activities that require qualified inspectors and test personnel and establish written procedures for the qualification of these personnel. The NRC staff determined that the designation of a qualified engineer to plan inspections, evaluate inspectors, or evaluate the inspector qualification programs is acceptable. The staff's review determined that there is no conflict with regulatory guidance, NQA-1-1994, or other industry guidance in this subject area.

- As an alternative to NQA-1-1994, Supplement 2S-2, for the qualification requirements of nondestructive examination personnel, the QAPD template provides guidance to follow the applicable standard cited in the version(s) of Sections III and XI of the ASME Boiler and Pressure Vessel Code. The regulation in 10 CFR 50.55a, "Codes and Standards," requires use of the latest edition and addenda of Sections III and XI. Therefore, the staff finds the use of Sections III and XI of the ASME Boiler and Pressure Vessel Code for qualification of nondestructive examination personnel acceptable.

- As an alternative to the requirement of NQA-1-1994, Supplement 2S-3, that prospective lead auditors must have participated in a minimum of five audits in the previous 3 years, the QAPD template follows the guidance provided in draft SRP Section 17.5, paragraph II.S.4.c:

  The prospective Lead Auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by the company, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification.

3.2.3 Design Control

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.C, for establishing the necessary measures to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. The QAPD template design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces with 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 quality assurance principles to review design documents to ensure that they contain the necessary quality assurance requirements.

The QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 3 and Supplement 3S-1, for establishing the program for design control and verification, Subpart 2.20 for the subsurface investigation requirements and Subpart 2.7 for the standards for computer software quality assurance controls.

3.2.4 Procurement Document Control

The QAPD template follows the guidance of draft 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 quality assurance 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 comply with the quality standards described in NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following clarifications and exceptions:

- As an alternative to NQA-1-1994, Supplement 4S-1, Section 2.3, which states that procurement documents must require suppliers to have a documented quality assurance program that implements NQA-1-1994, Part I, the QAPD proposes that suppliers have a documented quality assurance program that meets Appendix B to 10 CFR Part 50, as applicable to the circumstances of the procurement. Criterion IV, "Procurement Document Control," of Appendix B requires suppliers to have a quality assurance program consistent with Appendix B. Therefore, the staff determined that this clarification is acceptable, as delineated in draft SRP Section 17.5, paragraph II.D.2.d.

- The QAPD proposes that procurement documents allow the supplier to work under the applicant's QAPD, including implementing procedures, in lieu of the supplier having its own quality assurance program. Criterion IV of Appendix B requires suppliers to have a quality assurance program consistent with Appendix B. Therefore, the staff determined this clarification to be acceptable, as delineated in draft SRP Section 17.5, paragraph II.D.2.d.

- As an alternative to NQA-1-1994, Supplement 4S-1, Section 3, which requires procurement documents to be reviewed before award of the contract, the QAPD proposes to conduct the quality assurance review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements, before contract award. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive quality assurance review. The staff evaluated this proposed alternative and determined that it provides adequate quality assurance review of procurement documents before awarding the contract and after any change. Therefore, the staff concluded that this alternative is acceptable.

- Procurement documents for commercial-grade items that the applicant or holder will procure as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated. This alternative is consistent with staff guidance in Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989, and Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, as delineated in draft 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 draft 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, and drawings.

The QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 5, for establishing procedural controls.

3.2.6 Document Control

The QAPD template follows the guidance of draft 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 personnel can readily determine the appropriate document for use.

To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed and updated as necessary, consistent with staff guidance provided in draft SRP Section 17.5, paragraph II.F.8. If temporary procedure changes are necessary during the operational phase, changes that clearly do not alter the intent of the approved procedure may be implemented provided that two members of the staff knowledgeable in the areas affected by the procedure approve the changes. During the operational phase, temporary changes include a designation of the period of time during which it is acceptable to use the changed procedure.

In establishing provisions for document control, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

3.2.7 Control of Purchased Material, Equipment, and Services

The QAPD template follows the guidance of draft 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 program provides measures for evaluating prospective suppliers and selecting only those that are qualified. In addition, the program provides for 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 by properly reviewed and approved revisions to ensure that the items are suitable for the 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 comply with the quality standards described in NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

- The QAPD template proposes that other 10 CFR Part 50 licensees (i.e., other than the applicant or holder), authorized nuclear inspection agencies, the National Institute of Standards and Technology (NIST), and other State and Federal agencies that may provide items or services to the applicant or holder are not required to be evaluated or audited.

  The staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection 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 safety evaluation (Ref. ADAMS Accession No. ML003693241). The applicant or holder is still responsible for ensuring that the items or services conform with its Appendix B program, applicable ASME Boiler and Pressure Vessel 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.

- The QAPD template includes provisions consistent with the regulatory guidance provided in draft SRP Section 17.5, paragraph II.L.8, for the procurement of commercial-grade calibration services for safety-related applications. The QAPD template proposes not to require procurement source evaluation and selection measures provided each of the following conditions are met:

  – Purchase documents impose additional technical and administrative requirements to satisfy QAPD and technical requirements.

  – 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 accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or the American Association for Laboratory Accreditation, as recognized by NVLAP through the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.

    • The accreditation is based on ANS/ISO/IEC 17025.

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

- As an alternative to NQA-1-1994, Supplement 7S-1, Section 8.1, in terms of the requirement for documents to be available at the site, the QAPD template proposes that documents may be stored in approved electronic media under the applicant's, holder's or

supplier's control and not physically located at the plant site, as long as they are accessible from the respective nuclear facility. Following completion of the construction period, sufficient as-built documentation will be turned over to the licensee to support operations. The staff determined that this alternative meets 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.

- As an alternative to NQA-1-1994, Supplement 7S-1, Section 10, requirements for the control of commercial-grade items and services, the QAPD template commits the applicant to follow NRC guidance discussed in Generic Letter 89-02 and Generic Letter 91-05 as delineated in draft SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d.

- Consistent with the guidance mentioned above for commercial-grade items and services, the commercial-grade program provides for special quality verification requirements to be established and described in applicable documents to provide the necessary assurance that the item will perform satisfactorily in service. In addition, the documents provide for determining critical characteristics to ensure that an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

3.2.8 Identification and Control of Materials, Parts, and Components

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

In establishing provisions for identification and control of items, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

3.2.9 Control of Special Processes

The QAPD template follows the guidance of draft 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 the applicable codes, specifications, and standards of the specific work.

In establishing measures for the control of special processes, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 9 and Supplement 9S-1.

3.2.10 Inspection

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.J, for establishing the necessary measures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. 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. Properly qualified personnel who are independent of those who performed or directly supervised the work perform the inspections.

In establishing inspection requirements, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 10, Supplement 10S-1, and Subparts 2.4, 2.5 and 2.8, with the following clarifications and exceptions:

- NQA-1-1994, Subpart 2.4, commits the applicant or licensee, as applicable, to Institute of Electrical and Electronic Engineers (IEEE) Standard 336-1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities." IEEE 336-1985 refers to IEEE 498-1985, "IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities." Both of these standards use the definition of "safety systems equipment" from IEEE 603-1980, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." The QAPD template commits the applicant or licensee, as applicable, to the definition of safety systems equipment from IEEE 603-1980 but does not commit the applicant or holder to the balance of IEEE 603-1980. This definition applies only to equipment in the context of Subpart 2.4.

  The following is the definition of safety system in IEEE 603-1980:

  > Those systems (the reactor trip system, an engineered safety feature, or both, including all their auxiliary supporting features and other auxiliary feature) which provide a safety function. A safety system is comprised of more than one safety group of which any one safety group can provide the safety function.

  The QAPD needs to commit to the definition of safety systems equipment from IEEE 603-1980 in order to appropriately implement Subpart 2.4 of NQA-1-1994. The clarification is to reinforce the fact that the QAPD is not committing to the entirety of IEEE 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 clarifies the definition.

- As an alternative for sites that may not meet the requirement of NQA-1-1994, Supplement 10S-1, Section 3.1, for independent reporting, the QAPD proposes that the inspector must report to quality control management while performing the inspection. This alternative is consistent with staff guidance provided in draft SRP 17.5, paragraph II.J.1.

3.2.11 Test Control

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.K, for establishing the necessary measures and governing provisions to demonstrate that items subject to the provisions 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.

In establishing provisions for testing, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 11 and Supplement 11S-1.

In establishing provisions to ensure that computer software used in applications affecting safety is prepared, documented, verified, tested, and used such that the expected outputs are obtained and configuration control maintained, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Supplements 11S-2 and Subpart 2.7.

3.2.12 Control of Measuring and Test Equipment

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.L, for establishing the 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, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 12 and Supplement 12S-1, with the following clarifications and exceptions:

- The QAPD template clarifies that the out-of-calibration conditions, described in paragraph 3.2 of Supplement 12S-1 of NQA-1-1994, refer to cases where the measuring and test equipment are found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. The staff determined that the clarification for the out-of-calibration conditions is acceptable, on the basis that it clarifies a definition.

- As an alternative to the NQA-1-1994, Subpart 2.4, Section 7.2.1, calibration labeling requirements, the QAPD template proposes that the required calibration information be maintained in suitable documentation traceable to the device for measuring and test equipment which is impossible or impractical to mark because of equipment size or configuration. This alternative is consistent with the staff guidance provided in draft SRP 17.5, paragraph II.L.3.

3.2.13 Handling, Storage, and Shipping

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.M, for establishing the 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 comply with the quality standards described in NQA-1-1994, Basic Requirement 13 and Supplement 13S-1. The QAPD template also commits the applicant, during the

construction and preoperations phase of the plant, as applicable, to comply with the requirements of NQA-1-1994, Subparts 2.1, 2.2, and 2.15, with the following clarification and exception:

- As an alternative to the NQA-1-1994, Subpart 2.2, Section 6.6, "Storage Records," requirement for the preparation of records containing information on personnel access to quality assurance records, the QAPD template provides for documents to establish control of storage areas that describe those authorized to access the area and the requirements for recording access of personnel. The QAPD template proposes not to consider these records as quality records. The plants will retain these records in accordance with the plants' administrative controls. The staff determined that the proposed alternative is acceptable, on the basis that these records do not meet the classification of a quality record as defined in NQA-1-1994, Supplement 17S-1, Section 2.7.

3.2.14 Inspection, Test, and Operating Status

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

In establishing procurement verification control, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 14.

3.2.15 Nonconforming Materials, Parts, or Components

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.O, for establishing the 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 measures to implement a reporting program in accordance with the requirements of 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," 10 CFR 50.55(e), and/or 10 CFR Part 21, as applicable.

In establishing measures for nonconforming material, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 15 and Supplement 15S-1.

3.2.16 Corrective Action

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.P, for establishing the 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 measures to implement a program to identify, evaluate, and report defects and noncompliances in accordance with the requirements of 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable.

In establishing a corrective action program, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 16.

3.2.17 Quality Assurance Records

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

Concerning the use of electronic records storage and retrieval systems, the QAPD template provides for compliance with NRC guidance given in Generic Letter 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, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the following clarification and exception:

- As an alternative to the NQA-1-1994, Supplement 17S-1, Section 4.2(b), requirements for records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers, the QAPD template proposes that hard records be stored in steel cabinets or on shelving in containers, except that methods other than binders, folders, or envelopes may be used to organize records for storage. In a previous safety evaluation (Ref.6 ADAMS Accession No. ML052360625), the staff determined that this proposed alternative is acceptable.

3.2.18 Quality Assurance Audits

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.R, for establishing the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established. The audit program is also reviewed for effectiveness 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 overall QAPD. 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 quality assurance program elements is completed for each functional area within a period of 2 years after the determination that the program is well established. External audits determine the adequacy of a supplier's or contractor's quality assurance program. The responsible management documents and reviews audit results. Management responds to all audit findings and initiates corrective action where indicated. In addition, where corrective actions are indicated, documented followup of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

In establishing the independent audit program, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

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 draft 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 apply. The QAPD template applies specific controls to those items in a selected manner, targeting those characteristics or critical attributes that render the SSC a significant contributor to plant safety consistent with applicable sections of the QAPD.

3.3.2 Nonsafety-Related SSCs Credited for Regulatory Events

In establishing the quality requirements for nonsafey-related SSCs credited for regulatory events, the QAPD template follows the guidance of draft 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 Regulatory Guide 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 Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," issued Januray 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 Regulatory Guide 1.155, "Station Blackout," issued August 1988.

3.4 Regulatory Commitments

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.U, for establishing quality assurance program commitments. The QAPD template commits the applicant to comply with the following NRC regulatory guides and other quality assurance

standards to supplement and support the QAPD:

- Regulatory Guide 1.26, Revision 3, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," issued February 1976.

  The QAPD template commits the applicant to comply with the regulatory positions of this guidance with the exception of Criteria C.1, C.1.a, C.1.b, and C.3. As documented in the staff's "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design" (NUREG-1793), issued September 2000, and Supplement 1 to NUREG-1793, issued December 2005, the staff determined that the proposed exceptions are acceptable for use with the AP1000 design.

- Regulatory Guide 1.29, Revision 3, "Seismic Design Classification," issued September 1978.

  The QAPD template commits the applicant to comply with the regulatory positions of this guidance with the exception of Criteria C.1.d, C.1.g, and C.1.n. As documented in NUREG-1793 and Supplement 1 to NUREG-1793, the staff determined that the proposed exceptions are acceptable for use with the AP1000 design.

- ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described in Sections 3.2.1 through 3.2.18 of this safety evaluation report (SER).

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

4. ALTERNATIVES AND EXCEPTIONS NOT PREVIOUSLY REVIEWED AND APPROVED

During the QAPD template review, the staff needed to evaluate the following areas where the QAPD template takes exceptions or offers alternatives to the guidance of draft SRP Section 17.5 or NQA-1-1994:

- As an alternative to Appendix 2A-1 to NQA-1-1994, a qualified engineer may plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. As described in Section 3.2.2 of this SER, for purposes 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, or civil engineering) and has a minimum of 5 years of engineering work experience, with at least 2 years of this experience related to nuclear facilities. Supplement 2S-1 of NQA-1-1994 requires the organization to designate those activities that require qualified inspectors and test personnel and establish written procedures for the qualification of these personnel. The staff determined that the designation of a qualified engineer to plan inspections, evaluate inspectors, or evaluate the inspector qualification programs is acceptable.

- As an alternative to the NQA-1-1994, Supplement 4S-1, Section 3, requirements that procurement documents be reviewed before bid award of the contract, the QAPD provides for quality assurance review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements,

before bid award of the contract. As described in Section 3.2.4 of this SER, procurement document changes (e.g., changes in scope, technical, or quality requirements) will also receive quality assurance review. The staff evaluated this proposed alternative and determined that it provides adequate quality assurance review of procurement documents before bid award of the contract and after any change. Therefore, the staff concluded that this alternative is acceptable.

- As an alternative to the NQA-1-1994, Supplement 7S-1, Section 8.1, requirement for documents to be available at the site, the QAPD template considers documents that may be stored in approved electronic media under the applicant's, holder's, or supplier's control and that are not physically located at the plant site but are accessible from the facility, as meeting the requirement. As described in Section 3.2.7 of this SER, following completion of the construction period, sufficient as-built documentation will be turned over to the licensee to support operations. The staff determined that this alternative meets Appendix B, Criterion VII. Criterion VII requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. Therefore, accessing and reviewing the necessary procurement documents at the site before installation and use would meet the requirement.

- As an alternative to the NQA-1-1994, Subpart 2.2, Section 6.6, "Storage Records," requirement for the preparation of records containing information on personnel access, the QAPD template provides for documents to establish control of storage areas that describe those authorized to access the area and the requirements for recording access of personnel. As described in Section 3.2.13 of this SER, the QAPD template does not consider these records to be quality records. The plants will retain these records in accordance with the plants' administrative controls. The staff determined that the proposed alternative is acceptable, on the basis that these records did not meet the classification of a quality record as defined in NQA-1-1994, Supplement 17S-1, Section 2.7.

5. CONCLUSION

The staff used the provisions of Appendix B to 10 CFR Part 50 and the guidance of Draft SRP Section 17.5 as the basis for evaluating the acceptability of the QAPD template. On the basis of the staff's review of the QAPD template, the staff concludes that:

- The QAPD template provides adequate guidance for an applicant to describe the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.

- The QAPD template provides adequate guidance for an applicant to provide for organizations and persons to perform verification and self-assessment functions with the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.

- The QAPD template provides adequate guidance for an applicant to apply a QAPD to activities and items that are important to safety.

- The QAPD template provides adequate guidance for an applicant to establish controls that, when properly implemented, comply with the requirements of 10 CFR Part 52, Appendix B

to 10 CFR Part 50, 10 CFR Part 21, and 10 CFR 50.55(e), with the criteria contained in draft SRP Section 17.5, and with the commitments to regulatory guidance.

On the basis of its review, the staff concludes that the QAPD template provides adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance. Accordingly, the staff concludes that the QAPD template can be used by an applicant or holder for ESP, COL, construction, preoperation and/or operation activities, as applicable.

6. REFERENCES

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3. Heymer, A. P., Nuclear Energy Institute, to the U.S. NRC, “NEI Technical Report 06-14, *Template for an Industry Quality Program Description*, Revision 3," February 13, 2007.

4. NUREG-0800, “Standard Review Plan,” Draft Section 17.5, “Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants,” January 2006.

5. U.S. NRC, Office of Nuclear Reactor Regulation, “Edwin I. Hatch Nuclear Power Station, Units 1 and 2, Approval of Relief Request RR-27, Third-Year Interval Inservice Inspection Program (TAC Nos. MA6163 and MA6164)” (ADAMS Accession No. ML003693241), March 20, 2000.

6. U.S. NRC, Office of Nuclear Reactor Regulation, Safety Evaluation of the Proposed Change to the Quality Assurance Program, “Approval of Nuclear Management Company Quality Assurance Topical Report” (ADAMS Accession No. ML052360625), August 26, 2005.

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