

17.0 QUALITY ASSURANCE PROGRAM DESCRIPTION

17.1 Introduction

Southern Nuclear Operating Company (SNOG) submitted an Early Site Permit Application for the Vogtle site by letter, dated August 15, 2007. Chapter 17.0, Appendix 17.1A, "Nuclear Development Quality Assurance Manual" (QA Manual), establishes a quality assurance program that can be applied to the Early Site Permit application (ESP) and the limited work authorization (LWA) activities described in Supplement 2-S1.

This safety evaluation addresses Revision 6 of the Vogtle Early Site Permit Application QA Manual. Revision 6 of the QA manual incorporates the standard format and content of Nuclear Energy Institute (NEI) 06-14A, "Quality Assurance Program Description," and supersedes the staff's previous safety evaluation on Revision 3 of the Vogtle ESP QA Manual issued on August 30, 2007. NEI 06-14A covers a variety of applications, including combined licenses, construction, preoperation, and operation activities. However, this evaluation covers only those activities described in the Vogtle ESP Application and Supplement 2-S1.

17.2 Regulatory Evaluation

Title 10 of the Code of Federal Regulations (10 CFR) Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," establishes the Commission's QA requirements for the design, fabrication, construction, and testing of the structures, systems and components (SSCs) of the facility. These requirements apply to all activities affecting the safety-related functions of those SSCs. This includes designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

Section 52.17, "Contents of Applications; Technical Information," of 10 CFR establishes the technical information requirements for ESP applications. Subsection 52.17(1)(a)(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.

17.3 Technical Evaluation

The staff used Standard Review Plan (SRP) Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," (NUREG-0800, Section 17.5, "Quality Assurance Program Description") to evaluate the applicant's QA program description (QAPD). In developing SRP Section 17.5, the staff used American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, as supplemented by regulatory and industry guidance for nuclear operating facilities.

The QAPD is a top-level policy document that defines the quality policy and assigns major functional responsibilities. The QAPD applies to safety-related SSCs as well as selected elements of nonsafety-related SSCs that are nevertheless important to plant safety.

The QAPD cites a number of activities, such as operating, refueling, and decommissioning activities, that are outside the scope of this safety evaluation. This safety evaluation is limited to activities described by the Vogtle ESP application and LWA supplement.

17.3.1 Organization

The applicant's QAPD follows the guidance of 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 establishes independence between the organization responsible for checking a function and the organization that performs the function. In addition, the QAPD allows management to size the quality assurance organization according to the duties and responsibilities assigned.

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

17.3.2 Quality Assurance Program

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.B, to ensure that the QA Manual describes all aspects of work that are important to the safety of nuclear power plants. The quality assurance program comprises those planned and systematic actions necessary to provide confidence that SSCs will perform their intended safety function, as described in the applicant's final safety analysis report (FSAR). This includes certain nonsafety-related SSCs and activities that are important to plant safety. The appropriate facility maintains a list or system identifying SSCs and activities to which the QAPD applies.

The QAPD provides measures to assess its adequacy and to ensure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. Consistent with 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 follows the guidance of SRP Section 17.5, paragraphs II.S and II.T, for establishing and maintaining training programs for personnel who perform, verify, or maintain activities within the scope of the QAPD. The QAPD provides the minimum training requirements for managers responsible for QAPD implementation. It also provides the minimum training requirements for the individual responsible for planning, implementing, and maintaining the QAPD.

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

- ASME Standard NQA-1-1994, Supplement 2S-1, includes use of the guidance provided in Appendix 2A-1 to ASME Standard 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 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 ASME Standard 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 U. S. Nuclear Regulatory Commission (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 this approach is consistent with regulatory guidance, ASME Standard NQA-1-1994, or other industry guidance in this subject area.

- ASME Standard NQA-1-1994, Supplement 2S-2, describes the qualification requirements of nondestructive examination personnel. As an alternative, the applicant's QAPD 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 ASME Boiler and Pressure Vessel Code Sections III and XI. Therefore, the staff accepts the use of Sections III and XI of the ASME Code for qualification of nondestructive examination personnel.
- ASME Standard NQA-1-1994, Supplement 2S-3 requires that prospective lead auditors must have participated in a minimum of five audits in the previous 3 years. As an alternative, the applicant's QAPD follows the guidance provided in 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.

17.3.3 Design Control

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.C, for controlling 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 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 (e.g., design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (e.g., analyses, specifications, drawings, procedures, and instructions). In addition, the QAPD provides for individuals knowledgeable in quality assurance principles to review design documents for the necessary quality assurance requirements.

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

17.3.4 Procurement Document Control

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.D, for ensuring that procurement documents include or reference applicable regulatory, technical, and quality assurance program requirements. These 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 commits the applicant to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following clarifications and exceptions:

- ASME Standard NQA-1-1994, Supplement 4S-1, Section 2.3, states that procurement documents must require suppliers to have a documented quality assurance program that implements ASME Standard NQA-1-1994, Part I. As an alternative, 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 10 CFR Part 50, Appendix B requires suppliers to have a quality assurance program consistent with Appendix B. Therefore, the staff accepted this clarification, as delineated in 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 (in lieu of the supplier having its own quality assurance program). Criterion IV of 10 CFR Part 50, Appendix B requires suppliers to have a quality assurance program consistent with Appendix B. Therefore, the NRC staff accepted this clarification, as delineated in SRP Section 17.5, paragraph II.D.2.d.
- ASME Standard NQA-1-1994, Supplement 4S-1, Section 3, requires procurement documents to be reviewed before award of the contract. As an alternative, 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 NRC 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 NRC staff accepted this alternative.
- 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 NRC 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.d and II.U.1.e.

17.3.5 Instructions, Procedures, and Drawings

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

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

17.3.6 Document Control

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.F, for controlling 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 QAPD provides measures to ensure that the same organization that performed the original review and approval also reviews and approves changes, 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.

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

17.3.7 Control of Purchased Material, Equipment, and Services

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.G, for controlling the procurement of items and services to ensure conformance with 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 (e.g. source verification, receipt inspection, pre- and postinstallation tests) and review of documentation (e.g., 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 (e.g., 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 to maintain safety.

In establishing procurement verification control, the QAPD commits the applicant to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

- The QAPD proposes that other 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” 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 do not require evaluation or audit.

The NRC staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, NIST, and other State and Federal agencies perform work under acceptable quality programs, and require no additional evaluation. The applicant or holder is still responsible for ensuring that the items or services conform to 10 CFR Part 50, Appendix B program, applicable ASME Code requirements, and other regulatory requirements and commitments. The applicant or holder is also responsible for ensuring and documenting that the items or services are suitable for the intended use. The NRC staff accepted a similar exception in a previous safety evaluation (“Approval of Relief Request RR-27,” ADAMS No. ML003693241) and accepts the applicant’s exception because it provides an appropriate level of quality and safety.

- The QAPD includes provisions 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. The QAPD 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 by 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.

- ASME Standard NQA-1-1994, Supplement 7S-1, Section 8.1, describes requirements for documents to be available at the site. As an alternative, the QAPD 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 NRC staff determined that this alternative meets 10 CFR Part 50, 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.
- ASME Standard NQA-1-1994, Supplement 7S-1, Section 10, describes requirements for the control of commercial-grade items and services. As an alternative, the QAPD commits the applicant to follow NRC guidance discussed in GL 89-02 and GL 91-05 as delineated in SRP Section 17.5, paragraphs II.U.1.d and II.U.1.e.
- Consistent with the guidance mentioned above for commercial-grade items and services, the commercial-grade program provides for special quality verification requirements 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. It also provides for technical evaluation of the item, receipt requirements, and quality evaluation of the item.

17.3.8 Identification and Control of Materials, Parts, and Components

The applicant's QAPD follows the guidance of 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.

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

17.3.9 Control of Special Processes

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.I, to assure that special processes requiring interim process controls (e.g. welding, heat treating, chemical cleaning, and nondestructive examinations), are quality 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 commits the applicant to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 9 and Supplement 9S-1.

17.3.10 Inspection

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.J, to ensure that items, services, and activities that affect safety meet requirements and conform to 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. Inspectors are properly qualified personnel who are independent of those who performed or directly supervised the work.

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

- ASME Standard NQA-1-1994, Subpart 2.4, commits the applicant or licensee 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 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 ASME Standard NQA-1-1994, 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 ASME Standard NQA-1-1994. The clarification reinforces the fact that the QAPD is not committing to the entirety of IEEE 603-1980. The NRC staff accepts the definition of safety systems equipment in the context of ASME Standard NQA-1-1994, Subpart 2.4 because it clarifies the definition.

- As an alternative for sites that may not meet the requirement of ASME Standard 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 NRC staff guidance provided in SRP 17.5, paragraph II.J.1.

17.3.11 Test Control

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.K, 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 commits the applicant to comply with the quality standards described in ASME Standard 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 commits the applicant to comply with the quality standards described in ASME Standard NQA-1-1994, Supplements 11S-2 and Subpart 2.7.

17.3.12 Control of Measuring and Test Equipment

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.L, for controlling the calibration, maintenance, and use of measuring and test equipment that provides safety information.

In establishing provisions for control of measuring and test equipment, the QAPD commits the applicant to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 12 and Supplement 12S-1, with the following clarifications and exceptions:

The QAPD clarifies that the out-of-calibration conditions, described in paragraph 3.2 of Supplement 12S-1 of ASME Standard 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 NRC staff determined that the clarification for the out-of-calibration conditions is acceptable, on the basis that it clarifies a definition.

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

17.3.13 Handling, Storage, and Shipping

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.M, for controlling 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 commits the applicant to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 13 and Supplement 13S-1. The QAPD also commits the applicant, during the construction and preoperations phase of the plant, to comply with the requirements of

ASME Standard NQA-1-1994, Subparts 2.1, 2.2, and 2.15, with the following clarification and exception:

ASME Standard NQA-1-1994, Subpart 2.2, Section 6.6, "Storage Records," contains requirements for the preparation of records containing information on personnel access to quality assurance records. As an alternative, the QAPD 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 proposes not to consider these records as quality records. The plants will retain these records in accordance with the plants' administrative controls. The NRC 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 ASME Standard NQA-1-1994, Supplement 17S-1, Section 2.7.

17.3.14 Inspection, Test, and Operating Status

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.N, for identifying the inspection, test, and operating status of items and components subject to the QAPD. This maintains personnel and reactor safety and avoids inadvertent operation of equipment.

In establishing measures for control of inspection, test and operating status, the QAPD commits to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 14.

17.3.15 Nonconforming Materials, Parts, or Components

The QAPD follows the guidance of SRP Section 17.5, paragraph II.O, to control items, including services, which do not conform to specified requirements to prevent inadvertent installation or use. Instances of nonconformance 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. They are then documented and reported to upper management.

In addition, the QAPD 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), "Definitions"; and/or 10 CFR Part 21, "Reporting of Defects and Noncompliance."

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

17.3.16 Corrective Action

The QAPD follows the guidance of SRP Section 17.5, paragraph II.P, to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD requires personnel to identify conditions adverse to quality and find 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 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 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 commits the applicant to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 16.

17.3.17 Quality Assurance Records

The applicant's QAPD follows SRP Section 17.5, paragraph II.Q to ensure that 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 provides for compliance with NRC guidance given in 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.

The QAPD commits the applicant to comply with the records standards described in ASME Standard NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the following clarification and exception:

- ASME Standard NQA-1-1994, Supplement 17S-1, Section 4.2(b) requires records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. As an alternative, the QAPD 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 (ADAMS Accession No. ML052430024), the NRC staff accepted a similar alternative. Therefore this alternative is acceptable.

17.3.18 Quality Assurance Audits

The applicant's QAPD follows SRP Section 17.5, paragraph II.R, to audit activities covered by the QAPD. The audit program is reviewed as part of the overall audit process. The QAPD provides for the applicant or holder to conduct periodic internal and external audits. Internal audits determine the adequacy of the program and procedures and determine if they comply with the overall QAPD. Internal audits are performed with a frequency commensurate with safety significance. An audit of all applicable quality assurance program elements is completed for each functional area within 2 years after 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. In addition, where corrective actions are indicated, documented followup of applicable areas through inspections, review, reaudits, or other means is conducted to verify corrective action.

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

17.3.19 Non-safety-Related SSC Quality Assurance Control

17.3.19.1 Non-safety-Related SSCs Important to Plant Safety

The QAPD follows the guidance of SRP Section 17.5, paragraph II.V.1, for establishing specific program controls applied to nonsafety-related SSCs that are important to plant safety and to which 10 CFR Part 50, Appendix B does not apply. The QAPD applies specific controls to those items in a selected manner, targeting those characteristics or critical attributes that render the SSC important to plant safety consistent with applicable sections of the QAPD.

17.3.19.2 Nonsafety-Related SSCs Credited for Regulatory Events

The applicant's QAPD commitments refer to fire protection (10CFR 50.48, "Fire Protection"), anticipated transients without scram (10 CFR 50.62, "Requirements for Reduction of Risk from Anticipated Transients without Scram (ATWS) Events for Light-Water-Cooled Nuclear Power Plants"), and station blackout (10 CFR 50.63, "Loss of all Alternating Current Power"). These regulations are outside the scope of the application and, therefore, staff did not review them as part of this safety evaluation.

17.3.20 Regulatory Commitments

The QAPD follows the guidance of SRP Section 17.5, paragraph II.U, for establishing quality assurance program commitments. The QAPD 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 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," March 2007.

The QAPD 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 NUREG-1793, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," dated September 2000, and Supplement 1 to NUREG-1793, dated December 2005, the NRC staff determined that the proposed exceptions are acceptable for use with the AP1000 design.

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

The QAPD commits the applicant to comply with Regulatory Guide 1.29 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 NRC staff determined that the proposed exceptions are acceptable for use with the AP1000 design.

- ASME Standard NQA-1-1994, “Quality Assurance Requirements for Nuclear Facility Applications,” Parts I and II, as described in Sections 17.3.1 through 17.3.18 of this safety evaluation report (SER).
- NIRMA technical guides, as described in Section 17.3.17 of this SER.

17.4 Conclusion

- The NRC staff used the provisions of Appendix B to 10 CFR Part 50 and the guidance of SRP Section 17.5 to evaluate the QAPD. Staff concludes the following:
- The QAPD 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 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 provides adequate guidance for an applicant to apply the QAPD to activities and items that are important to safety.
- The QAPD provides adequate guidance for establishing controls that, when properly implemented, comply with the requirements of 10 CFR Part 52, 10 CFR Part 50, Appendix B, 10 CFR Part 21, 10 CFR 50.55(e); with the acceptance criteria contained in SRP 17.5, and with the commitments to applicable regulatory guidance.

On the basis of its review, the NRC staff concludes that the applicant’s QAPD provides adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by following the guidance of ASME Standard NQA-1-1994, as supplemented by regulatory and industry guidance. Accordingly, the NRC staff concludes that the QAPD can be used by the applicant for ESP and activities authorized by the limited work authorization.