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17 QUALITY ASSURANCE

17.5 Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants

17.5.1 Introduction

PSEG Power, LLC and PSEG Nuclear, LLC (PSEG) submitted on May 25, 2010, an Early Site Permit (ESP) application for a site near Salem, NJ. Under a separate May 25, 2010, letter PSEG submitted the "Quality Assurance Program Description" (QAPD) as part of the ESP application.

PSEG QAPD incorporates the standard format and content of Revision 8 of the Nuclear Energy Institute's (NEI's) "Quality Assurance Program Description" (NEI-06-14A). Although the U.S. Nuclear Regulatory Commission (NRC) has not endorsed this specific revision of NEI-06-14A, the staff finds its use acceptable based on the approval of NEI-06-14A, Revision 7. The changes made in NEI-06-14A, Revision 8, are related to quality assurance programs (QAPs) for operating nuclear power plants (NPPs).

NEI-06-14A covers a variety of applications, including combined licenses (COL), construction, pre-operation, and operation activities. However, this evaluation covers only those activities described in the PSEG ESP application and QAPD.

17.5.2 Summary of Application

PSEG ESP Site Safety Analysis Report (SSAR), Revision 1, Section 17.1, identified the QAPD implemented during the development of the ESP application. The QAPD is a top-level policy document that defines the quality policy and assigns major functional responsibilities. The QAPD applies to safety-related Structures, Systems, and Components (SSCs) as well as to selected elements of non-safety-related SSCs that are nevertheless important to plant safety.

The PSEG QAPD addresses the activities associated with the ESP. These activities include designing, procuring, handling, testing, siting, inspecting, storing, training, and shipping. The QAPD is based on the applicable portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Pants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and the American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Requirements for Nuclear Facilities."

17.5.3 Regulatory Basis

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," establishes the NRC Quality Assurance (QA)

requirements for the design, fabrication, construction, and testing of the facility SSCs. These requirements apply to all activities affecting the safety-related functions of those SSCs. This includes, but is not limited to, designing, procuring, handling, testing, siting, inspecting, storing, training, and shipping.

The technical information requirements for ESP applications are in 10 CFR 52.17, "Contents of Applications; Technical Information." 10 CFR 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.

17.5.4 Technical Evaluation

The staff used Standard Review Plan (SRP) (NUREG-0800), Chapter 17, "Quality Assurance," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," to evaluate the applicant's QAPD. To develop SRP Section 17.5, the staff used the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," as supplemented by regulatory and industry guidance for nuclear operating facilities.

The staff also conducted a QA implementation inspection of PSEG ESP activities for a proposed facility in Salem, NJ, from May 31 through June 3, 2011. The areas inspected included organization, programs, training and qualifications, procurement document control, internal and external audits, and other areas of interest. During the inspection, the inspectors identified one violation of NRC requirements. The violation was documented in NRC Inspection Report No. 05200043/2011-201 and Notice of Violation (NOV), July 27, 2011. The NOV was related to 10 CFR Part 50, Appendix B, Criterion II, "Quality Assurance Program," which states, in part, that the QAP shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant's implementing procedure, TQ-ND-101, "Nuclear Development Training and Indoctrination Procedure," Revision 1, May 16, 2011, establishes the requirements to indoctrinate and train PSEG Nuclear Development (ND) personnel performing safety-related activities that affect the quality of the PSEG Site ESP application. TQ-ND-101, Step 4.1 states, in part, that "required indoctrination and training shall be accomplished prior to performing activity governed by the implementing procedures."

Contrary to the above, the staff identified that PSEG ND personnel did not accomplish the required training before performing activities that are governed by the implementing procedures. Specifically, PSEG ND personnel who did not receive indoctrination training in accordance with TQ-ND-101 performed receipt inspections, an activity governed by PSEG implementing procedures, for safety-related calculations provided by Sargent and Lundy (Calculation Numbers 2011-03075 and 2009-10130). The staff did not identify any technical issues associated with the calculations.

In an August 24, 2011, response to the NOV, the applicant stated that each of the individuals assigned to perform the acceptance reviews of the vendor-generated calculations had more than 25 years of experience in the nuclear industry and each is considered a subject matter

expert. In addition, the applicant stated that it entered this issue into its corrective action program on June 3, 2011, and developed corrective steps to prevent similar violations.

The inspection report concluded that the implementation of the PSEG QAP was consistent with the regulatory requirements of 10 CFR Part 50, Appendix B, and the provisions of the PSEG QAPD and associated implementing procedures with the resolution of the NOV.

17.5.4.1 *Organization*

The staff notes that the applicant's QAPD follows the guidance of SRP Section 17.5, Paragraph II.A, which provides an organizational description that includes an organizational structure, functional responsibilities, levels of authority, and interfaces to establish, execute, and verify QAPD implementation. The QAPD establishes independence between the organization responsible to check a function and the organization that performs the function. In addition, the QAPD allows management to size the QA 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.

17.5.4.2 *Quality Assurance Program*

The staff notes that 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 NPPs. The QAP comprises those planned and systematic actions necessary to provide confidence that SSCs will perform their intended safety function, as described in the applicant's SSAR.

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 QAPD also follows the guidance of SRP Section 17.5, Paragraphs II.S and II.T, in 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 its implementation.

The applicant commits to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 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 ASME Standard NQA-1-1994, Appendix 2A-1. The following alternatives may be applied to the implementation of this supplement and appendix.

  As an alternative to the requirement in ASME Standard NQA-1-1994, 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 skill level 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 the personnel that 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 ASME Standard NQA-1-1994, Supplement 2S-1, the organization must designate those activities that require qualified inspectors and test personnel and establish written procedures for the qualification of these personnel. The staff finds the designation of a qualified engineer to plan inspections, evaluate inspectors, or evaluate the inspector qualification programs is acceptable. The staff finds this approach consistent with regulatory guidance, ASME Standard NQA-1-1994, or other industry guidance in this subject area.

- 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.

Based on the above, the staff finds the applicant's clarifications and exceptions acceptable.

17.5.4.3 *Design Control*

The staff notes that 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 set points) 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 who are knowledgeable in quality assurance principles to review design documents for the necessary quality assurance requirements (QAR).

The QAPD commits the applicant to conform to the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 3 and Supplement 3S-1, to establish the program for the subsurface investigation requirements contained in ASME Standard NQA-1-1994, Subpart 2.20 and for the standards for computer software QA controls contained in ASME Standard NQA-1-1994, Subpart 2.7.

17.5.4.4 *Procurement Document Control*

The staff notes that 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 QAP requirements. These requirements (such as specifications, codes, standards, tests, inspections, special processes, and 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 QAP that implements ASME Standard NQA-1-1994, Part I. As an alternative, the QAPD proposes that suppliers have a documented QAP that meets 10 CFR Part 50, Appendix B as applicable to the circumstances of the procurement. 10 CFR Part 50, Appendix B, Criterion IV, "Procurement Document Control requires suppliers to have a QAP consistent with 10 CFR Part 50, 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 (instead of the supplier having its own QAP). 10 CFR Part 50, Appendix B, Criterion IV requires suppliers to have a QAP consistent with, 10 CFR Part 50, Appendix B. Therefore, the staff finds this clarification acceptable, 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 staff evaluated this proposed alternative and concluded that it provides adequate quality assurance review of procurement documents before awarding the contract and after any change. Therefore, the staff finds this alternative 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 (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," March 21, 1989, and GL 91-05,

"License Commercial-Grade Procurement and Dedication Programs," April 9, 1991, as delineated in SRP Section 17.5, Paragraphs II.U.1.d and II.U.1.e.

17.5.4.5 *Instructions, Procedures and Drawings*

The staff notes that the applicant's QAPD follows the guidance of SRP Section 17.5, Paragraph II.E, to establish 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.

To establish provisions for control of instructions, procedures and drawings, the applicant commits to comply with the quality standards described in ASME Standard NQA-1-1994, Basic Requirement 5.

17.5.4.6 *Document Control*

The staff notes that the applicant's QAPD follows the guidance of SRP Section 17.5, Paragraph II.F, to control the preparation, review, approval, issuance, and changes of documents that specify quality requirements or prescribe measures for controlling activities that affect 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 that identify the current approved revision or date is maintained so personnel can readily determine the appropriate document for use.

To establish 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.

17.5.4.7 *Control of Purchased Material, Equipment, and Services*

The staff notes that the applicant's QAPD follows the guidance of SRP Section 17.5, Paragraph II.G, to control the procurement of items and services to comply with requirements. The program provides measures for evaluating prospective suppliers and selecting only those that are qualified. In addition, the program provides guidelines for auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services.

The staff notes that the program provides for acceptance actions (e.g., source verification, receipt inspection, pre- and post-installation tests) and review of documentation (e.g., conformance certificates) to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function.

To establish 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 staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, National Institute of Standards and Technology (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 staff accepted a similar exception in a previous safety evaluation ("Approval of Relief Request RR-27," September 12, 2010), 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 any additional technical and administrative requirements, as necessary, to comply with the PSEG QA Program and technical provisions. At a minimum, the purchase document shall require that the calibration/report include identification of the laboratory equipment/standard used.

    - 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 one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement:

            - National Voluntary Laboratory Accreditation Program, administered by the National Institute of Standards and Technology

            - American Association for Laboratory Accreditation

            - ACLASS Accreditation Services

            - International Accreditation Services

- ❖ Laboratory Accreditation Bureau
- ❖ Other NRC-approved laboratory accrediting body

- The accreditation encompasses American Nuclear Society's ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
- 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 the documents 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 concluded that this alternative meets 10 CFR Part 50, Appendix B, "Control of Purchased Material, Equipment, and Services," Criterion VII, which requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. Therefore, the staff finds that this provision, which would allow for accessing and reviewing the necessary procurement documents at the site before installation and use, meets 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. PSEG will also use other appropriate approved regulatory means and controls to support PSEG commercial-grade dedication activities and will assume 10 CFR Part 21 reporting responsibility for all items that PSEG dedicates as safety-related.

- Consistent with the guidance mentioned above for commercial-grade items and services, the staff finds that 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 (GL 89-02 and GL 91-05) provide for determining critical characteristics to ensure that an item is suitable for its intended use. The staff finds that the program also provides for technical evaluation of the item, receipt requirements, and quality evaluation of the item.

17.5.4.8 *Identification and Control of Materials, Parts, and Components*

The staff notes that 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.

To establish 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.

17.5.4.9 *Control of Special Processes*

The applicant's QAPD does not address special processes (e.g., welding, heat treating, chemical cleaning, and nondestructive examinations). In accordance with SRP Section 17.5, Paragraph II.I, control of special processes is not applicable to ESP applicants. Control of Special Processes will be addressed in the combined license application (COLA).

17.5.4.10 *Inspection*

The staff notes that 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.

To establish 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 (Std) 336-1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities." IEEE Std 336-1985 refers to IEEE Std 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 Std 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 Std 603-1980 but does not commit the applicant or holder to the balance of IEEE Std 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 Std 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 commits to the definition of safety systems equipment from IEEE Std 603-1980 to appropriately implement ASME Standard NQA-1-1994, Subpart 2.4. The clarification reinforces the fact that the QAPD is not committing to the entirety of IEEE Std 603-1980.

The staff finds the definition of safety systems equipment in the context of ASME Standard NQA-1-1994, Subpart 2.4, acceptable because it clarifies the definition.

17.5.4.11 *Test Control*

The staff notes that 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.

To establish 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.

To establish 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.

17.5.4.12 *Control of Measuring and Test Equipment*

The staff notes that 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.

To establish 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 ASME Standard NQA-1-1994, Supplement 12S-1, Paragraph 3.2, refer to cases in which the measuring and test equipment are found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. The staff finds the clarification for the out-of-calibration conditions 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. The staff finds this alternative consistent with the guidance provided in SRP 17.5, Paragraph II.L.3.

17.5.4.13 *Handling, Storage, and Shipping*

The staff notes that the applicant's QAPD follows the guidance of SRP Section 17.5, Paragraph II.M, for controlling the handling, storage, packaging, shipping, cleaning, and preserving items to prevent inadvertent damage or loss and to minimize deterioration.

To establish 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.

17.5.4.14 *Inspection, Test, and Operating Status*

This element is not applicable to the PSEG ESP application. Inspection, Test, and Operating Status does not apply to PSEG or its suppliers related to the ESP because they are not constructing a nuclear power plant and therefore they are not responsible to determine the operability of SSCs. Therefore, this element has not been reviewed or approved by the NRC staff.

17.5.4.15 *Nonconforming Materials, Parts, or Components*

The staff notes that the QAPD follows the guidance of SRP Section 17.5, Paragraph II.O, to control items, including services that 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. The results are then documented and reported to upper management.

In addition, the QAPD provides for the establishment of 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)(1), "Definitions"; and/or 10 CFR Part 21," Reporting of Defects and Noncompliance."

To establish 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.

17.5.4.16 *Corrective Action*

The staff notes that 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 staff notes that the QAPD provides for establishing the necessary measures to implement a program to identify, evaluate, and report defects and non-compliances in accordance with the requirements of 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable.

To establish 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.

17.5.4.17 *Quality Assurance Records*

The staff notes that 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.

Regarding the use of electronic records storage and retrieval systems, the QAPD provides for compliance with NRC guidance given in Regulatory Issue Summary (RIS) 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," October 23, 2000; and associated Nuclear Information and Records Management Association (NIRMA) guidelines TG 11-1998, "Authentication of Records and Media," TG 15-1998, "Management of Electronic Records," TG 16-1998, "Software Configuration Management and Quality Assurance," and TG 21-1998, "Electronic Records Protection and Restoration."

The staff notes that 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 ("Safety Evaluation by the Office of Nuclear Reactor Regulation Change to the Quality Assurance Program Duane Arnold Energy Center Monticello Nuclear Generating Plant Palisades Nuclear Plant Point Beach Nuclear Plant Units 1 and 2 Prairie Island Nuclear Generating Plant Units 1 and 2," September 15, 2005), the staff accepted a similar alternative. Therefore, the staff finds this alternative acceptable.

17.5.4.18 *Quality Assurance Audits*

The staff notes that 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 their compliance with the overall QAPD. Internal audits are performed with a frequency commensurate with safety significance. An audit of all applicable QAP 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 QAP. Audit results are documented and reviewed. Management responds to all audit findings and initiates corrective action. In addition,

where corrective actions are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other means is conducted to verify corrective action.

To establish 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.

17.5.4.19 *Non-Safety-Related SSC Quality Assurance Control*

17.5.4.19.1 **Non-Safety-Related SSCs Important to Plant Safety**

The staff notes that the guidance of SRP Section 17.5, Paragraph II.V.1, to establish specific program controls applied to non-safety-related SSCs that are important to plant safety does not apply to ESP applicants. Non-safety-related SSC QA control will be addressed during the combined operating license process.

17.5.4.20 *Regulatory Commitments*

The staff notes that the QAPD follows the guidance of SRP Section 17.5, Paragraph II.U, to establish QAP commitments. The QAPD commits the applicant to comply with the following NRC regulatory guides (RG) and other QA standards to supplement and support the QAPD.

- Regulatory Guide (RG) 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," March 2007. This regulatory guide does not apply to ESP only applications using a plant parameter envelope.

- RG 1.28, Revision 3, "Quality Assurance Program Requirements (Design and Construction)," August 1985. The QAPD utilizes the NRC endorsed NQA-1-1994 Standards.

- RG 1.29, "Seismic Design Classification," Revision 3, September 1978. The QAPD commits the applicant to comply with RG 1.29. Exceptions to this regulatory guide are addressed in SSAR Chapter 2, "Site Characteristics and Site Parameters."

- ASME Standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described in Sections 17.5.4.1 through 17.5.4.18 of this report.

- NIRMA technical guides, as described in Section 17.5.4.17 of this report.

17.5.5 Conclusion

The staff used the provisions of 10 CFR Part 50, Appendix B and the guidance of SRP Section 17.5 to evaluate the QAPD. The staff finds the following:

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

- The QAPD gives 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 Section 17.5 and with the commitments to applicable regulatory guidance.

On the basis of its review, the staff concludes that the applicant's QAPD provides adequate guidance for establishing a QAP that complies with 10 CFR Part 50, Appendix B by following the guidance of ASME Standard NQA-1-1994, as supplemented by regulatory and industry guidance. Accordingly, the staff concludes that the applicant can use the QAPD for ESP activities.