EXHIBIT NRC S11

Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition (NUREG-0800) (March 2007)

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

17.5 QUALITY ASSURANCE PROGRAM DESCRIPTION - DESIGN CERTIFICATION, EARLY SITE PERMIT AND NEW LICENSE APPLICANTS

REVIEW RESPONSIBILITIES

Primary - The organization responsible for quality assurance (QA)

Secondary - None

I. AREAS OF REVIEW

The QA staff reviews and evaluates QA program descriptions (QAPDs) submitted by applicants for a design certification (DC), combined license (COL), early site permit (ESP), construction permit (CP), and operating license (OL). QAPDs submitted by applicants for DC, COL, ESP CP, and OL are reviewed and evaluated in accordance with the applicable sections of this standard review plan (SRP).

A QAPD submitted by a DC applicant may be a QA topical report or part of a safety analysis report (SAR). A QAPD submitted by a DC applicant would only address design QA activities in support of a DC. The QAPD would not address construction and design QA activities that occur once construction begins. The QAPD submitted by the DC applicant would be reviewed and evaluated by the NRC prior to NRC approval of the DC.

March 2007

USNRC STANDARD REVIEW PLAN

This Standard Review Plan, NUREG-0800, has been prepared to establish criteria that the U.S. Nuclear Regulatory Commission staff responsible for the review of applications to construct and operate nuclear power plants intends to use in evaluating whether an applicant/licensee meets the NRC's regulations. The Standard Review Plan is not a substitute for the NRC's regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide an acceptable method of complying with the NRC regulations.

The standard review plan sections are numbered in accordance with corresponding sections in Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)." Not all sections of Regulatory Guide 1.70 have a corresponding review plan section. The SRP sections applicable to a combined license application for a new light-water reactor (LWR) are based on Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)."

These documents are made available to the public as part of the NRC's policy to inform the nuclear industry and the general public of regulatory procedures and policies. Individual sections of NUREG-0800 will be revised periodically, as appropriate, to accommodate comments and to reflect new information and experience. Comments may be submitted electronically by email to NRR_SRP@nrc.gov.

Requests for single copies of SRP sections (which may be reproduced) should be made to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Reproduction and Distribution Services Section, or by fax to (301) 415-2289; or by email to DISTRIBUTION@nrc.gov. Electronic copies of this section are available through the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/, or in the NRC's Agencywide Documents Access and Management System (ADAMS), at http://www.nrc.gov/reading-rm/adams.html, under Accession # ML06310019.

A QAPD submitted by a COL applicant applies to all phases of a facility's life, including design, construction, and operation. Construction and operational QA activities may be addressed in separate QAPDs.

COL applicants may reference an NRC-approved QAPD for the operational phase. However, this application will be reviewed against the SRP in effect 6 months prior to the docket date of the application.

A QAPD submitted by an ESP applicant would apply to site suitability QA activities and would be reviewed and evaluated by the NRC prior to issuing the ESP. A QAPD submitted by a CP applicant would apply to all design and construction QA activities and would be reviewed and evaluated by the NRC prior to issuing the CP. A QAPD submitted by an OL applicant would apply to operational QA activities and would be reviewed and evaluated by the NRC prior to issuing the OL.

SRP Sections 17.1 and 17.2 provide guidelines for review of QA programs based upon American National Standards Institute (ANSI) N45.2, "Quality Assurance Program Requirements for Nuclear Power Plants," and its daughter standards. SRP Section 17.3 provides guidelines for review of a QAPD developed following American Society of Mechanical Engineers (ASME) Standards NQA-1, "Quality Assurance Program for Nuclear Facilities," and and NQA-2, "Quality Assurance Requirements for Nuclear Facility Applications." SRP Section 17.5 outlines a standardized QA program for DC, ESP, CP, OL and COL applicants and holders. SRP Section 17.5 is based on ASME standard NQA-1 (1994 Edition), Regulatory Guide (RG) 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 3, RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3, RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2, and NRC Review Standard (RS)-002, "Processing Applications for Early Site Permits."

DC, ESP, CP, OL, and COL applicants are identified as an "applicant" and COL holders are identified as a "holder" throughout this SRP section.

Section II of this SRP is organized into 23 areas of activity (A through W). The areas that are not applicable to specific applicants are annotated as such in the detailed discussions in Section II of this SRP. DC, CP, OL, and COL applicants or COL holders that implement 10 CFR 50.69, "Risk-Informed Categorization of Structures, Systems and Components of Nuclear Power Reactors," are not required to specify the QA controls for SSCs that perform low safety significant functions in the QAPD.

The specific areas of review are as follows:

A. ORGANIZATION

B. QUALITY ASSURANCE PROGRAM

C. DESIGN CONTROL AND VERIFICATION

D. PROCUREMENT DOCUMENT CONTROL

E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

F. DOCUMENT CONTROL

G. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

H. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

I. CONTROL OF SPECIAL PROCESSES

J. INSPECTION

K. TEST CONTROL

L. CONTROL OF MEASURING AND TEST EQUIPMENT

M. HANDLING, STORAGE, AND SHIPPING

N. INSPECTION, TEST, AND OPERATING STATUS

O. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

P. CORRECTIVE ACTION

Q. RECORDS

R. AUDITS

S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE

T. TRAINING AND QUALIFICATION - INSPECTION AND TEST

U. QA PROGRAM COMMITMENTS

V. NONSAFETY-RELATED SSC QUALITY CONTROLS

W. INDEPENDENT REVIEW

X. COL Action Items and Certification Requirements and Restrictions. For a DC application, the review will also address COL action items and requirements and restrictions (e.g., interface requirements and site parameters).

For a COL application referencing a DC, a COL applicant must address COL action items (referred to as COL license information in certain DCs) included in the referenced DC. Additionally, a COL applicant must address requirements and restrictions (e.g., interface requirements and site parameters) included in the referenced DC.

Y. Operational Program Description and Implementation. For a COL application, the staff reviews the Quality Assurance Program - Operation program description and the proposed implementation milestones. The staff also reviews final safety analysis report

(FSAR) Table 13.x to ensure that the Quality Assurance Program - Operation and associated milestones are included.

Review Interfaces

Other SRP sections interface with this section as follows:

1. Specific SSCs subject to QA requirements are addressed in many other SRP subsections. (e.g., Sections 3.2.1, "Seismic Classification," 4.5.1, "Control Rod Drive Structural Materials," and 5.4.12, "Reactor Coolant System High Point Vents.")

2. For COL reviews of operational programs, the review of the applicant's implementation plan is performed under SRP Section 13.4, "Operational Programs."

The specific acceptance criteria and review procedures are contained in the referenced SRP sections.

II. ACCEPTANCE CRITERIA

Acceptance criteria are based on meeting the relevant requirements of the following Commission regulations:

1. Appendix A, General Design Criterion 1 (GDC 1), "Quality Standards and Records," to 10 CFR Part 50 requires that a QA program be established and implemented.

2. Appendix B to 10 CFR Part 50 specifies 18 quality criteria which must be addressed in a QAPD.

3. 10 CFR 50.34(b)(6)(ii) requires that the information on the controls to be used for a nuclear power plant include a discussion on how the applicable requirements of Appendix B will be satisfied.

4. 10 CFR 50.34(f)(3)(ii) and (iii) specify design and construction QA requirements which must be addressed in a QAPD.

5. 10 CFR 50.34(h) and 10 CFR 52.79(b) require that COL applicants or holders include an evaluation of the facility against the SRP that is in effect 6 months prior to the docket date of the application of a new facility. Alternatives to or differences from the SRP must be identified and justified in the application. These alternatives or differences are required to be discussed in the SER that is prepared by the NRC.

6. 10 CFR 50.54(a)(3)(ii) as it relates to changes to a QAPD that are not considered to be reductions in commitment, allows a licensee to use a QA alternative or exception approved by an NRC Safety Evaluation (SE) provided that the bases of the NRC approval are applicable to the licensee's facility.

7. 10 CFR 50.55a requires the SSCs be designated, fabricated, erected, constructed, tested, and inspected to quality standards commensurate with the importance of the safety function to be performed.

8. 10 CFR 52.17(a)(1)(xii) requires an Early Site Permit applicant to include a QAPD which satisfies applicable portions of Appendix B to 10 CFR Part 50.

9. 10 CFR 52.47(a)(21) requires a Standard Design Certification applicant to include a QAPD which satisfies applicable portions of Appendix B to 10 CFR Part 50.

10. 10 CFR 52.79(a)(25) requires a COL applicant to include a QAPD to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. The QAPD includes a discussion of how it satisfies applicable portions of Appendix B to 10 CFR Part 50.

11. The SRM on SECY 95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY 94-084)," Item A, RTNSS and Item E, Reliability Assurance Program, contains the Commission policy on nonsafety-related, risk-significant SSCs that provide defense in depth or result in significant improvement in the PRA evaluations.

12. The SRM on SECY-05-0197, "Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," contains Commission policy on the treatment of operational programs in a COL application. Specifically, the inclusion of implementation milestones for the operational phase of the QA Program (QAP).

13. 10 CFR 50.54(a)(1) requires a holder of a COL under 10 CFR Part 52 to implement the operation phase of a QAP 30 days prior to the scheduled date for the initial loading of fuel.

14. 10 CFR 52.47(b)(1), which requires that a DC application contain the proposed inspections, tests, analyses, and acceptance criteria (ITAAC) that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a plant that incorporates the design certification is built and will operate in accordance with the design certification, the provisions of the Atomic Energy Act, and the NRC's regulations.

15. 10 CFR 52.80(a), which requires that a COL application contain the proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the combined license, the provisions of the Atomic Energy Act, and the NRC's regulations.

SRP Acceptance Criteria

Specific SRP acceptance criteria acceptable to meet the relevant requirements of the NRC's regulations identified above are as follows for the review described in this SRP section. The SRP is not a substitute for the NRC's regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria

and evaluate how the proposed alternatives to the SRP acceptance criteria provide acceptable methods of compliance with the NRC regulations.

The source for each acceptance criterion is provided. Sources include industry standards (ANSI N18.7 and NQA-1-1994), NRC regulations, and regulatory guides. In addition, the staff has determined that certain QAP alternative or exceptions to specific acceptance criteria have general applicability to an overall QAP. These alternatives or exceptions have been included within the SRP acceptance criteria in that they have been determined to represent an acceptable method of complying with NRC regulations. The document accession number for the NRC SE that approved each QAP alternative or exception has been identified.

A. ORGANIZATION (10 CFR Part 50, Appendix B, Criterion I)

1. At the most senior management level, the applicant or holder (i.e., the organization applying to have its QAPD reviewed and accepted by the NRC) is to issue a written QAPD that establishes the quality policy and commits the organization to implement it. (ANSI N18.7)

2. Individual managers are to ensure that personnel working under their management are qualified in accordance with written procedures and that only qualified personnel are permitted to perform those activities for which they are qualified. (NQA-1)

3. The QAPD is to contain an organizational description that addresses the organizational structure, functional responsibilities, levels of authority, and interfaces. The organizational description is to include the onsite and offsite organizational elements that function under the cognizance of the QA program. Functional responsibilities include activities such as preparing, reviewing, approving, and verifying designs; qualifying suppliers; preparing, reviewing, approving, and issuing instructions, procedures, schedules, and procurement documents; purchasing; verifying supplier activities; identifying and controlling acceptable and nonconforming hardware and software; manufacturing; calibrating and controlling measuring and test equipment; qualifying and controlling special processes; constructing; inspecting; testing; startup; operating; performing maintenance; performing the audit function; and controlling records. For multiple organizations, the interface responsibilities are clearly defined. (Onsite/offsite, operational, and maintenance organizational elements are not applicable to DC applicants.) (NQA-1 and ANSI N18.7)

4. The QA program requires independence between the organization performing checking functions from the organization responsible for performing the functions. (This provision applies to DC applicant, ESP, and construction QA programs. This provision is not applicable to design reviews/verifications. The provision for design review/verification is addressed in C.2.f.)
(10 CFR 50.34(f)(3)(iii)(A))

5. Management positions in which the responsibility for carrying out the audit functions are established. The individuals filling these positions are to: (NQA-1)

a. have sufficient authority and organizational freedom to implement assigned responsibilities

b. be responsible for implementing the QA program and referring appropriate matters to the top management in a timely manner

c. report at a management level sufficiently high to ensure that cost and schedule considerations do not unduly influence decision making

d. have effective lines of communication with persons in other senior management positions

6. Major delegation of work to participants outside of the applicant or holder's organization is identified and described as follows: (NQA-1)

   a. The organizational elements responsible for delegated work are identified and documented.

   b. Management controls and lines of communication between the applicant's designated person or his designee (and the delegated organization) are identified and documented.

   c. Responsibility for the QA program and the extent of management oversight is established.

   d. The performance of delegated work is formally evaluated by the applicant or holder.

7. Management ensures that the size of the QA organization is commensurate with its duties and responsibilities. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(F))

8. Responsibility and authority to stop unsatisfactory work and control further processing, delivery, installation, or use of nonconforming items (e.g., SSCs, parts, materials, equipment, consumable materials, and software) is assigned by the applicant or holder such that cost and schedule considerations do not override safety considerations. (NQA-1)

9. Individuals assigned the responsibility for ensuring effective execution of any portion of the QA program at any location have direct access to such levels of management as may be necessary to perform this function. (NQA-1)

10. Personnel performing work activities such as, but not limited to, design, engineering, procurement, manufacturing, construction, installation, startup, maintenance, and modification are responsible for achieving acceptable quality. (NQA-1)

11. The applicant or holder may delegate part or all of the activities of planning, establishing, and implementing the overall QA program to others but is to retain the responsibility for the program. (NQA-1)

12. When the applicant or holder delegates responsibility for planning, establishing, or implementing any part of the overall QA program, sufficient authority to accomplish the assigned responsibility also is delegated. (NQA-1)

B. QUALITY ASSURANCE PROGRAM (10 CFR Part 50, Appendix B, Criterion II)

1. Management of those organizations implementing the QA program, or portions thereof, assess the adequacy of that part of the program for which they are responsible and assure its effective implementation at least once each year or at least once during the life of the activity, which is ever shorter. However, the period for assessing operational QA programs may be extended to once every two years. (Approved via a safety evaluation (SE) (Accession No. 9903310187).)

2. The QAPD includes the criteria used to identify the items and activities to which the QA program applies. A list of the SSCs and/or activities under the control of the QA program is required to be established and maintained at the applicant's or holder's facility. (10 CFR 50.34(f)(3)(ii))

3. The QA program ensures that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. (NQA-1)

4. The QA program is required to be documented by written policies, procedures, or instructions. (NQA-1)

5. The QA program is binding on all participating organizations from the top executive to all workers whose activities may influence quality. (NQA-1)

6. The applicant or holder retains and exercises the responsibility for the scope and implementation of an effective overall QA program. (NQA-1)

7. The applicant or holder is responsible for ensuring that the applicable portion of the QA program is properly documented, approved, and implemented (people are trained and resources are available) before an activity within the scope of the QA program is undertaken by the applicant/holder or by others. (NQA-1)

8. A general grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general grace period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity

is reset backwards by performing the activity early. (Approved via SE (Accession No. 9807270331).)

9. For a COL under 10 CFR Part 52, the implementation of the operational phase of the QAP complies with proposed 10 CFR 50.54(a)(1), and the operational phase of the QAP and implementation will be identified in Table 13.4X (Operational Programs) of the FSAR. (Proposed 10 CFR 50.54(a)(1) and SECY 05-0197)

C. DESIGN CONTROL AND VERIFICATION (10 CFR Part 50, Appendix B, Criterion III)

1. Design Control

a. A program is required to be established for the design of items. The program includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces. (NQA-1)

b. Design inputs (e.g., the design bases, performance and regulatory requirements, and codes and standards) are correctly translated into design outputs (e.g., specifications, drawings, procedures, and instructions). (NQA-1)

c. The final design (approved design output documents and approved changes) identifies assemblies and/or components that are part of the item being designed. (NQA-1)

d. The design process ensures that items and activities are selected and independently verified to ensure they are suitable for their intended application. (NQA-1)

e. Changes to final designs (including field changes and modifications) and dispositions of nonconforming items to use-as-is or repair are subject to design control measures commensurate with those applied to the original design and approved by the organization that performed the original design or a qualified designate. The designate has demonstrated competence in the specific design area of interest and has an adequate understanding of the requirements and intent of the original design. (NQA-1)

f. Interface controls (internal and external between participating design organizations and across technical disciplines) for the purpose of developing, reviewing, approving, releasing, distributing, and revising design inputs and outputs are defined. Design information transmitted across interfaces is documented and controlled. Transmittals identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal is confirmed promptly by a controlled document. (NQA-1)

g. Design records, maintained to provide evidence that the design was properly accomplished, include not only the final design output and revisions to the final output, but also the important design steps (e.g., calculations, analyses, and computer programs) and the sources of input that support the final output. (NQA-1)

h. Design analysis documents are legible and in a form suitable for record keeping. They are sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. (NQA-1)

i. Documentation of design analyses includes the following, as applicable: (NQA-1)

   (1) definition of the objective of the analyses

   (2) definition of design inputs and their sources

   (3) results of literature searches or other applicable background data

   (4) identification of assumptions and indication of those that must be verified as the design proceeds

   (5) identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem

   (6) review and approval

j. Control of computer programs used for design analysis includes the following: (NQA-1)

   (1) Computer program acceptability is preverified or the results verified with the design analysis for each application.

   (2) Computer programs are controlled to ensure that changes are documented and approved by authorized personnel.

k. Calculations are identifiable by subject (including the SSC to which the calculation applies), originator, reviewer, and date, or by other data such that the calculations are retrievable. (NQA-1)

l. Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, are

identified and documented, and their selection reviewed and approved by the responsible design organization. Changes from approved design inputs, including the reason for the changes, are identified, approved, documented, and controlled. (NQA-1)

m. Applicable information derived from experience, as set forth in reports or other documentation, is made available to cognizant design personnel. (NQA-1)

n. The QA role in design and analysis activities is defined. Design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(H))

o. Measures are required to be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the SSCs. (NQA-1)

p. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure is reviewed and modified as necessary. (NQA-1)

q. QA personnel are included in the documented review and concurrence in quality-related procedures associated with design, construction, and installation. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(C))

2. Design Verification

a. Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing. The responsible design organization is required to identify and document the particular design verification method(s) used. (NQA-1)

b. Design inputs, processes, outputs, and changes are verified. The final design (approved design output documents and approved changes thereto) is relatable to the design input by documentation in sufficient detail to permit design verification and the identification of the verifier clearly indicated. When applicable, design reviews answer the following questions: (NQA-1)

(1) Were the design inputs correctly selected?

(2) Are assumptions necessary to perform the design activity adequately described and reasonable? Are the assumptions adequately identified to enable subsequent reverifications after detailed design activities are completed?

(3) Was an appropriate design method used?

(4) Were the design inputs correctly incorporated into the design?

(5) Are the necessary design inputs and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

(6) Is the design output reasonable compared to the inputs?

c. Alternate calculations are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used are reviewed. (NQA-1)

d. Where design adequacy is verified by qualification tests, the tests are identified. The test configuration is clearly defined and documented. Testing demonstrates the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily are considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design are verified by other means. Test results are documented and evaluated by the responsible design organization to ensure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification is documented and the item modified and retested or otherwise verified to ensure satisfactory performance. When tests are being performed on models or mockups, scaling laws are required to be established and verified. The results of model test work are subject to error analysis, where applicable, prior to use in final design work. (NQA-1)

e. Design verification is completed before design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, manufacture, or construction. When this timing cannot be achieved, the unverified portion of the design is identified and controlled. In all cases, the design verification is completed before relying on the item to perform its intended function. (NQA-1)

f. The verifying or checking process is performed by individuals or groups other than those who performed the original design, but who may be from the same organization. The designer's immediate supervisor can perform the design verification provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification. (NQA-1)

g. Whenever changes to previously verified designs are made, design verification is required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to a previously verified design. (NQA-1)

h. The verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven design, with respect to meeting pertinent design inputs, is verified for each application. The original design and associated verification measures are documented in records for subsequent application of the design. (NQA-1)

D. PROCUREMENT DOCUMENT CONTROL (10 CFR Part 50, Appendix B, Criterion IV)

1. Applicable technical, regulatory, administrative, and reporting 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. (Approved via SE (Accession No. ML050700416).)

2. Procurement documents include provisions for the following: (NQA-1)

a. a statement of the scope of the work performed by the supplier

b. a specification of technical requirements, and where necessary, references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services furnished

c. identification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating the supplier's performance

d. the supplier's documented QA program that is determined to meet the applicable requirements of Appendix B to 10 CFR 50 as appropriate to the circumstances of procurement (or the supplier may work under the applicant's approved QA program)

e. access to the supplier's plant facilities and records for inspection or audit by the purchaser, his/her designated representative, and/or other parties authorized by the purchaser

f. identification of the documentation and date of submission required to be submitted for information, review, or approval by the purchaser

g. purchaser's requirements for reporting and approving disposition of nonconformances

3. Changes made as a result of the bid evaluations or pre-contract negotiations are incorporated into the procurement documents. The review of such changes and their effects are completed prior to contract award. Reviews are performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents. (NQA-1)

4. Procurement document changes are subject to the same degree of control as utilized in the preparation of the original documents. (NQA-1)

5. A review of the procurement documents and changes thereto are made to ensure that documents transmitted to the prospective supplier(s) include appropriate provisions to ensure that items or services will meet the specified requirements. (NQA-1)

6. The program is applied to all phases of procurement. As necessary, this may require verification of activities of suppliers below the first tier. (NQA-1)

E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS (CONTROLLED DOCUMENTS) (10 CFR Part 50, Appendix B, Criterion V)

1. Activities affecting quality are prescribed by documented instructions, procedures, or drawings and are accomplished in accordance with these instructions, procedures, or drawings. (NQA-1)

2. Instructions, procedures, or drawings include appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. (NQA-1)

F. DOCUMENT CONTROL (10 CFR Part 50, Appendix B, Criterion VI)

1. A program is required to be established to control the development, review, approval, issue, use, and revision of documents. (NQA-1)

2. The scope of the document control program is defined. Examples of controlled documents include design drawings, as-built drawings, engineering calculations, design specifications, purchase orders and related documents, vendor-supplied documents, audit and surveillance procedures, operating procedures, emergency operating procedures, technical specifications, nonconformance reports, corrective action reports, work instructions and procedures, calibration procedures, quality verification procedures, inspection and test reports, and all such documents made electronically available. (ANSI N18.7 and Appendix B/RIS 2000-18)

3. Revisions of controlled documents are reviewed for adequacy and approved for release by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable. The reviewing organization has access to pertinent background data or information necessary to base their approval. (NQA-1)

4. Controlled copies of instructions and procedural documents are distributed to and used by the person performing the activity. (NQA-1)

5. The distribution of new and revised controlled documents is in accordance with established source documents. Superseded documents are controlled. (ANSI N18.7)

6. The control system is documented as follows: (NQA-1)

   a. the identification of controlled documents

   b. the specified distribution of controlled documents for use at the appropriate location

   c. the individuals responsible for preparation, review, approval, and distribution of controlled documents are identified

   d. controlled documents are reviewed for adequacy, completeness, and correctness prior to distribution

   e. a method to ensure the correct documents are being used

7. Minor changes to documents, such as inconsequential editorial corrections, are not required to receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision are clearly delineated. (NQA-1)

8. Procedures used during the operational phase are reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every 2 years to determine if changes are necessary or desirable. (ANSI N18.7) Procedures do not have to be reviewed every 2 years provided that all of the following are met: (Approved via SE (Accession No. ML003675798).)

   a. Applicable procedures are reviewed following any modification to a system.

   b. Applicable procedures are reviewed following an unusual incident, such as an accident, significant operator error, or equipment malfunction.

   c. Procedures are updated during use when discrepancies are found.

   d. Procedures are reviewed prior to use if not used in the previous 2 years.

   e. A QA program audit of procedures is conducted every 2 years.

9. Procedures for control of the documents and changes thereto are required to be established to preclude the possibility or use of outdated or inappropriate documents. Document control measures provide for the following: (ANSI N18.7)

a. identifying the proper document to be used in performing the activity

b. coordinating and controlling interface documents

c. ascertaining that proper documents are being used

10. Temporary procedures include designation of the period of time during which it is valid to use them. (Applicable only to operational QAPDs.) (ANSI N18.7)

11. Temporary procedure changes which clearly do not change the intent of the approved procedure are approved by two members of the staff knowledgeable in the areas affected by the procedures. (Applicable only to operational QAPDs.) (ANSI N18.7)

12. Provisions are in place to continually improve work instructions through reviews and incorporation of feedback from users. (ANSI N18.7)

G. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES (10 CFR Part 50, Appendix B, Criterion VII)

1. A program is required to be established that ensures that purchased items and services conform to specified requirements. (NQA-1)

2. The program includes provisions for evaluating prospective suppliers and selecting only qualified suppliers. (ANSI N18.7)

3. The program includes provisions for ensuring that qualified suppliers continue to provide acceptable products and services. (ANSI N18.7)

4. The program includes provisions (e.g., source verification, receipt inspection, preinstallation and postinstallation tests, and certificates of conformance) for accepting purchased items and services. (NQA-1)

5. The program is to include provisions for ensuring that procurement, inspection, and test requirements have been satisfied before an item is placed in service or used. (Approved via SE (Accession No. ML050700416).)

6. The procurement of components, including spare and replacement parts, is subject to quality and technical requirements suitable for their intended service and to the purchaser's QA program requirements. (ANSI N18.7)

7. When the purchaser requires the supplier to maintain specific QA records, the retention times and disposition requirements are prescribed. (NQA-1)

8. Procurement activities are documented to ensure a systematic approach to the procurement process, identification of procurement methods, and organizational responsibilities. Procurement activities involve the following: (NQA-1)

a. procurement document preparation, review, and change control

b. selection of procurement sources

c. bid evaluation and award

d. purchaser control of supplier performance

e. verification (surveillance, inspection, or audit) activities by purchaser, including notification for hold and witness points

f. control of nonconformances

g. corrective action

h. acceptance of item or service

i. QA records

9. Measures for evaluation and selection of procurement sources, and the results therefrom, are documented and include any or all of the following: (NQA-1)

   a. evaluation of the supplier's history of providing an identical or similar product which performs satisfactorily in actual use

   b. supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated

   c. supplier's technical and quality capability as determined by a direct evaluation of its facilities and personnel and the implementation of its QA program

10. The purchaser of items and services is required to establish measures to interface with the supplier and to verify the supplier's performance as deemed necessary by the purchaser. The measures include the following: (NQA-1)

    a. establishing an understanding between purchaser and supplier of the provisions and specifications of the procurement documents

    b. requiring the supplier to identify planning techniques and processes utilized in fulfilling procurement document requirements

    c. reviewing supplier documents which are generated or processed during activities fulfilling procurement requirements

    d. identifying and processing necessary change information

    e. establishing a method of document information exchange between purchaser and supplier

f. establishing the extent of source surveillance and inspection activities

g. determining any additional or modified design criteria

h. analyzing exceptions or changes requested or specified by the supplier and determining the effects that such changes may have on the intent of the procurement documents or quality of the item or service furnished

i. ensuring that the purchaser's verification activities do not relieve the supplier of its responsibilities for verification of quality achievement

11. In certain cases involving procurement of services only, such as third party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the purchaser accepts the service by any or all of the following methods: (NQA-1)

    a. technical verification of data produced

    b. surveillance and/or audit of the activity

    c. review of objective evidence for conformance to the procurement document requirements (e.g., certifications, stress reports)

12. The purchaser and supplier are required to establish a documented method for the disposition of nonconforming items. (NQA-1)

13. The supplier is required to send the purchaser all nonconforming reports from procurement documentation requirements generated during the manufacturing process. As a minimum, nonconforming reports contain the following information: (NQA-1)

    a. description of nonconforming item

    b. evaluation of nonconforming item

    c. recommended corrective action (i.e, use-as-is or repair)

    d. technical justification for corrective action

14. The purchaser is required to approve the supplier's recommended disposition and technical justification for nonconformances that involve any of the following: (NQA-1)

    a. technical or material requirement is violated

    b. a requirement in purchaser-approved supplier document was violated

    c. nonconformance cannot be corrected by continuation of the original manufacturing process or by rework

d. the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired

15. Purchaser methods used to accept an item or related service from a supplier are supplier certificate of conformance, source verification, receiving inspection, postinstallation test, or a combination thereof. (NQA-1)

16. A certificate of conformance shall contain, as a minimum, the following criteria: (NQA-1)

    a. The purchased material or equipment is identified, such as by the purchase order number.

    b. The specific procurement requirements met by the purchased material or equipment, such as codes, standards, pre-installation tests, and other specifications, are identified. This may be accomplished by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified include any approved changes, waivers, or deviations applicable to the subject material or equipment.

    c. Any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances, are identified.

    d. The certificate is signed or otherwise authenticated by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.

    e. The certification system, including the procedures followed in filling out a certificate and the administrative procedures for review and approval of the certificates, is described in the purchaser's or supplier's QA program.

    f. Means are provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification is conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

17. Measures to verify the quality of purchased items and services are described. (ANSI N18.7)

18. Source verification is required to be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon purchaser acceptance of source verification, documented evidence of acceptance is furnished to the receiving destination of the item, to the purchaser, and to the supplier. (NQA-1)

19. When receiving inspection is used, purchased items are inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier. Receiving inspection is performed in accordance with procedures and inspection instructions, to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspection is coordinated with review of supplier documentation when procurement documents require such documentation furnished prior to receiving inspection. (NQA-1)

20. When post-installation testing is used for acceptance of purchased items, postinstallation test and acceptance documentation recommended by the supplier are required to be considered. (NQA-1)

H. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS (NOT APPLICABLE TO DC APPLICANTS) (10 CFR Part 50, Appendix B, Criterion VIII)

1. The program identifies and controls items (consumables, items with limited shelf life, materials, parts, and components, including partially fabricated assemblies) to prevent the use of incorrect or defective items. (NQA-1)

2. Identification of each item is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation. These measures require that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item. (NQA-1)

3. Items of production (batch, lot, component, part) are identified from the initial receipt and fabrication of the items up to and including installation and use. This identification relates an item to an applicable design or other pertinent specifying document. (NQA-1)

4. Physical identification is used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means are employed. (NQA-1)

5. Identification markings, when used, are applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided and cannot be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted. (NQA-1)

6. Provisions are made for the control of item identification consistent with the planned duration and conditions of storage, such as the following: (NQA-1)

    a. provisions for maintenance or replacement of markings and identification records from damage during handling or aging

b. protection of identifications on items subject to excessive deterioration from environmental exposure

c. provisions for updating existing plant records

I. CONTROL OF SPECIAL PROCESSES (NOT APPLICABLE TO ESP AND DC APPLICANTS) (10 CFR Part 50, Appendix B, Criterion IX)

1. A program is required to be established to ensure that special processes, such as welding, heat treating, and nondestructive examination, are properly controlled. (NQA-1)

2. The criteria that establish which processes are special are described. For the purpose of this standard review plan section, a special process is a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. (NQA-1)

3. Special processes are accomplished by personnel qualified in accordance with applicable codes, standards, specifications, criteria, and other special requirements. (NQA-1)

4. Processes are controlled by instructions, procedures, drawings, checklists, or other appropriate means. These means ensure that process parameters are controlled and that specified environmental conditions are maintained. (NQA-1)

5. Each special process instruction includes or references procedure(s), personnel, and equipment qualification requirements. (NQA-1)

6. Records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process. (NQA-1)

7. For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment are specified or referenced in the procedures or instructions. (NQA-1)

J. INSPECTION (10 CFR Part 50, Appendix B, Criterion X)

1. A program establishes the inspections to be performed (source, in-process, final, receipt, maintenance, modification, inservice, and operations). The inspection program may be implemented by or for the organization performing the activity inspected. (Approved via SE (Accession No. ML050700416).)

2. Provisions to ensure inspection planning is properly accomplished are required to be established. Planning activities are to identify the characteristics and activities inspected, the inspection methods, the acceptance criteria, and the organization responsible for performing the inspection. (NQA-1)

3. Provisions to identify inspection hold points, beyond which work is not to proceed without the consent of the inspection organization, are defined. (NQA-1)

4. Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings. (NQA-1)

5. Inspections are performed by individuals other than those who performed the activity being inspected. Inspection personnel do not report directly to the immediate supervisors who are responsible for performing the work being inspected. (Only applicable to operational QA programs.) (NQA-1)

6. Inspection requirements and acceptance criteria include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization. (NQA-1)

7. Modifications, repairs, or replacements of items performed subsequent to final inspection require reinspection or retest, as appropriate, to verify acceptability. (NQA-1)

8. Inspection records identify item inspected, date of inspection, the inspector's identity, type of observation, results, or acceptability, and reference to information on action taken in connection with nonconformances. (NQA-1)

9. Those activities that require qualified inspection personnel are defined. (NQA-1)

K. TEST CONTROL (10 CFR Part 50, Appendix B, Criterion XI)

1. A test control program is required to be established to demonstrate that items will perform satisfactorily in service. (NQA-1)

2. Criteria are defined that specify when testing is required and activities that require qualified test personnel. (NQA-1)

3. The test control program includes, as appropriate, proof tests before installation, preoperational tests, postmaintenance tests, postmodification tests, and operational tests. (NQA-1)

4. Test procedures are developed that specify the necessary calibrated instrumentation, instructions and prerequisites to perform the test, appropriate equipment, trained personnel, condition of test equipment and the item tested, suitable environmental conditions, acceptance criteria, mandatory test hold points as required, and provisions for data acquisition. (NQA-1)

5. Test results are documented and evaluated by a responsible authority to ensure the test requirements have been satisfied. (NQA-1)

6. Test records, at a minimum, identify the item tested, date of test, tester or data recorder, type of observation, results and acceptability, action taken in

connection with any deviations noted, and person evaluating test results. (NQA-1)

L. CONTROL OF MEASURING AND TEST EQUIPMENT (10 CFR Part 50, Appendix B, Criterion XII)

1. A program is required to be established to control the calibration, maintenance, and use of measuring and test equipment. (NQA-1)

2. The types of equipment covered by the program (e.g., instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment) are defined. (NQA-1)

3. Measuring and test equipment is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data. (Approved via SE (Accession No. ML050700416).)

4. Measuring and test equipment are calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented. (NQA-1)

5. Measuring and test equipment found out of calibration is tagged or segregated and not used until it is recalibrated. When measuring and test equipment is found out of calibration, an evaluation is made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. If any measuring or test equipment is consistently found out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect. (NQA-1)

6. Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy. (NQA-1)

7. Records of calibration status and the capability of measuring and test equipment to perform its intended function are maintained. (NQA-1)

8. For procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC), are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance provided that all of the following conditions are met: (Approved via SE (Accession No. ML052710224).)

a. The alternative method is documented in the QA program description.

b. Accreditation is to ANSI/ISO/IEC 17025, “General Requirements for the Competence of Testing and Calibration Laboratories.”

c. Use of the alternative method is limited to the National Voluntary Laboratory Accreditation Program and the American Association for Laboratory Accreditation, as recognized by ILAC signatories.

d. The scope of the accreditation covers the contracted services.

e. Purchase documents impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements.

f. Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

g. Purchase documents require identification of the laboratory equipment/standards used.

h. The alternative method is limited to the domestic calibration service suppliers.

i. The alternative method is applicable to subsuppliers of calibration service suppliers, provided the above conditions are met.

M. HANDLING, STORAGE, AND SHIPPING (NOT APPLICABLE TO DC APPLICANTS) (10 CFR Part 50, Appendix B, Criterion XIII)

1. Instructions for marking and labeling for packaging, shipment, handling, and storage of items are required to be established that adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls. (NQA-1)

2. Special protective measures (e.g., containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are specified and provided when required to maintain acceptable quality. (NQA-1)

3. Specific procedures/documents are developed and used for cleaning, handling, storage, packaging, shipping, and preserving items when required to maintain acceptable quality. (NQA-1)

4. Special handling tools and equipment are controlled to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained. (NQA-1)

5. Operators of special handling and lifting equipment are experienced or trained in use of the equipment. (NQA-1)

6. Controls for the packaging, shipping, handling and storage of items are required to be established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to ensure that no damage or deterioration exists which could effect their function. (Not applicable to construction QAPDs. Construction QAPD provisions are addressed in II.U.2.a of this SRP.) (Approved via SE (Accession No. ML052710224).)

7. Controls for hoisting, rigging, and transport activities are required to be established that protect the integrity of the item involved as well as potentially affected nearby structures and components. Applicable hoisting, rigging, and transportation regulations and codes are followed. (Not applicable to construction QAPDs. Construction QAPD provisions are addressed in II.U.2.f of this SRP.) (Approved via SE (Accession No. ML052710224).)

8. Cleanliness controls for work on safety related and risk-significant nonsafety related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Procedures require documented verification of absence of foreign material prior to system closure. (Not applicable to construction QAPDs. Construction QAPD provisions are addressed in II.U.1.c of this SRP.) (Approved via SE (Accession No. ML052710224).)

N. INSPECTION, TEST, AND OPERATING STATUS (NOT APPLICABLE TO DC AND ESP APPLICANTS) (10 CFR Part 50, Appendix B, Criterion XIV)

1. Measures are required to be established for indicating, by the use of marking such as stamps, tags, labels, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant. (NQA-1)

2. The application and removal of status indicators and other labels are controlled. (NQA-1)

3. Measures are required to be established for indicating the operating status of SSCs of the nuclear power plant, such as by tagging valves and switches, to prevent inadvertent operation. (NQA-1)

4. The authority for application and removal of tags, markings, labels, and stamps is specified. Procedures require independent verifications, where appropriate, to ensure that necessary measures such as tagging equipment, have been implemented correctly. (ANSI N18.7)

5. Temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point setting, are controlled by approved

procedures which include a requirement for independent verification. (Approved via SE (Accession No. 9811170129).)

O. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS (10 CFR Part 50, Appendix B, Criterion XV)

1. A nonconforming item (a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate) is properly controlled to prevent its inadvertent test, installation, or use. As appropriate, procedures are used for the identification, documentation, segregation, disposition and notification of the nonconforming items to the affected organizations. (NQA-1)

2. A nonconforming item is reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item is controlled pending an evaluation and an approved disposition by authorized personnel. (NQA-1)

3. The responsibility and authority for the evaluation and disposition of nonconforming items are defined. (NQA-1)

4. Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. (NQA-1)

5. The disposition, such as use as-is, reject, repair, or rework, of nonconforming items is identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as-is is documented. (NQA-1)

6. Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or specified alternatives. (NQA-1)

7. A nonconformance to design requirements dispositioned as use as-is or repair is subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, reflect the accepted deviation. (NQA-1)

P. CORRECTIVE ACTION (10 CFR Part 50, Appendix B, Criterion XVI)

1. A corrective action program is required to be established that includes prompt identification, documentation, classification, and correction of the conditions. The program is to include provisions that ensure that corrective actions are not inadvertently nullified by subsequent actions. (NQA-1)

2. For significant conditions adverse to quality, the cause of the condition shall be determined and corrective actions take to prevent recurrence. These shall be

reported to appropriate levels of management and follow-up action taken to verify implementation of corrective actions. (NQA-1)

3. Specific responsibilities within the corrective action program may be delegated, but the applicant or holder maintains responsibility for the program's effectiveness. (ANSI N18.7)

4. The program requires all personnel to identify conditions that are adverse to quality. (ANSI N18.7)

5. Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions and trends adverse to quality are reported to the appropriate level of management. (ANSI N18.7)

Q. RECORDS (10 CFR Part 50, Appendix B, Criterion XVII)

1. Measures are required to be established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. (ANSI N18.7)

2. The records system(s) is (are) defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. Records may be hard copy records or electronic records. (NQA-1)

3. For QA records in electronic media, the program includes provisions for the generation, distribution, use, maintenance, storage, and disposition of electronic records. The plan provides for all acceptable media on which electronic records are created and stored. Also, the program should include provisions to verify that the media is appropriate, suitable for the capture or storage of records, and error/defect free. The applicant's program must implement Generic Letter 88-18, "Plant Record Storage on Optical Disks." (Appendix B/RIS 2000-18)

4. The program is to provide provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records. All records must be retrievable, maintained in a readable format, and safeguarded against equipment malfunction or human error. Document access controls, user privileges, and other appropriate security controls must be established. (ANSI N18.7)

5. Design documentation and records, which provide evidence that the design and design verification processes were properly performed are collected, stored, and maintained in accordance with documented procedures. The documentation includes not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design. (ANSI N18.7)

6. The program requires that records be examined for adequacy, legibility and completeness. (NQA-1)

7. Requirements and responsibilities for record transmittal, location, distribution, retention, maintenance, and disposition are described. Training is provided for individuals or organizations in charge of electronic records generation, data/media storage, implementation of security measures, migration/regeneration, and recovery. (RIS 2000-18)

8. The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents specify the records generated, supplied, or maintained. (NQA-1)

9. Documents are considered valid records only if stamped, initialed, authenticated, or signed and dated by authorized personnel. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies. For electronic records, authentication is accomplished by manually affixing seal, signature, an electronic representation (user ID/password combination, digital signature) or other acceptable process control that ensures genuineness, validity, or reliability. Authorized personnel with access to electronic records and information systems should have a unique user ID/password for access. The system should provide controls for users who enter or alter information in electronic records to ensure its data integrity and prevent unauthorized alteration or erasure. Transfer of authentication authority is documented and controlled in accordance with written procedures. (RIS 2000-18)

10. Records and/or indexing system(s) provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which they apply. For electronic records, in addition to the minimum indexing information requirements, the software name, version, and equipment (hardware) used to produce and maintain the electronic media must be provided. (Appendix B/RIS 2000-18)

11. Records are classified as Lifetime or Nonpermanent. Lifetime records are those that meet one or more of the following criteria: (NQA-1)

    a. significant value in demonstrating capability for safe operation

    b. significant value in maintaining, reworking, repairing, replacing, or modifying an item

    c. significant value in determining the cause of an accident or malfunction of an item

    d. provision of required baseline data for inservice inspections and inservice tests

12. Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use. (NQA-1)

13. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. The retention period for nonpermanent records is established in writing. (NQA-1)

14. Electronic records classified as lifetime or nonpermanent are subject to the same retention requirements prescribed for paper records/hardcopies. Retention requirements for electronic records also identify and maintain the information system (software/hardware), the documentation that describes the information system operation and use, and the record standard it produces. (RIS 2000-18)

15. An electronic record migration/regeneration program is implemented for electronic records stored in media with a standard life expectancy that fails to meet the specific retention period. This program is implemented in accordance with documented procedures that provide for appropriate record authentication, quality verification of the completion, and accuracy of the data transferred. (RIS 2000-18)

16. Electronic media should be stored in a dust-free environment, away from electronic devices and demagnetizing equipment. Media should be maintained at the constant temperature of 40 to 80 degrees Fahrenheit, with a constant relative humidity of 30 to 50 percent. Magnetic and optical media should be tested periodically to identify any loss of data, to ensure that they are free of permanent errors, and that the record system hardware/software still supports the retrieval of the records. (RIS 2000-18)

17. Records are corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction includes the date and the identification of the person authorized to issue such correction. For records stored in electronic media, a new record is to be generated when substantial corrections or changes to previous electronic records are required. (RIS 2000-18 and NQA-1)

18. The person or organization responsible for receiving the records is designated. This designee is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage and for providing protection from damage or loss during the time that the records are in his/her possession. For electronic records, in addition to the requirements described above, the designee is also responsible for organizing and implementing an inventory of system applications, record formats, and programs required to process and retrieve electronic records. (NQA-1)

19. At a minimum, a receipt control system includes the following: (NQA-1)

    a. a method for designating the required records

    b. a method for identifying records received

c. procedures for receipt and inspection of incoming records

d. a method for submittal of completed records to the storage facility without unnecessary delay

20. Each receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process. (NQA-1)

R. AUDITS (10 CFR Part 50, Appendix B, Criterion XVIII)

1. Personnel performing audit activities are not to have direct responsibilities in the activity they are auditing. (NQA-1)

2. Audits are accomplished using instructions, procedures or checklists by qualified personnel. (NQA-1)

3. Internal Audits (NQA-1)

a. Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. Internal audits of activities, conducted after placing the facility in operation, should be performed in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area within a period of two years.

b. Internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any function area changes in responsibility, resources or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable.

c. Functional areas of an organization's QA program for auditing include at a minimum , verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of operating staff,

corrective actions, and observation of performance of operating, refueling, maintenance and modification activities, including associated record keeping.

4. The audit report is signed by the audit team leader and issued, and it includes the following information, as appropriate: (NQA-1)

   a. description of the audit scope

   b. identification of the auditors

   c. identification of persons contacted during audit activities

   d. summary of audit results, including a statement on the effectiveness of the QA program elements which were audited

   e. description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization

5. An audit process is developed and implemented. Periodic inspections of systems, software applications, and media are performed to ensure electronic records retrievability, integrity, and retention period. (RIS 2000-18)

6. A program of planned and periodic audits is required to be established to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively. The audit schedule is reviewed periodically and revised as necessary to ensure that coverage is maintained current. (NQA-1)

7. Audits provide a comprehensive independent evaluation of activities and procedures. (ANSI N18.7)

8. The auditing organization develops and documents an audit plan for each audit. This plan identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. (NQA-1)

9. Audit results are documented and reported to and reviewed by responsible management. Followup action of deficient areas is initiated as necessary. (NQA-1)

10. When any work carried out under the requirements of the QA program is delegated to others, the work is audited by the QA audit program. (ANSI N18.7)

11. Procurement audits of suppliers are accomplished as follows: (Regulatory Guide 1.28)

    a. Audits are not necessary for procuring the following items:

(1) those that are relatively simple and standard in design, manufacturing, and testing

(2) those that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery

b. Audits are conducted as follows for procurement of items not covered by the exceptions in 11(a) above:

(1) The supplier's QA program is audited on a triennial basis.

(2) The triennial period begins when the first audit is performed.

(3) An audit is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

(4) If a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period.

(5) If the supplier is implementing the same QA program for other customers that is proposed for use on the auditing party's contract, the preaward survey may serve as the first triennial audit. Therefore, when such preaward surveys are employed as the first triennial audits, they must satisfy the same audit elements and criteria as those used on other triennial audits.

(6) If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit should satisfy the needs of all of the purchasers, and the audit report should be distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

12. Evaluations of suppliers are documented and take into account the following, where applicable: (Approved via SE (Accession No. ML050700416).)

(a) Receipt inspection, operating experience, and supplier evaluation programs are reviewed on an ongoing basis as the information becomes available. The results of the review are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and

input to third party auditing entities, as warranted). Additionally, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

(b) If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of twelve months, an annual evaluation shall be performed as follows:

(1) review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions

(2) results of previous source verifications, audits, and receiving inspections

(3) operating experience of identical or similar products furnished by the same supplier

(4) results of audits from other sources (e.g., customer, ASME, or NRC audits)

S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (10 CFR Part 50, Appendix B, Criterion II)

1. Training programs to ensure that QA auditors achieve and maintain suitable proficiency are required to be established in accordance with one of the following methods: (NQA-1)

a. Orientation that provides a working knowledge and understanding of QA and the auditing organization's procedures for implementing audits and report results.

b. A training program that provides general and specialized training in audit performance. General training includes fundamentals, objectives, characteristics, organization, performance, and results for quality auditing. Specialized training includes methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

c. Training that includes planning, performing, reporting, and follow-up action involved in conducting audits

2. The individual responsible for management of the implementation of the QA plan is qualified as follows: (Regulatory Guide 1.8)

a. Education: baccalaureate in engineering or related science

b. Minimum experience for the position: 4 years of related experience (3 of the 4 years must include 2 years of nuclear power plant experience and 1 year of supervisory or management experience)

c. Special Requirements: management and supervisory skills and experience or training, including leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures

d. 1 year of experience performing quality verification activities

e. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

3. Individuals responsible for planning, implementing, and maintaining the QA plan are qualified as follows: (Regulatory Guide 1.8)

a. Education: high school diploma

b. Minimum experience: 1 year related experience

c. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

4. Lead auditors are qualified as follows:

a. demonstrated capability to communicate effectively, both in writing and orally (NQA-1)

b. demonstrated knowledge and understanding of the following: (NQA-1)

(1) QA program and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable

(2) general structure of QA programs as a whole and applicable elements

(3) auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings

(4) audit planning in the quality-related functions for designing, purchasing, fabricating, handling, shipping, receiving, storing,

cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and safety of the nuclear facility

c. participated in a minimum of five QA audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which is a nuclear QA audit within the year prior to qualification or for individuals with related industry experience, demonstrated ability to properly implement the audit process, to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification (Approved via SE (Accession No. ML050700416).)

d. successfully completed an examination, which may be oral, written, practical, or any combination of the three types (NQA-1)

5. Records of personnel qualifications for Auditors performing audits are required to be established and maintained. Records for each Lead Auditor are updated annually and each Lead Auditor is certified as being qualified to lead audits. (NQA-1)

6. Lead Auditor certification, at a minimum, documents the following: (NQA-1)

a. employer's name

b. auditor's name

c. date of certification or recertification

d. basis of qualification (i.e., education, experience, communication skills, training, examination)

e. signature of designated representative who is responsible for such certification

T. TRAINING AND QUALIFICATION - INSPECTION AND TEST (10 CFR Part 50, Appendix B, Criterion II)

1. The job performance of inspection and test personnel are reevaluated at periodic intervals not to exceed 3 years. (NQA-1)

2. Written procedures for the qualification of inspection and test personnel, and for the assurance that only those personnel who perform inspection and test activities are required to be established. (NQA-1)

3. Any person who has not performed inspection or testing activities in his/her qualified area for a period of 1 year is reevaluated prior to performing inspection and test activities. (NQA-1)

4. Training and certification records for inspection and test personnel are maintained as follows: (NQA-1)

   a. employer's name

   b. identification of person being certified

   c. activities certified to perform

   d. basis used for certification which includes such factors as education, experience, indoctrination, and training test results, where applicable

   e. results of periodic evaluation

   f. results of physical examinations, when required

   g. signature of employer's designated representative who is responsible for such certification

   h. examination results

   i. date of certification or recertification and date of certification expiration

   j. results of capability demonstration

5. Inspection and test personnel initial qualification requirements are based on education, training, and experience and demonstration of capability in performing the type of inspection or test commensurate with the job. (Approved via SE (Accession No. ML050700416).)

6. Inspections by persons during on-the-job training for qualification is performed under the direct observation and supervision of a qualified person and verification of the conformance is by the qualified person until certification is achieved. (Approved via SE (Accession No. ML050700416).)

U. QA PROGRAM COMMITMENTS

1. Regulatory Guides (RGs) and Generic Letters (GLs)

   The reviewer shall verify that the applicant or holder commits to the most recent revision of the RGs and GLs listed below. Exceptions or alternatives to the specific criteria in any of these RGs and GLs may be proposed by applicants or holders provided adequate justification is provided. The reviewer shall notify the organization responsible for the applicable RG or GL of any proposed exceptions or alternatives to the RG or GL. The organization responsible for the RG or GL shall evaluate any exceptions or alternatives. All commitments should be listed in the SER. Exceptions or alternatives should also be listed in the SER along with the organization responsible for evaluating the exceptions or alternatives.

a. RG 1.26, “Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants”

b. RG 1.29, “Seismic Design Classification”

c. RG 1.37, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants,” Revision 1 (Not applicable to operational QAPDs. Operational QAPD provisions are addressed in II.M.8 of this SRP.)

d. GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products”

e. GL 91-05, “Licensee Commercial-Grade Dedication Programs”

2. Standards

The reviewer shall verify that the applicant or holder commits to the standards listed below. Exceptions or alternatives to the specific criteria in any of these standards may be proposed by applicants or holders provided adequate justification is provided. The reviewer shall notify the organization responsible for the applicable standard of any proposed exceptions or alternatives to the standard. The organization responsible for the standard shall evaluate any exceptions or alternatives. All commitments should be listed in the SER. Exceptions or alternatives should also be listed in the SER along with the organization responsible for evaluating the exceptions or alternatives.

a. Subpart 2.2, “Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants,” ASME NQA-1-1994 Edition (Not applicable to operational QAPDs. Operational QAPD provisions are addressed in II.M.6 of this SRP.)

b. Subpart 2.4, “Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities,” ASME NQA-1-1994 Edition

c. Subpart 2.5, “Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants,” ASME NQA-1-1994 Edition

d. Subpart 2.7, “Quality Assurance Requirements of Computer Software for Nuclear Facility Applications,” ASME NQA-1-1994 Edition

e. Subpart 2.8, “Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants,” ASME NQA-1-1994 Edition

f. Subpart 2.15, “Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants,” ASME NQA-1-1994 Edition (Not applicable to operational QAPDs. Operational QAPD provisions are addressed in II.M.7 of this SRP.)

g. Subpart 2.20, “Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants,” ASME NQA-1-1994 Edition

h. Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 11-1998, “Authentication of Records and Media”

i. NIRMA TG 15-1998, “Management of Electronic Records”

j. NIRMA TG 16-1998, “Software Configuration Management and Quality Assurance”

k. NIRMA TG 21-1998, “Electronic Records Protection and Restoration”

l. Section 4, “Storage, Preservation, and Safekeeping,” of Supplement 17S-1, “Supplementary Requirements for Quality Assurance Records,” NQA-1-1994 Edition

V. NONSAFETY-RELATED SSC QUALITY CONTROLS (NOT APPLICABLE TO ESP APPLICANTS)

1. Nonsafety-related SSCs that are significant contributors to plant safety

This review addresses the SRM on SECY 95-132, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY 94-084),” Item A, RTNSS and Item E, Reliability Assurance Program, which contains the Commission policy on nonsafety-related SSCs that are identified as being significant contributors to plant safety. The reviewer shall verify that DC and COL applicants specify the following quality controls for SSCs that are identified as being significant contributors to plant safety.

a. Organization

The normal line organization may verify compliance with the following criteria. A separate or dedicated QA organization is not required.

b. QA Program

The supplier’s procedures describe the quality controls applied to the subject equipment. A new or separate QA program is not required.

c. Design Control

Measures are established to ensure that the contractually established design requirements are included in the design. Applicable design inputs are included or correctly translated into design documents, and deviations therefrom are controlled. Normal supervisory review of the designer's work is an adequate control measure.

d. Procurement Document Control

Applicable design bases and other requirements necessary to ensure component performance, including design requirements, are included or referenced in documents for procurement of items and services, and deviations therefrom are controlled.

e. Instructions, Procedures, and Drawings

Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. This may include such things as written instructions, plant procedures, cautionary notes on drawings, and special instructions on work orders. Any methodology which provides the appropriate degree of guidance to personnel performing activities important to the component functional performance is acceptable.

f. Document Control

The issuance and change of documents that specify quality requirements or prescribe activities affecting quality are controlled to ensure that correct documents are used.

g. Control of Purchased Items and Services

Measures are established that ensure that all purchased items and services conform to appropriate procurement documents.

h. Identification and Control of Purchased Items

Measures are established where necessary, to identify purchased items and preserve their functional performance capability. Examples of circumstances requiring such control include the storage of environmentally sensitive equipment or material, and the storage of equipment or material that has a limited shelf life.

i. Control of Special Processes

Measures are established to control special process, including welding, heat treating, and nondestructive testing. Applicable codes, standards, specification, criteria, and other special requirements may serve as the basis of these controls.

j. Inspection

Inspections are performed where necessary to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. Inspections need not be performed by personnel who are independent of the line organization. However, personnel that perform inspections must be knowledgeable.

k. Test Control

Measures are established that demonstrate that equipment conforms with design requirements. Tests are performed in accordance with test procedures. Test results are recorded and evaluated to ensure that test requirements are met.

l. Control of Measuring and Test Equipment

Measures are established to control, calibrate, and adjust measuring and test equipment at specific intervals.

m. Handling, Storage, and Shipping

Handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration.

n. Inspection, Test, and Operating Status

Measures are established to identify items that have satisfactorily passed required tests and inspection and to indicate the status of inspection, test, and operability as appropriate.

o. Control of Nonconforming Items

Items that do not conform to specified requirements are identified and controlled to prevent inadvertent installation or use.

p. Corrective Action

Measures are established to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

q. Records

Records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection and test activities have been met.

r. Audits

Audits independent of line management are not required, if line management periodically reviews and documents the adequacy of the supplier's process and takes any necessary corrective action. Line management is responsible for determining whether reviews conduced by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities.

2. Nonsafety-Related SSCs Credited for Regulated Events

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and station blackout (SBO) (10 CFR 50.63) SSCs that are not safety related. The reviewer shall verify that QAPDs address the documents listed below. The reviewer shall notify the organization responsible for the applicable document for review of any proposed exceptions or alternatives to the standard.

a. The applicant or holder commits to implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants."

b. The applicant or holder commits to implement the quality requirements to ATWS equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."

c. The applicant or holder commits to implement quality requirements to 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 RG 1.155, "Station Blackout."

W. INDEPENDENT REVIEW (10 CFR Part 50, Appendix B, Criterion XVIII)

This section is applicable to holders of a COL (operational phase) and OL applicants. Option I or Option II may be used.

Option I - Independent Review Body (Approved via SE (Accession No. ML050210276).)

1. A group may function as an independent review body (IRB). In discharging its review responsibilities, the IRB keeps safety considerations paramount when opposed to cost or schedule considerations. One or more organizational units may collectively perform this function.

2. The IRB performs the following:

   a. Reviews proposed changes to the facility as described in the safety analysis report (SAR). IRB also verifies that changes do not adversely effect safety and if a technical specification change or NRC review is required.

   b. Reviews proposed tests and experiments not described in the SAR. These tests and experiments are reviewed prior to implementation. IRB also verifies that tests or experiments do not require a technical specification change or NRC review.

   c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to implementation, except in those cases where the change is identical to a previously approved change.

   d. Reviews violations, deviations, and reportable events that are required to be reported to the NRC in writing within 24 hours. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

   e. Reviews any matter related to nuclear safety that is requested by the Site Vice President, Site Director, Plant Manager, or any IRB member,

   f. Reviews corrective actions for significant conditions adverse to quality.

   g. Auditing the adequacy of the audit program every two years.

3. IRB reviews are supplemented as follows:

   a. A qualified person, independent of the preparer, reviews proposed changes in the procedures as described in the SAR prior to implementation of the change to determine if a technical specification change or NRC approval is required.

   b. Audits of selected changes in the procedures described in the SAR are performed to verify that procedure reviews and revision controls are effectively implemented.

   c. Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.

4. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed, with a minimum of one such review being conducted yearly. This review is intended to support plant and corporate

management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.

a. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities.

b. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.

c. Results of the review are documented and reported to responsible management.

d. Plant and corporate management periodically consider issues that they determine warrant special attention, such as deficient plant programs, declining performance trends, employee concerns, or other issues related to safe plant operations and determine what issues warrant the review.

e. Plant and corporate management determine the scheduling and scope of review and the composition of the team performing the review.

Option II - Independent Review Committee (ANSI N18.7)

1. An independent review committee is assigned independent review responsibilities.

2. The independent review committee reports to a management level above the plant manager.

3. The independent review committee is composed of no less the 5 persons, no more than a minority of members are from the onsite operating organization. A minimum of the chairman or alternative chairman and 2 members must be present for all meetings.

4. During the period of initial operation, meetings are conducted no less frequently than once per calender quarter. Afterwards meetings are conduced no less than twice a year.

5. Results of the meeting are documented and be recorded.

6. The Independent Review committee is responsible for performing the following:

   a. Reviews proposed changes to the facility as described in the SAR. The Independent Review Committee also verifies that changes do not adversely effect safety and if a technical specification change or NRC review is required.

b. Reviews proposed tests and experiments not described in the SAR. These tests and experiments are reviewed prior to implementation. The Independent Review Committee also verifies that tests or experiments do not require a technical specification change or NRC review.

c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to implementation, except in those cases where the change is identical to a previously approved change.

d. Reviews violations, deviations, and reportable events that are required to be reported to the NRC in writing within 24 hours. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

e. Reviews any matter related to nuclear safety that is requested by the Site Vice President, Site Director, Plant Manager, or any Independent Review Committee member,

f. Reviews corrective actions for significant conditions adverse to quality.

g. Auditing the adequacy of the audit program every two years.

7. Consultants and contractors are used for the review of complex problems beyond the expertise of the independent review committee.

8. Persons on the independent review committee are qualified as follows: (Regulatory Guide 1.8)

   a. Supervisor or Chairman of the Independent Review Committee

      Education: baccalaureate in engineering or related science

      Minimum experience: 6 years combined managerial and technical support

   b. Independent Review Committee members

      Education: Baccalaureate in engineering or related science for those independent review personnel who are required to review problems in nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, nondestructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering. High school diploma for those independent review personnel who are required to review problems in administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment.

Minimum experience: 5 years experience in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, nondestructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment)

Technical Rationale

The technical rationale for application of these requirements to the QAPD is discussed in the following paragraphs.

1. Appendix A, General Design Criterion 1 (GDC 1), "Quality Standards and Records," to 10 CFR Part 50 requires that a QA program be established and implemented. GDC 1 is applicable because it mandates the establishment of a QA program. Meeting the requirements of GDC 1 provides assurance that SSCs important to safety will be designed, fabricated, constructed, and tested in a manner that will facilitate the satisfactory performance of their intended function.

2. Appendix B to 10 CFR Part 50 is applicable to this section because it specifies the criteria for establishing a QA program for all phases of a facility's life, including design, construction, operation, and modification. This SRP provides guidance related to staff review and approval of the required QA program and describes methods acceptable to the staff for establishing and implementing such a program. Compliance with Appendix B to 10 CFR Part 50 pursuant to 10 CFR 50.34(b)(6)(ii) and 10 CFR 50.34(h), requires that every applicant or holder provide a description of its QA program for the design, fabrication, construction, and testing of the SSCs important to safety to the NRC for review. Furthermore, proposed 10 CFR 50.54(a)(1) provides specific implementation requirements for the operational phase of the QAP.

3. The requirements of 10 CFR 50.34(f)(3)(ii) and (iii) are applicable because they require 1) all SSCs important to safety be listed in accordance with Criterion II of Appendix B to 10 CFR Part 50; 2) independence between organizations performing checking functions and those responsible for performing the function; 3) QA be implemented during construction; 4) QA personnel be included in the documented review and concurrence in quality-related procedures associated with design, construction, and installation; 5) QA personnel be qualified; 6) sizing the staff commensurate with its duties and responsibilities; 7) establishing procedures for maintenance of as-built documentation; 8) providing a QA role in design and analysis activities; and 9) establishing criteria for QA programmatic requirements.

III. REVIEW PROCEDURES

The reviewer will select material from the procedures described below, as may be appropriate for a particular case.

These review procedures are based on the identified SRP acceptance criteria. For deviations from these acceptance criteria, the staff should review the applicant's evaluation of how the proposed alternatives provide an acceptable method of complying with the relevant NRC requirements identified in Subsection II.

Manual Chapters 2501, 2502, and 2504 specify inspections to be performed to assess the applicant's or holder's interpretation and translation of the QAPD commitments into its procedures, processes, and organizational staffing. These inspections will focus on the effectiveness of the QAPD implementation. Through review of the information provided by the applicant or holder and, as required, meetings with the applicant or holder; review of applicable NRC inspection reports; and discussion with involved NRC inspectors, a judgment is made of the applicant's or holder's capability to carry out its QA responsibilities. The reviewer's satisfaction with the QA program commitments, the description of how the commitments will be met, the organizational arrangements, and the capabilities to fulfill the QAPD should lead to the conclusion of acceptability as described in Subsection IV of this document.

The reviewer verifies that the Quality Assurance Program - Operation is fully described and that implementation milestones have been identified. The reviewer verifies that the program and implementation milestones are included in FSAR Table 13.x.

Implementation of this program will be inspected in accordance with NRC Inspection Manual Chapter IMC-2504, "Construction Inspection Program - Non-ITAAC Inspections."

For review of a DC application, the reviewer should follow the above procedures to verify that the design set forth in the final safety analysis report (FSAR) meets the acceptance criteria. DCs have referred to the FSAR as the design control document (DCD). The reviewer should also consider the appropriateness of identified COL action items. The reviewer may identify additional COL action items; however, to ensure these COL action items are addressed during a COL application, they should be added to the DC FSAR.

For review of a COL application, the scope of the review is dependent on whether the COL applicant references a DC, an early site permit (ESP) or other NRC approvals (e.g., manufacturing license, site suitability report or topical report).

For review of both DC and COL applications, SRP Section 14.3 should be followed for the review of ITAAC. The review of ITAAC cannot be completed until after the completion of this section.

IV. EVALUATION FINDINGS

The reviewer verifies that the applicant has provided sufficient information and that the review and calculations (if applicable) support conclusions of the following type to be included in the staff's safety evaluation report. The reviewer also states the bases for those conclusions.

On the basis of the staff's detailed review and evaluation of the QAPD in the (topical report, safety analysis report or DCD) for (facility), we conclude the following:

1. The application includes an evaluation of the facility against this SRP section. Alternatives to or differences from this SRP section as described in the applicable section of this safety evaluation are acceptable.

2. The QAPD acceptably describes the authority and responsibility of management and supervisory personnel, performance/verification personnel, and audit personnel.

3. The organizations and persons responsible for performing the verification and audit functions have the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.

4. The QAPD describes a philosophy and controls that, when properly implemented, comply with the requirements of 10 CFR 50.34(f)(3)(ii) and (iii), Appendix B to 10 CFR Part 50 pursuant to 10 CFR 50.34(b)(6)(ii) and 10 CFR 50.34(h), and GDC 1 of Appendix A to 10 CFR Part 50.

5. The QA program for items that are important to safety is acceptable.

6. The program for the QA treatment of nonsafety-related SSCs is acceptable.

7. For a COL review, the findings include a specific conclusion that the implementation of the operational phase of the QAP complies with 10 CFR 50.54(a)(1) (proposed). In addition, the program and implementation will be identified in Table 13.4X (Operational Programs) of the FSAR.

All commitments should be listed in the SER. Exceptions or alternatives to the criteria in Section II should also be listed in the SER along with the organization responsible for evaluating the exceptions or alternatives. The SER should state the basis for the staff's approval of the exception or alternative. A brief description of the applicant or holder's QA program that highlights the more important aspects of the program should also be provided in the SER.

For DC and COL reviews, the findings will also summarize the staff's evaluation of COL action items relevant to this SRP section.

V. IMPLEMENTATION

The staff will use this SRP section in performing safety evaluations of DC applications and license applications submitted by applicants pursuant to 10 CFR Part 50 or 10 CFR Part 52. Except when the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the staff will use the method described herein to evaluate conformance with Commission regulations.

The provisions of this SRP section apply to reviews of applications submitted six months or more after the date of issuance of this SRP section, unless superseded by a later revision.

VI. REFERENCES

1. NRC Letter to All Holders of Operating Licenses and Construction Permits for Nuclear Power Reactors, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (Generic Letter 89-02).”

2. NRC Letter to All Holders of Operating Licenses and Construction Permits for Nuclear Power Reactors, “Licensee Commercial-Grade Procurement and Dedication Programs (Generic Letter 91-05).”

3. 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.”

4. American Society of Mechanical Engineers. “Quality Assurance Program Requirements for Nuclear Facility Applications,” ANSI/ASME Standard NQA -1, Washington, DC. 1983.

5. 10 CFR 50.34, “Contents of Applications; Technical Information.”

6. 10 CFR 50.55a, “Codes and Standards.”

7. 10 CFR Part 50, Appendix A, “General Design Criteria for Nuclear Power Plants,” General Design Criterion 1, “Quality Standards and Records.”

8. 10 CFR 50.69, “Risk-Informed Categorization of Structures, Systems and Components of Nuclear Power Reactors.”

9. Regulatory Guide 1.8, “Qualification and Training of Personnel for Nuclear Power Plants” (endorses ANSI/ANS 3.1 for selected positions and ANSI N18.1 for others).

10. Regulatory Guide 1.26, “Quality Group Classification, and Standards for Water, Steam, and Radioactive Waste Containing Components of Nuclear Power Plants.”

11. Regulatory Guide 1.28, “Quality Assurance Program Requirements (Design and Construction)” (Rev. 3 endorses ANSI/ASME NQA-1).

12. Regulatory Guide 1.29, “Seismic Design Classification.”

13. Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation).”

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

15. Regulatory Guide 1.155, “Station Blackout.”

16. Generic Letter 85-06, “Quality Assurance Guidance for ATWS Equipment that is Not Safety Related.”

17. AP1000 Design Control Document.

18. US Nuclear Regulatory Commission, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety System (RTNSS) for Passive Plant Designs,” SECY-95-132, Washington, DC.

19. US Nuclear Regulatory Commission, “Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria.” SECY-05-0197, Washington, DC.

20. Nuclear Information and Records Management Association, “Management of Electronic Records.” NIRMA TG 15-1998, Windham, NH.

21. Nuclear Information and Records Management Association, “Required Records Protection, Disaster Recovery, and Business Continuation” NIRMA TG 21, Windham, NH.

22. NIRMA TG 16-1998, “Software Configuration Management and Quality Assurance.”

23. NIRMA TG 21-1998, Electronic Records Protection and Restoration.”

24. US Nuclear Regulatory Commission, “Processing Applications for Early Site Permits,” RS-002, Washington, DC.

25. American National Standards Institute, “Administrative Controls and Quality Assurance for the Operation Phase of Nuclear Power Plants.” ANSI N18.7-1976, Washington, DC.

26. US Nuclear Regulatory Commission, “Guidance on Managing Quality Assurance Records in Electronic Media.” RIS 2000-18, Washington, DC.

27. American National Standards Institute, “General Requirements for the Competence of Testing and Calibration Laboratories,” ANSI/ISO/IEC 17025. Washington, DC.

28. American Society of Mechanical Engineers, “Quality Assurance Requirements for Nuclear Facility Applications,” NQA-2. ASME: Washington, DC.

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PAPERWORK REDUCTION ACT STATEMENT

The information collections contained in the Standard Review Plan are covered by the requirements of 10 CFR Part 50 and 10 CFR Part 52, and were approved by the Office of Management and Budget, approval number 3150-0011 and 3150-0151.

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