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

Secondary - None

I. AREAS OF REVIEW

The quality assurance (QA) staff reviews and evaluates quality assurance 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). The 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 the construction begins. The QAPD submitted by the DC applicant would be reviewed and evaluated by the U.S. Nuclear Regulatory Commission (NRC) prior to NRC approval of the DC.

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.

The COL applicant may reference an NRC-approved QAPD for the operational phase. NOTE: most operational QAPDs do not include all design and construction quality requirements. Where a COL applicant references an NRC-approved QAPD that does not include design and construction quality requirements, the reviewer must verify that the COL applicant addresses these requirements in the final safety analysis report (FSAR). Design and construction quality requirements are discussed later in this SRP section.

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 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 Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, **"**Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The following are used as a means to describe methods that NRC staff considers acceptable for complying with the provisions of 10 CFR Part 50, Appendix B: Regulatory Guide (RG) 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 3; RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 4; RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2; NRC Review Standard (RS)-002, "Processing Applications for Early Site Permits," and any NRC endorsed QA industry standard.

The 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 22 areas of activity (A through V). The areas that are not applicable to specific applicants are annotated as such in the detailed discussions in Section II of this SRP. If the area of review is a criterion under 10 CFR Part 50, Appendix B, then the criterion is indicated in parentheses next to the area of review. The 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 structures, systems and components (SSCs) that perform low safety significant functions in the QAPD.

The specific areas of review are as follows:

A. ORGANIZATION (Criterion I)

B. QUALITY ASSURANCE PROGRAM (Criterion II)

C. DESIGN CONTROL (Criterion III)

D. PROCUREMENT DOCUMENT CONTROL (Criterion IV)

E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS (Criterion V)

F. DOCUMENT CONTROL (Criterion VI)

G. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES (Criterion VII)

H. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS (Criterion VIII)

I. CONTROL OF SPECIAL PROCESSES (Criterion IX)

J. INSPECTION (Criterion X)

K. TEST CONTROL (Criterion XI)

L. CONTROL OF MEASURING AND TEST EQUIPMENT (Criterion XII)

M. HANDLING, STORAGE, AND SHIPPING (Criterion XIII)

N. INSPECTION, TEST, AND OPERATING STATUS (Criterion XIV)

O. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS (Criterion XV)

P. CORRECTIVE ACTION (Criterion XVI)

Q. QUALITY ASSURANCE RECORDS (Criterion XVII)

R. AUDITS (Criterion XVIII)

S. TRAINING AND QUALIFICATION CRITERIA (Criterion II)

T. TRAINING AND QUALIFICATION - INSPECTION AND TEST (Criterion II)

U. NONSAFETY-RELATED SSC QUALITY CONTROLS

V. QUALITY ASSURANCE PROGRAM COMMITMENTS

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., SRP 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 Criteria for Nuclear Power Plants," 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. Regulations in 10 CFR 50.34(b)(6)(ii) requires that the information on the managerial and administrative controls to be used for a nuclear power plant include a discussion on how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

4. Regulations in 10 CFR 52.79(a)(27) requires that the information on the managerial and administrative controls to be used for a COL include a discussion on how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

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

6. Regulations in 10 CFR 50.34(h) requires that nuclear power plant OLs include an evaluation of the facility against the SRP that is in effect 6 months prior to the docket date of the application. Alternatives to or differences from the SRP must be identified and justified in the application. These alternatives or differences shall be discussed in the Safety Evaluation Report (SER).

7. Regulations in 10 CFR 52.17(a)(1)(xi) requires an ESP applicant to include a QAPD which satisfies applicable portions of Appendix B to 10 CFR Part 50.

8. Regulations in 10 CFR 52.17(a)(1)(xii) requires that applications for ESPs include an evaluation of the site against the applicable sections of the SRP that are in effect 6 months prior to the docket date of the application. Alternatives to or differences from the SRP must be identified and justified in the application. These alternatives or differences shall be discussed in the SER.

9. Regulations in 10 CFR 52.47(a)(19) requires a Standard DC applicant to include a QAPD that satisfies applicable portions of Appendix B to 10 CFR Part 50.

10. Regulations in 10 CFR 52.47(a)(9) requires that applications for nuclear power plant DCs include an evaluation of the facility against the SRP that is in effect 6 months prior to the docket date of the application. Alternatives to or differences from the SRP must be identified and justified in the application. These alternatives or differences shall be discussed in the SER.

11. Regulations in 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.

12. Regulations in 10 CFR 52.79(a)(41) requires that applications for nuclear power plant combined licenses include an evaluation of the facility against the SRP that is in effect 6 months prior to the docket date of the application. Alternatives to or differences from the SRP must be identified and justified in the application. These alternatives or differences shall be discussed in the SER.

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

14. Regulations in 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.

15. Per SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY 94-084)," and associated staff requirements memorandum (SRM), applicants should specify the quality controls for nonsafety-related SSCs that are identified as being significant contributors to plant safety. Nonsafety-related SSC quality controls are detailed in SRP Acceptance Criteria "*U. Nonsafety-related SSC Quality Controls*," of this SRP section.

16. Per SECY-05-0197, "Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," and associated SRM, applicants should provide implementation milestones for operational programs that do not have ITAAC in the FSAR for COL applications. Specifically, applicants should supply implementation milestones for the operational phase of the QA program in COL applications.

17. Regulations in 10 CFR 52.17(a)(3), which requires that emergency plans submitted under paragraph (b)(2)(ii) of this section must include the proposed inspections, tests, and analyses that the holder of a COL referencing the ESP 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 are met, the facility has been constructed and will be operated in conformity with the emergency plans, the provisions of the Act, and the Commission's rules and regulations.

18. Regulations in 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 are met, a plant that incorporates the DC is built and will operate in accordance with the DC, the provisions of the Atomic Energy Act (AEA), of 1954 and the NRC regulations.

19. Regulations in 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 are met, the facility has been constructed and will operate in conformity with the combined license, the provisions of the AEA, and the NRC regulations.

SRP Acceptance Criteria

Specific SRP acceptance criteria acceptable to meet the relevant requirements of the NRC 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 given in order to provide NRC staff with a means to interpret the requirements of 10 CFR Part 50, Appendix B, NRC regulations, and RGs. In addition, the staff has determined that certain QA program alternative or exceptions to specific acceptance criteria have general applicability to an overall QA program. 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 QA program alternative or exception is identified throughout this SRP section as the alternative or exception is discussed. A listing of each SE is also provided in Subsection VI, (References) of this SRP section.

A. ORGANIZATION (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. The responsibility for the overall program is retained and exercised by the applicant (ANSI/American Nuclear Society (ANS) 3.2).

2. The applicant has identified and described major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.

3. The QA program requires independence between the organization performing checking functions from the organization responsible for performing the functions. (This provision does not apply to ESP applicant QA programs. This provision is not applicable to design reviews/verifications. The provision for design review/verification is addressed in Section II (10 CFR 50.34(f)(3)(iii)(A)).

4. When major portions of the applicant's program are delegated:

   a. The applicant describes how responsibility is exercised for the overall program. The extent of management oversight should be addressed, including the location, qualifications, and criteria for determining the number of personnel performing these functions.

   b. The applicant evaluates the performance of work by the delegated organization at a frequency of once per year. The frequency may be extended based on an evaluation of individual elements.

   c. Qualified individual(s) or organizational element(s) are identified within the applicant's organization as responsible for the quality of the delegated work prior to initiation of activities.

5. Clear management controls and effective lines of communication exist for QA activities among the applicant and the principal contractors to ensure adequate direction of the QA program.

6. The organization description clearly identifies all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program (such as design, engineering, procurement, manufacturing, construction, inspection, test, instrumentation and control, nuclear engineering, operations and maintenance, etc.), and the lines of responsibility. 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 (M&TE); 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 (ANSI/ANS 3.2)).

7. The applicant identifies a management position that retains overall authority and responsibility for the QAP (normally, this position is the QA Manager) and this position has the following characteristics:

   a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as engineering, procurement, construction, and operation) and is sufficiently independent from cost and schedule.

   b. Has effective communication channels with other senior management positions.

   c. Has responsibility for approval of QA Manual(s).

   d. Has sufficient authority and organizational freedom to implement the QA program, and is sufficiently independent from cost and schedule.

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

8. Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization who do not have direct responsibility for performing the work being verified or by individuals or groups trained and qualified in QA concepts and practices and independent of the organization responsible for performing the task. (This does not apply to design reviews/verifications when meeting provision for design reviews/verifications in Section II.C.19.)

   Additional independent verification are addressed in the respective section of the SRP or other staff guidance documents.

9. Persons and organizations performing QA functions have direct access to management levels which will ensure the ability to:

   a. Identify quality problems.

   b. Initiate, recommend, or provide solutions through designated channels.

   c. Verify implementation of solutions.

   Those persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.

10. 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.

11. 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)).

12. Provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between QA personnel and other department (engineering, procurement, manufacturing, etc.) personnel.

13. The person responsible for directing and managing the onsite QA program is identified and has appropriate organizational position, responsibility, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to ensuring that the QA program at the plant site is being effectively implemented.

14. 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.

15. 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.

B. QUALITY ASSURANCE PROGRAM (Criterion II)

1. Provisions are included for regular management review of the QA program to assess the effectiveness and the adequacy of the scope and implementation. The persons performing the review are management above or outside the QA organization to ensure an objective assessment.

2. The QA program is binding on all participating organizations from the top executive to all workers whose activities may influence quality.

3. 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 ensure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. However, the period for assessing operational QA programs may be extended to once every 2 years for the following activities as approved in the safety evaluation by the Office of Nuclear Reactor Regulation of the Proposed Revisions to the Quality Assurance Program Descriptions of Indian Point Nuclear Generating Unit No. 3 and James A. Fitzpatrick Nuclear Power Plant (Agencywide Documents Access and Management System (ADAMS) Accession No. ML100361087):

a. Conformance to the Technical Specifications and License Conditions.

b. Training and qualification of the facility staff.

c. Results of actions taken to correct deficiencies in the facility equipment, structures, systems, or methods of operation.

d. Radiological environmental monitoring program and the results thereof.

4. The applicant or holder retains and exercises the responsibility for the scope and implementation of an effective overall QA program.

5. 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. This does not apply to ESP applicant QA programs (10 CFR 50.34(f)(3)(ii)).

6. The QA program ensures that activities affecting quality will be accomplished under suitable controlled conditions, including (1) the use of appropriate equipment, (2) a suitable environment for accomplishing the activity, e.g., adequate cleanliness, and (3) compliance with necessary prerequisites for the given activity.

7. The QA program is required to be documented by written policies, procedures, or instructions.

8. The QA program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

9. The QA program should describe adequate indoctrination and training of personnel performing activities affecting quality to ensure that suitable proficiency is achieved and maintained. The QA program should describe how the indoctrination and training program will ensure that:

   a. Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

   b. Personnel verifying activities affecting quality are trained and qualified in the principles, techniques, and requirements of the activity being performed.

   c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.

10. 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 July 22, 1998 SE, ADAMS Accession No. ML101820108.)

11. The QAPD includes provisions to ensure the QA program for operations is implemented at least 90 days prior to fuel loading.

12. For a COL under 10 CFR Part 52, the implementation of the operational phase of the QAP complies with 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, (10 CFR 50.54(a)(1) and SECY05-0197).

13. Independent Review Activities for the operational phase can use Option I or Option II below (does not apply to DC and ESP applicants' QA programs).

    a. Option I - Independent Review Body. (Approved via January 13, 2005 SE, ADAMS 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:

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

            ii. Reviews the 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.

            iii. Reviews the 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.

            iv. 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.

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

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

vii. Audits the adequacy of the audit program every 2 years.

(3) IRB reviews are supplemented as follows:

i. A qualified person, independent of the preparer, reviews the 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.

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

iii. 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.

i. 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.

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

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

iv. 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.

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

b. Option II - Independent Review Committee (ANSI/ANS 3.2)

(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 than five persons, no more than a minority of members are from the onsite operating organization. A minimum of the chairman or alternative chairman and two members must be present for all meetings.

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

(5) Results of the meeting are documented and recorded.

(6) The IRC is responsible for performing the following:

i. Reviews the proposed changes to the facility as described in the SAR. The IRC also verifies that changes do not adversely affect safety, if a technical specification change is required, and if an NRC review is required. (The acronym “IRC” will be used for independent review committee).

ii. Reviews the 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.

iii. Reviews the 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.

iv. 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.

v. 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.

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

vii. Audits the adequacy of the audit program every 2 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: (RG 1.8)

i. Supervisor or Chairman of the Independent Review Committee education:

- Baccalaureate in engineering or related science
- Minimum experience: 6 years combined managerial and technical support

ii. 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 QA 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 QA practices, training, and emergency plans and related procedures and equipment).

C. DESIGN CONTROL AND VERIFICATION (Criterion III)

1. A program is required to describe the design control measures that ensure (1) applicable regulatory requirements, codes and standards, and design bases for safety-related structures, systems, and components are correctly translated into specifications, drawings, procedures, and instructions; (2) appropriate quality standards are specified in design documents; and (3) deviations from such standards are controlled.

2. Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures.

3. 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.

4. 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. Documentation of design analyses includes the following, as applicable:

   a. Definition of the objective of the analyses.

   b. Definition of design inputs and their sources.

   c. Results of literature searches or other applicable background data.

   d. Identification of assumptions and indication of those that must be verified as the design proceeds.

e. 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.

f. Review and approval.

5. The design process ensures that items and activities are selected and independently verified to ensure they are suitable for their intended application.

6. 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.

7. Applicable information derived from experience, as set forth in reports or other documentation, is made available to cognizant design personnel.

8. 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. (Does not apply to ESP applicants' QA programs.) (10 CFR 50.34(f)(3)(iii)(H))

9. QA personnel are included in the documented review and concurrence in quality-related procedures associated with design, construction, and installation. (Does not apply to ESP applicants' QA programs.) (10 CFR 50.34(f)(3)(iii)(C))

10. Errors and deficiencies in approved design documents, including design methods (such as computer codes), that could adversely affect structures, systems, and components important to safety are documented; and action is taken to ensure that all errors and deficiencies are corrected.

11. 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.

12. 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.

13. Deviations from specified quality standards are identified and procedures are established to ensure their control.

14. Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving design interfaces to ensure structures, systems, and components are compatible geometrically, functionally, and with processes and environment. Design information transmitted across interfaces is documented and controlled.

15. Procedures are established and described requiring a documented check to verify the dimensional accuracy and completeness of design drawings and specifications.

16. Procedures are established and described requiring that design drawings and specifications be reviewed by the QA organization to ensure that the documents are prepared, reviewed, and approved in accordance with company procedures and that the documents contain the necessary QA requirements such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results.

17. Measures are provided that will ensure design changes, including field changes, are subject to the same design controls that were applied to the original design and are reviewed and approved by the organization that performed the original design unless the originating organization designates another responsible organization.

18. Measures are provided to ensure that responsible plant personnel are made aware of design changes/modifications which may affect the performance of their duties.

19. Procedures are established and described for design verification activities which ensure the following:

    a. The verifier is qualified and is not directly responsible for the design (i.e., neither the performer nor his immediate supervisor). In exceptional circumstances, the designer's immediate supervisor can perform the verification provided:

        i. The supervisor is the only technically qualified individual.

ii. The need is individually documented and approved in advance by the supervisor's management.

iii. QA audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse.

b. Design verification, if other than by qualification testing of a prototype or lead production unit, is completed prior to release for procurement, manufacturing, construction or to another organization for use in other design activities. In those cases where this timing cannot be met, the design verification may be deferred, provided that the justification for this action is documented and the unverified portion of the design output document and all design output documents, based on the unverified data, are appropriately identified and controlled. Construction site activities associated with a design or design change should not proceed without verification past the point where the installation would become irreversible (i.e., require extensive demolition and rework). In all cases, the design verification should be complete prior to fuel load for a plant under construction, or in the case of an operating plant, prior to relying upon the component, system, or structure to perform its function.

c. Procedural control is established for design documents; this control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, SAR when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

d. The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

20. The following provisions are included if the verification method is only by test:

a. Procedures provide criteria that specify when verification should be by test.

b. Prototype, component or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreversible.

c. Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

21. Procedures are established to ensure that verified computer codes are certified for use and that their use is specified.

22. Control of computer programs used for design analysis includes the following:

    a. Computer program acceptability is pre-verified or the results verified with the design analysis for each application.

    b. Computer programs are controlled to ensure that changes are documented and approved by authorized personnel.

23. Design and specification changes, including field changes, are subject to the same design controls that were applicable to the original design.

D. PROCUREMENT DOCUMENT CONTROL (Criterion IV)

1. Procedures are established for the review of procurement documents to determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with QAP requirements. To the extent necessary, procurement documents should require contractors and subcontractors to provide an acceptable QA program. The review and documented concurrence of the adequacy of quality requirements stated in procurement documents is performed by independent personnel trained and qualified in QA practices and concepts.

2. 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 the procurement of items and services.

3. Organizational responsibilities are described for (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS (Criterion V)

1. Activities affecting quality (i.e., design, procurement, manufacturing, construction and installation, testing, inspection, and auditing) shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.

2. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

3. Operational procedures shall include the following elements as appropriate to the purpose or task to be described to include, Title/Status, Purpose/Statement of Applicability/Scope, References, Prerequisites/Initial Conditions, Precautions, Limitations, Main body, Acceptance criteria, and Checklists (ANSI/ANS 3.2).

F. DOCUMENT CONTROL (Criterion VI)

1. Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality.

2. These measures shall ensure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed.

3. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

4. 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/ANS 3.2 and Appendix B/RIS 2000-18).

5. Procedures for the review, approval, and issuance of documents and changes thereto are established and described to ensure technical adequacy and inclusion of appropriate quality requirements prior to implementation. The QA organization, or an individual other than the person who generated the document but qualified in QA, reviews and concurs with these documents with regards to QA-related aspects.

6. Operational phase procedures for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation and other instructions appropriate for operations of systems related to the safety of the plant shall be delineated in system procedures. Procedures for correcting off-normal conditions shall be developed for those events where system complexity may lead to operator uncertainty (ANSI/ANS 3.2).

7. The distribution of new and revised controlled documents is in accordance with established source documents. Superseded documents are controlled (ANSI/ANS 3.2).

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/ANS 3.2). Procedures do not have to be reviewed every 2 years provided that all of the following are met: (Approved via January 13, 2000 SE, ADAMS Accession No. ML003675798.)

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

    b. Applicable procedures are reviewed following an unusual incident, unexpected transient, significant operator error, or equipment failure.

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

    d. Procedures are reviewed by knowledgeable individuals 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/ANS 3.2)

    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/ANS 3.2)).

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/ANS 3.2)).

12. Provisions are in place to continually improve work instructions through reviews and incorporation of feedback from users (ANSI/ANS 3.2).

G. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES (Criterion VII)

1. Measures shall be established to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.

2. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

3. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant site prior to installation or use of such material and equipment.

4. This documentary evidence shall be retained at the nuclear power plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications met by the purchased material and equipment.

5. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

6. The program includes provisions for evaluating prospective suppliers and selecting only qualified suppliers (ANSI/ANS 3.2).

7. The program includes provisions for ensuring that qualified suppliers continue to provide acceptable products and services (ANSI/ANS 3.2).

9. 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 March 24, 2005 SE, ADAMS Accession No. ML050700416.)

9. 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/ANS 3.2).

10. Measures to verify the quality of purchased items and services are described (ANSI/ANS 3.2).

11. The supplier is required to send the purchaser all nonconforming reports from procurement documentation requirements generated during the manufacturing process.

12. For procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology (NIST) and by the American Association

for Laboratory Accreditation (AALA), 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 February 9, 2015 SE, ADAMS Accession No. ML14322A535 which endorsed NEI-14-05).

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

b. Accreditation is to ANSI/ISO/IEC 17025-2005, "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.

H. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS (Criterion VIII)

1. Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies.

2. These measures shall ensure 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, as required throughout fabrication, erection, installation, and use of the item and that the method and location of the identification does not affect the function or quality of the item being identified.

3. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.

I. CONTROL OF SPECIAL PROCESSES (NOT APPLICABLE TO ESP AND DC APPLICANTS) (Criterion IX)

1. Measures shall be established to ensure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

2. Measures shall be established to ensure that qualifications of special processes, personnel performing special processes, and equipment are kept current and those records thereof are maintained.

3. Each special process instruction includes or references procedure(s), personnel, and equipment qualification requirements.

4. Records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process.

J. INSPECTION (Criterion X)

1. A program for inspection of activities affecting quality (source, in-process, final, receipt, maintenance, modification, inservice, and operations) shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity.

2. Such inspection shall be performed by individuals other than those who performed the activity being inspected and who are appropriately qualified.

3. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to ensure quality.

4. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided.

5. Both inspection and process monitoring shall be provided when control is inadequate without both.

6. If mandatory inspection hold points, which require witnessing or inspecting by an applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents.

7. Measures established shall ensure that, (1) inspection procedures and instructions are made available with necessary drawings and specifications for use prior to performing the inspections, (2) inspectors' qualifications or

certifications are kept current, (3) replaced or reworked items are inspected in accordance with original inspection requirements, and (4) modified or repaired items are inspected by methods that are equivalent to the original inspection method.

8. 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.

9. 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.

K. TEST CONTROL (Criterion XI)

1. A test program shall be established to ensure that all testing is required to demonstrate that SSCs will perform satisfactorily in service is identified.

2. The test program is performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents and are executed by qualified personnel.

3. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear power plant or fuel reprocessing plant operation, of SSCs.

4. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

5. Test results shall be documented and evaluated to ensure that test requirements have been satisfied.

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 the person evaluating test results.

L. CONTROL OF MEASURING AND TEST EQUIPMENT (Criterion XII)

1 Measures shall be established to ensure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

2. M&TE is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data. (Approved via March 24, 2005 SE, ADAMS Accession No. ML050700416.)

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

4. M&TE 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.

5. M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When M&TE 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.

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

7. Records of calibration status and the capability of M&TE to perform its intended function are maintained.

M. HANDLING, STORAGE, AND SHIPPING (NOT APPLICABLE TO DC APPLICANTS) (Criterion XIII)

1. Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration.
2. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.

3. 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 affect their function (not applicable to construction QAPDs). (Approved via March 24, 2005 SE, ADAMS Accession No. ML050700416.)

4. 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 QAPD). (Approved via March 24, 2005 SE, ADAMS Accession No. ML050700416.)

5. 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 QAPD). (Approved via March 24, 2005 SE, ADAMS Accession No. ML050700416.)

6. 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.

7. Provisions are described for the storage of chemicals, reagents (including control of shelf life), lubricants, and other consumable materials.

N. INSPECTION, TEST, AND OPERATING STATUS (NOT APPLICABLE TO DC AND ESP APPLICANTS) (Criterion XIV)

1. Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant.

2. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests.

3. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation.

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/ANS 3.2).

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 November 6, 1998 SE, ADAMS Accession No. 9811170129 - Microform Addresses: A5868:015 – A5868:025.)

6. Maintenance or modifications which may affect functioning of safety-related SSCs shall be performed in a manner to ensure quality at least equivalent to that specified in original design bases and requirements, materials specifications and inspection requirements (ANSI/ANS 3.2).

O. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS (Criterion XV)

1. Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation.

2. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.

3. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

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.

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.

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

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.

P. CORRECTIVE ACTION (Criterion XVI)

1. Measures shall be established to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified, documented, classified and corrected.

2. For significant conditions adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude repetition. These shall be reported to appropriate levels of management and follow-up action taken to verify implementation of corrective actions.

3. Specific responsibilities within the corrective action program may be delegated, but the applicant or holder maintains responsibility for the program's effectiveness (ANSI/ANS 3.2).

4. The program requires all personnel to identify conditions that are adverse to quality (ANSI/ANS 3.2).

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/ANS 3.2).

Q. QUALITY ASSURANCE RECORDS (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/ANS 3.2). Sufficient records shall be maintained to furnish evidence of activities affecting quality.

2. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.

3. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment.

4. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

5. Records shall be identifiable and retrievable.

6. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility for protecting records from destruction by fire, flooding, tornadoes, insects, and rodents and from deterioration by extremes in temperature and humidity.

7. 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 (GL) 88-18, "Plant Record Storage on Optical Disks" (Appendix B/RIS 2000-18).

8. 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/ANS 3.2).

9. 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/ANS 3.2).

10. 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).

11. 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).

12. 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).

13. 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).

14. 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).

15. 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).

16. Records are corrected in accordance with procedures that 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).

R. AUDITS (Criterion XVIII)

1. Planned and periodic audits shall be carried out to verify compliance with all aspects of the QAP and to determine the effectiveness of the program.

2. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited.

3. Audit results shall be documented and reviewed by management having responsibility in the area audited.

4. Follow-up action, including re-audit of deficient areas, shall be taken where indicated.

5. The program features cover the functions listed below:

   a. External audits to be performed by the applicant and his principal contractors on their respective suppliers.

   b. Internal audits to be performed by the applicant and his principal contractors within their respective organizations.

   c. The planning and scheduling of audits to ensure that they are regularly scheduled on the basis of the status and safety importance of the activities being performed and are initiated early enough to ensure effective QA during design, procurement, manufacturing, construction and installation, inspection, and testing.

6. 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).

7. Audits provide a comprehensive independent evaluation of activities and procedures (ANSI/ANS 3.2).

8. When any work carried out under the requirements of the QAP is delegated to others, the work is audited by the QA audit program (ANSI/ANS 3.2).

9. Evaluations of suppliers are documented and take into account the following, where applicable: (Approved via March 24, 2005 SE, ADAMS 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 12 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).

10. Procurement audits of suppliers are accomplished as follows (per RG 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 discussed 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 QAP for other customers that are 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.

S. TRAINING AND QUALIFICATION CRITERIA (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:

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: (RG 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. One 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: (RG 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.

   b. Demonstrated knowledge and understanding of the following:

(1) QA program and other nuclear-related codes, standards, regulations, and RGs, 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 June 26, 1997, SE ADAMS Accession No. 9707070180 - Microform Addresses: 93643:326-93643:329)

d. Successfully completed an examination, which may be oral, written, practical, or any combination of the three types.

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.

6. Lead Auditor certification, at a minimum, documents the following:

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 (Criterion II)

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

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.

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

4. Training and certification records for inspection and test personnel are maintained as follows:

   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 March 24, 2005 SE, ADAMS Accession No. ML050700416.)

6. Inspections by persons during on-the-job training for qualification are 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 March 24, 2005 SE, ADAMS Accession No. ML050700416.)

U. NONSAFETY-RELATED SSC QUALITY CONTROLS

1. Non-safety 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. Quality Assurance 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 M&TE 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 non-conformances 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, and 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 conducted 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 GL 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."

V. QUALITY ASSURANCE PROGRAM COMMITMENTS

1. Regulatory Guides and Generic Letters

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.

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 or ASME NQA-1-2008/2009a Edition.

b. Subpart 2.4, "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a 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 or ASME NQA-1-2008/2009a Edition.

d. Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a 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 or ASME NQA-1-2008/2009a Edition.

f. Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition.

g. Subpart 2.15, "Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition.

h. Subpart 2.20, "Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition.

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

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

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

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

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

Technical Rationale

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

1. Appendix A, GDC 1, 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, the proposed 10 CFR 50.54(a)(1) provides specific implementation requirements for the operational phase of the QA program.

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, 2504 and 2508 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 QAP - 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 – Inspection of Construction and Operational Programs."

For review of a DC application, the reviewer should follow the above procedures to verify that the design set forth in the 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 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 SE 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, SAR 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 SE 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). 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 writing SEs of DC applications and license applications submitted by applicants pursuant to 10 CFR Part 50 or 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." 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.

VI. REFERENCES

1. American National Standards Institute (ANSI) and American Society of Mechanical Engineers (ASME), ANSI/ASME Standard NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Facility Applications," New York, NY, 1983.

2. American National Standards Institute (ANSI) and American Nuclear Society (ANS), ANSI/ANS 3.2-1976, “Administrative Controls and Quality Assurance for the Operation Phase of Nuclear Power Plants,” LaGrange Park, IL, 1976.

3. American National Standards Institute (ANSI) and American Society of Mechanical Engineers (ASME), ANSI/ISO/IEC 17025, “General Requirements for the Competence of Testing and Calibration Laboratories,” Geneva, Switzerland, 1999.

4. American National Standards Institute, ANSI N45.2, “Quality Assurance Program Requirements for Nuclear Power Plants,” Washington, DC, 1977.

5. American Society of Mechanical Engineers, ASME NQA-2, “Quality Assurance Requirements for Nuclear Facility Applications,” New York, NY, 1989.

6. Nuclear Information and Records Management Association, “Required Records Protection, Disaster Recovery, and Business Continuation,” NIRMA TG 21, Stamford, CT, 1998.

7. Nuclear Information and Records Management Association, “Software Configuration Management and Quality Assurance,” NIRMA TG 16-1998, Stamford, CT, 1998.

8. Nuclear Information and Records Management Association, “Electronic Records Protection and Restoration,” NIRMA TG 21-1998, Stamford, CT, 1998.

9. Nuclear Information and Records Management Association (NIRMA), “Management of Electronic Records,” NIRMA TG 15-1998, Stamford, CT, 1998.

10. *U.S. Code of Federal Regulations,* “Domestic Licensing of Production and Utilization,” Part 50, Chapter 1, Title 10, Appendix A, “General Design Criteria for Nuclear Power Plants,” General Design Criterion 1, “Quality Standards and Records.”

11. *U.S. Code of Federal Regulations,* “Domestic Licensing of Production and Utilization,” Part 50, Chapter 1, Title 10, “Energy,” Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.”

12. *U.S. Code of Federal Regulations,* “Contents of Applications; Technical Information,” §50.34, Title 10, “Energy.”

13. *U.S. Code of Federal Regulations,* “Risk-Informed Categorization of Structures, Systems and Components of Nuclear Power Reactors,” §50.69, Title 10, “Energy.”

14. U.S. Nuclear Regulatory Commission, “Quality Assurance Guidance for ATWS Equipment that is not Safety Related.” Generic Letter (GL) 1985-06, January 16, 1985.

15. U.S. Nuclear Regulatory Commission, “Plant Record Storage on Optical Disks,” GL 1988-18, October 20, 1988.

16. U.S. Nuclear Regulatory Commission, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” GL 1989-02, March 21, 1989.

17. U.S. Nuclear Regulatory Commission, “Licensee Commercial-Grade Procurement and Dedication Programs,” GL 1991-05, April 9, 1991

18. U.S. Nuclear Regulatory Commission, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety System (RTNSS) for Passive Plant Designs,” SECY-95-132, May 22, 1995, ADAMS Accession No. ML003708005.

19. U.S. 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, October 28, 2005, ADAMS Accession No. ML052770225.

20. U.S. Nuclear Regulatory Commission, “Processing Applications for Early Site Permits,” Review Standard (RS)-002.

21. U.S. Nuclear Regulatory Commission, “Guidance on Managing Quality Assurance Records in Electronic Media,” RIS 2000-18, May 3, 2004, ADAMS Accession No. ML040700094.

22. U.S. Nuclear Regulatory Commission, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems in Passive Plant Designs,” SECY 94-084, March 28, 1984, ADAMS Accession No. ML003708068.

23. U.S. Nuclear Regulatory Commission, “Qualification and Training of Personnel for Nuclear Power Plants” (endorses ANSI/ANS 3.1 for selected positions and ANSI N18.1 for others), Regulatory Guide 1.8, ADAMS Accession No. ML003706932.

24. U.S. Nuclear Regulatory Commission, “Quality Group Classification, and Standards for Water, Steam, and Radioactive Waste Containing Components of Nuclear Power Plants,” Regulatory Guide 1.26, Revision 4, March 2007, ADAMS Accession No. ML070290283.

25. U.S. Nuclear Regulatory Commission, “Quality Assurance Program Requirements (Design and Construction)” (Revision 4 endorses ANSI/ASME NQA-1), Regulatory Guide 1.28, Revision 4, June 2010, ADAMS Accession No. ML100160003.

26. U.S. Nuclear Regulatory Commission, “Seismic Design Classification,” Regulatory Guide, Revision 4, March 2007, ADAMS Accession No. ML070310052.

27. U.S. Nuclear Regulatory Commission, “Quality Assurance Program Requirements (Operation),” Regulatory Guide 1.33, Revision 3, June 2013, ADAMS Accession No. ML13109A458.

28. U.S. Nuclear Regulatory Commission, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants,”

Revision 1, Regulatory Guide 1.37, Revision 1, March 2007, ADAMS Accession No. ML070250571.

29. U.S. Nuclear Regulatory Commission, “Station Blackout,” Regulatory Guide 1.155, Revision 0, August 1988, ADAMS Accession No. ML003740034.

30. U.S. Nuclear Regulatory Commission, “Fire Protection for Operating Nuclear Power Plants,” Regulatory Guide 1.189, Revision 2, October 2009, ADAMS Accession No. ML092580550.

31. U.S. Nuclear Regulatory Commission, Safety Evaluation by the Office of Nuclear Reactor Regulation Proposed Revisions to the Quality Assurance Program Descriptions Power Authority of the State of New York Indian Point Nuclear Generating Unit No. 3 and James A. Fitzpatrick Nuclear Power Plant, Docket Nos. 50-286 and 50.333, March 25, 1999, ADAMS Accession No. ML100361087.

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33. U.S. Nuclear Regulatory Commission, Safety Evaluation by the Office of Nuclear Reactor Regulation for Vermont Yankee Nuclear Power Corporation Review of Safety Classification and Periodic Procedure Review of Vermont Yankee Nuclear Power Station Docket No. 50-271, January 13, 2000, ADAMS Accession No. ML003675798.

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35. U.S. Nuclear Regulatory Commission, Safety Evaluation by the Office of Nuclear Reactor Regulation for the Proposed Change to the Quality Assurance Program Commercial-Grade Calibration Services for the Arizona Public Service Company, Et. Al., Palo Verde Nuclear Generating Station, Units 1, 2 and 3, Docket Nos. 50-528, 50-529, and 50-230, September 28, 2005, ADAMS Accession No. ML052710224.

36. U.S. Nuclear Regulatory Commission, Safety Evaluation by the Office of Nuclear Reactor Regulation, Quality Assurance Independent Review Program Alternative, Duane Arnold Energy Center, Kewaunee Nuclear Power Plant, Monticello Nuclear Generating Plant, Palisades Nuclear Plant, Point Beach Nuclear Plant, Unit 1 and 2, Prairie Island Nuclear Generating Plant, Units 1 and 2, Docket Nos.: 50-331, 50-305, 50-263, 50-255, 50-266, 50-301, 50-282, 50-306, Revision 1, January 13, 2005, ADAMS Accession No. ML050210276.

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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 numbers 3150-0011 and 3150-0151.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Standard Review Plan Section 17.5
Revision Change Summary

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

This SRP section affirms the technical accuracy and adequacy of the guidance previously provided in Section 17.5, Revision 0 dated March 2007 of this SRP (ADAMS Accession No. ML063190019).

Technical changes incorporated in this revision include:

1. Guidance simplified to reflect plain language throughout in accordance with the NRC's Plain Writing Action Plan;

2. Guidance is aligned with the latest revision of RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 4;

3. Guidance is aligned with RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2; and

4. Guidance reflects alignment with the latest edition of NQA-1-2008/2009a which staff found acceptable for meeting the requirement of Appendix B to 10 CFR Part 50.