DRAFT

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR REACTOR REGULATION

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

REVIEW RESPONSIBILITIES

Primary - The organization responsible for quality assurance (QA).

Secondary - None

I. AREAS OF REVIEW

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

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

ATTACHMENT 1

USNRC STANDARD REVIEW PLAN

Standard review plans are prepared for the guidance of the Office of Nuclear Reactor Regulation staff responsible for the review of applications to construct and operate nuclear power plants. These documents are made available to the public as part of the Commission's policy to inform the nuclear industry and the general public of regulatory procedures and policies. Standard review plans are not substitutes for regulatory guides or the Commission's regulations and compliance with them is not required. The standard review plan sections are keyed to the Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants. Not all sections of the Standard Format have a corresponding review plan.

Public comments are being solicited on this draft Standard Review Plan section. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments may be submitted electronically by email to NRCREP@nrc.gov or through the NRC's Draft NUREG-Series Publications for Comment Web page at http://www.nrc.gov/reading-rm/doc-collections/nuregs/docs4comment.html. The comment period is 60 days from issuance of a notice of availability in the *Federal Register*. The notice of availability is expected within one week of publication of this Standard Review Plan section. Comments submitted after the comment period will be considered as long as it is practicable to do so.

Requests for single copies of draft or active SRP sections (which may be reproduced) should be made to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Reproduction and Distribution Services Section, or by fax to (301) 415-2289; or by email to DISTRIBUTION@nrc.gov. Electronic copies of this section are available through the NRC's public Web site at http://ww w.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/, or in the NRC's Agencywide Documents Access and Management System (ADAMS), at http://www.nrc.gov/ reading-rm/adams.html, under Accession # ML060110089.

A QAPD submitted by a COL applicant applies to all phases of a facility's life, including design, construction, and operation. However, a COL applicant's QAPD may be submitted in two phases. The first phase could apply to construction QA activities and the second phase could apply to operational QA activities. The QAPD for the construction and operational phases would be reviewed and evaluated by the NRC prior to issuing the COL. The operational phase is considered to begin once initial fuel load has commenced. SECY-05-0197, "Review of Operational Programs in a Combined License application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," requires that within 12 months after COL issuance, the licensee submit to the NRC an implementation schedule for the operational programs listed in Table 13.X of the Final Safety Analysis Report (FSAR). SECY-05-0197 identifies the QA operational program as one of the operational programs the must be listed in Table 13.X of the FSAR. NRC inspections of the QA operational program will be based on the implementation date in Table 13.X of the FSAR.

10 CFR 50.34(h) and 10 CFR 52.79(b) require that COL applicants or holders include an evaluation of the facility against the SRP that is in effect 6 months prior to the docket date of the application of a new facility. COL applicants may use an existing QAPD for the operational phase that is approved by the NRC for current use provided that alternatives to or differences from the SRP in effect 6 months prior to the docket date of the application of a new facility are identified and justified.

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

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

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

Section II of this SRP is organized into 26 areas of activity (A through Z). Sections A through X apply to safety-related systems, structures and components (SSCs). Section Y is applicable

only to nonsafety-related SSCs. Sections A through Y are applicable to CP, OL, and COL applicants and COL holders. Section Z is applicable only to holders of a COL (operational phase) and OL applicants. The areas that are not applicable to specific applicants are annotated as such in the detailed discussions in Section II of this SRP. DC, CP, OL, and COL applicants or COL holders that implement 10 CFR 50.69, "Risk-Informed Categorization of Structures, Systems and Components of Nuclear Power Reactors," are not required to specify the QA controls for SSCs that perform low safety significant functions in the QAPD. All areas are discussed in detail in Section II of this SRP as follows:

A. ORGANIZATION

B. QUALITY ASSURANCE PROGRAM

C. DESIGN CONTROL AND VERIFICATION

D. PROCUREMENT DOCUMENT CONTROL

E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

F. DOCUMENT CONTROL

G. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

I. CONTROL OF SPECIAL PROCESSES

J. INSPECTION

K. TEST CONTROL

L. CONTROL OF MEASURING AND TEST EQUIPMENT

M. HANDLING, STORAGE, AND SHIPPING

N. INSPECTION, TEST, AND OPERATING STATUS

O. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

P. CORRECTIVE ACTION

Q. RECORDS

R. AUDITS

S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE

T. TRAINING AND QUALIFICATION - INSPECTION AND TEST

U. QA PROGRAM COMMITMENTS

V. 10 CFR PART 21 AND 10 CFR PART 50.55(e) PROGRAMS FOR REPORTING DEFECTS AND NONCOMPLIANCE

W. COMMERCIAL GRADE DEDICATION

X. DIGITAL EQUIPMENT SOFTWARE VERIFICATION AND VALIDATION QUALITY CONTROLS

Y. NONSAFETY-RELATED SSC QUALITY CONTROLS

Z. INDEPENDENT REVIEW

Review Interfaces

Specific SSCs subject to QA requirements are addressed in the many other SRP subsections developed by NRR organizations other than the QA staff (e.g., Sections 3.2.1, "Seismic Classification," 4.5.1, "Control Rod Drive Structural Materials," and 5.4.12, "Reactor Coolant System High Point Vents"). The NRR branch that develops the relevant SRP subsection is responsible for reviewing the adequacy of the QA requirements in its SRP section.

II. ACCEPTANCE CRITERIA

The QA staff reviews and evaluates QAPDs submitted by applicants and holders in accordance with the applicable sections of this SRP.

Exceptions or alternatives to these specific criteria may be proposed by applicants or holders and may be found acceptable by the staff if adequate justification is provided. Exceptions or alternatives to the regulatory requirements listed in the "Technical Rationale" section of this SRP are not permitted unless the applicant or COL holder requests an exemption from a regulatory requirement. A QAPD is considered to be acceptable if the specific criteria in this section are addressed, acceptable alternatives are justified, or an exemption to regulatory requirements is either approved, or specifically approved by the NRC in advance.

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.

A. ORGANIZATION

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.

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

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

4. There is independence between persons and organizations performing activities and those executing verification and audit activities. (Only applicable to operational QA and ESP programs.)

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

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

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

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

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

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

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

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

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

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

7. Management ensures that the size of the QA organization is commensurate with its duties and responsibilities.

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

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

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

11. Personnel performing verification activities are responsible for verifying the achievement of acceptable quality.

12. The applicant or holder may delegate part or all of the activities of planning, establishing, and implementing the overall QA program to others but is to retain the responsibility for the program.

13. When the applicant or holder delegates responsibility for planning, establishing, or implementing any part of the overall QA program, sufficient authority to accomplish the assigned responsibility also is delegated.

14. The manager responsible for their implementation is to approve the procedures that implement the QA program.

15. There is independence between the organization performing checking functions from the organization responsible for performing the functions. (This applies to DC applicants and construction QA programs.)

B. QUALITY ASSURANCE PROGRAM

1. Management of organizations participating in the QA program regularly review the status and adequacy of the QA program.

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

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

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

5. The QA program is binding on management personnel having responsibility for costs and schedules.

6. The manager responsible for QA is to assess annually the adequacy of the QA program's implementation.

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

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

C. DESIGN CONTROL AND VERIFICATION

1. Design Control

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

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

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

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

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

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

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

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

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

(1) definition of the objective of the analyses

(2) definition of design inputs and their sources

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

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

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

(6) review and approval

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

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

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

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

l. Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, are identified and documented, and their selection reviewed and approved by the responsible design organization. Changes from approved design inputs, including the reason for the changes, are identified, approved, documented, and controlled.

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

n. The QA role in design and analysis activities is defined. (The objective of this provision is to prevent design errors.) (This applies to DC applicants and construction QA programs.)

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

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

q. QA personnel are included in the documented review and concurrence in quality-related procedures associated with design, construction, and installation. (This applies to DC applicants and construction QA programs.)

2. Design Verification

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

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

(1) Were the design inputs correctly selected?

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

(3) Was an appropriate design method used?

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

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

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

c. Alternate calculations are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or

analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used are reviewed.

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

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

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

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

h. The verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven design,

with respect to meeting pertinent design inputs, is verified for each application. The original design and associated verification measures are documented in records for subsequent application of the design.

D. PROCUREMENT DOCUMENT CONTROL

1. Applicable technical, regulatory, administrative, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, "Reporting of Defects and Noncompliance," are invoked for procurement of items and services.

2. Procurement documents include provisions for the following:

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

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

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

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

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

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

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

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

4. Procurement document changes are subject to the same degree of control as utilized in the preparation of the original documents.

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

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

E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS (CONTROLLED DOCUMENTS)

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

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

F. DOCUMENT CONTROL

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

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

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

4. Controlled copies of instructions and procedural documents are distributed to and used by the person performing the activity.

5. The distribution of new and revised controlled documents is in accordance with established source documents. Superseded documents are controlled.

6. The control system is documented as follows:

a. the identification of controlled documents

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

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

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

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

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

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. Procedures do not have to be reviewed every 2 years provided that all of the following are met:

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

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

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

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

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

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

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.)

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.)

12. Personnel from the QA organization review and concur with quality related procedures associated with design, construction and installation. (Applicable only to DC applicants and construction QAPDs.)

13. Provisions are in place to continually improve work instructions through reviews and incorporation of feedback from users.

G. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

2. The program includes provisions for evaluating prospective suppliers and selecting only qualified suppliers.

3. The program includes provisions for ensuring that qualified suppliers continue to provide acceptable products and services.

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

5. The program is to include provisions for ensuring that procurement, inspection, and test requirements have been satisfied before an item is placed in service or used.

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

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

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

   a. procurement document preparation, review, and change control

b. selection of procurement sources

c. bid evaluation and award

d. purchaser control of supplier performance

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

f. control of nonconformances

g. corrective action

h. acceptance of item or service

i. QA records

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

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

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

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

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

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

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

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

   d. identifying and processing necessary change information

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

f. establishing the extent of source surveillance and inspection activities

g. determining any additional or modified design criteria

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

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

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

    a. technical verification of data produced

    b. surveillance and/or audit of the activity

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

12. The purchaser and supplier are required to establish a documented method for the disposition of nonconforming items.

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

    a. description of nonconforming item

    b. evaluation of nonconforming item

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

    d. technical justification for corrective action

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

    a. technical or material requirement is violated

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

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

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

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

16. A certificate of conformance shall contain, as a minimum, the following criteria:

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

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

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

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

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

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

17. Measures to verify the quality of purchased items and services are described.

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

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

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

H. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS (NOT APPLICABLE TO DC APPLICANTS)

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

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

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

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

5. Identification markings, when used, are applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an

identified item when subdivided and cannot be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

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

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

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

   c. provisions for updating existing plant records

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

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

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

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

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

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

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

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

J. INSPECTION

1. A program establishes the inspections to be performed (source, in-process, final, receipt, maintenance, modification, inservice, and operations). The inspection program may be implemented by or for the organization performing the activity inspected.

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

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

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

5. Inspections are performed by individuals other than those who performed the activity being inspected. Inspection personnel do not report directly to the immediate supervisors who are responsible for performing the work being inspected.

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

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

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

9. Those activities that require qualified inspection personnel are defined.

K. TEST CONTROL

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

2. Criteria are defined that specify when testing is required and activities that require qualified test personnel.

3. The test control program includes, as appropriate, proof tests before installation, preoperational tests, postmaintenance tests, postmodification tests, and operational tests.

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

5. Test results are documented and evaluated by a responsible authority to ensure the 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 person evaluating test results.

L. CONTROL OF MEASURING AND TEST EQUIPMENT

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

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

3. Measuring and test equipment is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.

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

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

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 measuring and test equipment to perform its intended function are maintained.

8. For procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC), are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance provided that all of the following conditions are met:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5. Operators of special handling and lifting equipment are experienced or trained in use of the equipment.

6. Controls for the packaging, shipping, handling and storage of items are required to be established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to ensure that no damage or deterioration exists which could effect their function. (Not applicable to construction QAPDs.)

7. Controls for hoisting, rigging, and transport activities are required to be established that protect the integrity of the item involved as well as potentially affected nearby structures and components. Applicable hoisting, rigging, and transportation regulations and codes are followed. (Not applicable to construction QAPDs.)

8. Cleanliness controls for work on safety related and risk-significant nonsafety related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Procedures require documented verification of absence of foreign material prior to system closure. (Not applicable to construction QAPDs.)

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

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

2. The application and removal of status indicators and other labels are controlled.

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

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.

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.

O. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

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

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

3. The responsibility and authority for the evaluation and disposition of nonconforming items are defined.

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

1. A corrective action program is required to be established that includes prompt identification, documentation, classification, cause analysis, and correction of the conditions. Additionally, for significant conditions adverse to quality, the cause of the condition shall be determined and corrective actions take to prevent recurrence. The program is to include provisions that ensure that corrective actions are not inadvertently nullified by subsequent actions. These shall be reported to appropriate levels of management and follow-up action take to verify implementation of corrective actions.

2. Specific responsibilities within the corrective action program may be delegated, but the applicant or holder maintains responsibility for the program's effectiveness.

3. The program requires all personnel to identify conditions that are adverse to quality; suggest, recommend, or provide solutions to the problems; and verify resolution of the issue.

4. Measures within the corrective action program are required to be established to determine the cause of significant conditions adverse to quality.

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.

Q. RECORDS

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

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

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

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

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

6. The program requires that records be examined for adequacy, legibility and completeness.

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

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

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

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

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

    a. significant value in demonstrating capability for safe operation

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

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

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

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

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

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

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

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

17. Records are corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction includes the date and the identification of the person authorized to issue such correction. For records stored in electronic media, a new record is to be

generated when substantial corrections or changes to previous electronic records are required.

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

19. At a minimum, a receipt control system includes the following:

    a. a method for designating the required records

    b. a method for identifying records received

    c. procedures for receipt and inspection of incoming records

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

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

R. AUDITS

1. Personnel performing audit activities are not to have direct responsibilities in the area they are auditing.

2. Audits are accomplished using instructions/procedures and checklists by qualified personnel.

3. Internal Audits

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

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

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

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

   a. description of the audit scope

   b. identification of the auditors

   c. identification of persons contacted during audit activities

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

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

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

6. A program of planned and periodic audits is required to be established to confirm that activities affecting quality comply with the QA program and that the QA

program has been implemented effectively. The audit schedule is reviewed periodically and revised as necessary to ensure that coverage is maintained current.

7. Audits provide a comprehensive independent evaluation of activities and procedures.

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

9. Audit results are documented and reviewed by management having responsibility in the area audited. Followup action, including a relook at deficient areas, is initiated as necessary.

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

11. Procurement audits of suppliers are accomplished as follows:

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

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

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

    b. Audits are conducted as follows for procurement of items not covered by the exceptions in 13(a) above:

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

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

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

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

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

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

12. Evaluations of suppliers are documented and take into account the following, where applicable:

(a) Receipt inspection, operating experience, and supplier evaluation programs are reviewed on an ongoing basis as the information becomes available. The results of the review are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). Additionally, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

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

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

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

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

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

S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE

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

   a. orientation to provide a working knowledge and understanding of QA and the auditing organization's procedures for implementing audits and report results

   b. training program to provide general and specialized training in audit performance

   c. general training that includes fundamentals, objectives, characteristics, organization, performance, and results for quality auditing

   d. specialized training for methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings

   e. training for 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:

   a. Education: baccalaureate in engineering or related science

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

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

   d. 1 year of experience performing quality verification activities

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

3. Individuals responsible for planning, implementing, and maintaining the QA plan are qualified as follows:

   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 regulatory guides, as applicable

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

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

      (4) audit planning in the quality-related functions for designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and safety of the nuclear facility

   c. participated in a minimum of five QA audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which is a nuclear QA audit within the year prior to qualification or for individuals with related industry experience, demonstrated ability to properly implement the audit process, to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification

   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 and Lead Auditors performing audits are required to be established and maintained as follows.

   a. Records for each Lead Auditor are updated annually.

   b. Each Lead Auditor is certified as being qualified to lead audits.

6. The Auditor and 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

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 1 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.

6. Inspections by persons during on-the-job training for qualification is performed under the direct observation and supervision of a qualified person and verification of the conformance is by the qualified person until certification is achieved.

U. QA PROGRAM COMMITMENTS

1. Regulatory Guides (RGs)

The reviewer shall verify that the applicant or holder commits to the appropriate revision of the RGs listed below. Exceptions or alternatives to the specific criteria in any of these RGs may be proposed by applicants or holders provided adequate justification is provided. The reviewer shall notify the NRR organization responsible for the applicable RG of any proposed exceptions or alternatives to the RG. The organization in NRR that is responsible for the RG 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 NRR 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 1.54, "Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants"

d. RG 1.97, "Instrumentation for Light-Water Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident"

e. RG 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants"

f. RG 1.152, "Criteria for Digital Computers in Safety Systems of Nuclear Power Plants"

g. RG 1.168, "Verification, Validation, Reviews, and Audits for Digital Computer Software Uses in Safety Systems of Nuclear Power Plants"

h. RG 1.169, "Configuration Management Plans for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

i. RG 1.170, "Software Test Documentation for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

j. RG 1.171, "Software Unit Testing for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

k. RG 1.172, "Software Requirements Specifications for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

l. RG 1.173, "Developing Software Live Cycle Processes for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

m. RG 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment"

n. RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material"

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 NRR organization responsible for the applicable standard of any proposed exceptions or alternatives to the standard. The organization in NRR that is 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 NRR organization responsible for evaluating the exceptions or alternatives.

a. Subpart 2.1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants," ASME, NQA-1-1994 Edition, "Quality Assurance Requirements for Nuclear Facility Applications" (not applicable to operational QAPDs)

b. Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants," ASME NQA-1-1994 Edition (not applicable to operational QAPDs)

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

d. 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

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

f. 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

g. Subpart 2.15, "Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants," ASME NQA-1-1994 Edition (not applicable to operational QAPDs)

h. Subpart 2.20, "Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants," ASME NQA-1-1994 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" Section 4, "Storage, Preservation, and Safekeeping," of Supplement 17S-1, "Supplementary Requirements for Quality Assurance Records," NQA-1-1994 Edition

V. 10 CFR PART 21 AND 10 CFR 50.55(e) PROGRAMS

DC, COL and ESP applicants are subject to the requirements of 10 CFR Part 21, which address the reporting of defects and failures to comply with the Atomic Energy Act of 1954, as amended, or any rule, regulation, order, or license (including technical specifications) of the Commission. The applicant's QA program must address the applicant's procedures for identifying and evaluating deviations; and reporting defects or failures to comply pursuant to that regulation. Note that, prior to fuel load authorization, COL applicants and holders are subject to the requirements of 10 CFR 50.55(e). However, once the Commission has authorized the loading of fuel, COL holders are subject to the requirements of 10 CFR Part 21. CP applicants are subject to the requirements of 10 CFR 50.55(e).

10 CFR Part 21 and 10 CFR 50.55(e) programs must address the following elements:: These elements apply to both regulations unless otherwise indicated. For applicants or COL holders that choose to implement 10 CFR 50.69, the following elements only apply to safety-related SSCs that perform safety-significant functions.

1. The following posting requirements apply to 10 CFR Part 21 programs. There are no posting requirements in 10 CFR 50.55(e).

    a. Paragraph 21.6(a) requires conspicuous, onsite posting of Section 206 of the Energy Reorganization Act of 1974, the current version of 10 CFR Part 21, and the procedures developed that implement this regulation. The program addresses how it will ensure compliance with those requirements. The program specifies that the Part 21 postings are in all locations where there are activities involving basic components.

    b. If the posting requirements of Section 21.6(a) are not practicable, the applicant may implement the requirements of Section 21.6(b). If paragraph 21.6(b) is implemented, in addition to posting Section 206, the applicant may post a notice. Section 206 may be a part of the notice or posted separately. The contents of the notice are described or an example notice is provided. The description or sample notice addresses or contains the following:

        (1) a description of the regulation in 10 CFR Part 21

        (2) a description of the procedures that implement 10 CFR Part 21

        (3) the location where the regulation in 10 CFR Part 21 and the implementing procedures may be examined

        (4) the name or title and contact information of the responsible individual to whom personnel at the facility should contact to make a 10 CFR Part 21 report

c. The location where the notice is posted in the applicant's facilities is consistent with requirements in paragraph 21.6(a)(2).

2. The program ensures that all procurement documents for basic components specify the applicability of 10 CFR Part 21 to the purchase or contract, pursuant to 10 CFR 21.31, "Procurement Documents."

3. Compliance with 10 CFR Part 21 requires establishment of procedures to evaluate deviations and report defects, and failures to comply associated with substantial safety hazards. Procedures should describe the following:

   a. acquiring information sufficient to identify a deviation or failure to comply

   b. performing an analysis of deviations and failures to comply

   c. reaching a conclusion based on the analysis as to whether the deviation could be a defect; or whether the failure to comply could create a substantial safety hazard if it were to remain uncorrected

   d. reporting conforms with the format and schedule described in the regulation

   e. providing feedback of deficiencies identified in any phase of the commercial-grade dedication process and also screening for 10 CFR Part 21 applicability

4. The regulation in 10 CFR 21.21, Notification of a Failure to Comply or Existence of a Defect and its Evaluation," describes notification requirements for failures to comply or existence of a defect and its evaluation. The QAPD describes how its program will achieve the following:

   a. Ensure notification of the defect or failure to comply will be provided to a director or responsible officer within 5 days of completion of the evaluation.

   b. Provide an interim report to the Commission if the evaluation of an identified deviation or failure to comply cannot be completed within 60 days of discovery.

   c. Provide notification to the Commission upon determination that a failure to comply or a defect exists. Provide initial notification within 2 days and written notification within 30 days.

5. Notification to the Commission from the applicant indicating that a failure to comply or defect exists must include a written report. The program should ensure that the report will contain information required in 10 CFR 21.21(d)(4).

6. The program ensures that records necessary to document the applicant's compliance with 10 CFR Part 21 are prepared, maintained, and made available for inspection by the Commission if necessary, pursuant to 10 CFR 21.51, "Maintenance of Inspection Records."

W. COMMERCIAL-GRADE DEDICATION (NOT APPLICABLE TO ESP AND DC APPLICANTS)

The provision for commercial-grade dedication, the key definitions, and requirements are codified in 10 CFR Part 21. The overall function of a dedication program is to provide an alternate means of satisfying the requirements of 10 CFR Part 50, Appendix B, with regard to procurement and acceptance of commercial-grade items (and services) for use as (for) basic components. A dedication program must include provisions to demonstrate that a dedicated item or service is suitable for safety-related applications, and that the dedication process is controlled under a 10 CFR Part 50, Appendix B, QA program.

10 CFR Part 50, Appendix B, Quality Assurance Requirements

The QAPD must describe how the commercial-grade dedication program meets the requirements of Appendix B to 10 CFR Part 50. Specific elements of the criteria in Appendix B that must be described are detailed below.

1. Criterion II - Quality Assurance Program

   a. Dedication programs are documented by written procedures or instructions and shall be carried out in accordance with those procedures or instructions.

   b. The dedication program provides for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of that quality.

   c. The dedication program provides for training, such as, indoctrination, training, qualification, continuing training, and periodic refresher training of personnel.

2. Criterion III - Design Control

   a. Engineering personnel specify regulatory and design requirements (which may reference the original design basis) and translate these requirements into instructions, procedures, and drawings. Some of the requirements may need to be included on the purchase documents for replacement components. Design control measures are applied to the delineation of critical characteristics and the acceptance criteria for inspections and tests.

b. The dedication program provides for the review of materials, parts, equipment, and processes for suitability of application.

c. The commercial-grade dedication process includes engineering involvement commensurate with the nature, complexity, and application of the items to be dedicated.

3. Criterion IV - Procurement Document Control

a. Procurement documents specify the technical and quality requirements and may also specify the acceptance methods and criteria consistent with the technical evaluation.

b. Procurement documents invoke the commercial-grade supplier's commercial quality program documents by revision and/or date, and also establish requirements for documented traceability.

4. Criterion V - Instructions, Procedures, and Drawings

a. Instructions, procedures, and drawings containing qualitative and quantitative acceptance criteria must be relevant to the specific item or service and to the specific plant application.

b. The dedication program elements, including receipt inspection, commercial-grade surveys, source verification, surveillances (including witness/hold points as appropriate), special tests and inspections, use of supplier and product performance history, and post-installation tests are prescribed by documented procedures.

5. Criterion VI - Document Control

a. Documents that specify or prescribe the dedication process must be appropriately controlled. Controls should provide for the review of documents for adequacy, approval of changes by authorized personnel, and their adequate use.

6. Criterion VII - Control of Purchased Items and Services

a. Measures are established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.

b. Measures are established to evaluate the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quality of the product or service.

c. Measures are established for the examination of products upon delivery or prior to delivery if necessary to verify critical characteristics.

7. Criterion VIII - Identification and Control of Purchased Items

a. Measures are established to control the identification or traceability of a commercial-grade item to its original manufacturer and to the results of dedication inspections and tests. Unique identifiers are to be maintained either on the item or on records traceable to the item.

8. Criterion IX - Control of Special Processes

a. Measures are established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures.

b. The requirements of applicable codes, standards, specifications, acceptance criteria, and other special requirements are to be included or referenced in procedures or instructions utilized in the dedication process.

9. Criterion X - Inspection

a. Measures are established for the planning and execution of inspections required to verify conformance of an item or activity.

b. Inspection requirements (e.g., characteristics subject to inspection, inspection methods, mandatory hold points) and acceptance criteria are to be included in the dedication plan.

10. Criterion XI - Test Control

a. Measures are established for the control of all testing required to verify conformance of an item to specified requirements, or to demonstrate satisfactory performance for service.

b. Test procedures 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.

c. Test results are to be documented and evaluated to assure that test requirements have been satisfied.

11. Criterion XII - Control of Measuring and Test Equipment

a. A procedure is required to be established to control the calibration and adjustment of measuring and test equipment.

12. Criterion XIII - Handling, Storage, and Shipping

a. Measures are established to control the handling, storage, shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions, specifications, or procedures.

13. Criterion XIV - Inspection, Test, and Operating Status

a. Measures are 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.

14. Criterion XV - Nonconforming Materials, Parts, or Components

a. A procedure is required to be established to provide feedback of deficiencies identified in any phase of the commercial-grade dedication process and also screening for 10 CFR Part 21 applicability.

15. Criterion XVI - Corrective Action

a. A procedure is required to be established to provide for screening of deficiencies and evaluating applicability to 10 CFR Part 21 that considers the following:

(1) Whether the nonconformance involves anything that is a basic component in the facility or anything that is to be delivered or offered for use in a NRC-licensed facility as a basic component;

(2) whether the nonconformance constitutes a deviation or failure to comply with the potential for creating a substantial safety hazard; and

(3) whether the nonconformance should have been corrected prior to the goods or services being installed, used, delivered, or offered for use.

16. Criterion XVII - Quality Assurance Records

a. Auditable dedication-related documentation, including dedication plans and results, must be retained by the licensee or the dedicating entity as a quality assurance record for the life of the dedicated commercial-grade item in the nuclear power plant.

17. Criterion XVIII - Audits

    a. Dedication program audits are to be performed to determine its effectiveness. Audits are to be prescribed by written procedures or checklists and conducted by appropriately trained personnel. Audit results are to be documented and reviewed by responsible management. Follow-up actions shall be taken where indicated.

Technical Evaluations

Technical evaluations are conducted and documented by the responsible engineering organization. Technical evaluations identify the necessary technical and quality requirements that ensure the item will meet the intended design conditions. These requirements should include:

1. Determination of the item's safety function, performance requirements, component/part functional classification, and application requirements (e.g., service conditions).

2. Review of the manufacturer's technical data as well as industry operating experience, including feedback from previous dedication activities, NRC bulletins and information notices, supplier information letters, and available industry data, to identify relevant technical information that may affect the suitability of the item.

3. Performance of a detailed Failure Modes and Effects Analyses (FMEA) to identify the credible failure mechanisms of the item in the specific application under consideration.

4. The identification of the item's critical characteristics based on the information developed above that will assure the suitability of all parts, materials, and services for their intended safety-related applications. Factors that should be considered include:

    a. The important design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function.

    b. Active/passive safety-related functions, long-term reliability/durability, system safety/non-safety interfaces, and system compatibility under all design basis conditions.

    c. Any changes in design, material, or manufacturing process that could impact the functional characteristics of the item.

    d. Appropriate interface with manufacturer to identify and characterize the design and functional parameters of specific parts.

e. The number and nature of the critical characteristics are to be based on the intended safety function, application requirements, complexity, credible failure modes and effects, and performance requirements of the item.

f. Those critical characteristics that cannot be effectively verified during post-receipt dedication inspection and testing should be identified in order to apply an appropriate verification method during the manufacturing process.

All critical characteristics, i.e., those that are important for the item to perform its safety function (as determined in the technical evaluation), are to be verified. Not all design requirements need to be considered critical characteristics; however, licensees must assure the suitability of all parts, materials, and services for their intended safety-related applications. This may involve the performance of surveys, special tests and/or inspections, or source verification on commercial-grade suppliers as part of the supplier selection process to verify the adequacy of the supplier controls (see Acceptance Methods section below).

5. Determination of the appropriate verification methods for each critical characteristic.

6. Identification of the acceptance criteria for the verification method used for the identified critical characteristics consistent with the plant-specific application.

Additional considerations for dedication of commercial-grade items for applications requiring environmental or seismic qualification:

1. Utilization of non-destructive methods to verify the critical characteristics of the item to provide reasonable assurance that each individual production commercial-grade item will perform in the design-basis accident/event harsh environment (e.g., LOCA, HELB, OBE, SSE). Like-for-like replacements should demonstrate performance at least as well as the qualified prototype.

2. The commercial-grade item's safety function(s), functional performance requirements, and success criteria determinations should include:

   a. Detailed analysis of vulnerabilities/sensitivities to environmental stressors,

   b. Detailed material and durability analysis, and

   c. Required operating/mission times (including post-accident).

   d. Design service conditions (harsh environment, seismic)

3. Seismic and environmental qualification should be treated as critical characteristics to be verified.

Acceptance Methods

The following are the four acceptance methods that should be included in the dedication program and may be used to accept commercial-grade items. The most appropriate acceptance method(s) should be selected for each critical characteristic.

Method 1: Special Test and Inspections

1. Special test and inspections should be used after the commercial-grade item is received or during manufacture to assure that the purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, meet the technical and quality requirements.

2. Tests and inspections specified for acceptance should be verified by developing a documented plan or checklist that should include:

   - The test and inspections to be performed
   - The test methods and inspection techniques to be utilized
   - Verification of the identified critical characteristics consistent with the acceptance criteria determined in the technical evaluation
   - Documentation of the inspection and test results

3. Receipt inspection activities establish and maintain traceability of commercial-grade items.

4. Post-installation testing, functional tests before installation, and/or operational tests after installation may be performed to verify critical characteristics of the commercial-grade item.

5. Measuring and test equipment should be calibrated properly, approved vendors should be used to perform tests, and qualified personnel should be used to perform the tests.

6. Sampling plans for testing should be used in accordance with nationally recognized industry standards, appropriately controlled, and have adequate technical basis, considering lot traceability and homogeneity, complexity of the item, and adequacy of the supplier's controls. These controls should include an acceptable commercial qualitycontrols as confirmed by survey. The commercial-grade item sampling process should be documented to develop the necessary objective evidence of the supplier's ability to consistently provide acceptable items.

7. Inspections should include verification of objective quality evidence and performance of visual, dimensional, electrical and mechanical inspections, or tests (as necessary) to assure product and material quality.

8. When the verification of one or more critical characteristics is based on vendor certified material test reports or certificates of conformance, the validity of these documents should be ensured (see Method 2 below). Acceptance of an item using this method will be completed by performing a receipt inspection with the accompanying supplier's certificate of conformance or certified material test report.

9. Reliance on part number verification and certification documentation alone on receipt is insufficient to ensure the quality and suitability of commercially procured products.

Method 2: Commercial-grade Survey of Supplier

1. Commercial-grade surveys should be used when the purchaser desires to verify one or more critical characteristics based on the merits of a vendor/supplier's commercial quality controls.

2. The vendor/supplier should have a documented and effectively implemented program and/or procedures to control the critical characteristics of the item or items being procured.

3. The survey should be conducted by an individual(s) that is also trained in auditing and knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified.

4. The verification is accomplished by reviewing the vendor's program/procedures controlling these characteristics and observing the actual implementation of these controls in the manufacture of items identical or similar to the items being purchased.

5. Critical characteristics that are not adequately controlled should be addressed by the contract requiring the vendor to institute additional controls or by utilizing other verification methods.

6. If the vendor's controls are determined to be satisfactory, purchase orders for these items should invoke these controls as contract requirements by referencing the applicable program/procedure(s) and revision. Specific controls reviewed and accepted during the survey should be implemented during the manufacturing process.

7. Commercial-grade survey plans should include the identification of the item or items for which the vendor is being surveyed, identification of the critical characteristics of these items that the vendor is expected to control, identification of the controls to be applied (program/procedure and revision), and a description of the verification activities performed.

8. For survey reports prepared by third parties (e.g., a NUPIC joint or member survey), the following factors should be considered:

   a. Review and acceptance of the surveyors' procedure(s), checklists, and personnel (e.g., the NUPIC commercial-grade survey procedure and checklist).

   b. Ensure that the survey is pertinent to the item(s) being procured and to the plant application.

   c. The survey report should demonstrate that the critical characteristics required for the purchaser's own application are in fact verified to be controlled by the supplier.

9. Actual handling of the item by a distributor should be addressed in terms of the distributor's controls (e.g., segregation of customer returns). However, other factors may be taken into account that may warrant the need for a distributor survey, such as:

   a. The need for documented, verifiable traceability to the original equipment manufacturer.

   b. Presence and integrity of original equipment manufacturer packaging/markings, etc.

   c. The susceptibility of the item to undetectable damage or tampering.

   d. History or experience with the particular vendor and distributor(s).

   A survey of the distributor may not be necessary if there is a low probability of a distributor being able to have any material effect on an item merely by having it in its physical possession, and where the distributor has rigorous controls on items during possession.

10. Commercial-grade surveys should be conducted at sufficient frequency to ensure that the process controls applicable to the critical characteristics of the item procured continue to be effectively implemented. Such verifications should be conducted at intervals commensurate with the vendor's past performance. Factors to be considered in determining the frequency of commercial-grade surveys include the complexity of the item, frequency of procurement, receipt

inspection, item performance history, and knowledge of changes in the vendor's controls.

11. The dedicating entity is responsible for the control of subsuppliers of parts, materials, or services. The dedicating entity is required to impose the necessary controls on subsuppliers consistent with the importance of the subcontracted item or service. Control of subsuppliers should also be adequately addressed by survey so that the supplier has an adequate basis to accept test results and certifications.

12. A certificate of conformance or certified material test report by the original equipment manufacturer/vendor or material supplier may be acceptable, provided:

    a. Documented, verified traceability to the original equipment manufacturer/vendor has been established, and

    b. The purchaser has verified that the original equipment manufacturer or material supplier has implemented adequate quality controls for the activity being certified.

13. Acceptance Method 2 should not be employed as the sole basis for accepting items from suppliers with undocumented commercial quality control programs or with programs that do not effectively implement their own necessary controls. Likewise, Method 2 should not be employed as the basis for accepting items from distributors unless the survey includes the part manufacturer(s) and the survey confirms adequate controls by both the distributor and the part manufacturer(s).

Method 3: Source Verification

1. Method 3 involves witnessing quality-related activities before releasing the commercial-grade item from the supplier or test laboratory facility to directly confirm that the selected critical characteristics of the item being procured are satisfactorily controlled by the supplier. Source verification could also be used when specialized tests and/or inspections are required to verify selected critical characteristics and the equipment to perform these tests is available only at the supplier's facilities.

2. Source verifications should be controlled by a plan. Factors to be considered in the plan include:

    a. The identification of a specific process of interest that may be correlated with a manufacturing or testing phase.
    b. The verification method utilized to verify the critical characteristics for acceptance.

c. Appropriate hold points to verify design, material, and performance characteristics during manufacture and/or testing relevant to the safety function of the item when those characteristics cannot be verified after the item has been completely manufactured.

d. A dedicating entity inspector(s) who performs direct observations of the verification of commercial-grade item's critical characteristics and manufacture at the supplier facility. The inspector(s) should be a technical specialist skilled in audit practice and knowledgeable in operation of the item(s) and the associated critical characteristics to be verified.

e. Documentation of the source verification results. This includes the critical characteristics for acceptance and the actual results obtained during verification. Deficiencies observed should be corrected by the supplier before shipping.

3. The dedicating entity inspector authorizes shipping and establishes initial traceability.

Method 4: Acceptable Supplier/Item Performance Record

1. This method could be used to accept one or more critical characteristics based upon a confidence in the supplied item achieved through proven performance of the item. The purchaser can also take credit for item performance based upon historical verification, acceptable quality control of critical characteristics, or acceptable industry-wide performance.

2. Information pertinent to the commercial-grade item's quality of performance obtained from outside sources (e.g., operational event reports, NRC, vendor equipment technical information program, and Institute of Nuclear Power Operations) and from commercial-grade surveys, source verifications, receipt inspections, previous dedication or qualification, and operational history is factored into the dedication process.

3. The established historical record is based on acceptable industry-wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application.

4. This method should not be employed alone unless the established historical record is based on industry-wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application.

5. This method should be used in combination with one or more of the methods explained above to collect the objective evidence necessary to ensure acceptable historical performance of the supplier.

6. This method is more suited to providing a basis for sampling plans.

Like-for-like Commercial-Grade Item Replacements

1. A like-for-like replacement is a replacement of an item with one that is identical. A replacement may be considered identical if:

   - The item was purchased from the same manufacturer (successor companies may be accepted provided all product changes can be identified, analyzed, and verified acceptable for the specific application), and

   - The item has the same model or part number (number changes where no product change is verified may be accepted, considering drawing revision and/or date as drawings may change without an associated change in part number), and

   - The item has the same manufacturing time frame as determined by, for example, date purchased or date shipped from factory, date code, same batch or lot number.

2. Equivalency evaluations should demonstrate that a like-for-like replacement is identical in form, fit, function process and material to the item it is replacing, and that it will function under all design conditions (including design basis event conditions).

3. A like-for-like determination should not be based solely on the selection of commercial-grade supplier with items manufactured to meet the same industry standards of the item that was originally supplied. Meeting the same industry standards may be a necessary condition, but is not a sufficient condition for a like-for-like determination.

4. If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements and critical characteristics need not be redetermined. However, qualification of suppliers and examination of products is still required.

5. If differences from the original item are identified in the replacement item, then the item is not identical, but similar to the item being replaced, and additional evaluation is necessary to determine if any changes in design, material, manufacturing process, safety, form, fit, or interchangeability could impact the functional characteristics and ultimately the component's ability to perform its required safety function.

6. Equivalency evaluations should not be used as the sole basis to accept a commercial-grade item for safety-related use. All critical characteristics should still be verified as part of the acceptance process.

Acceptance Phase

Verification activities are to be performed at various stages of the dedication process to verify critical characteristics identified in the technical evaluation. Verification activities should contain provisions for the following:

1. Source verifications, commercial-grade surveys, manufacturing/post-manufacture tests and inspections, post-installation tests and inspections, receiving inspections, and post-storage inspections. These activities are to be prescribed by documented procedures and the supplier's commercial quality program.

2. For items with critical characteristics that can be verified for the most severe or limiting plant application, the purchaser must identify and verify the item's critical characteristics to qualify the item for that application. However, if the item will not be used in the most limiting application, the item may be dedicated for its specific application.

10 CFR Part 21 Requirements

1. Entities performing dedication activities are responsible for the identification, evaluation of deviations, reporting of defects or failures to comply, and maintain auditable records for the dedication process.

2. Nonconforming conditions identified before the basic component or dedicated commercial-grade item is delivered to a purchaser for use would not be deviations, as defined in Part 21 (see deviation, defect, definitions in 21.3). When nonconformances are corrected before delivery, evaluation per 21.21(a)(1) is not applicable. If a basic component or a dedicated commercial-grade item has been delivered to the purchaser for use, nonconformances identified and uncorrected become deviations or failures to comply, and evaluation is required per 21.21(a)(1) by the dedicating entity or if the dedicating entity is not capable of performing the 21.21(a)(1) evaluation, then 21.21(b) is followed.

3. Suppliers of basic components, or entities providing services associated with basic components (except NSSS suppliers, Architects/Engineers, and NPP licensees) are not expected to be capable of performing an adequate evaluation per 21.21(a)(1) because they would not necessarily be expected to know the plant application and/or the effect(s) of the deficiencies in their product on the affected plant(s). It is preferred that they notify affected licensees and/or purchasers in accordance with 21.21(b). However, suppliers are expected to

perform evaluations to analyze the extent of condition (i.e., the potential or actual applicability of the deficiencies to exist in other basic components, activities, or projects for generic applicability) and inform purchasers or affected licensees.

4. An individual, manufacturer, or supplier of commercial-grade items not subject to the regulations in Part 21 may still report to the Commission any known or suspected defect or failure to comply that could create a substantial safety hazard.

Definitions

Basic component: A structure, system, component, or part thereof that affects its safety function necessary to assure:

- The integrity of the reactor coolant pressure boundary;
- The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in 10 CFR 50.34(a)(1), 10 CFR 50.67(b)(2), or 10 CFR 100.11, as applicable.

Basic components are items designed and manufactured under a QA program complying with 10 CFR Part 50, Appendix B, or commercial-grade items which have successfully completed the dedication process.

In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

Certificate of Compliance: A document attesting that the materials are in accordance with specified requirements.

Certified Material Test Report: A document attesting that the material is in accordance with specified requirements, including the actual results of all required chemical analyses, treatments, tests, and examinations.

Commercial-grade item: A structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component.

Commercial-grade survey: Activities conducted by the purchaser or its agent to verify that a supplier of commercial-grade items controls, through quality activities, some or all of the critical characteristics of the specifically designated commercial-grade items to be purchased, as a method to accept those characteristics. The commercial grade survey should include verification of the supplementary documentation and the effective implementation of the commercial-grade quality program.

Commercial-grade dedication package: An auditable collection of documents that is the result of the commercial-grade dedication process for a specific item and specific safety function. These documents contain the technical and quality basis for satisfying the commercial-grade item dedication process, and provide the objective evidence to reasonably assure that the dedicated commercial-grade item will perform its required safety function.

Critical characteristics: Those important design, material, and performance characteristics of a commercial-grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity: The organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, and/or the licensee itself. The dedicating entity is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication: An acceptance process undertaken to provide reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial-grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

Engineering Judgment: A process of logical reasoning that leads from stated premises to a conclusion. This process should be supported by sufficient documentation to permit verification by a qualified individual.

Like-for-like Replacement: Replacement of an item with one that is identical.

Procurement document: A contract that defines the technical and quality requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Source Verification: Activities witnessed at the supplier's facilities by the purchaser or its agent for specific items to verify that a supplier of a commercial-grade item controls some or all the critical characteristics of that item, as a method to accept those characteristics only.

Traceability: Is the ability to verify the history, location, or application of an item by means of recorded identification. Traceability to the manufacturer is required when the manufacturer is relied upon to verify one or more critical characteristics.

X. DIGITAL EQUIPMENT SOFTWARE VERIFICATION AND VALIDATION QUALITY CONTROLS

1. Organization (Criterion I of Appendix B to 10 CFR Part 50)

The design of digital equipment, supplier's processes and software QA program implementation are required to be monitored. This includes evaluating the supplier's program for software/hardware configuration control, documented procedures, failure analyses, verification, validation, testing activities, and documented evidence of operating history data. The purchaser assumes ultimate responsibility for the adequacy of the supplier's digital equipment software development process, documentation, quality and reliability of the final product.

Personnel working in digital equipment verification, validation, review, and audit activities are qualified in accordance with written procedures. These personnel have sufficient authority to observe, participate as needed, identify and report problems at a management level sufficiently high to ensure that cost and schedule considerations do not unduly influence decision making.

There is independence between persons and organizations executing performance activities and those executing verification and audit activities. A separate or dedicated QA organization is not required.

2. QA Program (Criterion II of Appendix B to 10 CFR Part 50)

Procedures describe the quality controls and verification and validation activities applied to digital equipment. Suppliers must work under an Appendix B QAP that includes a software QA plan and a software verification and validation plan. For suppliers not working under an Appendix B QA program, detailed procedures and guidance must be included for the evaluation and acceptance of commercial-grade digital equipment used in nuclear safety applications.

3. Design Control (Criterion III of Appendix B to 10 CFR Part 50)

The purchaser ensures that the supplier implements the Institute of Electrical and Electronics Engineers (IEEE) Std 1012-1998, "IEEE Standard for Software Verification and Validation," endorsed by RG 1.168, to establish the appropriate software integrity level based on its intended use and application. Software used in nuclear power plant safety systems should be assigned integrity level 4 or equivalent, as stated in the IEEE standard.

The purchaser monitors the life cycle phases of the software development process. As defined in IEEE Std 1012-1998, the life cycle process is the set of activities that results in the development or assessment of software products. Strict compliance with IEEE Std 1012-1998 is not required provided the appropriate activities are encompassed.

The purchaser ensures that the supplier conducts appropriate risk and failure analyses to identify functional and performance requirements, system configurations, interfaces, safety and security requirements, and vulnerabilities. These analyses are used to establish the minimum security requirements for the system (hardware and/or software).

The purchaser establishes measures to ensure the contractually established design requirements are included in the design and correctly translated into design documents. Design changes are subject to design control measures commensurate with those applied to the original design.

Training and qualification requirements, human factors engineering, software and hardware documentation, installation, acceptance, operation, execution, and maintenance activities are properly defined and documented.

Verification and validation tasks are performed during all the life cycles of the software development process to verify conformance of an activity to specified requirements, or to verify that activities are satisfactorily accomplished. Personnel performing inspections must be knowledgeable and proficient in software engineering.

4. Procurement Document Control (Criterion IV of Appendix B to 10 CFR Part 50)

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

Analyses for commercial off-the-shelf digital equipment must include the identification of the critical characteristics that provide reasonable assurance that the item will perform its intended function. Also, equipment documentation, security vulnerabilities, and documented operating experience are identified and reviewed.

Dedication activities for digital equipment include, but are not limited to the following:

- technical evaluation to define the requirements for the device
- selection of the digital equipment's critical characteristics for acceptance

- identification of additional verification activities such as special tests, inspections, source verification, or performance records to verify such characteristics

5. Test Control (Criterion XI of Appendix B to 10 CFR Part 50)

Measures are established to ensure that system security requirements are validated by execution of integration, system, and acceptance tests where practical and necessary. Testing includes hardware configuration including all external connectivity, software integration testing, software qualification testing, system integration testing, system qualification testing, and system factory acceptance testing. Tests are performed in accordance with written test procedures, properly recorded, and evaluated to ensure that test requirements are met and that the final product conforms to identified and documented QA requirements.

An independent acceptance review and safety system test should be performed prior to the installation of the equipment to ensure that installation of the digital system will not compromise the security of the digital system, other systems, or the plant.

The purchaser ensures that the system features allow post-installation testing of the system to verify that the security requirements have been incorporated into the system appropriately.

The purchaser performs periodic monitoring of digital equipment performance in its operational environment. Maintenance activities include software modifications, migration, or replacement. The purchaser tracks software/hardware revisions and is responsible for maintaining the validity of the digital equipment for as long as the device remains in service. Software and hardware upgrades require appropriate technical evaluation and testing in accordance with written procedures.

6. Corrective Action (Criterion XVI of Appendix B to 10 CFR Part 50)

The purchaser establishes measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected using the corrective action process. Contractual agreements or other suitable method must be established as a reporting mechanism between the purchaser and the supplier.

7. Audits (Criterion XVIII of Appendix B to 10 CFR Part 50)

Periodic audits are conducted to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. The software verification and validation plan provides for audits in each phase of

the life cycle process, including functional audits, in-process audits, and physical audits of software.

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

1. Nonsafety-Related SSCs That Perform Safety Significant Functions

This section applies to nonsafety-related SSCs that perform safety significant functions. The reviewer shall verify that QAPDs for passive advanced light water reactor designs and applicants or COL holders that choose to implement 10 CFR 50.69 specify the following quality controls for nonsafety-related SSCs that perform safety significant functions.

a. Organization

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

b. QA Program

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

c. Design Control

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

d. Procurement Document Control

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

e. Instructions, Procedures, and Drawings

Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. This may include such things as written instructions, plant procedures, cautionary notes on drawings, and special instructions on work orders. Any methodology which provides the

appropriate degree of guidance to personnel performing activities important to the component functional performance is acceptable.

f. Document Control

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

g. Control of Purchased Items and Services

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

h. Identification and Control of Purchased Items

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

i. Control of Special Processes

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

j. Inspection

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

k. Test Control

Measures are established that demonstrate that test equipment conforms with design requirements. These measures must be implemented prior to the installation of the test equipment. Tests are performed in accordance with test procedures. Test results are recorded and evaluated to ensure that test requirements are met.

l. Control of Measuring and Test Equipment

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

m. Handling, Storage, and Shipping

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

n. Inspection, Test, and Operating Status

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

o. Control of Nonconforming Items

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

p. Corrective Action

Measures are established to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected. Cause determinations and corrective actions for design and operational errors that degrade nonsafety-related, risk-significant SSCs are specified in the QAPD.

q. Records

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

r. Audits

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

2. Nonsafety-Related SSCs Credited for Regulated Events

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

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

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

c. The applicant or holder commits to implement quality requirements to SBO equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in RG 1.155, "Station Blackout."

Z. INDEPENDENT REVIEW

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

Option I - Independent Review Body

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.

2. The IRB performs the following:

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

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

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

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

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

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

g. Auditing the adequacy of the audit program on a yearly basis.

3. IRB reviews are supplemented as follows:

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

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

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

4. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed, with a minimum of one such review being conducted yearly. This review is intended to support plant and corporate management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.

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

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

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

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

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

Option II - Independent Review Committee

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

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

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

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

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

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

   a. Reviews proposed changes to the facility as described in the SAR. These changes are reviewed prior to implementation. The Independent Review Committee also verifies that changes do not adversely effect safety and if a technical specification change or NRC review is required.
   b. Reviews proposed tests and experiments not described in the SAR. These tests and experiments are reviewed prior to implementation. The Independent Review Committee also verifies that tests or experiments do not require a technical specification change or NRC review.

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

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

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

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

g. Auditing the adequacy of the audit program on a yearly basis.

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

8. Persons on the independent review committee are qualified as follows :

a. Supervisor or Chairman of the Independent Review Committee

Education: baccalaureate in engineering or related science

Minimum experience: 6 years combined managerial and technical support

b. Independent Review Committee members

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

Minimum experience: 5 years experience in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, nondestructive testing,

instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment)

Technical Rationale

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

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

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

10 CFR 50.34(b)(6)(ii) requires that the information on the controls to be used for a nuclear power plant include a discussion on how the applicable requirements of Appendix B will be satisfied. The applicant or holder must describe how each of the acceptance criteria is met.

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

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.

Compliance with 10 CFR Part 21 and 10 CFR 50.55(e) requires reporting of defects or failures to comply with regulations. These regulations specify what constitutes a defect and the format and schedule for such reporting. These regulations are applicable because potential reportable degradations are identified, evaluated, and reported under the 10 CFR Part 50, Appendix B, QA program as failure to comply. Meeting the requirements of 10 CFR Part 21 and 10 CFR 50.55(e) ensure that substantial safety hazards are 1) evaluated, 2) subject to proper corrective action, and 3) identified to the NRC so it can evaluate the adequacy of corrective actions and consider any generic implications.

Compliance with 10 CFR 50.55a requires the SSCs be designated, fabricated, erected, constructed, tested, and inspected to quality standards commensurate with the importance of the safety function to be performed. The regulation in 10 CFR 50.55a is applicable because it determines what SSCs are safety related. The requirements in Appendix B to 10 CFR Part 50 apply to safety-related SSCs.

Compliance with10 CFR 52.47(a)(1)(ii) and 10 CFR 52.79(b) requires compliance with 10 CFR 50.34(f)(3)(ii) and (iii). 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

QAPDs will be reviewed by the QA staff against the acceptance criteria described in Subsection II of this document. Any exceptions or alternatives to this SRP section will be reviewed to ensure that they are defined and that an adequate basis exists for their acceptance. When required, the QA staff will prepare a request for additional information for the applicant or holder and review the response for acceptability.

Upon concluding that the QAPD describes an acceptable QA program, Manual Chapters 2502 and 2504 specify inspections to be performed to assess the applicant's or holder's interpretation and translation of the QAPD commitments into its procedures, processes, and organizational staffing. These inspections will focus on the effectiveness of the QAPD implementation.

Through review of the information provided by the applicant or holder and, as required, meetings with the applicant or holder; review of applicable NRC inspection reports; and discussion with involved NRC inspectors, a judgment is made of the applicant's or holder's capability to carry out its QA responsibilities. The reviewer's satisfaction with the QA program commitments, the description of how the commitments will be met, the organizational arrangements, and the capabilities to fulfill the QAPD should lead to the conclusion of acceptability as described in Subsection IV of this document.

IV. EVALUATION FINDINGS

The reviewer will verify that sufficient information has been provided and that the review is sufficiently complete to support conclusions of the following type in the staff's SER:

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

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

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

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

4. The QAPD describes a philosophy and controls that, when properly implemented, comply with the requirements of 10 CFR Part 21 or 10 CFR 50.55(e), 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.

Accordingly, the staff concludes that the DC, ESP, CP, OL, or COL applicant or COL holder's QAPD complies with the applicable NRC regulations and industry standards and can be implemented for the (specify the application).

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 NRR 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.

V. IMPLEMENTATION

The following is intended to provide guidance to applicants and holders regarding the NRC staff's plan for using this SRP section.

Except in those cases in which the applicants or holders propose an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described herein will be used by the staff to evaluate conformance with Commission regulations.

Exceptions or alternatives may be proposed by applicants or holders provided acceptable justification is provided. The COL applicant or holder need only address aspects of the program not addressed by the DCD applicant.

This SRP section will be used by the staff when performing safety evaluations of license applications submitted by applicants and holders pursuant to 10 CFR Part 50 (CP and OL) and 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants" (DC, ESP and COL).

The provisions of this SRP section apply to reviews of applications docketed 6 months or more after the date of issuance of this SRP section.

VI. REFERENCES

NRC Letter to All Holders of Operating Licenses and Construction Permits for Nuclear Power Reactors, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (Generic Letter 89-02)," March 21, 1989.

EPRI NP-5652, "Guideline for the Utilization of Commercial - Grade Items in Nuclear Safety-Related Applications (NCIG-07)."

NRC Letter to All Holders of Operating Licenses and Construction Permits for Nuclear Power Reactors, "Licensee Commercial-Grade Procurement and Dedication Programs (Generic Letter 91-05)," April 9, 1991.

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

ANSI/ASME Standard NQA-1, "Quality Assurance Program Requirements for Nuclear Facility Applications," 1994 Edition.

10 CFR Part 21, "Reporting of Defects and Noncompliance."

10 CFR 50.34, "Contents of Applications; Technical Information."

10 CFR 50.55(e), "Conditions of Construction Permits."

10 CFR 50.55a, "Codes and Standards."

10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants," General Design Criterion 1, "Quality Standards and Records."
10 CFR 50.69, "Risk-Informed Categorization of Structures, Systems and Components of Nuclear Power Reactors."

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

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

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

Regulatory Guide 1.29, "Seismic Design Classification."

Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)."

Regulatory Guide 1.54, "Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants."

Regulatory Guide 1.97, "Instrumentation for Light-Water-Cooled Nuclear Power Plants to Access Plant and Environs Conditions During and Following an Accident."

Regulatory Guide 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants."

Regulatory Guide 1.152, "Criteria for Programmable Digital Computer System Software in Safety-Related Systems of Nuclear Power Plants"

Regulatory Guide 1.155, "Station Blackout."

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

AP1000 Design Control Document, Revision 0.

SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety System (RTNSS) for Passive Plant Designs."

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

NIRMA TG 15-1998, "Management of Electronic Records."

NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance."

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

RG 1.160, "Maintenance Rule."

RG 1.168, "Verification, Validation, Reviews, and Audits for Digital Computer Software Uses in Safety Systems of Nuclear Power Plants."

RG 1.169, "Configuration Management Plans for Digital Computer Software Used in Safety Systems of Nuclear Power Plants."

RG 1.170, "Software Test Documentation for Digital Computer Software Used in Safety Systems of Nuclear Power Plants."

RG 1.171, "Software Unit Testing for Digital Computer Software Used in Safety Systems of Nuclear Power Plants."

RG 1.172, "Software Requirements Specifications for Digital Computer Software Used in Safety Systems of Nuclear Power Plants."

RG 1.173, "Developing Software Live Cycle Processes for Digital Computer Software Used in Safety Systems of Nuclear Power Plants."

RG 1.189, "Fire Protection for Operating Nuclear Power Plants."

RG 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment."

RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material."

Review Standard 002, "Processing Applications for Early Site Permits."

PAPERWORK REDUCTION ACT STATEMENT

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

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.