U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR REACTOR REGULATION

17.1 QUALITY ASSURANCE DURING THE DESIGN AND CONSTRUCTION PHASES

REVIEW RESPONSIBILITIES

Primary - Quality Assurance Branch (QAB)

Secondary - Mechanical Engineering Branch
Instrumentation & Control Systems Branch
Power Systems Branch
Accident Evaluation Branch
Radiological Assessment Branch
Hydrologic & Geotechnical Engineering Branch
Containment Systems Branch

I. AREAS OF REVIEW

QAB reviews and evaluates the description of the quality assurance (QA) program for the design and construction phases in each application for a construction permit (CP), a manufacturing license, or a standardized design approval in accordance with applicable portions of this section of the Standard Review Plan. The secondary review branches review the listing of structures, systems, and components (QA list) covered by the QA program for their areas of review responsibility in accordance with 2A1 of this section of the Standard Review Plan and documents the acceptability of the listing including any items that should be added or clarified by memo to the QAB. The review by MEB in this regard also addresses the areas of review responsibility normally assigned to ASB, RSB, CEB, PSB (except electrical), and SEB.

Pre-Docketing

Prior to docketing a CP application, the NRC performs a substantive review of the applicant's QA program description relative to ongoing design and procurement activities. This review and associated inspection are performed immediately after tendering of a CP application to determine that a satisfactory QA program has been established and is being implemented.

The pre-docketing substantive review places particular emphasis on the areas of organization, QA program, design control, procurement document control, and

audit. The application is not docketed unless the established and implemented program in these areas has no substantive deviation from NRC QA guidance applicable to activities conducted prior to docketing. Representatives from the offices of NRR and IE may meet with the applicant's representatives nine to twelve months prior to tendering of the application to provide a clear understanding of what is expected in the QA program description and the implemented program in order for the program to be accepted during the substantive review and associated inspection.

Where an NRC-accepted QA topical report is referenced in the application, the referenced QA program is not re-reviewed except for conformance to the applicable staff positions in this SRP section and the Regulatory Guides in effect at the time of docketing the application. For the case of CP applications referencing a standard design that includes an approved QA program directly or by reference, the applicant need not conform to new or revised Regulatory Guides unless they contain regulatory positions determined to be significant to safety, as indicated in the implementation section of each guide.

Post-Docketing

The QAB review, after docketing, covers the QA controls to be applied by the applicant and principal contractors to activities that may affect the quality of structures, systems, and components important to safety. These activities include site testing and evaluation (starting with evaluation of exposed excavated surfaces, determination of site characteristics, and testing), designing, purchasing, fabricating, constructing, handling, shipping, storing, cleaning, erecting, installing, inspecting, and testing. This review extends to the determination of how the applicable requirements of the eighteen criteria of Appendix B to 10 CFR 50 are satisfied by the proposed QA program.

The areas of review are as follows:

1. ORGANIZATION

   A. Organizational description and charts of the lines, interrelationships and areas of responsibility and authority for all organizations performing quality-related activities, including the applicant's organization and principal contractors (architect engineer, nuclear steam supply system vendor, constructor, and construction manager when other than the constructor).

   B. Organizational location, degree of independence from the performing organization, and authority of the individuals assigned the responsibility for performing QA functions.

   C. Organizational provisions for assuring the proper implementation of the QA program.

2. QUALITY ASSURANCE PROGRAM

   A. Scope of the QA program.

   B. Provisions to assure proper definition of the QA program.

   C. Programmatic provisions to assure proper implementation of the QA program.

D. Provisions to assure adequacy of personnel qualifications.

3. DESIGN CONTROL

A. Scope of the QA program for design activities.

B. The organizational structure, activity, and responsibility of the positions or groups responsible for design activities.

C. Provisions to carry out design activities in a planned, controlled, and orderly manner.

D. Provisions for interface control.

E. Provisions to verify or check the technical adequacy of design documents.

F. Provisions to control design changes.

4. PROCUREMENT DOCUMENT CONTROL

A. Provisions which assure that applicable regulatory requirements, technical requirements, and QA program requirements are included or referenced in procurement documents.

B. Provisions for review and approval of procurement documents.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

A. Provisions for assuring that activities affecting quality are prescribed by and accomplished in accordance with documented instructions, procedures, or drawings.

B. Provisions for including quantitative and qualitative acceptance criteria in instructions, procedures, and drawings.

6. DOCUMENT CONTROL

A. Provisions to assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.

B. Provisions to prevent the inadvertent use of obsolete or superseded documents.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

A. Provisions for the control of purchased material, equipment, and services; for selection of suppliers; and for assessing the adequacy of quality.

B. Provisions to assure that documented evidence of the conformance of material and equipment to procurement requirements is available at the plant site prior to installation or use.

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

   A. Provisions to identify and control materials, parts, and components.

   B. Provisions to assure that incorrect or defective items are not used.

9. CONTROL OF SPECIAL PROCESSES

   A. Provisions to assure the acceptability of special processes such as welding, heat treating, nondestructive testing, and chemical cleaning.

   B. Provisions to assure that special processes are performed by qualified personnel using qualified procedures and equipment.

10. INSPECTION

   A. Provisions for the inspection of activities affecting quality, including the items and activities to be covered.

   B. Organizational responsibilities and qualifications established for individuals or groups performing inspections.

   C. Prerequisites to be provided in the written inspection procedures with provisions for documenting and evaluating inspection results.

11. TEST CONTROL

   A. Provisions for tests which assure that structures, systems, and components will perform satisfactorily in service.

   B. Prerequisites to be provided in written test procedures with provisions for documenting and evaluating test results.

   C. Personnel qualification programs established for test personnel.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

   Provisions to assure that tools, gages, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals.

13. HANDLING, STORAGE, AND SHIPPING

   Provisions to control handling, storage, shipping, cleaning, and preservation of items in accordance with work and inspection instructions to prevent damage, loss, and deterioration by environmental conditions such as temperature or humidity.

14. INSPECTION, TEST, AND OPERATING STATUS

   Provisions to indicate the inspection, test, and operating status of items to prevent inadvertent use or bypassing of inspection and tests.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Provisions to control the use or disposition of nonconforming materials, parts, or components.

16. CORRECTIVE ACTION

Provisions to assure that conditions adverse to quality are promptly identified and corrected and that measures are taken to preclude repetition.

17. QUALITY ASSURANCE RECORDS

Provisions for the identification, retention, retrieval, and maintenance of records that furnish evidence of activities affecting quality.

18. AUDITS

A. Provisions for audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the QA program.

B. Responsibilities and procedures for auditing, documenting and reviewing audit results, and designating management levels to review and assess audit results.

II. ACCEPTANCE CRITERIA

The applicant (and its principal contractors such as the NSSS vendor, A/E, constructor and construction manager) must establish a QA program for the design and construction phases in accordance with Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The applicant's QA program (including its principal contractors) must describe in the PSAR or SSAR how each criterion of Appendix B will be met. The acceptance criteria used by the QAB to evaluate this QA program are listed in the following eighteen subsections. The acceptance criteria include a commitment to comply with the regulations, regulatory positions presented in the appropriate issue of the Regulatory Guides, and the Branch Technical Position listed in subsection V. Thus, the commitment constitutes an integral part of the QA program description and requirements. Exceptions and alternatives to these acceptance criteria may be adopted by applicants provided adequate justification is given; the QAB review allows for considerable flexibility in defining methods and controls while still satisfying pertinent regulations. When the QA program description meets the applicable acceptance criteria of this subsection or provides acceptable exceptions or alternatives, the program is considered to be in compliance with pertinent NRC regulations.

The review will ascertain that the commitments and the description of how the commitments are implemented, to the extent necessary, are objective and stated in inspectable terms.

The Organization (17.1.1) elements responsible for the QA program are acceptable if:

1A1.* The responsibility for the overall program is retained and exercised by the applicant.

1A2. The applicant has identified and described major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.

1A3. When major portions of the applicant's program are delegated:

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

b. Applicant evaluates the performance (frequency and method stated - once per year although longer cycle acceptable with other evaluations of individual elements) of work by the delegated organization.

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

1A4. Clear management controls and effective lines of communication exist for QA activities among the applicant and the principal contractors to assure direction of the QA program.

1A5. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program (such as design, engineering, procurement, manufacturing, construction, inspection, test, instrumentation and control, nuclear engineering, etc.), the lines of responsibility, and a description of the criteria for determining the size of the QA organization including the inspection staff.

1A6. The applicant (and principal contractors) describes the QA responsibilities of each of the organizational elements noted on the organization charts.

1B1. The applicant (and principal contractors) identifies a management position that retains overall authority and responsibility for the QA program (normally, this position is the QA Manager) and this position has the following characteristics:

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

*The alphanumeric designation for each acceptance criterion in subsection II indicates its relationship to the areas of review identified in subsection I.

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

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

d. Has no other duties or responsibilities unrelated to QA that would prevent his full attention to QA matters.

1B2. Verification of conformance to established requirements (except for designs, ref. 3E2) is accomplished by individuals or groups within the QA organization who do not have direct responsibility for performing the work being verified or by individuals or groups trained and qualified in QA concepts and practices and independent of the organization responsible for performing the task.

1B3. Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

a. Identify quality problems.

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

c. Verify implementation of solutions.

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

1B4. a. Designated QA personnel, sufficiently free from direct pressures for cost/schedule, have the responsibility delineated in writing to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material.

b. The organizational positions with stop work authority are identified.

1B5. Provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between QA personnel and other department (engineering, procurement, manufacturing, etc.) personnel.

1B6. Designated QA individuals are involved in day-to-day plant activities important to safety (i.e., the QA organization routinely attends and participates in daily plant work schedule and status meetings to assure they are kept abreast of day-to-day work assignments throughout the plant and that there is adequate QA coverage relative to procedural and inspection controls, acceptance criteria, and QA staffing and qualification of personnel to carry out QA assignments).

1C1. Policies regarding the implementation of the QA program are documented and made mandatory. These policies are established at the Corporate President or Vice President level.

1C2. Position description (see 1B1) assures that the individual directly responsible for the definition, direction, and effectiveness of the overall QA program has sufficient authority to effectively implement

responsibilities. This position is to be sufficiently free from cost and schedule responsibilities. Qualification requirements for this individual are established in a position description which includes the following prerequisites:

a. Management experience through assignments to responsible positions.

b. Knowledge of QA regulations, policies, practices, and standards.

c. Experience working in QA or related activity in reactor design, construction, or operation or in a similar high technological industry.

The qualifications of the QA Manager should be at least equivalent to those described in Section 4.4.5 of ANSI/ANS-3.1-1978, "Selection and Training of Nuclear Power Plant Personnel," as endorsed by the regulatory positions in Regulatory Guide 1.8.

1C3. The person at the construction site responsible for directing and managing the site QA program is identified by position and has appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to assuring that the QA program at the plant site is being effectively implemented.

Activities related to Quality Assurance Program (17.1.2) are acceptable if:

2A1. The scope of the QA program includes:

a. A commitment that activities affecting structures, systems, and components important to safety will be subject to the applicable controls of the QA program. The structures, systems, components, and related consumables covered by the QA program are identified (QA list) in Section 3.2.1 of the SAR.*

b. A commitment that the preoperational test program will be conducted in accordance with the QA program and a description of how the QA program will be applied.

c. A commitment that the development, control, and use of computer code programs will be conducted in accordance with the QA program and a description of how the QA program will be applied.

* Rulemaking is currently underway to clarify the requirement that structures, systems, and components important to safety as derived from the General Design Criteria of Appendix A to 10 CFR Part 50 shall be subjected to the pertinent requirements of the quality assurance criteria of Appendix B to 10 CFR 50. Until this rulemaking process is completed, staff reviewers should assure that the applicant's list of structures, systems, and components includes all those items necessary to prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public as stated in the Introduction to Appendix B. Guidance for identifying such items is provided in Regulatory Guide 1.29.

d. The identification of fire protection in SRP Section 9.5.1 as a system covered by the QA program or identification of the QA controls for fire protection. These controls are reviewed and accepted using the guidelines contained in BTP ASB 9.5-1 and 10 CFR Part 50 Appendix B as appropriate.

e. A commitment that special equipment, environmental conditions, skills, or processes will be provided as necessary.

2A2. A brief summary of the company's corporate QA policies is given.

2B1. a. Provisions are established to assure that quality-affecting procedures required to implement the QA program are consistent with QA program commitments and corporate policies and are properly documented, controlled, and made mandatory through a policy statement or equivalent document signed by the responsible official.

b. The QA organization reviews and documents concurrence with these quality-related procedures.

c. The organizational group or individual having responsibility for the policy statement should be identified.

d. The quality affecting procedural controls of the principal contractors should be provided for the applicant's review with documented agreement of acceptance prior to initiation of activities affected by the program.

2B2. Provisions are included for notifying NRC of changes (1) for review and acceptance in the accepted description of the QA program as presented or referenced in the SAR or SSAR prior to implementation, and (2) in organizational elements within 30 days after announcement. (Note - editorial changes or personnel reassignments of a non-substantive nature do not require NRC notification).

2B3. The applicant (and the principal contractors) commits to comply with the regulatory position in the appropriate issue of the Regulatory Guides listed in Subsection V; to comply with 10 CFR Part 50, §50.55a; to conduct activities under 10 CFR Part 50, §50.55(e) in accordance with the QA program; and to comply with 10 CFR Part 50 Appendix A, General Design Criterion 1. For systems, components, and structures covered by the ASME Code Section III (Classes 1, 2 and 3), the quality assurance code requirements should be supplemented by the specific guidance addressed in the regulatory positions of the applicable Regulatory Guides. The commitment identifies the Regulatory Guides and ANSI standard by number, title, and revision or date. Any alternatives or exceptions are clearly identified and supporting information presented in the docket. QA Regulatory Guides should be addressed which have an implementation date prior to the submittal or docket date of the QA program description.

Although primary responsibility for Regulatory Guides 1.26 and 1.29 is assigned to ASB (SRP Sections 3.2.1 and 3.2.2), their use as acceptance criteria in this SRP section is necessary to assure that

adequate quality assurance requirements are specified for systems, components, and structures addressed by those guides.

The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific structures, systems, and components. This effort involves applying a defined graded approach to certain structures, systems, and components in accordance with their importance to safety and affects such disciplines as design, procurement, document control, inspection tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B.

2B4. Existing or proposed QA procedures are identified reflecting that Regulatory Guides listed in subsection VI, General Design Criterion 1 of Appendix A to 10 CFR Part 50, 10 CFR Part 50, §50.55a, and each criterion of 10 CFR Part 50, Appendix B will be met by documented procedures. In addition, activities conducted under 10 CFR Part 50, §50.55(e) shall conform to the requirement of the QA program.

2B5. A description is provided that emphasizes how the docketed QA program description, particularly the 10 CFR Part 50 regulations and Regulatory Guides listed in subsection V, will be properly carried out.

2C1. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

a. Frequent contact with program status through reports, meetings, and/or audits.

b. Performance of an annual assessment preplanned and documented. Corrective action is identified and tracked.

2C2. Quality-related activities (such as design, procurement, and site investigation) initiated prior to formal NRC acceptance of the QA program are controlled under a QA program in accordance with this SRP and, accordingly, with the requirements of 10 CFR Part 50, Appendix B. Approved procedures and a sufficient number of trained personnel should be available to implement the applicable portion of the QA program prior to the initiation of the activity.

2C3. A summary description is provided on how responsibilities and control of quality-related activities are transferred from the principal contractors to the applicant during the phaseout of design and construction and during preoperational testing and plant turnover.

2D. Indoctrination, training, and qualification programs are established such that:

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

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

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

d. Proficiency tests are given to those personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified.

e. Certificate of qualifications clearly delineates (a) the specific functions personnel are qualified to perform and (b) the criteria used to qualify personnel in each function.

f. Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining, and/or recertifying as determined by management or program commitment.

g. The description of the training program provisions listed above satisfies the regulatory position in Regulatory Guide 1.58.

Activities related to Design Control (17.1.3) are acceptable if:

3A. The scope of the design control program includes design activities associated with the preparation and review of design documents including the correct translation of applicable regulatory requirements and design bases into design, procurement and procedural documents. Included in the scope are such activities as field design engineering; physics, seismic, stress, thermal, hydraulic, radiation, and the SAR accident analyses; associated computer programs; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and quality standards.

3B. Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures.

3C1. Errors and deficiencies in approved design documents, including design methods (such as computer codes), that could adversely affect structures, systems, and components important to safety are documented; and action is taken to assure that all errors and deficiencies are corrected.

3C2. Deviations from specified quality standards are identified and procedures are established to ensure their control.

3D. Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving design interfaces to assure structures, systems, and

components are compatible geometrically, functionally, and with processes and environment.

3E1. Procedures are established and described requiring a documented check to verify the dimensional accuracy and completeness of design drawing and specifications.

3E2. Procedures are established and described requiring that design drawings and specifications be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with company procedures and that the documents contain the necessary quality assurance requirements such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results.

3E3. Guidelines or criteria are established and described for determining the method of design verification (design review, alternate calculations, or test).

3E4. Procedures are established and described for design verification activities which assure the following:

a. The verifier is qualified and is not directly responsible for the design (i.e., neither the performer or his immediate supervisor). In exceptional circumstances, the designer's immediate supervisor can perform the verification provided:

(1) The supervisor is the only technically qualified individual.

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

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

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

c. Procedural control is established for design documents that reflect the commitments of the SAR; this control differentiates between documents that receive formal design verification by

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

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

3E3. The following provisions are included if the verification method is only by test:

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

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

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

3E4. Procedures are established to assure that verified computer codes are certified for use and that their use is specified.

3F1. Design and specification changes, including fields changes, are subject to the same design controls that were applicable to the original design.

3F2. The description of the design control provisions satisfies the criteria of Regulatory Guide 1.64.

Activities related to Procurement Document Control (17.1.4) are acceptable if:

4A1. Procedures are established for the review of procurement documents to determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. To the extent necessary, procurement documents should require contractors and subcontractors to provide an acceptable quality assurance program. The review and documented concurrence of the adequacy of quality requirements stated in procurement documents is performed by independent personnel trained and qualified in QA practices and concepts.

4A2. Procedures are established to assure that procurement documents identify applicable regulatory, technical, administrative, and

reporting requirements; drawings; specifications; codes and industrial standards; test and inspection requirements; and special process instructions that must be complied with by suppliers..

4B1. Organizational responsibilities are described for (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

4B2. The description of the procurement document control provisions listed above satisfies the regulatory position in Regulatory Guide 1.123.

Activities related to Instructions, Procedures, and Drawings (17.1.5) are acceptable if:

5A. Organizational responsibilities are described for assuring that activities affecting quality are (1) prescribed by documented instructions, procedures, and drawings and (2) accomplished through implementation of these documents.

5B. Procedures are established to assure that instructions, procedures, and drawings include quantitative (such as dimensions, tolerances, and operating limits) and qualitative (such as workmanship samples) acceptance criteria for determining that important activities have been satisfactorily accomplished.

Activities related to Document Control (17.1.6) are acceptable if:

6A1. The scope of the document control program is described, and the types of controlled documents are identified. As a minimum, controlled documents include:

a. Design documents (e.g., calculations, drawings, specifications, analyses) including documents related to computer codes.

b. Procurement documents.

c. Instructions and procedures for such activities as fabrication, construction, modification, installation, test, and inspection.

d. As-built documents.

e. Quality assurance and quality control manuals and quality-affecting procedures.

f. Topical reports.

g. SAR.

h. Nonconformance reports.

6A2. Procedures for the review, approval, and issuance of documents and changes thereto are established and described to assure technical

adequacy and inclusion of appropriate quality requirements prior to implementation. The QA organization, or an individual other than the person who generated the document but qualified in quality assurance, reviews and concurs with these documents with regards to QA-related aspects.

6A3. Procedures are established to assure that changes to documents are reviewed and approved by the same organizations that performed the initial review and approval or by other qualified responsible organizations delegated by the applicant.

6A4. Procedures are established to assure that documents are available at the location where the activity will be performed prior to commencing the work.

6B1. Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner.

6B2. A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. When such a list is used, it should be updated and distributed to predetermined responsible personnel.

6C1. Procedures are established and described to provide for the preparation of as-built drawings and related documentation in a timely manner to accurately reflect the actual plant design.

Activities related to Control of Purchased Material, Equipment, and Services (17.1.7) are acceptable if:

7A1. Organizational responsibilities are described for the control of purchased material, equipment, and services including interfaces between design, procurement, and QA organizations.

7A2. Verification of suppliers' activities during fabrication, inspection, testing, and shipment of materials, equipment, and components is planned and performed with QA organization participation in accordance with written procedures to assure conformance to the purchase order requirements. These procedures, as applicable to the method of procurement, provide for:

a. Specifying the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these procedures.

b. Audits, surveillance, or inspections which assure that the supplier complies with the quality requirements.

7A3. Selection of suppliers is documented and filed. If an LCVIP letter of confirmation or the "CASE" Register is used to establish the qualifications of the supplier, the documentation should identify the "letter" or "audit" used.

7A4. Procurement of spare or replacement parts for structures, systems, and components important to safety is subject to present QA program controls, to codes and standards, and to technical requirements equal to or better than the original technical requirements, or as required to preclude repetition of defects.

7B1. Receiving inspection is performed to assure:

a. The material, component, or equipment is properly identified and corresponds to the identification on the purchase document and the receiving documentation.

b. Material, components, equipment, and acceptance records satisfy the inspection instructions prior to installation or use.

c. Specified inspection, test and other records, (such as certificates of conformance attesting that the material, components, and equipment conform to specified requirements) are available at the nuclear power plant prior to installation or use.

7B2. Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.

7B3. The supplier furnishes the following records to the purchaser:

a. Documentation that identifies the purchased item and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item.

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."

The review and acceptance of these documents should be described in the purchaser's QA program.

7B4. For commercial "off-the-shelf" items where specific quality assurance controls appropriate for nuclear applications cannot be imposed in a practicable manner, special quality verification requirements shall be established and described to provide the necessary assurance of an acceptable item by the purchaser.

7B5. Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.

7B6. The description of the control of procurement provisions listed above satisifies the regulatory position in Regulatory Guide 1.38 and Regulatory Guide 1.123.

Activities related to Identification and Control of Materials, Parts, and Components (17.1.8) are acceptable if:

8A. Controls are established and described to identify and control materials (including consumables), parts, and components including partially fabricated subassemblies. The description should include organizational responsibilities.

8B1. Procedures are established which assure that identification is maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.

8B2. Identification of materials and parts important to the function of structures, systems, and components important to safety can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.

8B3. Correct identification of material, parts, and components is verified and documented prior to release for fabrication, assembling, shipping, and installation.

Activities related to Control of Special Processes (17.1.9) are acceptable if:

9A1. The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, should be provided. Some examples are welding, heat treating, NDT, and chemical cleaning.

9A2. Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

9B1. Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to assure they are satisfactorily performed.

9B2. Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

9B3. Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

Activities related to Inspection (17.1.10) are acceptable if:

10A. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining the accuracy requirements of inspection equipment and criteria for determining when inspections are

required or define how and when inspections are performed. The QA organization participates in the above functions.

10B1. Organizational responsibilities for inspection are described. Individuals performing inspections are other than those who performed or directly supervised the activity being inspected and do not report directly to the immediate supervisors who are responsible for the activity being inspected. If the individuals performing inspections are not part of the QA organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule should be reviewed and found acceptable by the QA organization prior to the initiation of the activity.

10B2. A qualification program for inspectors (including NDT personnel) is established and documented, and the qualifications and certifications of inspectors are kept current.

10C1. Inspection procedures, instructions, or checklists provide for the following:

a. Identification of characteristics and activities to be inspected.

b. A description of the method of inspection.

c. Identification of the individuals or groups responsible for performing the inspection operation in accordance with the provisions of item 10B1.

d. Acceptance and rejection criteria.

e. Identification of required procedures, drawings and specifications and revisions.

f. Recording inspector or data recorder and the results of the inspection operation.

g. Specifying necessary measuring and test equipment including accuracy requirements.

10C2. Procedures are established and described to identify, in pertinent documents, mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

10C3. Inspection results are documented, evaluated and their acceptability determined by a responsible individual or group.

Activities related to Test Control (17.1.11) are acceptable if:

11A1. The description of the scope of the test control program indicates an effective test program has been established for tests including proof tests prior to installation and preoperational tests. Program procedures provide criteria for determining the accuracy requirements of test equipment and criteria for determining when a test is required or how and when testing activities are performed.

11B1. Test procedures or instructions provide as required for the following:

a. The requirements and acceptance limits contained in applicable design and procurement documents.

b. Instructions for performing the test.

c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation including their accuracy requirements, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.

d. Mandatory inspection hold points for witness by owner, contractor, or inspector (as required).

e. Acceptance and rejection criteria.

f. Methods of documenting or recording test data and results.

g. Provisions for assuring test prerequisites have been met.

11C1. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group.

Activities related to Control of Measuring and Test Equipment (17.1.12) are acceptable if:

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established. This information indicates an effective calibration program has been established.

12.2 QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) that is used in the measurement, inspection, and monitoring of structures, systems, and components. The review and documented concurrence of these procedures is described and the organization responsible for these functions is identified.

12.4 Measuring and test equipment is identified and traceable to the calibration test data.

12.5 Measuring and test equipment is labeled or tagged or "otherwise controlled" to indicate due date of the next calibration. The method of "otherwise controlled" should be described.

12.6 Measuring and test equipment is calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

Calibration of this equipment should be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified.

12.7 Calibrating standards have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified.

12.8 Reference and transfer standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration.

12.9 Measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration when measuring and test equipment is found to be out of calibration. Inspections or tests are repeated on items determined to be suspect.

Activities related to Handling, Storage, and Shipping (17.1.13) are acceptable if:

13.1 Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

13.2 Procedures are established and described to control the cleaning, handling, storage, packaging, and shipping of materials, components, and systems in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

13.3 The description of the control of handling, storage, and shipping listed above satisfies the regulatory position in Regulatory Guide 1.38.

Activities related to Inspection, Test, and Operating Status (17.1.14) are acceptable if:

14.1 Procedures are established to indicate the inspection, test, and operating status of structures, systems, and components throughout fabrication, installation, and test.

14.2 Procedures are established and described to control the application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps.

14.3 Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety. Such actions should be subject to the same controls as the original review and approval.

14.4 The status of nonconforming, inoperative, or malfunctioning structures, systems, and components is documented and identified to prevent inadvertent use. The organization responsible for this function is identified.

Activities related to Nonconforming Materials, Parts, or Components (17.1.15) are acceptable if:

15.1 Procedures are established and described for identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, components and as applicable to services (including computer codes) if disposition is other than to scrap. The procedures provide identification of authorized individuals for independent review of nonconformances, including disposition and closeout.

15.2 QA and other organizational responsibilities are described for the definition and implementation of activities related to nonconformance control. This includes identifying those individuals or groups with authority for the disposition of nonconforming items.

15.3 Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition. Nonconformances are corrected or resolved prior to the initiation of the preoperational test program on the item.

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

15.5 Nonconformance reports are periodically analyzed by the QA organization to show quality trends, and the significant results are reported to upper management for review and assessment.

Activities related to Corrective Action (17.1.16) are acceptable if:

16.1 Procedures are established and described indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.

16.2 Corrective action is documented and initiated following the determination of a condition adverse to quality (such as a nonconformance, failure, malfunction, deficiency, deviation, and defective material and equipment) to preclude recurrence. The QA organization is involved in the documented concurrence of the adequacy of the corrective action.

16.3 Followup action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.

16.4 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.

Activities related to Quality Assurance Records (17.1.17) are acceptable if:

17.1 The scope of the records program is described. QA records include results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports; and corrective action reports.

17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.

17.3 Inspection and test records contain the following where applicable:

a. A description of the type of observation.

b. The date and results of the inspection or test.

c. Information related to conditions adverse to quality.

d. Inspector or data recorder identification.

e. Evidence as to the acceptability of the results.

f. Action taken to resolve any discrepancies noted.

17.4 Suitable facilities for the storage of records are described and satisfy the regulatory position given in Regulatory Guide 1.88 (endorses N45.2.9). Alternatives to the fire protection rated provisions are acceptable if records storage facilities conform to NFPA No. 232 Class 1 for permanent-type records and that the 2-hour fire rating requirement contained in the proposed N45.2.9 standard is met by applicants in any one of the following three ways. Specifically, (1) a 2-hour vault meeting NFPA No. 232; (2) 2-hour rated file containers meeting NFPA No. 232 (Class B); or (3) a 2-hour rated fire resistant file room meeting NFPA No. 232 if the following additional provisions are provided.

1. Early warning fire detection and automatic fire suppression should be provided, with electronic supervision at a constantly attended central station.

2. Records should be stored in fully enclosed metal cabinets. Records should not be permitted on open steel shelving. No storage of records should be permitted on the floor of the facility. Adequate access and aisle ways should be maintained at all times throughout the facility.

3. Work not directly associated with records storage or retrieval should be prohibited within the records storage facility. Examples of such prohibited activities include but are not limited to: records reproduction, film developing, and fabrication of microfiche cards.

4. Smoking and eating/drinking should be prohibited throughout the records storage facility.

5. Ventilation, temperature, and humidity control equipment should be protected inside with standard fire-door dampers where they penetrate fire barriers bounding the storage facility.

17.5 The description of the control of records provisions listed above satisfies the regulatory position of Regulatory Guide 1.88.

Activities related to Audits (17.1.18) are acceptable if:

18A1. Audits to assure that procedures and activities comply with the overall QA program are performed by:

a. The QA organization to provide a comprehensive independent verification and evaluation of quality-related procedures and activities.

b. The applicant (and principal contractors) to verify and evaluate the QA programs, procedures, and activities of suppliers.

18A2. An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. Audits should be regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA during design, procurement, manufacturing, construction, installation, inspection, and testing.

18A3. Audits include an objective evaluation of quality-related practices, procedures, instructions; activities and items; and review of documents and records to ensure that the QA program is effective and properly implemented.

18A4. Provisions are established requiring that audits be performed in all areas where the requirements of Appendix B to 10 CFR Part 50 are applicable. Areas which are often neglected but should be included are activities associated with:

a. The determination of site features which affect plant safety (e.g., core sampling, site and foundation preparation, and methodology). (PSAR only).

b. The preparation, review, approval, and control of early procurements. (PSAR only).

c. Indoctrination and training programs.

d. Interface control among the applicant and the principal contractors.

e. Corrective action, calibration, and nonconformance control systems.

f. SAR and SSAR commitments.

g. Activities associated with computer codes.

18B1. Audit data are analyzed by the QA organization and the resulting reports indicating any quality problems and the effectiveness of the QA program, including the need for reaudit of deficient areas, are reported to management for review and assessment.

18B2. Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.

18B3. The description of the conduct of audit provisions satisfies the regulatory position in Regulatory Guides 1.144 and 1.146.

III. REVIEW PROCEDURES

Each element of the QA program description will be reviewed against the acceptance criteria described in subsection II, including the regulations, Regulatory Guides, and Branch Technical Position listed in subsection V. QAB will interface with the secondary review branches to assure that they have documented to the QAB by memo the acceptability of the identification of structures, systems, and components covered by the QA program (Q-List). QAB will process the necessary requests for additional information to the applicant and coordinate the response with the appropriate branches for acceptance. Changes to the QA program will be evaluated to assure at a minimum that such changes have not degraded the previously approved program. Consideration should be given to the current regulatory position in the area of the change in determining acceptability of the change. The reviewer's judgment during the review is to be based on an assessment of the material presented, the similarity of the material to that recently reviewed on other plants, and whether items of special safety significance are involved. Any exceptions or alternatives to this SRP section, including the regulations and regulatory positions presented in the Regulatory Guides in subsection V, will be carefully reviewed to assure that they are clearly defined and that an adequate basis exists for acceptance.

The acceptability of the QA program is determined by the following review procedures:

1. The QA program description is reviewed in detail to determine if each of the criteria of 10 CFR Part 50, Appendix B has been acceptably addressed and if there is an adequate commitment to comply with the regulations and regulatory positions in the appropriate issue of the Regulatory Guides in subsection V, as identified by number, title, revision or date. The QA program description is also reviewed to assure that the applicant's approach to meeting the QA criteria and commitments is acceptable.

2. The measures described to implement 10 CFR Part 50, Appendix B are evaluated for:

   a. Technical acceptability (i.e., do they meet the Regulations and Regulatory Guides?)

b. Workability (i.e., do they seem to fit into an overall plan of action that can be implemented?)

c. Management support (i.e., do QA program measures have adequate review, approval, and endorsement of management?)

This evaluation is based primarily on the acceptance criteria contained in subsection II.

3. The duties, responsibility, and authority of personnel performing QA functions are reviewed to assure they provide sufficient independence to effectively perform these functions.

4. Through review of information provided, meetings with the applicant, by review of the acceptability of QA program and plant activities including performance and capability of personnel, and by review of the Office of Inspection and Enforcement position statement and inspection reports, a judgment is made of the applicant's capability to carry out its QA responsibilities.

5. Satisfaction with program commitments and descriptions of how the commitments will be met, organizational arrangements, and capabilities to fulfill QA requirements should lead to the conclusion of acceptability, as described in subsection IV.

IV. EVALUATION FINDINGS

The reviewer verifies that sufficient information has been provided and that his review is sufficiently complete and adequate to support conclusions of the following type to be included in the staff's Safety Evaluation Report:

Based on our detailed review and evaluation of the QA program description contained in the (topical report or SAR) for (nuclear facility), we conclude that:

1. The organizations and persons performing QA functions have the required independence and authority to effectively carry out the QA program without undue influence from those directly responsible for costs and schedules.

2. The QA program describes requirements, procedures, and controls that, when properly implemented, comply with the requirements of Appendix B to 10 CFR Part 50 with the requirements of 10 CFR Part 50, §50.55a and §55(e); with the criteria contained in SRP Section 17.1; and with the regulatory positions presented in the following Regulatory Guides.

Reg. Guide/ANSI Std.	Title	Revision or Date

A brief description of the applicant's QA program is provided highlighting the more important aspects of the program.

3. The QA program covers activities affecting structures, systems, and components important to safety as identified in the PSAR.

Accordingly, the staff concludes that the applicant's description of the QA program is in compliance with applicable NRC regulations and industry standards and can be implemented for the (specify) phases of (specify application).

V. IMPLEMENTATION

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

Except in those cases in which the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described herein will be used by the staff in its evaluation of conformance with Commission regulations.

Implementation schedules for conformance to parts of the method discussed herein are contained in the referenced guides and NUREGs.

VI. REFERENCES

1. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

2. 10 CFR Part 50, §50.55a, "Codes and Standards."

3. 10 CFR Part 50, §50.55(e), "Conditions of Construction Permits" (reporting significant QA deficiencies).

4. 10 CFR Part 50, §50.34(a.7), "Contents of Application; Technical Information" (Preliminary Safety Analysis QA program description).

5. 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants."

6. Regulatory Guide 1.8, "Personnel Selection and Training" (endorses ANSI/ANS 3.1).

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

8. Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)" (endorses N45.2).

9. Regulatory Guide 1.29, "Seismic Design Classification."

10. Regulatory Guide 1.30, "Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment" (endorses N45.2.4).

11. Regulatory Guide 1.37, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants" (endorses N45.2.1).

12. Regulatory Guide 1.38, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants" (endorses N45.2.2).

13. Regulatory Guide 1.39, "Housekeeping Requirements for Water-Cooled Nuclear Power Plants" (endorses N45.2.3).

14. Regulatory Guide 1.58, "Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel" (endorses N45.2.6).

15. Regulatory Guide 1.64, "Quality Assurance Requirements for the Design of Nuclear Power Plants" (endorses N45.2.11).

16. Regulatory Guide 1.74, "Quality Assurance Terms and Definitions" (endorses N45.2.10).

17. Regulatory Guide 1.88, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records" (endorses N45.2.9).

18. Regulatory Guide 1.94, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants" (endorses N45.2.5).

19. Regulatory Guide 1.116, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems" (endorses N45.2.8).

20. Regulatory Guide 1.123, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" (endorses N45.2.13).

21. Regulatory Guide 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants" (endorses N45.2.12).

22. Regulatory Guide 1.146, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants" (endorses N45.2.23).

23. Branch Technical Position (BTP) ASB 9.5-1 (attached to SRP Section 9.5.1).