U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR REACTOR REGULATION

SECTION 17.2 QUALITY ASSURANCE DURING THE OPERATIONS PHASE

REVIEW RESPONSIBILITIES

Primary - Quality Assurance Branch (QAB)

Secondary - None

I. AREAS OF REVIEW

QAB will review and evaluate the operational quality assurance (QA) program description of the applicant. This operating license (OL)-stage review will cover both the "offsite" and "onsite" QA controls to be applied to those activities that may affect the quality of safety-related items during the op ration, maintenance, and modification of a nuclear power plant. A detailed OL-stage review ill cover the QA controls to be applied to those activities (e.g., designing, constructing purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, ma' caining, modifying, operating, inspecting, and testing) that may affect the quality of ' ety-related structures, systems, and components.

This review will extend to the determination of how the appli le requirements of the eighteen criteria of Appendix B to 10 CFR Part 50 will be satisfied by the proposed QA program.

The areas of review are as follows:

1. ORGANIZATION
   a. Organizational descriptions of the lines, interrelationships, and areas of responsibility and authority for all organizations performing quality-related activities. Organization charts should show the lines of authority.
   b. The "offsite" and "onsite" organizational locations and the freedom and authority of the individuals or groups assigned the responsibility for checking, auditing, inspecting, or verifying that an activity has been correctly performed.
   c. The applicant's mechanism for maintaining responsiblity for the QA program, including verification of the adequacy and implementation of the suppliers' QA programs, even for those cases where the applicant has delegated to other organizations the work of establishing and implementing the quality assurance program or any part thereof.
   d. Qualification requirements for the principal management positions in QA/QC organizations.

2. QUALITY ASSURANCE PROGRAM

   a. Identification of the structures, systems, and components covered by the QA program.

   b. Documentation of policies, procedures, or instructions implementing the program to Appendix B requirements.

   c. The measures provided to assure that suppliers[1/] meet the requirements of Appendix B.

   d. Indoctrination or training programs for personnel performing quality-related and QA activities.

   e. Regulatory Guides and standards met by the QA program.

   f. Preoperational testing phase controls.

3. DESIGN CONTROL

   a. The design control measures for:

      · Translation of design bases into design documents.

      · Specification of appropriate quality standards in design documents and control of deviations from these standards.

      · Accessibility for inservice inspection, maintenance and repair.

      · The selection and review of suitability of application of materials, parts, equipment, and processes.

      · The identification and control of design interfaces and coordination among participating design organizations.

      · Verifying or checking the adequacy of design, such as by design reviews, alternate calculational methods, or testing programs.

      · Assuring that design changes, including field changes, be subject to the same measures applied to the original design.

   b. The organization structure, authority, and responsibilities of those positions or groups responsible for design and design verification activities.

4. PROCUREMENT DOCUMENT CONTROL

   a. The procurement document control measures which assure that applicable regulatory requirements, design bases, and other QA program requirements are included or referenced in procurement documents.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

   a. The means for assuring that activities affecting quality will be prescribed by and accomplished in accordance with documented instructions, procedures, or drawings.

   b. Provisions for inclusion of quantitative and qualitative acceptance criteria in instructions, procedures, and drawings.

[1/] Supplier refers to the A/E, the NSSS vendor, the constructor, construction manager when other than the constructor, consultants performing quality-related services, and those contractors, subcontractors, and vendors providing safety-related structures, systems, components, and services.

6. DOCUMENT CONTROL

   a. Document control measures which 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. Control measures for obsolete or superseded documents to prevent inadvertent use.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

   a. Provisions for evaluation and selection of suppliers.

   b. The measures for the control of purchased material, equipment, and services including provisions for assessing the adequacy of quality furnished by suppliers; for surveillance at the supplier source; and for receiving inspection.

   c. Control measures taken to assure that documentary evidence of the conformance of material and equipment to procurement requirements is available at the plant site prior to installation or use.

   d. Assessment by the utility of the effectiveness of the control of quality by suppliers.

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

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

   b. Measures which assure traceability of each item identified.

   c. Control measures to assure that incorrect or defective items will not be used.

9. CONTROL OF SPECIAL PROCESSES

   a. Control measures to assure adequate performance of special processes such as welding, heat treating, nondestructive testing, and cleaning.

   b. Provisions for qualification requirements of procedures, equipment, and personnel connected with special processes.

   c. Measures to assure that special processes are performed by qualified personnel using qualified procedures.

10. INSPECTION

   a. Organization of the individuals or groups performing inspections, including their independence from the group performing the activity being inspected.

   b. The program for the inspection of activities affecting quality including the items and activities to be covered.

   c. Provisions for preparation and use of inspection procedures, instructions, and check lists.

   d. Provisions for mandatory inspection hold points.

11. TEST CONTROL

   a. The test program which demonstrates that structures, systems, and components will perform satisfactorily in service.

   b. Prerequisites to be provided in the written test procedures.

   c. Provisions for documenting and evaluating test results.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

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

b. Provisions for the identification of measuring and test equipment and identification of the corresponding calibration data.

13. HANDLING, STORAGE, AND SHIPPING

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

14. INSPECTION, TEST, AND OPERATING STATUS

a. The measures to indicate the inspection and test status of items to prevent inadvertent bypassing of such inspections and tests.

b. The measures for indicating the operating status of structures, systems, and components to prevent inadvertent use.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

a. The measures to control nonconforming materials, parts, or components to prevent their inadvertent use or installation.

b. The methods for identification, documentation, segregation, and disposition of nonconforming items and notification to affected organizations.

16. CORRECTIVE ACTION

a. The corrective action measures established to assure that conditions adverse to quality are identified and corrected.

b. Measures established to assure that the causes of significant conditions adverse to quality are determined and corrective action is taken to preclude repetition.

17. QUALITY ASSURANCE RECORDS

a. The program for the maintenance of records to furnish evidence of activities affecting quality.

b. Measures established for identification, retrieval and retention of records.

18. AUDITS

a. The system of audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the QA program.

b. Measures established for documenting responsibilities and procedures for auditing, the required frequency of audits, documenting and reviewing audit results, and designating management levels to review and assess audit results.

II. ACCEPTANCE CRITERIA

The applicant must establish a QA program for the operations phase, which includes operation, maintenance, and modification of the nuclear power plant, in accordance with 10 CFR Part 50,

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." To fulfill the requirements of Section 17.2 of the Standard Format (Ref. 12), this program must be described in the SAR to the extent of demonstrating how each criteria of Appendix B will be met.

The detailed acceptance criteria used by the QAB in its evaluation of this program are listed in the following 18 subsections. If the QA program for the operations phase meets these acceptance criteria, the program is considered in compliance with NRC regulations and is acceptable.

The Organization (17.2.1) elements responsible for the QA program are acceptable if:

1. The responsibility for the QA program is retained and exercised by the applicant.

2. The QA/QC functions, performed by the applicant's QA organization or delegated to other organizations, are identified and described, providing controls to assure all elements of Appendix B will be implemented.

3. Clear and effective lines of communication between the QA organizations of the applicant are established to assure proper direction of the QA program and resolution of QA problems.

4. Organization charts identify the "onsite" and "offsite" organizational elements which function under the control of the QA program (such as design engineering, procurement, manufacturing, construction, inspecting, testing, and QA/QC).

5. The QA responsibilities of each organizational element identified in item 4 above are described and demonstrate assignment of responsibilities for requirements of Appendix B.

6. A high level of management is responsible for establishing the corporate or company QA policies, goals, and objectives and this management level maintains a continuing involvement in QA matters. Communication through any intermediate levels of management between this position and the Manager (or Director) of QA must be shown to be effective.

7. The applicant designates a position to be filled by a qualified individual to retain overall authority and responsibility for the QA program.

8. The authority and independence of the individual responsible for managing the QA program are such that he can direct and control the organization's QA/QC program, can effectively assure the conformance to quality requirements, and is independent of undue influences and responsibilities for schedules and costs. An acceptable organization structure would have this individual report to at least the same organizational level as the highest line manager directly responsible for performing quality-affecting activities. In the case where the "onsite" QA organization reports directly to the plant superintendent, the "offsite" manager maintains an overview of onsite QA activities, through audits, surveillance, inspection, etc., as further delineated in subsequent sections.

9. Positions and groups responsible for defining the content and changes to the QA program and manual(s) and the management level responsible for the final review and approval of the QA program and manual(s) are identified.

10. The person responsible for the QA program at the plant site has appropriate organizational position, responsibilities, and authority to exercise proper control over these functions. This individual can give full attention to assuring that the QA program at the plant site is being effectively implemented. In the case where the "onsite" QA organization reports to the plant superintendent, a formal line of communication is established between the "onsite" QA organization and the "offsite" QA organization.

11. The qualification requirements for the principal QA/QC management positions demonstrate competence commensurate with the responsibilities of these positions.

12. Verification of conformance to established requirements is accomplished by individuals or groups who do not have direct responsibility for performing the work being verified.

13. Personnel performing QA/QC functions have direct access to management levels which will assure accomplishment of quality-affecting activities. These personnel have sufficient authority and organization freedom to perform their QA/QC functions effectively and without reservation. They can:
    a. Identify quality problems.
    b. Initiate, recommend, or provide solutions through designated channels.
    c. Verify implementation of solutions.

14. Designated QA individuals have the responsibility and authority, delineated in writing, to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material.

15. Regulatory Guide 1.28 (Ref. 4) and the requirements and guidelines of ANSI 18.7 (Ref. 16) are complied with or acceptable alternatives are provided.

The Quality Assurance Program (17.2.2) description is acceptable if:

1. Measures are provided by the applicant and, when applicable, his contractors that demonstrate how their QA program meets 10 CFR Part 50, Appendix B criteria throughout the operations phase, which includes preoperational testing, operation, maintenance, modification, and refueling.

2. Management (i.e., above or outside the QA organization) regularly assesses the scope, status, implementation, and effectiveness of the QA program to assure that the program is adequate and complies with 10 CFR Part 50, Appendix B criteria.

3. Measures are provided by the applicant to assure that trained, qualified personnel within his organization are assigned to determine that functions delegated to his principal contractors are being properly accomplished.

4. A brief summary of the corporate QA policies, goals, and objectives is given and a meaningful channel for transmittal of these policies, goals, and objectives down through the levels of management is established.

5. The QA program procedures are derived from QA policies, goals, and objectives.

6. QA/QC responsibilities are designated for the implementation of major activities contained in the QA manual.

7. Provisions are established to control the distribution of the QA manuals and revisions thereto.

8. Provisions are established for communicating to all responsible organizations and individuals that quality policies, QA manuals, and procedures are mandatory requirements which must be implemented and enforced.

9. A listing of QA procedures plus a matrix of these procedures cross referenced to each criterion of Appendix B to 10 CFR Part 50 demonstrates that Appendix B provisions are procedurally controlled.

10. The safety-related structures, systems, and components controlled by the QA program are identified.

11. The applicant reviews and documents agreement with the QA program provisions of his suppliers to the extent that he can be assured that Appendix B will be implemented.

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

13. An indoctrination and training program is established for those personnel, both "offsite" and "onsite," performing quality-affecting activities such that they are knowledgeable in the QA procedures and requirements and proficient in implementing these procedures. The indoctrination and training program shall assure 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 performing quality-affecting activities are trained and qualified in the principles and techniques of the activity being performed.
    c. The scope, the objective, and the method of implementing the indoctrination and training program are documented.
    d. Proficiency of personnel performing quality-affecting activities is maintained by retraining, reexamining, and/or recertifying.
    e. Methods are provided for documenting training sessions describing content; who attended; when attended; and the results of the training session.

14. Quality-related activities are performed with specified equipment under suitable environmental conditions, and prerequisites have been satisfied prior to inspection and test.

15. The applicant demonstrates that his QA program complies with the Regulatory Guides (current issue) and ANSI Standards listed in Section V of this SRP or describes acceptable alternatives to the controls contained in these documents in equivalent detail. Additional Regulatory Guides dealing with QA whose implementation dates (as identified in the Regulatory Guide) are prior to FSAR submittal shall be similarly addressed.

16. A summary description of advance planning demonstrates the control of quality-related activities including management and technical interfaces between the constructor, architect-engineer (A/E), nuclear steam supply system (NSSS) vendor, and utility during the phaseout of design and construction and during preoperational testing and plant turnover.

17. Controls are provided which assure that appropriate Appendix B requirements will be applied to the preoperational test program.

18. Provisions are provided describing how changes to the SAR QA program are identified and incorporated into the FSAR.

19. Regulatory Guides 1.8 (Ref. 3) and 1.28 are complied with or acceptable alternatives are provided.

Activities related to Design Control (17.2.3) are acceptable if:

1. Measures are established to carry out design activities in a planned, controlled, and orderly manner.

2. Measures are established to correctly translate the applicable regulatory requirements and design bases into specifications, drawings, written procedures, and instructions.

3. Quality standards are specified in the design documents, and deviations and changes from these quality standards are controlled.

4. Suitable design controls are applied to such activities as reactor physics; seismic, stress, thermal, hydraulic, radiation, and accident analyses; compatibility of materials; and accessibility for inservice inspection, maintenance, and repair.

5. Designs are reviewed to assure that (1) design characteristics can be controlled, inspected and tested, and (2) inspection and test criteria are identified.

6. Internal and external design interface controls are established. These controls include the review, approval, release, distribution, and revision of documents involving design interfaces with participating organizations.

7. Proper selection and accomplishment of design verification or checking processes such as by design reviews, alternate calculations, or qualification testing are performed. When a test program is used to verify the adequacy of a design, a qualification test of a prototype unit under adverse design conditions should be used.

8. Individuals or groups responsible for design verification are other than the original designer and the designer's immediate supervisor.

9. Design and specification changes, including those originating "onsite," are subject to the same design controls and approvals that were applicable to the original design unless the applicant designates another qualified responsible organization.

10. Errors and deficiencies in the design process including the design that could adversely affect safety-related structures, systems, and components are documented, and corrective action is taken to preclude repetition.

11. Materials, parts, and equipment which are standard, commercial (off the shelf), or which have been previously approved for a different application are reviewed for suitability prior to selection.

12. The positions or groups responsible for design reviews and other design verification activities and their authority and responsibility are identified and controlled by written procedures.

13. Measures are established for the selection of suitable materials, parts, equipment, and processes for safety-related structures, systems, and components which include the use of valid industry standards and specifications.

14. Regulatory Guide 1.64 (Ref. 11) is complied with or acceptable alternatives are provided.

Activities related to Procurement Document Control (17.2.4) are acceptable if:

1. Procedures are established that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents.

2. A review and concurrence of the adequacy of quality requirements stated in procurement documents is performed by qualified personnel. This review should determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed, and approved in accordance with QA program requirements.

3. The review and approval of procurement documents are documented prior to release and are available for verification.

4. Procurement documents identify the applicable 10 CFR Part 50, Appendix B requirements which must be complied with and described in the supplier's QA program. This QA program or portions thereof shall be reviewed and concurred with by qualified personnel in QA prior to initiation of activities affected by the program.

5. Procurement documents contain or reference the design basis technical requirements including the applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instructions.

6. Procurement documents identify the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted, to the purchaser for review and approval.

7. Procurement documents identify those records to be retained, controlled, and maintained by the supplier and those delivered to the purchaser prior to use or installation of the hardware.

8. Procurement documents contain the procuring agency's right of access to supplier's facilities and records for source inspection and audits.

9. Changes and revisions to procurement documents are subject to at least the same review and approval as the original document.

10. Procurement documents for spare or replacement parts of safety-related structures, systems, and components are subject to controls at least equivalent to those used for the original equipment.

11. The requirements and guidelines of ANSI N45.2.13 (Ref. 19) are complied with or acceptable alternatives are provided.

Activities related to Instructions, Procedures, and Drawings (17.2.5) are acceptable if:

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

2. Provisions are established which clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures, and drawings.

3. Methods for complying with each of the 18 criteria of 10 CFR Part 50, Appendix B are specified in instructions, procedures, and drawings.

4. Instructions, procedures, and drawings include quantitative (such as dimensions, tolerances, and operating limits) and qualitative (such as workmanship samples) acceptance criteria to verify that important activities have been satisfactorily accomplished.

5. The "offsite" or "onsite" QA organization reviews and concurs with inspection plans; test, calibration, special process, maintenance, modification and repair procedures; drawings and specifications; and changes thereto or acceptable alternatives are provided. In the case where the "onsite" QA organization reports to the plant superintendent and reviews and concurs in the procedures, the "offsite" QA organization reviews these procedures thru surveillance and audit to assure they meet QA program requirements.

Activities related to Document Control (17.2.6) are acceptable if:

1. The review, approval, and issue of documents (such as listed in Item 8 below) and changes thereto, prior to release, are procedurally controlled to assure they are adequate and the quality requirements are stated.

2. Provisions are established which identify those individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto.

3. Changes to documents are reviewed and approved by the same organizations that performed the original review and approval or by other qualified responsible organizations delegated by the applicant.

4. Approved changes are included in instructions, procedures, drawings, and other documents prior to implementation of the change.

5. Obsolete or superseded documents are controlled to prevent inadvertent use.

6. Documents are available at the location where the activity will be performed prior to commencing the work.

7. A master list or equivalent is established to identify the current revision number of instructions, procedures, specifications, drawings, and procurement documents. This list is updated and distributed to predetermined, responsible personnel to preclude the use of superseded documents.

8. The documents that are controlled under this subsection are identified. As a minimum this should include:
   a. Design specifications.
   b. Design, manufacturing, construction, and installation drawings.
   c. Procurement documents.
   d. QA manual and maintenance, modification and operating procedures.
   e. Final safety analysis report (FSAR).
   f. Manufacturing, inspection, and testing instructions.
   g. Test procedures.

h. Design change requests.

i. Nonconformance reports.

Activities related to Control of Purchased Material, Equipment, and Services (17.2.7) are acceptable if:

1. Qualified personnel evaluate the suppliers' capability to provide acceptable quality services and products before the award of the procurement order or contract. The QA and engineering groups participate in the evaluation of those suppliers providing critical components.

2. The evaluation of suppliers is based on one or more of the following:
   a. The supplier's capability to comply with the elements of 10 CFR Part 50, Appendix B that are applicable to the type of material, equipment, or service being procured.
   b. A review of previous records and performance of suppliers who have provided similar articles of the type being procured.
   c. A survey of the supplier's facilities and QA program to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

3. Results of supplier evaluations are documented and filed.

4. Surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment, and components is planned and performed in accordance with written procedures to assure conformance to the purchase order requirements. These procedures provide for:
   a. Instructions that specify 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 instructions.
   b. Audits and surveillance which assure that the supplier complies with the quality requirements. Surveillance should be performed on those items where verification or procurement requirements cannot be determined upon receipt.

5. The supplier furnishes the following records as a minimum to the purchaser:
   a. Documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, specifications) met by the items.
   b. Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances dispositioned "accept as is" or "repair."

   The review and acceptance of these documents shall be described in the purchaser's QA program, and as a minimum, shall be undertaken by a responsible QA individual.

6. Supplier's certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid.

7. Receiving inspection of the supplier-furnished material, equipment, and services is performed to assure:
   a. The material, component, or equipment is properly identified and corresponds with the identification on the receiving documentation.
   b. Material, components or equipment, and acceptance records are inspected and judged acceptable in accordance with predetermined inspection instructions, prior to installation or use.
   c. Inspection records or certificates of conformance attesting to the acceptance of material, components, and equipment are available at the nuclear power plant prior to installation or use.
   d. 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.

8. The effectiveness of the control of quality by suppliers is assessed by the applicant at intervals consistent with the importance, complexity, and quantity of the item.

9. Spare or replacement parts of safety-related structures, systems, and components are subject to controls at least equivalent to those used for the original equipment.

Activities related to Identification and Control of Materials, Parts, and Components (17.2.8) are acceptable if:

1. Procedures are established to identify and control materials, parts, and components including partially fabricated subassemblies.

2. The identification and control procedures assure that identification is maintained either on the item, or on records traceable to the item, to preclude the use of incorrect or defective items.

3. Identification of materials and parts important to the function of safety-related structures, systems, and components 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.

4. The location and the method of identification do not affect the fit, function, or quality of the item being identified.

5. Correct identification of materials, parts, and components is verified and documented prior to release for fabrication, assembling, shipping, and installation.

Activities related to Control of Special Processes (17.2.9) are acceptable if:

1. Special processes such as welding, heat treating, nondestructive testing, and cleaning are controlled.

2. Procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards and specifications.

3. Special processes are performed by qualified personnel and accomplished in accordance with written process sheets, or equivalent with recorded evidence of verification.

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

5. Regulatory Guides 1.37 (Ref. 6), 1.39 (Ref. 8) and 1.54 (Ref. 9) are complied with or acceptable alternatives are provided.

Activities related to Inspection (17.2.10) are acceptable if:

1. An inspection program which verifies conformance of quality affecting activities with requirements is established, documented, and accomplished in accordance with written controlled procedures.

2. Inspection personnel are independent from the individuals performing the activity being inspected.

3. Inspection procedures, instructions, and check lists provide for the following:
   a. Identification of characteristics and activities to be inspected.
   b. Identification of the individuals or groups responsible for performing the inspection operation.
   c. Acceptance and rejection criteria.
   d. A description of the method of inspection.
   e. Recording evidence of completing and verifying a manufacturing, inspection, or test operation.
   f. Recording the inspector or data recorder and the results of the inspection operation.

4. Inspection procedures or instructions are used with necessary drawings and specifications when performing inspection operations.

5. Modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

6. Provisions are established that identify mandatory inspection hold points for witness by an inspector.

7. Provisions are established for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is not possible.

8. Inspectors are qualified in accordance with applicable codes, standards, and company training programs, and their qualifications and certifications are kept current.

9. Maintenance and modification procedures are reviewed by qualified personnel knowledgeable in QA to determine the need for a) inspection, b) identification of inspection personnel, and c) documenting inspection results.

10. Regulatory Guides 1.30 (Ref. 5), 1.58 (Ref. 10), 1.94 (Ref. 15), and the requirements and guidelines of ANSI N45.2.13 (Ref. 19) are complied with or acceptable alternatives are provided.

Activities related to Test Control (17.2.11) are acceptable if:

1. A test program (proof, preoperational, and operational tests) to demonstrate that the item will perform satisfactorily in service is established, documented, and accomplished in accordance with written controlled procedures.

2. Modifications, repairs, and replacements are tested in accordance with the original design and testing requirements or acceptable alternatives.

3. Written test procedures incorporate or reference:
   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 and appropriate equipment.
      - Trained, qualified, and licensed or certified personnel.
      - Completeness of item to be tested.
      - Suitable and controlled environmental conditions.
      - Provisions for data collection and storage.
   d. Mandatory inspection hold points for witness by owner, contractor, or inspector.
   e. Acceptance and rejection criteria.
   f. Methods of documenting or recording test data and results.

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

5. Regulatory Guides 1.30 (Ref. 5), 1.58 (Ref. 10), 1.94 (Ref. 15) and the requirements and guidelines of ASNI N45.2.8 (Ref. 17) are complied with or acceptable alternatives are provided.

Activities related to Control of Measuring and Test Equipment (17.2.12) are acceptable if:

1. Provisions contained in procedures establish the calibration technique and frequency, maintenance, and control of all measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) which are used in the measurement, inspection, and monitoring of safety-related components, systems, and structures.

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

3. Measuring and test equipment is labeled or tagged to indicate the date of the next calibration.

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

5. Measures are taken and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.

6. Calibrating standards have an uncertainty (error) requirement of no more than 1/4 of the tolerance of the equipment being calibrated. A greater uncertainty may be acceptable when limited by the "state-of-the-art."

7. The complete status of all items under the calibration system is recorded and maintained.

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

Activities related to Handling, Storage, and Shipping (17.2.13) are acceptable if:

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

2. Procedures are prepared which control the cleaning, handling, storage, packaging, shipping, and preservation of materials, components and systems in accordance with design and specification requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

3. Regulatory Guide 1.38 (Ref. 7) is complied with or acceptable alternatives are provided.

Activities related to Inspection, Test, and Operating Status (17.2.14) are acceptable if:

1. Identification of the inspection, test, and operating status of structures, systems, and components is known by affected organizations.

2. The application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps are procedurally controlled.

3. Bypassing of required inspections, tests, and other critical operations is procedurally controlled under the cognizance of the QA organization.

4. The status of operating, nonconforming, inoperative, or malfunctioning structures, systems, or components is identified to prevent inadvertent use.

Activities related to Nonconforming Materials, Parts, or Components (17.2.15) are acceptable if:

1. The identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, components, or services are procedurally controlled.

2. Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition.

3. Provisions are established identifying those individuals or groups delegated the responsibility and authority for the disposition and approval of nonconforming items.

4. Nonconforming items are segregated from acceptable items and identified as discrepant until properly dispositioned.

5. Acceptability of rework or repair of materials, parts, components, systems, and structures is verified by reinspecting and retesting the item as originally inspected and tested or by a method which is equivalent to the original inspection and testing method; and inspection, testing, rework, and repair procedures are documented.

6. Nonconformance reports dispositioned "accept as is" or "repair" are made part of the inspection records and forwarded with the hardware to the utility for review and assessment.

7. Nonconformance reports are periodically analyzed to show quality trends, and the results are reported to management for review and assessment.

Activities related to Corrective Action (17.2.16) are acceptable if:

1. Evaluation of conditions adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective material and equipment) is conducted to determine need for corrective action in accordance with established procedures.

2. Corrective action is initiated following the determination of a condition adverse to quality to preclude recurrence.

3. Follow-up reviews are conducted to verify proper implementation of corrective actions and to close out the corrective action documentation.

4. Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken are reported to cognizant levels of both "offsite" and "onsite" management including QA, for review and assessment.

Activities related to Quality Assurance Records (17.2.17) are acceptable if:

1. Sufficient records are maintained to provide documentary evidence of the quality of items and the activities affecting quality.

2. QA records include plant history; operating logs; principal maintenance and modification activities; abnormal occurrences; 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.

3. Records are identifiable and retrievable.

4. Requirements and responsibilities for record transmittals, retention (such as duration, location, fire protection and assigned responsibilities), and maintenance subsequent to completion of work are consistent with applicable codes, standards, and procurement documents.

5. Inspection and test records contain the following where applicable:
   a. A description of the type of observation.
   b. Evidence of completing and verifying a manufacturing, inspection, or test operation.
   c. The date and results of the inspection or test.
   d. Information related to conditions adverse to quality.
   e. Inspector or data recorder identification.
   f. Evidence as to the acceptability of the results.

6. Record storage facilities are constructed, located, and secured to prevent destruction of the records by fire, flooding, theft, and deterioration by environmental conditions such as temperature or humidity.

7. Regulatory Guide 1.88 (Ref. 14) is complied with or acceptable alternatives are provided.

Activities related to Audits (17.2.18) are acceptable if:

1. Audits are performed in accordance with preestablished written procedures or check lists and conducted by trained personnel not having direct responsibilities in the areas being audited. Where the "onsite" QA organization reports to the plant superintendent, the "offsite" QA organization conducts audits sufficient to verify adequacy of activities conducted by the "onsite" QA organization.

2. Audits results are documented and then reviewed with management having responsibility in the areas audited.

3. Responsible management takes the necessary action to correct the deficiencies revealed by the audit.

4. Deficient areas are reaudited on a timely basis to verify implementation of corrective actions which minimize recurrence of the deficiencies.

5. Audits include an objective evaluation of quality-related practices, procedures, and instructions and the effectiveness of implementation.

6. Audits include the objective evaluation of work areas, activities, processes, and items and the review of documents and records.

7. Audits to assure the procedures and activities are meaningful and 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. Results of audits performed by the "onsite" QA organization are provided to the "offsite" QA organization for review and assessment.
   b. The applicant and his principal contractors to verify and evaluate their suppliers' QA programs, procedures, and activities.

8. Provisions are established requireing that audits be performed in those areas where the requirements of Appendix B to 10 CFR Part 50 being implemented. These areas shall include those safety-related activities associated with:
   a. Operation, maintenance and modification.
   b. The preparation, review, approval, and control of designs, specifications, procurement documents, instructions, procedures, and drawings.
   c. Receiving and plant inspections.
   d. Indoctrination and training programs.
   e. The implementation of operating and test procedures.
   f. Calibration of measuring and testing equipment.

9. Audits are regularly scheduled on the basis of the status and safety importance of the activities being performed. Where the "onsite" QA organization reports to the plant superintendent, the "offsite" QA organization reviews and concurs in the schedule and scope of audits performed by the "onsite" QA organization.

10. Audit data are analyzed and the reports, which indicate quality trends and the effectiveness of the QA program, are reported to management for review and assessment.

11. The requirements and guidelines of ANSI N45.2.12 (Ref. 18) are complied with or acceptable alternatives are provided.

III. REVIEW PROCEDURES

Selection and emphasis of various aspects of the areas covered by this review plan will be made by the reviewer on each case. The judgment on the areas to be given attention during the review is to be based on an inspection 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.

The acceptability of the QA program proposed for the operations phase is determined by the following review procedure:

1. The FSAR is reviewed in detail to determine if each of the criteria of Appendix B is addressed within the QA program description.

2. The measures described to implement 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 a 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 Part II of this Standard Review Plan.

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 meetings with the applicant and by review of the Office of Inspection and Enforcement inspection reports, a judgment is made of the applicant's capability to carry out his QA responsibilities.

5. Satisfaction with program commitments, organization arrangements, and capabilities to fulfill QA requirements will lead to the conclusion of acceptability expressed in Part IV of this Standard Review Plan.

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, which are to be included in the staff's Safety Evaluation Report:

"Our review of the applicant's quality assurance (QA) program description for the operations phase has verified that all applicable requirements of Appendix B to 10 CFR Part 50 are included in the QA program requirements. Further, this review has determined that the QA organizations are structured such that they can effectively carry out their responsibilities related to quality without undue influence from other groups.

"Based on our detailed review and evaluation of the QA Program description contained in the FSAR for (nuclear facility), we conclude that:

1. The QA organization of the (utility) is provided sufficient independence from cost and schedule when opposed to safety considerations, authority to effectively carry out the QA programs, and sufficient access to management at a level necessary to perform their QA functions.

2. The QA program describes adequate QA procedures, requirements, and controls demonstrating compliance with the requirements of Appendix B to 10 CFR Part 50."

V. REFERENCES

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

2. 10 CFR Part 55, "Operators' Licenses."

3. Regulatory Guide 1.8, "Personnel Selection and Training" (endorses N18.1).

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

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

6. 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).

7. 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).

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

9. Regulatory Guide 1.54, "Quality Assuarance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants" (endorses N101.4).

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

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

12. Regulatory Guide 1.70, "Standard Format and Contents of Safety Analysis Reports for Nuclear Power Plants."

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

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

15. 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).

16. ANSI N18.7 (latest revision), "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," American National Standards Institute.

17. ANSI N45.2.8 (Draft 3, Rev. 3 - April 1974), "Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems for the Construction Phase of Nuclear Power Plants," American National Standards Institute.

18. ANSI N45.2.12 (Draft 3, Ref. 4 - February 1974), "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants," American National Standards Institute.

19. ANSI N45.2.13 (Draft 2, Rev. 4 - April 1974), "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants," American National Standards Institute.

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