RS-002, "PROCESSING APPLICATIONS FOR EARLY SITE PERMITS"

ATTACHMENT 2

17.1.1 EARLY SITE PERMIT QUALITY ASSURANCE MEASURES

REVIEW RESPONSIBILITIES

Primary - Emergency Preparedness and Plant Support Branch (IEPB)

Secondary - Mechanical and Civil Engineering Branch (EMEB)
Probabilistic Safety Assessment Branch (SPSB)

I. AREAS OF REVIEW

The IEPB reviews and evaluates the description of the quality assurance (QA) measures of each early site permit (ESP) applicant in accordance with the applicable portions of this guidance. To support this review, inspections of QA measures are also conducted. As requested by IEPB, the secondary review branches will review the scope of ESP activities within their area of responsibility and determine if the applicant has included within the scope of the QA measures activities that would affect the capability of systems, structures, and components (SSCs) important to safety that would be constructed at the site. The EMEB will determine the appropriateness of site exploration and laboratory tests, if any, in accordance with applicable regulatory guides, and will provide input to the safety evaluation, if needed.

Regulatory Basis

Under 10 CFR 52.18, "Standard for Review of Applications," the staff reviews ESP applications in accordance with the applicable regulations of 10 CFR Part 50 and its appendices and Part 100 as they apply to construction permits. The current regulations do not require implementation of a QA program compliant with Appendix B to 10 CFR Part 50. However, the applicant is expected to implement quality assurance measures equivalent in substance to the measures described in Appendix B to 10 CFR Part 50 to provide reasonable assurance that information derived from ESP activities that would be used in design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs in service.

In accordance with 10 CFR 52.79(a)(1), if an application for a combined license (COL) references an ESP, it must contain information sufficient to demonstrate that the design of the facility falls within the site characteristics specified in the ESP. If the COL applicant references a certified design and an ESP, and does not request a variance from the ESP in accordance with 10 CFR 52.39(b), the applicant must show that the site parameters postulated for the certified design fall within the parameters specified in the ESP. If the COL applicant submits a custom design (one not certified) or has requested a variance, the site characteristics specified in the ESP could be inputs to that design. In either case, there must be reasonable assurance of the reliability and integrity of data contained in or supporting the ESP application, which in turn supports the COL application. Therefore, QA measures are needed whether an ESP is coupled with a certified or custom design. For consistency with Appendix B to 10 CFR Part 50,

this guidance is written in terms of information that would affect the design of SSCs important to safety that might be constructed on the proposed site.

“Equivalent in substance" to Appendix B to 10 CFR Part 50, means that the applicant's QA measures should provide reasonable assurance of integrity and reliability of data that would affect design or construction of SSCs important to safety. Appendix B defines a substantive and procedural framework of measures that collectively help provide such assurance, and that framework has been proven through many years of safe nuclear power plant operation. This section of RS-002 describes a QA control framework that the staff considers to be equivalent in substance to 10 CFR Part 50, Appendix B. The staff will not base a regulatory finding on the ESP application solely on the equivalence of the applicant’s QA measures to 10 CFR Part 50, Appendix B measures. While these criteria closely parallel those of Appendix B to 10 CFR Part 50 and some are identical, the staff does not intend to focus on strict adherence to Appendix B. Rather, staff findings will be based on whether or not the applicant has provided adequate measures to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety. Therefore, any deviations of the applicant’s QA measures from this guidance will be evaluated for their effect on the integrity and reliability of data supporting the ESP application.

Quality assurance criteria are applicable to those ESP activities that are directly related to the pedigree or genesis of SSCs important to safety. For example, activities involved in data collection, analysis, and evaluation for soil composition, geology, hydrology, meteorology, and seismology determinations should be controlled at an equivalent level of quality to that provided by the measures described in Appendix B to 10 CFR Part 50, to the extent such activities would affect SSCs important to safety. Further, some information is derived from recognized authorities (such as the Census Bureau or the National Oceanic and Atmospheric Administration). Evaluations and analyses that use such information and would affect the design or construction of SSCs important to safety should be subjected to quality measures comparable to the measures described in Appendix B to 10 CFR Part 50. Processes for maintaining data integrity, traceability, document control, and record storage for this information should also be subjected to quality measures comparable to the measures described in Appendix B to 10 CFR Part 50.

The site safety assessment establishes information, such as analyses and data, that is material to the reliable performance of SSCs important to safety and would be used in the design, construction, and operation of reactor systems that might be constructed on the proposed site. The regulations at 10 CFR 52.39 provide for finality of determinations made at the ESP stage, in that matters resolved in the ESP proceeding remain resolved at the COL stage, except under certain limited conditions specified in the regulations. Therefore, the staff plans to evaluate quality measures for activities associated with generation of this design-related information to ensure the measures are adequate to provide reasonable assurance of the integrity and reliability of the information, using the criterion that these measures be equivalent in substance to Appendix B to 10 CFR Part 50.

Pre-Docketing

The IEPB staff should plan to meet with the applicant prior to tendering of the application (preferably prior to commencement of significant site characterization activities) to discuss what constitutes acceptable QA measures for ESP activities.

IEPB may also conduct a pre-docketing inspection of the applicant's QA measures to facilitate this review. Although there is no regulatory requirement for a pre-docketing review of an applicant's quality control processes, this review is likely to be beneficial to both the staff and the applicant in that it facilitates early identification of issues and supports timely completion of the ESP application review. The decision to perform this inspection will be made by IEPB on a case-by-case basis with agreement by the potential applicant. Since the pre-docketing review places particular emphasis on ongoing ESP activities, the inspection should be conducted during a period of significant site exploration and characterization activities.

Post-Docketing of ESP Application

The IEPB post-docketing review covers QA measures to be applied by the applicant and principal contractors to activities that may affect the capability of SSCs important to safety to perform adequately in service. This review and associated inspection are performed shortly after tendering of an ESP application to determine that satisfactory QA measures have been established and implemented. The scope of this review includes determination of the equivalence between the applicant's QA measures and the corresponding criteria of Appendix B to 10 CFR Part 50. The applicant's implemented quality measures should provide reasonable assurance of the integrity and reliability of data that support the site safety assessment and would be used as input to design or construction of SSCs important to safety.

The following areas should be reviewed, from the perspective that they are indicators of the effectiveness of quality assurance measures. As stated in Subsection IV, the staff's findings will be based on judgments about the effectiveness of the QA measures. The applicant may choose to use different methods of ensuring quality from those described below. In such cases, the NRC staff will evaluate the applicant's measures to ensure they are adequate to provide reasonable assurance of the integrity and reliability of the data that support the site safety assessment and would be used as input in design or construction of SSCs important to safety, with the expectation that they be equivalent in substance to those stated below.

It is possible that not all QA measures described below will be applicable to a given ESP application, depending on the applicant's organization, as well as the type and extent of ESP-related activities. The staff will make a determination of which QA measures are applicable on an application-specific basis.

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, are provided.

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

C. Organizational provisions exist for ensuring the proper implementation of QA measures.

2. QUALITY ASSURANCE PROGRAM

A. Scope of the QA measures is adequate to ensure that appropriate quality controls are applied to all site characterization data that relate to the design and analysis of SSCs important to safety that might be constructed on the proposed site.

B. Provisions exist to ensure proper definition of QA measures.

C. Programmatic provisions exist to ensure proper implementation of QA measures.

D. Provisions exist to ensure adequacy of personnel qualifications.

3. DESIGN CONTROL

A. Scope of QA measures covers ESP activities that would affect design and construction activities for SSCs important to safety that might be constructed on the site.

B. The organizational structure, activity, and responsibility of the positions or groups responsible for design activities important to safety (if any) are defined.

C. Provisions exist to carry out design activities important to safety in a planned, controlled, and orderly manner (if such activities occur at the ESP stage).

D. Provisions exist for interface control between functional units of the applicant's organization.

E. Provisions exist to verify the technical adequacy of design documents (if any) applicable to ESP activities that would affect SSCs important to safety.

F. Provisions exist to control design changes applicable to ESP activities that would affect SSCs important to safety (if any).

4. PROCUREMENT DOCUMENT CONTROL

A. Provisions exist to ensure that applicable technical requirements and QA measures are included or referenced in procurement documents related to ESP activities that would affect SSCs important to safety.

B. Provisions exist for review and approval of procurement documents for ESP activities that would affect SSCs important to safety.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

A. Provisions exist for ensuring that ESP activities that would affect SSCs important to safety are prescribed by and accomplished in accordance with documented instructions, procedures, or drawings.

B. Provisions exist for including quantitative and qualitative acceptance criteria in instructions, procedures, and drawings related to ESP activities that would affect SSCs important to safety.

6. DOCUMENT CONTROL

Provisions exist to ensure that documents related to ESP activities that would affect SSCs important to safety, 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.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

A. Provisions exist for the control of purchased material, equipment, and services related to ESP activities that would affect SSCs important to safety; for selection of suppliers; and for assessing the adequacy of quality.

B. Provisions exist to ensure that documented evidence of the conformance to procurement specifications of material and equipment related to ESP activities that would affect SSCs important to safety is available at the site prior to installation or use.

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

A. Provisions exist to identify and control materials, parts, and components related to ESP activities that would affect SSCs important to safety.

B. Provisions exist to ensure that incorrect or defective items are not used in ESP activities that would affect SSCs important to safety.

9. CONTROL OF SPECIAL PROCESSES

A. Provisions exist to ensure the acceptability of special processes used for ESP activities that would affect SSCs important to safety.

B. Provisions exist to ensure that special processes related to ESP activities that would affect SSCs important to safety are performed by qualified personnel using qualified procedures and equipment.

10. INSPECTION

A. Provisions exist for the inspection of activities affecting the quality of ESP activities that would affect SSCs important to safety, including the items and activities to be covered.

B. Organizational responsibilities and qualifications are established for individuals or groups performing inspections of ESP activities that would affect SSCs important to safety.

C. Provisions exist for inspection personnel to be independent of the performance of the activity being inspected.

11. TEST CONTROL

A. Provisions exist to ensure that tests performed related to ESP activities that would affect SSCs important to safety are appropriately controlled to provide confidence that these SSCs would perform adequately in service.

B. Provisions exist to ensure that prerequisites are provided in written test procedures and test results are documented and evaluated for activities related to ESP activities that would affect SSCs important to safety.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

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

13. HANDLING, STORAGE, AND SHIPPING

Provisions exist to control handling, storage, shipping, cleaning, and preservation of items related to ESP activities that would affect SSCs important to safety 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 exist to indicate the inspection, test, and operating status of items related to ESP activities that would affect SSCs important to safety in order to prevent inadvertent use or bypassing of inspection and tests.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Provisions exist to control the use or disposition of nonconforming materials, parts, or components related to ESP activities that would affect SSCs important to safety.

16. CORRECTIVE ACTION

Provisions exist to ensure that conditions adverse to quality are promptly identified and corrected. For significant conditions adverse to quality, those provisions should preclude recurrence.

17. QUALITY ASSURANCE RECORDS

Provisions exist for the identification, retention, retrieval, and maintenance of quality records.

18. AUDITS

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

B. Responsibilities and procedures are provided for conducting, documenting, and reviewing results of audits (including designating management levels to review and assess audit results).

II. ACCEPTANCE CRITERIA

The applicant and its principal contractors should establish QA measures to provide adequate confidence that SSCs important to safety designed and constructed using data and/or analyses derived from ESP activities would perform satisfactorily in service. For example, activities involved with data collection, as well as analysis and evaluation of site characteristics (such as geology, hydrology, and seismology) should be subjected to adequate quality measures. The applicant is expected to demonstrate that quality measures equivalent in substance to 10 CFR Part 50, Appendix B have been implemented. The applicant is also expected to demonstrate that these measures provide reasonable assurance of the integrity and reliability of data that support the site safety assessment and that would be used as input to design or construction of SSCs important to safety. The acceptance criteria used to evaluate the QA measures are listed in the following 18 subsections. The IEPB review allows flexibility in defining methods and measures that are equivalent in substance to the pertinent Appendix B criteria.

“Equivalent in substance" to 10 CFR Part 50, Appendix B means that the applicant's QA measures should provide reasonable assurance of integrity and reliability of data that would affect design or construction of SSCs important to safety that might be constructed on the proposed site. Appendix B to 10 CFR Part 50 defines a substantive and procedural framework of measures that helps provide such assurance, and that framework has been proven through many years of safe nuclear power plant operation. This Section of RS-002 describes a QA control framework that the staff considers to be equivalent in substance to 10 CFR Part 50, Appendix B. The staff will not base a regulatory finding on the ESP application on the equivalence of the applicant’s QA measures to 10 CFR Part 50, Appendix B. Rather, staff findings will be based on whether or not the applicant has provided adequate measures to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety. Therefore, any deviations of the applicant’s QA measures from this guidance will be evaluated for their effect on the integrity and reliability of data supporting the ESP application.

The Organization (17.1.1.1) elements responsible for QA measures are acceptable if:

1A1.[1] The responsibility for QA measures is retained and exercised by the applicant.

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

1A3. Clear management measures and effective lines of communication exist for QA activities among the applicant and the principal contractors.

1A4. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the applicable QA measures (such as design, engineering, procurement, manufacturing, construction, inspection, testing, instrumentation and control, nuclear engineering), the lines of responsibility, and a description of the criteria for determining the size of the QA organization, including the inspection staff.

1A5. The applicant and its principal contractors describe the QA responsibilities of each of the organizational elements noted on the organization charts.

1B1. The applicant and its principal contractors identify a management position that retains overall authority and responsibility for QA measures, and this position has the following characteristics:

a. Has the organizational freedom and authority to report to a management level that assures organizational freedom and authority.

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

1B2. Persons and organizations performing QA functions have direct access to management levels which will ensure the ability to:

a. Identify quality problems.

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

c. Verify implementation of solutions.

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

1B3. Designated QA personnel, sufficiently free from direct pressures for cost/schedule, have the responsibility delineated in writing to identify quality problems; initiate, recommend, or provide solutions; and verify implementation of solutions.

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

1B4. Provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between QA personnel and other department personnel.

1B5. Designated QA individuals are involved in site activities important to safety, and there is adequate QA coverage relative to procedural and inspection measures, acceptance criteria, and QA staffing and qualification of personnel to carry out QA assignments.

1C1. Policies regarding the implementation of the QA measures are documented and followed.

1C2. The position description (see 1B1) ensures that the individual with direct overall responsibility for the definition, direction, and effectiveness of QA measures has sufficient authority to effectively implement responsibilities.

Activities related to Quality Assurance (17.1.1.2) are acceptable if:

2A1. The scope of the QA measures includes:

a. A commitment that activities affecting SSCs important to safety will be subject to the applicable QA measures.

b. A commitment that the development, control, and use of computer code programs related to ESP activities that would affect SSCs important to safety will be conducted in accordance with QA measures, and a description of how the QA measures will be applied.

c. A commitment that appropriate equipment, environmental conditions, skills, or processes will be provided as necessary for ESP activities that would affect SSCs important to safety.

2B1. a. Provisions are established to ensure that procedures needed to implement QA measures are properly documented, controlled, and followed as set forth in a policy statement or equivalent document signed by the responsible official.

b. The QA organization reviews and documents concurrence with procedures necessary to implement QA measures.

c. The procedures used by principal contractors to implement QA measures should be provided for the applicant's review with documented agreement of acceptance prior to initiation of activities affected by the measures.

2B2. Changes to QA measures will be evaluated to ensure that changes have not degraded the previously approved quality assurance measures.

2B3. The QA organization and the necessary technical organizations participate early in the QA measures definition stage to determine and identify the extent QA measures are to be applied to specific activities or SSCs.

2B4. Existing or proposed QA procedures are identified reflecting how 10 CFR Part 50, Appendix B criteria (or criteria equivalent in substance) will be implemented through documented procedures.

2C1. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, and adequacy of the QA measures. These measures should include:

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

b. Performance of regular preplanned and documented assessments. Corrective action is identified and tracked.

2C2. Quality-related activities (such as design, procurement, and site investigation related to ESP activities that would affect SSCs important to safety) initiated prior to docketing are controlled under QA measures in accordance with guidance in this section of this review standard. Approved procedures and a sufficient number of trained personnel should be available to implement applicable QA measures prior to the initiation of quality-related activities.

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

a. Personnel responsible for performing activities related to quality are instructed as to the purpose, scope, and implementation of the associated 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. Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining, and/or recertifying as determined by management or program commitment.

Activities related to Design Control (17.1.1.3) are acceptable if:

3A. The scope of the design control program related to ESP activities that would affect SSCs important to safety 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.

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, if any, that are related to ESP activities that would affect SSCs important to safety.

3C1. Errors and deficiencies in approved design documents, including design methods (such as computer codes), that would adversely affect SSCs important to safety are documented; and action is taken to ensure 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 measures, 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, if any, related to ESP activities that would affect SSCs important to safety.

3E1. Procedures are established and described providing for a documented check to verify the dimensional accuracy and completeness of design drawing and specifications, if any, related to ESP activities that would affect SSCs important to safety.

3E2. Procedures are established and described providing that design drawings and specifications related to ESP design activities (if any) that would affect SSCs important to safety be reviewed by the QA organization to ensure that the documents are prepared, reviewed, and approved in accordance with procedures and that the documents contain the necessary quality assurance provisions such as inspection and test criteria, acceptance criteria, 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 tests) for ESP design activities (if any) that would affect SSCs important to safety.

3E4. Procedures are established and described for design verification activities (related to ESP activities that would affect SSCs important to safety, (if any) which ensure the following:

a. The verifier is qualified and is not directly responsible for the design (i.e., the verifier is neither the performer nor the immediate supervisor of the performer).

b. 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.

3E5. Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

3E6. Procedures are established to ensure that verified computer codes are certified for use and that their use is specified for ESP activities that would affect SSCs important to safety.

3F1. Design and specification changes, if any, related to ESP activities that would affect SSCs important to safety, including fields changes, are subject to the same design measures that were applicable to the original design.

Activities related to Procurement Document Control (17.1.1.4) are acceptable if:

4A1. Procedures are established for the review of procurement documents related to ESP activities that would affect SSCs important to safety to determine that quality standards 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 measures. To the extent necessary, procurement documents related to ESP activities that would affect SSCs important to safety should provide that contractors and subcontractors establish an acceptable quality assurance plan.

4A2. Procedures are established to ensure that procurement documents related to ESP activities that would affect SSCs important to safety identify applicable regulatory, technical, administrative, and reporting guidelines; drawings; specifications; codes and industrial standards; test and inspection standards; and special process instructions with which suppliers should conform.

4B1. Organizational responsibilities are described for (a) procurement planning; (b) the preparation, review, approval, and control of procurement documents; (c) supplier selection; (d) bid evaluations; and (e) review and concurrence of supplier QA programs prior to initiation of activities affected by QA measures. The involvement of the QA organization is described.

Activities related to Instructions, Procedures, and Drawings (17.1.1.5) are acceptable if:

5A. Organizational responsibilities are described for ensuring that ESP activities that would affect SSCs important to safety are (a) prescribed by documented instructions, procedures, and drawings and (b) accomplished through implementation of these documents.

5B. Procedures are established to ensure that instructions, procedures, and drawings related to ESP activities that would affect SSCs important to safety include quantitative acceptance criteria (such as dimensions, tolerances, and limits) and qualitative acceptance criteria (such as workmanship samples) for determining that important activities have been satisfactorily accomplished.

Activities related to Document Control (17.1.1.6) are acceptable if:

6A1. The scope of the document control program for ESP activities that would affect SSCs important to safety is described, and the types of controlled documents are identified. Controlled documents may 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, testing, and inspection.

d. Quality assurance and quality control manuals and quality affecting procedures.

e. Nonconformance reports.

6A2. Procedures for the review, approval, and issuance of documents related to ESP activities that would affect SSCs important to safety and changes thereto are established and described to ensure technical adequacy and inclusion of appropriate quality standards prior to implementation. The QA organization, or an individual other than the person who generated the document but who is qualified in quality assurance, reviews and concurs with these documents with regard to their QA-related aspects.

6A3. Procedures are established to ensure that changes to documents related to ESP activities that would affect SSCs important to safety are reviewed and approved by the same organizations that performed the initial review and approval or by other qualified responsible organizations to which the applicant has delegated review and approval authority.

6A4. Procedures are established to ensure that documents related to ESP activities that would affect SSCs important to safety are available at the location where the activity will be performed before the work begins.

6B1. Procedures are established and described to ensure that obsolete or superseded documents related to ESP activities that would affect SSCs important to safety are removed from work areas and replaced by applicable revisions in a timely manner.

Activities related to Control of Purchased Material, Equipment, and Services (17.1.1.7) are acceptable if:

7A1. Organizational responsibilities are described for the control of purchased material, equipment, and services related to ESP activities that would affect SSCs important to safety, including interfaces between design, procurement, and QA organizations.

7A2. Verification of suppliers' activities during fabrication, inspection, testing, and shipment of materials, equipment, and components related to ESP activities that would affect SSCs important to safety is planned and performed with QA organization participation in accordance with written procedures to ensure conformance to the purchase order specifications. 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 provided; and those responsible for implementing these procedures.

b. Audits, surveillance, or inspections to ensure that the supplier complies with the quality standards.

7A3. The selection of suppliers for ESP activities that would affect SSCs important to safety is documented and filed.

7A4. Procurement of parts related to ESP activities that would affect SSCs important to safety is subject to present QA measures, to codes and standards, and to technical criteria specified by the applicant's procurement documents.

7B1. A receiving inspection of incoming material associated with ESP activities that would affect SSCs important to safety is performed to ensure:

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 standards) are available at the site prior to installation or use.

7B2. Items related to ESP activities that would affect SSCs important to safety that are 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 for items related to ESP activities that would affect SSCs important to safety furnishes the following records to the purchaser:

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

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

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

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

7B4. Suppliers' certificates of conformance for activities that would affect SSCs important to safety are periodically evaluated by audits, independent inspections, or tests to ensure they are valid and the results documented.

Activities related to Identification and Control of Materials, Parts, and Components (17.1.1.8) are acceptable if:

8A. Measures are established and described to identify and control materials (including consumables), parts, and components, including partially fabricated subassemblies, if any, that are related to ESP activities that would affect SSCs important to safety. The description should include organizational responsibilities.

8B. Procedures are established to ensure that identification of items related to ESP activities that would affect SSCs important to safety is maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.

Activities related to Control of Special Processes (17.1.1.9) are acceptable if:

9A1. The criteria for determining those processes that are controlled as special processes are described.

9A2. Organizational responsibilities, including those for the QA organization, are described for qualification of special processes, equipment, and personnel related to ESP activities that would affect SSCs important to safety.

9B1. Procedures, equipment, and personnel associated with special processes related to ESP activities that would affect SSCs important to safety are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to ensure they are satisfactorily performed.

9B2. Procedures are established for recording evidence of acceptable accomplishment of special processes related to ESP activities that would affect SSCs important to safety using qualified procedures, equipment, and personnel.

9B3. Qualification records of procedures, equipment, and personnel associated with special processes related to ESP activities that would affect SSCs important to safety are established, filed, and kept current.

Activities related to Inspection (17.1.1.10) are acceptable if:

10A. The scope of the inspection program described indicates that an effective inspection program has been established for ESP activities that would affect SSCs important to safety. Program procedures provide criteria for determining the accuracy criteria for inspection equipment and criteria for determining when inspections are necessary, or defining how and when inspections are performed. The QA organization participates in the above functions.

10B1. Organizational responsibilities for inspection of ESP activities that would affect SSCs important to safety 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 constraints should be reviewed and found acceptable by the QA organization prior to the initiation of the activity.

10B2. A qualification program for inspectors of ESP activities that would affect SSCs important to safety is established and documented, and the qualifications and certifications of inspectors are kept current.

10C1. Inspection procedures, instructions, or checklists related to ESP activities that would affect SSCs important to safety 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 needed procedures, drawings, and specifications and revisions.

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

g. Specifying necessary measuring and test equipment, including accuracy criteria.

10C2. Procedures are established and described to identify, in pertinent documents related to ESP activities that would affect SSCs important to safety, inspection hold-points beyond which work would not proceed until inspected by a designated inspector.

10C3. Inspection results related to ESP activities that would affect SSCs important to safety are documented and evaluated, and their acceptability is determined by a responsible individual or group.

Activities related to Test Control (17.1.1.11) are acceptable if:

11A1. The description of the scope of the test control program indicates that tests related to ESP activities that would affect SSCs important to safety are appropriately controlled to provide confidence that SSCs important to safety that might be constructed on the proposed site would perform adequately in service. Program procedures provide standards for ensuring the accuracy of test equipment and for determining when a test is needed or how and when testing activities are performed.

11B1. Test procedures or instructions for ESP activities that would affect SSCs important to safety provide, as needed, for the following:

a. The standards and acceptance criteria 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 criteria; suitable and controlled environmental conditions; and provisions for data collection and storage.

d. Inspection hold-points for witness by owner, contractor, or inspector (as needed).

e. Acceptance and rejection criteria.

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

g. Provisions for ensuring test prerequisites have been met.

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

Activities related to Control of Measuring and Test Equipment (17.1.1.12) are acceptable if:

12.1 The scope of the program for the control of measuring and test equipment related to ESP activities that would affect SSCs important to safety 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 ensuring effectiveness of the calibration program related to ESP activities that would affect SSCs important to safety.

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 ESP activities that would affect SSCs important to safety. The review of and documented concurrence in these procedures is described and the organization responsible for these functions is identified.

12.4 Measuring and test equipment related to ESP activities that would affect SSCs important to safety is identified and traceable to the calibration test data.

12.5 Measuring and test equipment related to ESP activities that would affect SSCs important to safety is labeled or tagged or otherwise controlled to indicate the due date of the next calibration. The method of control should be described.

12.6 Measuring and test equipment related to ESP activities that would affect SSCs important to safety is calibrated at specified intervals based on the needed accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

12.7 Reference and transfer standards related to ESP activities that would affect SSCs important to safety should be traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration.

12.8 Measures should be taken and documented to determine the validity of previous inspections of ESP activities that would affect SSCs important to safety 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 that may not be reliable.

Activities related to Handling, Storage, and Shipping (17.1.1.13) are acceptable if:

13.1 Special handling, preservation, storage, cleaning, packaging, and shipping specifications for ESP activities that would affect SSCs important to safety are established and accomplished 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 related to ESP activities that would affect SSCs important to safety in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

Activities related to Inspection, Test, and Operating Status (17.1.1.14) are acceptable if:

14.1 Procedures are established to indicate the inspection, test, and operating status of equipment used to establish information that would be used to design and construct SSCs important to safety.

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, as appropriate, related to ESP activities that would affect SSCs important to safety.

14.3 Procedures are established and described to control altering the sequence of specified tests, inspections, and other operations related to ESP activities that would affect SSCs important to safety. Sequence alterations should be subject to the same measures as the original review and approval.

14.4 The status of nonconforming, inoperative, or malfunctioning equipment used to establish information that would be used to design and construct SSCs is documented and identified to prevent inadvertent use. The organization responsible for this function is identified.

Activities related to Nonconforming Materials, Parts, or Components (17.1.1.15) are acceptable if:

15.1 For ESP activities that would affect SSCs important to safety, 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 for ESP activities that

would affect SSCs important to safety. 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 standards; and includes signature approval of the disposition.

15.4 Reworked, repaired, and replacement items related to ESP activities that would affect SSCs important to safety are inspected and tested in accordance with the original inspection and test standards or acceptable alternatives.

15.5 Nonconformance reports related to ESP activities that would affect SSCs important to safety 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 (17.1.1.16) are acceptable if:

16.1 Procedures are established and described indicating that an effective corrective action program for ESP activities that would affect SSCs important to safety 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, or defect in material and equipment) for ESP activities that would affect SSCs important to safety to preclude recurrence. The QA organization is involved in the documented concurrence in the adequacy of the corrective action.

16.3 Follow-up 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 For significant conditions adverse to quality associated with ESP activities that would affect SSCs important to safety, 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 (17.1.1.17) are acceptable if:

17.1 The scope of the records program for ESP activities that would affect SSCs important to safety 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 related to ESP activities that would affect SSCs important to safety 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.

Activities related to Audits (17.1.1.18) are acceptable if:

18A1. Audits to ensure that procedures and activities related to ESP activities that would affect SSCs important to safety conform to overall QA measures 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 QA measures, 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 ensure effective QA during ESP activities that would affect SSCs important to safety.

18A3. Audits include an objective evaluation of quality-related practices, procedures, instructions, activities, and items, as well as a review of documents and records to ensure that QA measures are effective and properly implemented.

18A4. Provisions are established providing that audits be performed in all areas related to ESP activities that would affect SSCs important to safety. Areas which may often be neglected but should be included are activities associated with:

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

b. The preparation, review, approval, and control of early procurements.

c. Indoctrination and training programs.

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

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

f. Safety assessment 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 measures, including the need for re-audit of deficient areas, are reported to management for review and assessment.

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

III. REVIEW PROCEDURES

Each element of the applicable QA measures will be reviewed against the acceptance criteria described in Subsection II. Secondary review branches will assist IEPB in determining that the specified QA measures (or measures equivalent in substance) are applied to all ESP activities that would affect SSCs important to safety. IEPB will process any necessary requests for additional information to the applicant and coordinate the response with the appropriate branches for acceptance. Any exceptions or alternatives to this guidance will be carefully reviewed to ensure that they are clearly defined and that an adequate basis exists for acceptance.

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

1. QA measures are reviewed in detail to determine if each applicable criterion in Subsection II above (or criteria equivalent in substance, if elected by the applicant), has been acceptably addressed.

2. The applicant's measures are evaluated for:

   a. Technical acceptability

   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 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 ensure they provide sufficient independence to effectively perform these functions.

4. Through review of information provided; through meetings with the applicant; by review of the acceptability of QA measures and site activities, including performance and capability of personnel; and by review of inspection reports, a judgment is made of the

applicant's capability to assure the reliability and integrity of the information supporting the ESP application.

5. Satisfaction of commitments related to QA measures and descriptions of how the commitments will be met, organizational arrangements, and the applicant's capability to implement the QA measures 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 the 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 review and evaluation of the quality assurance (QA) measures contained in the safety assessment for [site] as set forth above, the staff concludes that:
>
> 1. The organizations and persons performing QA functions have the independence and authority necessary to effectively carry out QA measures without undue influence from those directly responsible for costs and schedules.
>
> 2. The QA procedures and measures, when properly implemented, are equivalent in substance to the criteria of Appendix B to 10 CFR Part 50 and conform to the guidance in Review Standard (RS)-002, Section 17.1.1.
>
> 3. The QA measures are applied to all ESP activities that establish information material to (1) the design and construction of SSCs important to safety that might be constructed on the proposed site or (2) the establishment of site characteristics for comparison to the values of site parameters postulated in a certified design. The measures provide adequate confidence that information provided in the ESP application and accepted by the NRC is reliable and, when used as input for design or construction of SSCs important to safety, would not adversely impact their ability to perform satisfactorily in service. In addition, use of that information to establish the site characteristics for comparison to the values of site parameters postulated for a certified design is acceptable.

Therefore, the staff concludes that the applicant's QA measures conform to the guidance in RS-002 and appropriate industry standards, and can be implemented for the early site permit.

V. IMPLEMENTATION

The following is intended to provide guidance to applicants and licensees regarding the NRC staff's plan for using guidance in this review standard, Section 17.1.1. Guidance in this section

will be used by the staff when performing safety evaluations of ESP applications submitted by applicants pursuant to 10 CFR Part 52.

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 compliance with Commission regulations.

VI. REFERENCES

1. 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

2. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

3. 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants."

4. NRC Inspection Manual Chapter 2501, "Nuclear Reactor Inspection Program - Early Site Permit."