PRE-DOCKETING COMBINED LICENSE QUALITY ASSURANCE CONTROLS INSPECTION

PROGRAM APPLICABILITY: 2502

35005-01 INSPECTION OBJECTIVE

To determine whether the quality assurance (QA) program used in the development of the application for a combined license (COL) is consistent with Appendix B to 10 CFR Part 50. To determine whether the QA program have been adequately implemented in support of the preparation of the application.

To determine whether the applicant provides adequate oversight of contracted activities in support of the application.

35005-02 INSPECTION REQUIREMENTS

Verify the extent and effectiveness of the implementation of the QA program, with particular emphasis on the areas listed below.

02.01 QA Program. The applicant's QA controls should be in compliance with the Appendix B to 10 CFR Part 50 requirements. This review will include the following QA program attributes:

- QA Organization
- QA Program
- Training and Qualifications
- Instruction, Procedures, and Drawings
- Document Control
- QA Record Control

02.02 QA Program Implementation. The applicant's QA program must be effectively implemented to provide reasonable assurance of the integrity and reliability of the COL data or analyses that would affect the performance of future safety-related systems, structures, and components (SSCs). This review will include the following QA program attributes:

- Design Control
- Corrective Action

02.03 Oversight of Contracted Activities . Applicants who delegate work (e.g., design, site characterization) to others (e.g., consultants, architect-engineering firms, nuclear steam supply vendor) must include applicable regulatory requirements and QA program attributes in procurement documents. Review the applicant's surveillance of contractor activities to assure that each QA program attribute is being established and implemented consistently. The review will include the following QA program criteria:

- Procurement Control
- Control of Purchased Material, Equipment, and Services
- Audits

35005-03 INSPECTION GUIDANCE

The regulations in 10 CFR Part 52 require that an Appendix B to 10 CFR Part 50 quality assurance program be implemented in support of COL applications. This requirement ensures that COL safety-related activities are controlled by QA measures sufficient to provide reasonable assurance that information used as input for design, construction, or testing of future safety-related SSCs, would not adversely impact their ability to perform satisfactorily in service.

The regulations in 10 CFR Part 52 provides the option to the applicant for a COL to reference an early site permit (ESP) issued under 10 CFR Part 52 Subpart A. For COL applications that do not reference an ESP, Inspection Procedure 35004, "Pre-Docketing Early Site Permit Quality Assurance Controls Inspection," provides guidance related to the review of an applicant's QA controls for site characterization activities.

03.01 QA Program. Review the applicant's QA control framework to determine if the quality related activities are consistent with an Appendix B to 10 CFR Part 50 quality assurance program. This review will include the following QA program attributes:

a. Organization (SRP 17.5 Section II.A). Review the organizational description of the applicant. This review will include the following:

1. Verify that the QA program provides an organizational description, interrelationships, and areas of responsibility and authority for all organizations performing quality-related activities in support of the application.

2. Verify that the QA program provides independence between the organization performing checking functions from the organization performing the functions.

3. Verify that the size of the QA organization is commensurate with its duties and responsibilities.

4. Verify that major delegation of work outside the organization is identified and described.

b. QA Program (SRP 17.5 Section II.B). Assess the QA program by reviewing the following:

1. Verify the scope of the QA program.

2. Verify that the QA program provides documentation of activities in written policies, procedures, or instructions in a manner that, if appropriately implemented, assures compliance with the requirements of applicable codes, industrial standards, and regulatory agencies.

3. Verify that the QA program provides for QA program activities to be conducted under suitably controlled conditions.

4. Verify that the applicant's QA program retains the responsibility for the establishment and implementation of all QA controls, including those aspects of the program delegated to contractors and consultants.

Specific Guidance. Review the quality assurance program description.

c. Training and Qualifications (SRP 17.5 Section II.S). Assess the training and qualification requirements by reviewing the following:

1. Verify that the QA program provides for indoctrination and training of personnel performing activities affecting quality to assure that proficiency is achieved and maintained.

Specific Guidance. Review a sample of training documents and determine if procedures for indoctrination and training of personnel performing activities affecting quality have been adequately implemented.

d. Instruction, Procedures, and Drawings (SRP 17.5 Section II.E). Review the QA program controls for instructions, procedures, and drawings. This review will include the following:

1. Verify that quality-related activities are documented into instructions, procedures, and drawings of a type appropriate to the circumstances.

2. Verify that quality-related activities are accomplished in accordance with the instructions, procedures, and drawings as outlined in the QA program.

3. Verify that instructions, procedures, and drawings include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

4. Verify that QA personnel is included in the documented review and concurrence of quality-related procedures associated with design.

Specific Guidance. Review a sample of instructions and procedures and determine if controls for instructions, procedures, and drawings have been adequately implemented.

e. Document Control (SRP 17.5 Section II.F). Review the QA program controls for quality-related documents. This review will include the following:

1. Verify that quality-related documents are developed, reviewed, approved, issued, used, and revised under an established program.

2. Verify the scope of the document control program.

3. Verify that document changes of controlled documents are reviewed and approved by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable.

4. Verify that the control system includes:

- the identification of controlled documents,
- the specified distribution,
- the individual responsible for preparation, review, approval and distribution,
- a review for adequacy, completeness, and correctness, and
- a method to ensure that correct and current documents are being used.

Specific Guidance. Review a suitable number of quality-related documents and determine if controls have been adequately implemented.

f. Record Control (SRP 17.5 Section II.Q). Review QA program controls for QA records. This review will include the following:

1. Verify that the QA program provides for the preparation of sufficient records to furnish documentary evidence of activities affecting quality.

2. Verify that design records include evidence that the design and design verification process were properly performed. The documentation includes not only the final design documents, but also documentation which identifies the important steps, including sources of design inputs that support the final design.

3. Verify that the QA program provides provisions for the administration, identification, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records.

4. For electronic records, verify that the program includes provisions for an acceptable media on which electronic records are created and stored. The program must implement Generic Letter 88-18, "Plant Record Storage on Optical Disks," or RIS 2000-18. (Nuclear Information and Records Management Association, Inc. Technical Guides: NIRMA TG 11-1998, NIRMA TG 15-1998, NIRMA TG 16-1998, NIRMA TG 21-1998)

5. Verify that records have been stamped, initialed, authenticated or signed and dated by authorized personnel. For electronic records, authentication is accomplished by manually affixing seal, signature, an electronic representation (user ID/password combination, digital signature) or other acceptable process control that ensures genuineness, validity, or reliability.

6. Verify that requirements for record retention, such as duration, location, and assigned responsibility, are developed and implemented.

Specific Guidance. Review a sample of records and determine if controls for the record preparation and retention have been adequately implemented.

03.02 QA Implementation. Review the applicant's COL-related design activities to verify implementation of QA controls.

a. Design Control (SRP 17.5 Section II.C). Assess the adequacy of design control by reviewing the following:

1. Verify that the design control program provides provisions to control design inputs, processes, output changes, interfaces, records, and organizational interfaces.

2. Verify that applicable design inputs (regulatory requirements, design bases, codes and standards, and test specification requirements) are correctly translated into design outputs (specifications, drawings, procedures, and instructions).

3. Verify that provisions are established to assure that appropriate quality standards are specified and included in design documents.

4. Verify that changes or deviations from specified design requirements and quality standards are identified, documented, and controlled.

5. Verify that QA role in design and analysis activities is defined. Design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the document contain the necessary QA requirements.

6. Verify that computer data acquisition software and documentation is controlled as required by the QA program.

7. Verify that the program provides for design verification. Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing.

8. Verify that design verification has been completed before design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, manufacture, or construction. When this timing cannot be achieved, the unverified portion of the design is identified and controlled.

9. Verify that the program provides for additional design verification when changes are made to previously verified designs, including evaluation of the effects of those changes on the overall design and on any design analyses.

Specific Guidance. Review a sample of design documents and determine if design controls have been adequately implemented. Select a sample of design documents where changes to previously verified designs were made.

b. Corrective Action (SRP 17.5 Section II.P). Review the corrective action program. This review will include the following:

1. Verify that measures are established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

2. In the case of significant conditions adverse to quality, verify that the cause of the condition is identified and that the corrective action taken to preclude its recurrence is documented.

3. Verify that the QA program provides for reporting to appropriate levels of management significant conditions adverse to quality and actions taken to correct them.

4. Verify that the QA program provides for the establishment of requirements to assure that, when necessary, corrective action controls are extended to subcontractors and suppliers.

Specific Guidance. Review a sample of identified problems and determine if the facility adequately implemented these controls.

03.03 Oversight of Contracted Activities . Verify that the applicant's QA program provides adequate oversight of contracted activities in support of the application. This review will include the following QA program attributes:

a. Procurement Control (SRP 17.5 Section II.D). Assess Procurement Document Control by reviewing the following:

1. Verify that provisions to ensure that applicable regulatory requirements, technical requirements, and QA program requirements are included or referenced in procurement documents.

2. Verify that procurement documents include the following provisions:

- scope of work,

- specification of technical requirements
- identification of test, inspection, and acceptance requirements
- supplier's documented QA program that is determined to meet the applicable requirements of Appendix B to 10 CFR Part 50 as appropriate to the circumstances of the procurement (or the supplier may work under the applicant's QA program)
- access to the supplier's plant facilities and records for inspection or audit
- identification of the documentation and date of submission required to be submitted for information, review, or approval
- requirements for reporting and approving disposition of nonconformances

3. Verify that provisions are established for the review and approval of procurement documents. Procurement document changes are subject to the same degree of control as those utilized in the preparation of the original documents.

Specific Guidance. Review a sample of procurement documents and determine if controls have been adequately implemented.

b. Control of Purchased Material, Equipment, and Services (SRP 17.5 Section II.G). Review QA program controls for purchased materials, equipments, and services. This review will include the following:

1. Verify that measures are established to assure that purchased material, equipment, and services, whether purchased directly or through suppliers, conform to the procurement documents.

2. Verify that procedures provide for source evaluation or audit, as necessary, to assure the required quality of an item or service.

3. Verify that the QA program provides for the control of the quality of purchased items or services, as appropriate, by reviewing objective evidence provided by the supplier, inspection or audit at the supplier's facilities, or examination of items upon delivery.

Specific Guidance. Review a sample of procurement documents and determine if controls of purchased material, equipment, and services have been adequately implemented.

c. Audits (SRP 17.5 Section II.R). Assess the adequacy of audits by reviewing the following:

1. Verify that the program implements a planned and periodic audit to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

2. Verify that the program provides for a triennial audit of supplier's QA program.

3. Verify that responsibilities and procedures for auditing, documenting, and reviewing audit results, and designating management levels to review and assess audit results have been established. Verify if followup action of deficient

areas is initiated when necessary.

Specific Guidance. Review a sample of audit reports and determine if controls have been adequately implemented.

35005-04 RESOURCE ESTIMATE

This inspection procedure supports review of an COL application per the guidance contained in Section 17.5 of the SRP. The resource estimate for this inspection procedure is approximately 200 hours of direct inspection effort.

35005-05 REFERENCES

NUREG-0800, Standard Review Plan, Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants"

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