INSPECTION PROCEDURE 35005

PRE-APPLICATION QUALITY ASSURANCE PROGRAM AUDIT

PROGRAM APPLICABILITY: 2501, 2502, 2508, and 2518

35005-01 INSPECTION OBJECTIVE

01.01 To verify that quality processes for the development of the application are adequately described to provide reasonable assurance of the accuracy and completeness of the application in accordance with the requirements of 10 CFR 50.9.

01.02 To verify that the quality assurance program for quality activities that support the development of the application is being adequately implemented in accordance with the applicant's Appendix B to 10 CFR Part 50 (Appendix B) quality assurance (QA) program.

01.03 To verify that the applicant provides adequate oversight of contracted activities in support of the application.

This procedure is to be used in combination with Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformances."

35005-02 INSPECTION REQUIREMENTS

02.01 QA Program. The development of the application must be performed in a manner to ensure accuracy and completeness of the application in accordance with the requirements of 10 CFR 50.9. The regulations in 10 CFR Part 50 and 52 require that an Appendix B quality assurance program be implemented during Construction Permit (CP), Design Certification (DC), Early Site Permit (ESP) and Combined License (COL) quality related activities. This requirement ensures that 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 structures, systems, and components (SSCs), would not adversely impact their ability to perform satisfactorily in service.

02.02 QA Program Implementation. Applicant and designee QA programs must be effectively implemented to provide reasonable assurance of the integrity and reliability

of the data or analyses that would affect the performance of safety-related SSCs. This review will typically include the following QA program attributes:

- Design Control
- Document Control
- Corrective Action
- QA Record Control
- Training and Qualifications

02.03 Oversight of Contracted Activities. Applicants and designees who subcontract work (e.g., design, site characterization) to others (e.g., consultants, architect-engineering firms, nuclear steam supply vendors) should ensure that applicable regulatory requirements and QA program attributes are included 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 typically include the following QA program criteria:

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

35005-03 INSPECTION GUIDANCE

Verify the extent and effectiveness of the implementation of the Appendix B QA program as applied to quality activities, with particular emphasis on the areas listed below. When the applicant's controls differ from the requirements of Appendix B, an assessment will be made as to the significance of the differences with respect to the integrity and reliability of the data or analyses applied in support of the application.

03.01 QA Program. The QA processes applied during the development of the application will be reviewed during the QA program implementation section of this inspection procedure.

03.02 QA Program Implementation. Review the applicant's QA program controls using the applicable requirements of Appendix B as the basis of comparison. Review the applicant's and its contractors' activities in support of the application to verify implementation of the QA program(s). This review will include the following QA program attributes:

a. Design Control (SRP 17.5 Section II.C). Review a representative sample of the applicant's and its contractor's design packages and determine if design controls

have been adequately implemented. Select a sample of design packages where changes to previously verified designs were made, if applicable. A representative sample could include one structural and one major mechanical component or system with its related representative drawings and calculations prepared by the applicant and two or three of its contractors.

NOTE: For pre-COL Audits a representative sample could include a combination of design activities such as: (1) incorporating a design detail by reference to a certified or standardized design; (2) a design detail that is a deviation from the certified or standardized design; and (3) a design detail that requires site-specific characterization and design).

For the selected packages, verify that:

1. Design inputs, processes, output changes, interfaces, records, and organizational interfaces have been adequately implemented consistent with the applicant's and/or its contractor's quality program.

2. Design inputs (regulatory requirements, design bases, codes and standards, and test specification requirements) have been correctly translated into design outputs (specifications, drawings, procedures, and instructions).

3. Quality standards have been specified and included in design documents.

4. Changes or deviations from specified design requirements and quality standards have been identified, documented, and controlled.

5. Design documents have been reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements.

6. Computer data acquisition software and documentation have been controlled as required by the QA program.

7. Design verification has been performed consistent with the QA program. Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing.

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

9. Additional design verification has been performed when changes were made to previously verified designs, including evaluation of the effects of those changes on the overall design and on any design analyses.

b. Document Control (SRP 17.5 Section II.F). Review a representative sample of quality-related documents of the applicant and its contractors and determine if controls have been adequately implemented. A representative sample could include the same sample used for the evaluation of design control. For the selected documents, verify that:

1. Quality-related documents have been developed, reviewed, approved, issued, used, and revised under the established program.

2. Document changes of controlled documents, if any, have been reviewed and approved by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable.

3. The control system includes:

   (a) the identification of the controlled document

   (b) the specified distribution

   (c) the individual responsible for preparation, review, approval and distribution

   (d) a review for adequacy, completeness, and correctness

   (e) a method to ensure that correct and current documents are being used

c. Corrective Action (SRP 17.5 Section II.P). Review a representative sample of the applicant's and its contractors' identified problems and determine if the corrective action program was adequately implemented. A representative sample could include the applicant and two or three of its contractors. To the selected corrective action reports, verify that:

1. Conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances had been promptly identified and corrected.

2. For any identified significant conditions adverse to quality, the cause of the condition had been identified, and the corrective action taken to preclude its recurrence has been documented.

3. Appropriate levels of management had been reported of significant conditions adverse to quality and actions taken to correct them.

4. Corrective action controls had been extended to subcontractors and suppliers, when necessary.

d. QA Record Control (SRP 17.5 Section II.Q). Records are of great importance to the overall project administration. The applicant should have comprehensive procedures or instructions for generation and control and use of all QA/QC records subject to the QA program. Review a representative sample of records of the applicant and its contractors and determine if controls for the record preparation and retention have been adequately implemented. A representative sample could include the applicant and two or three of its contractors. To the selected sample of records, verify that:

1. Sufficient records to furnish documentary evidence of activities affecting quality have been prepared consistent with the program.

2. Design records included evidence that the design and design verification process were properly performed consistent with the program.

3. Administration, identification, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records have been adequately performed.

4. If an electronic records system is being implemented, an acceptable media on which electronic records are created and stored has been used. Reference: 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. Records have been stamped, initialed, authenticated or signed and dated by authorized personnel. If an electronic records system is being implemented, 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. Requirements for record retention, such as duration, location, and assigned responsibility, have been developed and implemented.

e. Training and Qualifications (SRP 17.5 Section II.S). Review a representative sample of training procedures and records for the applicant and its contractors and determine if procedures for indoctrination and training of personnel performing activities affecting quality have been adequately implemented consistent with the respective procedure or instruction. A representative sample could include the applicant and two or three of its contractors. Assess the training and qualification requirements by verifying that:

1. The indoctrination and training of personnel performing activities affecting quality has been performed consistent with the program.

2. Qualification records and certifications of personnel performing activities affecting quality exist and are certified in accordance with the program.

03.03 Oversight of Contracted Activities. Verify that the applicant's QA program provides adequate oversight of contracted activities in support of the application (i.e., COL development and early site characterization).

a. Procurement Control (SRP 17.5 Section II.D). Review a representative sample of the applicant's and its contractors' procurement documents and determine if controls have been adequately implemented. A representative sample could include the applicant and two or three of its contractors, if applicable. Select at least two procurement packages (in process or completed) for review. With the assistance of the cognizant procurement supervisor and in reference to the selected procurement packages, verify that:

1. Applicable regulatory requirements, technical requirements, and QA program requirements are included or referenced in procurement documents.

2. Procurement documents include the following provisions:

   (a) scope of work

   (b) specification of technical requirements

   (c) identification of test, inspection, and acceptance requirements

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

   (e) access to the supplier's plant facilities and records for inspection or audit

   (f) identification of the documentation and date of submission required to be submitted for information, review, or approval

   (g) requirements for reporting and approving the disposition of nonconformances

3. Procurement documents were adequately reviewed and approved consistent with the program. Procurement document changes are subject to the same degree of control as those utilized in the preparation of the original documents.

b. Control of Purchased Material, Equipment, and Services (SRP 17.5 Section II.G). Review a representative sample of the applicant's and its contractors' procurement documents and determine if controls for purchased material, equipment, and services have been adequately implemented. A representative sample could include the applicant and two or three of its contractors. For the selected procurement packages, verify that:

1. Source evaluation or audit, as necessary, was performed to assure the required quality of an item or service.

2. The control of the quality of purchased items or services, as appropriate, was implemented by reviewing objective evidence provided by the supplier, inspection or audit at the supplier's facilities, or examination of items upon delivery.

c. Audits (SRP 17.5 Section II.R). Examine a representative sample of the applicant's and its contractors' audits and determine that audits for procurement activities were planned and were conducted in a timely manner. Review at least two audits associated with procurement control to determine if QA controls were effectively implemented. Assess the adequacy of audits by verifying that:

1. A planned and periodic audit (triennial audit) was performed to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

2. Responsibilities and procedures for auditing, documenting, and reviewing audit results, and designating management levels to review and assess audit results have been adequately performed consistent with the program.

3. Follow up action of deficient areas were initiated when necessary.

35005-04 RESOURCE ESTIMATE

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"

Attachment 1: Revision History

END

Attachment 1

Revision History Sheet for IP 35005

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Ascension #
N/A	06/22/05	1. Initial issue to support inspection programs described in IMC 2502.	N	N/A	N/A
N/A	10/03/07 CN 07-030	1. Modified to support inspection program described in IMC 2501, IMC 2502, and IMC 2508. 2. Incorporated guidance of IP35004. 3. Incorporates guidance of SRP 17.5. 4. Completed 4 year historical CN search.	N	N/A	N/A
N/A	XX/XX/XX	1. Revised to expand applicability to audits of Pre-CP audits under 10CFR Part 50. ~~1.~~2. Minor editorial and formatting corrections.	No	N/A	ML112101747