QUALITY ASSURANCE IMPLEMENTATION INSPECTION

PROGRAM APPLICABILITY: 2501, 2502, and 2508

35017-01 INSPECTION OBJECTIVE

01.01 To verify that the applicant's NRC-approved quality assurance (QA) program was appropriately translated into implementing procedures

01.02 To verify that the implementing procedures are effective in support of the activities affecting quality conducted while an Early Site Permit (ESP), Combined License (COL), or Design Certification (DC) application (application) is under NRC review.

01.03 To verify that the applicant provides adequate oversight of contracted activities affecting quality and that contracted activities are being implemented in accordance with the applicant's NRC-approved QA program while the application is under NRC review.

This procedure is to be used in combination with the following inspection procedures, when applicable: Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformances," and IP 37802, "First-of-a-Kind Design Engineering Inspections."

35017-02 INSPECTION REQUIREMENTS

02.01 QA Program. The regulations in 10 CFR Part 52 require that a QA program that meets the requirements of Appendix B to 10 CFR Part 50 be approved by the NRC for DC, ESP, and COL quality-related activities. Verify that the description of the QA program applied to the design and to be applied to the fabrication, construction, and testing, of the safety-related structures, systems, and components (SSCs) of the plant include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied, including a discussion of how the QA program will be implemented.

02.02 QA Program Implementation. Verify that the applicant's NRC-approved QA program and associated procedures are implemented to demonstrate compliance with Appendix B to 10 CFR Part 50. Based on the scope of the activities described in the application, the inspection will typically include, but is not limited to, review of the following QA program criteria:

- QA Organization

- Design Control
- Corrective Action
- Audits (Internal)

02.03 Oversight of Contracted Activities. Applicants and its designees who subcontract activities affecting quality (e.g., design, site characterization) to others (e.g., consultants, architect-engineering firms, nuclear steam supply vendor) shall ensure that procurement documents include applicable regulatory requirements and QA program attributes. Verify that the applicant's audit of contractor activities ensure establishment and implementation of each QA program attribute in accordance with the applicant's NRC-approved QA program. The inspection in this area typically includes the following QA program criteria:

- Procurement Control
- Audits (External)

35017-03 INSPECTION GUIDANCE

General Guidance

03.01 QA Program.

a. Verify that the applicant has adequate controls in place for ensuring that the applicable portion of the QA program is properly documented, approved, and implemented (personnel are trained and resources are available) before an activity within the scope of the QA program is undertaken.

03.02 QA Program Implementation. Verify the implementation of the applicant's NRC-approved QA program and that associated procedures demonstrate compliance with Appendix B to 10 CFR Part 50. Based on the scope of the activities described in the application, the inspection will typically include, but is not limited to, the following QA program criteria:

a. QA Organization.

    1. Verify that the applicant's QA program identifies individuals responsible for implementation of QA/Quality Control procedures or instructions.

    2. Verify that the QA program establishes and maintains adequate qualification requirements for QA personnel at all levels of the organization.

    3. Verify that the QA program establishes controls for the review and approval of QA program procedures and instructions, including revisions to these documents.

b. Design Control.

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

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

3. Verify that provisions exist to ensure that design documents specify and include appropriate quality standards and requirements.

4. Verify that provisions exist to ensure the identification, documentation, and control of changes or deviations from specified design requirements and quality standards.

5. Verify that the QA program provides for documented indoctrination and training of personnel performing design activities affecting quality to ensure that proficiency is achieved and maintained.

6. Verify that the QA role in design and analysis activities is adequately defined. Specifically, verify that individuals that are knowledgeable and qualified in QA review design documents to ensure the documents contain the necessary QA requirements.

7. Verify that provisions exist for the control of computer programs used for design analysis and documentation as required by the QA and software procurement programs.

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

9. 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, ensure that the unverified portions of the design are identified and controlled to be later verified.

10. Verify that the QA program provides for additional design verification when changes are made to previously verified and approved designs. This includes evaluating the effects of changes on the overall design and on any design analyses or bases.

Specific Guidance. Review a representative sample of the applicant's and its contractors' design documents and verify that design controls have been adequately implemented. Review a sample of training records for the personnel performing design activities to verify that procedures for indoctrination and training of personnel performing activities affecting quality have been adequately implemented. Select a sample of design change documents to verify that changes were subject to design control measures commensurate with those applied to the original design and the effects of the changes on the overall design and any analyses were evaluated, if applicable. A representative sample could include the applicant and two or three of its contractors.

c. Corrective Action.

1. Verify that measures exist to ensure 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 properly identified and the corrective action taken to preclude its recurrence is documented.

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

4. Verify that the QA program provides for the establishment of requirements to ensure that, when appropriate, corrective action controls extend to subcontractors and suppliers.

5. Verify that the process to control nonconformances provides a connection to the 10 CFR Part 21 procedures. No assessment of the evaluation and reporting of deviations or failures to comply is necessary as this will be completed in accordance with IP 36100.

Specific Guidance. Review a representative sample of the applicant's and its contractors' corrective action documents and records and verify that the corrective action program was adequately implemented. A representative sample could include documents of the applicant and two or three of its contractors.

d. Audits (Internal).

1. Verify that internal audits are performed to confirm that activities affecting quality comply with the NRC-approved QA program and have been implemented effectively.

2. Verify that audits of all elements of the QA program are performed, or scheduled to be performed, within a 2-year period.

3. Verify that responsibilities and procedures for auditing, documenting and reviewing audit results, and designating management levels to review and assess audit results are established and implemented.

4. Verify that corrective actions associated with audit findings are, or are scheduled to be, implemented.

5. Verify that audits are accomplished using approved procedures by qualified personnel.

03.03 Oversight of Contracted Activities. Verify that the applicant's QA program provides adequate oversight of contracted activities for the scope of quality related activities conducted during the application review phase (e.g., Design Engineering Services, long lead component procurement, First-of-a-Kind engineering, etc.). This review will include the following QA program attributes:

a. Procurement Document Control.

1. Verify that provisions exist to ensure that procurement documents include or incorporate by reference applicable regulatory requirements, technical requirements, and QA program requirements.

2. Verify that procurement activities are conducted in accordance with appropriate QA procedures.

3. Verify that procurement documents include the following provisions, if applicable:

(a) Scope of work,
(b) Specification of technical requirements,
(c) Identification of test, inspection, and acceptance requirements,
(d) Supplier's documented QA program meets the applicable requirements of Appendix B to 10 CFR Part 50 (a supplier may work in accordance with 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, and
(g) Requirements for reporting and approving disposition of nonconformances,

4. Verify that procurement documents invoke 10 CFR Part 21, "Reporting of Defects and Noncompliance," requirements.

5. Verify that provisions exist for the review and approval of procurement documents. Ensure that changes to procurement documents are subject

to the same degree of control, review, and approval as those utilized in the preparation of the original documents.

Specific Guidance. Review a representative sample of the applicant's and its contractors' procurement documents, and verify that controls have been adequately implemented. A representative sample could include documents of the applicant and two or three of its contractors.

b. Audits (External).

1. Verify that audits are performed to confirm that activities affecting quality comply with the NRC-approved QA program and have been implemented effectively.

2. Verify that triennial audits are performed, or scheduled to be performed, of the applicant's contractors' QA programs.

3. Verify that responsibilities and procedures for auditing, documenting and reviewing audit results, and designating management levels to review and assess audit results are established.

4. Verify that corrective actions associated with audit findings are, or are scheduled to be, implemented.

5. Verify that audits are accomplished using approved procedures by qualified personnel.

Specific Guidance. Review a representative sample of the applicant's and its contractors' audit reports and verify that controls have been adequately implemented. A representative sample could include reports of the applicant and two or three of its contractors, if applicable.

35017-04 RESOURCE ESTIMATE

This inspection procedure verifies the implementation of the QA program that was approved by the NRC as part of an ESP, COL, or DC 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.

35017-05 REFERENCES

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

Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance."

Inspection Procedure 37802, “First-of-a-Kind Design Engineering Inspections.”

END

Attachment: Revision History Sheet for IP 35017

Attachment 1

Revision History Sheet for IP 35017

Quality Assurance Implementation Inspection

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
NA	06/22/2005	Initial Issue	None	Not Applicable	
NA	07/29/08 CN 08-021	Complete re-write. Change Program Applicability to include MC 2501 and 2508. Revision to align with NUREG-0800	None	Not Applicable	ML081420178