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PRE-DOCKETING EARLY SITE PERMIT QUALITY ASSURANCE CONTROLS INSPECTION

PROGRAM APPLICABILITY: 2501

35004-01 INSPECTION OBJECTIVE

To ascertain whether the applicant's proposed quality assurance (QA) program, as applicable to elements of early site permit (ESP) activities, is consistent with Appendix B to 10 CFR Part 50.

35004-02 INSPECTION REQUIREMENTS

02.01 QA Program. The applicant's QA controls must be in compliance with the Appendix B to 10 CFR Part 50 requirements. A pre-docketing audit of the applicant's QA controls facilitates review of the ESP application. The decision to perform this audit will be made on a case-by-case basis with agreement by the potential applicant.

02.02 Pre-Docketing QA Controls Audit Objective. Provide an assessment of the effectiveness and implementation of QA controls at this stage in the ESP application development to facilitate and support early identification of issues and support timely completion of the ESP application review following submission of the application. The staff will inspect a suitable sample of in-process ESP- related site characterization activities to verify consistent implementation of QA controls.

35004-03 INSPECTION GUIDANCE

General Guidance

A QA control substantive finding is a deficiency that (1) reflects a significant departure from established NRC and industry standards and (2) results in a lack of assurance of the integrity and reliability of the ESP data or analyses.

The current regulations in 10 CFR Part 52 require that a Part 50 Appendix B quality assurance program be implemented in support of ESP applications. Guidance for assessing the attributes of the applicant's QA controls is provided in SRP 17.5.

ESP activities involve site characterization. Typical site characterization activities involve data collection, analysis, and evaluation for soil composition, geology, hydrology, meteorology, and seismology. Additionally, data information obtained from recognized authorities, such as the National Oceanic and Atmospheric Administration, must be controlled using processes for maintaining data integrity, traceability, document control, evaluation, analysis, and record storage consistent with Appendix B to 10 CFR Part 50, to the extent such activities would affect future SSCs important to safety.

03.01 QA Program. Verify that the applicant's QA program is consistent with the guidance contained in SRP Section 17.5. The applicant's QA program should provide reasonable assurance of the integrity and reliability of ESP data or analyses that would affect the performance of future SSCs important to safety. In particular, the staff will assess the following attributes of the QA program:

1. Verify that the QA program is applied to all ESP related activities that would affect data or analyses used to design and construct future SSCs important to safety.

2. 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.

3. Verify that the QA program includes programmatic measures to the extent necessary for personnel from the applicant's organization to make a determination during each phase of the project that an acceptable program has been established and is being implemented in accordance with the requirements of the program.

4. Verify that preparation of analysis, calculations, design drawings, specifications and procurement documents, related verification reviews, and control of engineering documents and changes thereto are being controlled in a consistent manner.

03.02 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 staff will consider the following quality control attributes during this audit:

a. Instruction, Procedures, and Drawings (SRP 17.5 Section II.E). Review a sample of instructions and procedures and Verify that documented instructions, procedures, and drawings are used for site characterization activities.

b. Test Control (SRP 17.5 Section II.K). Review QA program controls for testing. This review will include the following:

   1. Verify that a test program is established to assure that all testing required to demonstrate that systems and component(s), as applicable, will perform satisfactorily in service, is identified and performed in accordance with written test procedures which incorporate or reference the requirements and acceptance limits contained in the applicable design documents.

   2. Verify that test procedures include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that testing is performed under suitable environmental conditions.

   3. Verify that the QA program provides for test results to be documented and evaluated to assure that test requirements have been satisfied.

   Specific Guidance. Review a sample of completed tests and determine if controls for testing have been adequately implemented.

c. Control of Measuring and Test Equipment (SRP 17.5 Section II.L). Review QA program controls for calibration. This review will include the following:

   1. Verify that measures are established to assure that tools, gages, instruments, and other inspection, measuring, and testing equipment and devices used in activities affecting quality are of the proper range, type, and accuracy to verify conformance to established requirements.

   2. Verify that the QA program provides for inspection, measuring, and test equipment to be controlled, calibrated, adjusted, and maintained at prescribed intervals, using national standards as a basis for calibration, when such standards are available.

   3. Verify that the QA program provides for special calibration or maintenance of test equipment when accuracy is suspect, and verification of the validity of previous inspections and test results.

   4. Verify that the results of calibration is documented.

   Specific Guidance. Review a sample of measuring and test equipment and determine if controls for calibration have been adequately implemented.

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d. Handling, Storage, and Shipping (SRP 17.5 Section II.M). Review QA program controls for handling and storage. This review will include the following:

1. Verify that instructions for marking and labeling for packaging, handling and storage of items have been established to adequately identify, maintain, and preserve the item, including indication of special environments or the need for special controls.

2. Verify that special protective measures (e.g., containers, special moisture content levels, and temperature levels) have been specified and provided to maintain acceptable quality.

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

e. Corrective Action (SRP 17.5 Section II.P). Review the corrective action program. Verify that measures exist to identify and resolve non-conformance and conditions adverse to quality. Review a sample of identified problems and determine if the facility adequately implemented these controls.

f. Procurement Control. 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.

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g. 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.

h. 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.

35004-04 RESOURCE ESTIMATE

The resource estimate for this inspection procedure is approximately 120 hours of direct inspection effort.

35004-05 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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