INSPECTION PROCEDURE 35004

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 suitable for being implemented without substantive deviations.

35004-02 INSPECTION REQUIREMENTS

02.01 Audit Planning. As applicable, conduct a pre-docketing audit of the applicant's QA controls to facilitate 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.

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.

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.

Guidance for assessing the attributes of the applicant's QA controls is provided in Review Standard (RS) 002, Section 17.1.1, "Early Site Permit Quality Assurance Controls."

The current regulations in 10 CFR Part 52 do not require that a Part 50 Appendix B quality assurance program be implemented in support of ESP applications. However, ESP activities associated with site safety should be controlled by QA measures sufficient to provide reasonable assurance that information used as input for design or construction of future systems, structures, and components (SSCs) important to safety, would not adversely impact their ability to perform satisfactorily in service. The regulations in 10 CFR 52.39, with certain exceptions, require the Commission to treat matters resolved in an ESP proceeding as resolved in making findings for issuance of a construction permit, operating license, or combined license (COL). Because of this finality, conclusions made during the ESP phase will be relied upon for use in the subsequent design, construction, fabrication, and operation of a reactor that might be constructed on the site for which an ESP is issued.

For these reasons, applicants must apply quality controls to each ESP activity associated with the generation of design information for future SSCs important to safety that are equivalent to the controls specified in Appendix B for similar activities. The staff plans to evaluate quality controls for such activities using the criterion that these controls shall be equivalent in substance to controls specified in Appendix B.

Specific Guidance

03.01 Audit Planning

a. If the applicant has agreed to the conduct of a pre-docketing QA controls audit, the staff shall request that the applicant provide information related to the QA controls applied to ESP activities. An applicant may choose to submit a QA program description to more efficiently provide this QA control information. If an applicant does not voluntarily submit a description of the ESP QA controls, the staff will discontinue use of this procedure and resume audits of the QA controls after the application is received.

b. The staff will review the applicant's QA control framework to determine if the quality related activities are consistent with the guidance contained in Section 17.1.1 of RS-002. The applicant's QA controls should be equivalent in substance to the guidance in Section 17.1.1 to 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 control framework:
   1. QA controls are applied to all ESP related activities that would affect data or analyses used to design and construct future SSCs important to safety.

2. The QA control framework should be established such that the applicant retains the responsibility for the establishment and execution of all QA controls, including those aspects of the program delegated to contractors and consultants.

3. For applicants who delegate the authority for design to others (consultants, architect-engineering firms, nuclear steam system supply vendor), the staff will review the applicant's applicable procurement and vendor surveillance program instructions. Where the applicant has delegated design or procurement activities to others, the review shall examine the applicant's surveillance of contractor activities to assure that each delegated element of ESP QA controls is being established and executed consistently.

4. The ESP QA control framework should include 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.

5. 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 Pre-Docketing QA Controls Audit Guidance

a. 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, will be controlled using processes for maintaining data integrity, traceability, document control, evaluation, analysis, and record storage that are equivalent in substance to those described in Appendix B to 10 CFR Part 50, to the extent such activities would affect future SSCs important to safety. The staff will consider the following quality control attributes during this audit:

1. Documented instructions, procedures, and drawings are used for site characterization activities.

2. Measures are implemented for test control and control of special processes.

3. Measures exist to identify and resolve non-conformance and conditions adverse to quality.

4. For site characterization activities performed by vendors, appropriate oversight and procurement controls are implemented.

b. Assessment of Acceptability of QA Controls

1. Section 17.1.1 of RS-002 provides guidance for determining the acceptability of QA program implementation. The Equipment and Human Performance Branch of NRR will review the applicant's QA control framework for consistency with Section 17.1.1.

2. With respect to completing the inspection requirements of this procedure, should the inspector question the sufficiency or appropriateness of the guidance contained in RS-002 to determine acceptability of the applicant's QA controls, the inspector will bring the matter to the attention of Equipment and Human Performance Branch (IEHB) management by a memorandum.

3. The region may perform an independent review of the applicant's QA controls for ESP activities for consistency with Section 17.1.1 of RS-002. Substantive inconsistencies will be identified in writing to IEHB as they may represent a "lack of control" by the applicant.

4. The Region may consult by telephone with IEHB as may be appropriate. It is important that IEHB be provided with complete comments before IEHB issues a substantive QA findings. Early discussions may result in highlighting other considerations not readily apparent in the application.

5. Inspection Procedure 35012, "Early Site Permit Quality Assurance Controls Assessment and Conclusion," provides guidance for evaluating and resolving pre-docketing ESP QA control findings and determining if substantive deviations exist. Inspection Procedure 35006, "Post-Docketing Early Site Permit Quality Assurance Controls Inspection," provides additional guidance related to the review of an applicant's ESP QA controls.

35004-04 RESOURCE ESTIMATE

This inspection procedure supports review of an ESP application per the guidance contained in Section 17.1.1 of RS-002. The resource estimate for this inspection procedure is approximately 120 hours of direct inspection effort.

35004-05 REFERENCES

Review Standard (RS) 002, Section 17.1.1, "Early Site Permit Quality Assurance Controls."

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