POST-DOCKETING EARLY SITE PERMIT QUALITY ASSURANCE CONTROLS INSPECTION

PROGRAM APPLICABILITY: 2501

35006-01 INSPECTION OBJECTIVE

Ascertain whether the applicant's quality assurance (QA) program, as applicable to elements of early site permit (ESP) activities, was implemented without substantive deviations.

35006-02 INSPECTION REQUIREMENTS

02.01 QA Control Framework Document. The staff will review the applicant's QA control framework document to determine if the quality- related activities are consistent with the guidance contained in Section 17.1.1 of RS 002, "Early Site Permit Quality Assurance Controls." 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 safety-related SSCs.

02.02 QA Control Implementation. The inspector will verify that the applicant's QA controls were effectively implemented. This review will include the following QA control attributes:

- QA Organization
- Design Control
- Procurement Control
- Supplier/Contractor Surveillance
- Corrective Action
- QA Record Control
- Audits

02.03 Resolution of Issues From Pre-Docketing QA Inspection. If a pre-docketing inspection was performed, the inspectors will review issues that were either (1) found unacceptable, (2) not examined because QA manual provisions were identified as unacceptable, or (3) not examined because related activities were not in progress during the pre-docketing inspection but were underway during the post-docketing inspection.

35006-03 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 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 specific 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 QA Control Framework Guidance

If not otherwise provided in the ESP application, the staff will issue a request for additional information (RAI) to obtain information related to the QA controls applied to ESP activities in order to provide reasonable assurance of the integrity and reliability of data that would affect the performance of future safety-related SSCs. Applicants may choose to submit a QA program description to more efficiently provide this QA control information.

In the process of reviewing the applicant's QA control framework for the ESP application, the inspector will:

a. Avoid repetition of reviews in areas of the QA control framework previously found acceptable.

b. Complete reviews in areas of the program not previously examined because activities were not underway at that time but now are repeat reviews of all revised QA manual provisions, with specific attention given to instructions previously identified as unacceptable.

Section 17.1.1 of RS-002, "Processing Applications for Early Site Permits," provides guidance for determining the acceptability of QA program implementation. The Equipment and Human Performance Branch (IEHB) of NRR will review the applicant's QA control framework for consistency with Section 17.1.1.

03.02 QA Control Implementation Guidance. The inspector's review of the QA control implementation will include the following QA control attributes:

a. QA Organization

1. The applicant's QA control framework should identify individuals responsible for implementation of QA/QC procedures or instructions. The applicant should establish qualification requirements for QA personnel for at all levels of the organization.

2. Review controls for the review and approval of QA control procedures and instructions. Persons who prepare procedures for control of their own work should not have final approval responsibility regarding acceptable translation of QAM requirements within the same procedures.

b. Design Control. As applicable to ESP activities at the proposed site, the inspector will review QA controls for design activities. This review will include the following QA control attributes:

1. QA/QC procedures are readily available.

2. Engineering personnel are knowledgeable of QA control requirements.

3. Procedures exist for review of calculations, drawings, specifications, and procurement documents.

4. Training on QA control requirements was conducted for personnel involved in design activities.

c. Procurement Control. Ascertain whether the implementation of the QA controls for activities listed below is consistent with the status of procurement activities in process. Where possible, selections will relate to individuals, activities, and/or areas of the implemented QA program not previously selected for examination during the pre-docketing inspection.

1. The organization is staffed as described in the QA controls for QA personnel and others performing activities affecting quality.

2. QA staff personnel responsible for procurement demonstrate knowledge of applicant's ESP QA controls.

3. The current QA/QC procedures to control the activities of procurement are in use to the extent applicable (examine one set).

4. Examine the schedule and records of internal/external applicants ESP QA controls 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.

5. Select at least two procurement packages (in process or completed) for review. With the assistance of the cognizant procurement supervisor or buyer and in reference to the selected procurement packages, ascertain whether:

   (a) QA/QC procedures for procurement control are readily available.

   (b) Purchasing agents and buyers are knowledgeable of the applicant's ESP QA controls requirements.

   (c) Prior to requests for quotations:

      (1) Drawings and specifications were reviewed and approved.

      (2) Supplier capability was evaluated.

      (3) Final procurement package was reviewed.

      (4) Authorization to request quotations was granted

   (d) Subsequent to receipt of quotations:

      (1) Quotation was compared to procurement package.

      (2) Technical exceptions were evaluated.

      (3) Authorization of contract award follows the prescribed procedures or instructions

   (e) Records reflecting the above are available.

   (f) Training was conducted for procurement QA/QC personnel.

d. Supplier/Contractor Surveillance. As applicable, ascertain if the applicant adequately monitored and controlled ESP- related activities performed by contractors and suppliers. The inspector must at all times keep in mind that this is an inspection of the applicant and *not* of the contractor. The primary purpose of the inspections will be to examine the implementation of applicant's QA control surveillance responsibilities by doing the following:

1. Select at least two contracts for review, preferably one involving the procurement of services and the second involving material and equipment.

2. Review and evaluate the adequacy of procurement QA controls relating to the applicant's conduct of the following contractor surveillance activities:

   (a) Execution of surveillance by members of the applicant's organization.

   (b) Identification and summarization of deficiencies.

   (c) The attainment of planned surveillance objectives.

   (d) The attainment of required and timely contractor corrective actions.

e. Site Testing and Evaluation. Site testing and evaluation will be performed under Inspection Procedure 45051, "Geo-technical/Foundations Activities Procedure Review."

f. Corrective Action. Corrective action is an area of major importance and is applicable to all ESP activities important to safety. The applicant should have detailed procedures or instructions covering the following items:

   1. Identification and correction of the causes of significant or reoccurring deviation relating to site testing and evaluation or other ESP activities important to safety.

   2. Identification and correction of generic deviations

   3. Documentation of corrective actions

   The inspector will review a suitably sized sampling of identified problems to verify the applicant adequately implemented these controls.

g. QA Record Control. Records are of great importance to the overall project administration; thus, adequate coverage in the QA manual is a necessity. The applicant should have comprehensive procedures or instructions for generation and control and use of all QA/QC records subject to the QA program. These procedures or instructions should address the following attributes of QA record control:

   1. Types of records required for various levels of management reviews

   2. Types of records required at project level for each activity

   3. Standards for content and quality of:

      (a) Design and procurement document technical records

      (b) Design and procurement document quality verification records

4. Assignment of responsibility for records

5. Protection and preservation of records

h. Audits. The inspector will verify that the applicant has detailed procedures or instructions covering the following items:

1. Procedures identify auditor positions having responsibility for applicant internal or external audits of design, procurement, vendor surveillance, and site testing and evaluation

2. The authority and responsibilities of QA audit personnel are clearly defined.

3. Qualification requirements, including the maintenance thereof are clearly defined.

4. The accountability (reporting channels) of QA audit personnel should be identified.

5. Standards should be provided to measure performance and effectiveness of audited activities.

6. Audit procedures and methods should be described in QA control framework as appropriate for each phase of the project.

7. Access of auditors to activities to be audited should be assured.

8. Access of auditors to responsible management should be assured.

9. The audit reporting process and standards for content of audit records should be defined.

10. Procedures must provide the means for the auditor to verify corrective actions initiated by the audited organization.

11. Criteria should be provided for determining when to perform routine audits, when special followup is required to verify resolution of significant audit findings, and frequency of routine followup audits.

12. The current auditing schedule is included in QA control framework.

13. Measures, other than followup audits, are provided to assure corrective action followup by the audited organization if necessary .

The inspector will review a suitable number of completed audits to verify that controls for the performance of audits have been adequately implemented.

03.03 Resolution of Issues From Pre-Docketing QA Inspection Guidance. For areas found to be unacceptable, the applicant should have responded to and corrected any substantive concerns identified during the pre-docketing inspection. If other program

deviations or unresolved items were identified in the pre-docketing QA control inspection report issued, the inspector will review the applicant's response to these issues. The inspector will verify the of corrective actions, the adequacy of revised QA control procedures and instructions, and the acceptability of program implementation or ongoing activities.

Refer to Inspection Procedure 35012, "Early Site Permit Quality Assurance Controls Assessment and Conclusion," for additional guidance on the evaluation and resolution of ESP QA control inspection findings and substantive deviations.

35006-04 RESOURCE ESTIMATE

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

35006-05 REFERENCES

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

Inspection Procedure (IP) 35012, "Early Site Permit Quality Assurance Controls Assessment and Conclusion."

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