INSPECTION PROCEDURE 35002

EARLY SITE PERMIT PRE-DOCKETING QUALITY ASSURANCE CONTROLS MEETING

PROGRAM APPLICABILITY: 2501

35002-01 MEETING OBJECTIVE

To inform potential applicants of the pre-docketing and post-docketing reviews and inspections of the quality assurance controls expected for early site permit (ESP) activities.

35002-02 MEETING REQUIREMENTS

02.01 Early QA Program Meeting Agenda. The staff will meet with the applicant prior to submission of the ESP application (preferably prior to commencement of significant site characterization activities) to discuss what QA controls are acceptable for ESP activities.

The meeting will address the following topics:

a. Introduction by the Equipment and Human Performance Branch (IEHB)

b. Submittal and review of QA program description (IEHB)

c. ESP QA program areas of emphasis (IEHB)

d. Proposed ESP QA controls (applicant)

02.02 Meeting Responsibilities

a. IEHB

1. Schedule, coordinate and conduct the meeting.

2. Issue meeting summary as required by NRR Office Instruction COM-202, “Meetings With Applicants, Licensees, Vendors, or Other Members of the Public.”

b. Regional

1. Prior to the meeting, IEHB and Regional meeting representatives will discuss the meeting agenda and objective.

2. Regional inspection personnel will participate in the ESP pre-docketing QA controls meeting. The regional representative will provide background information to support subsequent regional QA program reviews conducted in accordance with Inspection Procedure 35004, “Pre-Docketing Early Site Permit Quality Assurance Controls Inspection,” and IP 35006, "Post-Docketing Early Site Permit Quality Assurance Controls Inspection.”

35002-03 INSPECTION GUIDANCE

General Guidance

The current regulations in 10 CFR Part 52 do not require that a 10 CFR Part 50, Appendix B, QA 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 SSCs’ 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. The applicant’s proposed QA controls for ESP activities should be 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. The meeting is conducted prior to submittal. The purpose of the meeting is to provide the applicant with information related to the staff review of QA controls for ESP activities and to develop an understanding of the licensee’s proposed QA program, as applicable to ESP activities. Two to three NRC staff members, including representation from the associated regional office will conduct the meeting.

Specific Guidance

03.01 Meeting Agenda

a. IEHB will provide a brief overview of pre-Docketing ESP QA control review activities, including associated inspection procedures (IPs). The QA controls review is performed in accordance with Review Standard (RS)-002, Section 17.1.1, “Early Site Permit Quality Assurance Controls.” Typical ESP QA control inspection activities include the following:

1. ESP Pre-Docketing Quality Assurance Controls Meeting (IP 35002)

2. Pre-Docketing Early Site Permit Quality Assurance Controls Inspection (IP 35004)

3. Post-Docketing Early Site Permit Quality Assurance Controls Inspection (IP 35006)

4. Early Site Permit Quality Assurance Controls Assessment and Conclusion (IP 35012)

b. Pre-Docketing Review of ESP QA Controls

1. IEHB may conduct a pre-docketing audit of the applicant's QA controls to facilitate the ESP application review. 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. The decision to perform this audit will be made by IEHB on a case-by-case basis with agreement by the potential applicant. Since the pre-docketing review places particular emphasis on ongoing ESP activities, the audit will be conducted during a period of significant site characterization activities.

2. Note that discussions of details regarding the significance of issues identified during the initial review may be deferred to the performance of the post-docketing review and audit of QA controls.

3. If a pre-docketing QA controls review is performed, the review will be conducted in accordance with the guidance contained in RS-002, Section 17.1.1, and IP 35004.

c. Post-Docketing Review of ESP QA Controls

1. The IEHB post-docketing review covers QA controls to be applied by the applicant and principal contractors to activities that may affect the capability of future SSCs important to safety to perform adequately in service. This review and associated inspections are performed shortly after tendering of an early site permit application to determine that satisfactory QA controls have been established and implemented. The scope of this review includes determination of the equivalence between the applicant's proposed QA controls and the applicable requirements contained in the 18 criteria of 10 CFR Part 50, Appendix B.

2. 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.

3. The post-docketing QA controls review will be conducted in accordance with the guidance contained in RS-002, Section 17.1.1, and IP 35006.

4. The staff will emphasize that the unavailability of a description of the QA controls implemented for ESP activities, incomplete information, or significant deviations from the guidance of Section 17.1.1 of RS-002 may result in considerable delays in completing the application review.

d. General Guidance for ESP QA Controls. The following areas will be reviewed, from the perspective that they are indicators of the effectiveness of quality assurance controls. QA controls must provide reasonable assurance of integrity and reliability of data that might affect design or operation of future SSCs important to safety. Appendix B to 10 CFR part 50 defines a substantive and procedural framework of controls that collectively help provide such assurance, and that framework has been

proven through many years of licensing and operation of commercial nuclear power plants. However, any deficiencies in the applicant's QA controls will be cited based on lack of assurance of the integrity and reliability of the information in question, without reference to Appendix B. The applicant may choose to use different methods of ensuring quality from those described below. In such cases, the staff will evaluate the applicant's controls for adequacy, with the expectation that they will be equivalent in substance to those stated below.

The staff will briefly discuss the Appendix B criteria and their application to all ESP activities that would affect SSCs important to safety. Note that the quality assurance requirements apply to all these activities, not just those activities subsequent to submittal of the ESP application. Furthermore, a principal objective of the staff's review is to determine that the applicant has evaluated the acceptability of contractor programs prior to contract award and that the applicant is maintaining effective oversight of contractor programs.

IEHB will describe focus areas of emphasis for the ESP QA controls review. Although these focus areas are expected to vary depending of the type of planned ESP- related activities, the discussion will include the following topics:

e. The applicant will describe the QA organizational structure and program that will be used for ESP- related activities.

   1. The QA program should address the control of ESP activities related to the preparation of safety-related analyses, calculations, design drawings, specifications and procurement documents, related verification reviews, and control of engineering documents and changes thereto which support the plant parameter envelope.

   2. The applicant's ESP QA controls should address procurement controls exercised for ESP related activities. These may include awards and contract activities.

   3. Clarify that the staff's conclusions will consider if the applicant's QA controls are equivalent in substance to 10 CFR 50, Appendix B and the impact of QA control deviations on the reliability and integrity of ESP derived data and analyses. Substantive findings related to the ESP QA Program are discussed in IP 35012, "ESP Quality Assurance Controls Assessment and Conclusion" and may result in not docketing the application.

   4. Discuss the acceptability of using other methods for implementing Appendix B requirements and the staff's process for evaluating other methods proposed by applicants. Staff guidance for the review of ESP QA controls is contained in Section 17.1.1 of RS-002.

f. Special Reporting Requirements. Emphasize the applicability of the 10 CFR part 21 reporting requirements to contracts for activities conducted prior to submission of the application. Note that the applicant should have procedures specifying how these requirements are met, and that the procedures must conform with the QA program.

g. Proposed QA Controls. The applicant should make a presentation on planned QA controls for ESP activities. In order to facilitate an efficient NRC review of the QA controls, the applicant should identify significant ESP- related activities and describe their proposed schedule.

03.02 Meeting Responsibilities

No Guidance

The inspectors will review the most recent revision to Section 17.1.1 of RS-002.

35002-04 RESOURCE ESTIMATE

This inspection procedure supports the review of an ESP application per the guidance contained in Section 17.1.1of RS-002. The resource estimate for this inspection procedure is approximately 72 hours of total effort.

35002-05 REFERENCES

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

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