

NRC INSPECTION MANUAL

IIPB

INSPECTION PROCEDURE 35012

EARLY SITE PERMIT QUALITY ASSURANCE CONTROLS ASSESSMENT AND CONCLUSION

PROGRAM APPLICABILITY: 2501

35012-01 INSPECTION OBJECTIVE

Provide a summary evaluation of early site permit (ESP) quality assurance (QA) control audit findings and to provide guidance on documenting conclusions regarding the QA control summary evaluation.

35012-02 INSPECTION REQUIREMENTS

02.01 Assessment of QA Controls

- a. After completing the evaluation of the QA controls in accordance with Inspection Procedures 35004 and/or 35006, the NRR Equipment and Human Performance Branch (IEHB) shall prepare and forward the ESP QA Assessment and Conclusion memorandum to the applicable regional administrator and project manager.
- b. The applicable NRR project manager will complete a review of the assessment and conclusions and forward the conclusions to the applicant.
- c. If substantive findings exist in the applicant's QA controls, a meeting will be held with the applicant to discuss the QA deficiencies.

02.02 Evaluation of Inspection Findings. The inspector, with assistance from IEHB staff, shall evaluate the significance of all findings identified during the review of the applicant's ESP QA controls. The significance of a finding is based on the impact of the finding on the integrity and reliability of site characterization data and analysis.

IEHB shall thoroughly assess whether the QA controls are adequate and make a determination on whether substantive findings exist.

02.03 Prepare IEHB QA Assessment and Conclusions. Based on the determination made during completion of the review, IEHB shall prepare the IEHB QA Assessment and Conclusion memorandum. A sample format for the QA Assessment and Conclusion memorandum is provided in the attachment to this procedure.

02.04 Conduct Substantive QA Finding Meeting With Applicant (if required). If substantive findings are identified during the ESP QA controls review, a meeting with the applicant will be conducted to discuss the QA deficiencies.

35012-03 INSPECTION GUIDANCE

General Guidance

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 (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.

The staff will not make findings based directly on QA control equivalence to 10 CFR Part 50, Appendix B. Rather, staff findings will be based on whether or not the applicant has provided adequate controls to provide reasonable assurance of the integrity and reliability of site-related data used as input in design or operation of future SSCs important to safety. Therefore, any weaknesses in the applicant's QA controls will be evaluated for their effect on integrity and reliability of data supporting the ESP application

Specific Guidance

03.01 Assessment of QA Controls. 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.

03.02 Evaluation of Inspection Findings. The inspector will identify a QA control finding for each significant deviation from the NRC QA guidance contained in Section 17.1.1 of Review Standard (RS) 002. The inspector will then determine the impact of the QA control deviation on the reliability and integrity of ESP related data and analysis. A QA control finding should be considered to be a substantive finding when it results in any of the following conditions:

- a. An activity important to safety related to site characterization data or analysis was not performed as required.
- b. An activity important to safety related to site characterization data or analysis was performed incorrectly.
- c. The applicant lacks objective evidence to establish that the activity important to safety related to site characterization data or analysis was adequately completed.

As an example, if the QA control framework does not provide instructions or procedures addressing an ESP activity important to safety, or if specified QA controls were not implemented, this finding by itself is not a sufficient basis for identifying an ESP QA control substantive finding. However, if the inspector also identified a deficiency in the end product (e.g., inaccurate site characteristics data, drawing specification) related to the lack of instructions or procedural controls, this issue would have sufficient substance by itself to identify a substantive finding. As a practical matter, if such site characterization data or analyses were not obtained using procedures or instructions, the applicant would be expected to provide significantly more information to provide reasonable assurance in the integrity and reliability of the data.

03.03 Preparation of Quality Assurance Assessment and Conclusions Memorandum. Refer to the attachments to this procedure for sample guidance regarding the format of the Quality Assurance Assessment and Conclusion memo from IEHB to the project manager.

The region will perform an evaluation of the IEHB substantive findings before IEHB issues the Quality Assurance Assessment and Conclusion memorandum.

03.04 Meeting Guidance

- a. The applicable NRR project manager will schedule the meeting and notify the applicant.
- b. IEHB will inform the applicant of the elements and/or parts of the QA control framework that were not consistent with NRC guidance. The IEHB staff will clearly identify which of the findings require corrective actions prior to a subsequent QA control review.

- c. A pre-meeting discussion between IEHB, the applicable NRR project manager, and regional personnel will be conducted to prevent any inconsistency at the meeting.
- d. The level of staff in attendance at the meeting will depend on the extent of the discussions of the finding(s).
- e. The meeting will be briefly summarized in the NRC meeting minutes. All communications associated with this meeting shall be consistent with NRR Office Instruction COM-202, "Meeting With Applicants, Licensees, Vendors, and Other Members of the Public."

35012-04 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 152 hours of direct inspection effort.

35012-05 REFERENCES

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

NRR Office Instruction COM-202, "Meeting With Applicants, Licensees, Vendors, and Other Members of the Public."

END

Attachment: Sample Memo

ATTACHMENT - SAMPLE MEMO

Date

TAC No(s).

MEMORANDUM FOR: Name [Project Manager]
 Project Directorate [Region]
 Division of Licensing Project Management

FROM: Name, Chief
 Quality and Maintenance Section
 Equipment and Human Performance Branch (IEHB)

SUBJECT: EARLY SITE PERMIT QUALITY ASSURANCE
 ASSESSMENT AND CONCLUSION - AJAX ELECTRIC
 COMPANY

The enclosed is forwarded to your office for review and transmittal to the Ajax Electric Company, Ajax Units No. 1 and No. 2.

Consistent with NRC procedures for [nuclear power plant] the pre-docketing/post-docketing review of early site permit applications, IEHB has conducted a substantive audit relating to QA controls for the subject applicant.

Our conclusion is that the applicants's QA controls and procedures, when properly implemented, are [are not] equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and comply [do not comply] with the guidance contained in Review Standard (RS) 002, Section 17.1.1. (If conclusion is that the QA controls are not equivalent in substance to Appendix B of 10 CFR Part 50, then add: Please arrange for (applicant) to be notified of the date established by the Division of Licensing Project Management for the meeting with the applicant to discuss the substantive pre-docketing review and audit findings.

Chief
Quality and Maintenance Section
Equipment and Human Performance Branch

Enclosure as stated

cc: Regional Administrator
 Additional, as needed

Issue Date: 05/29/03

A-1

35012 Attachment

Enclosure to SAMPLE MEMORANDUM

EARLY SITE PERMIT QUALITY ASSURANCE ASSESSMENT AND CONCLUSION AJAX ELECTRIC COMPANY, TAC NO[S]. ____

Review Scope

The Equipment and Human Performance Branch (IEHB) has conducted a pre-docketing (post-docketing) review of the Ajax Electric Company quality assurance (QA) controls for early site permit (ESP) related activities to determine whether the QA program has been executed without substantive deviation from the NRC QA guidance contained in Review Standard (RS) 002, Section 17.1.1.

The review focused on site characterization and procurement activities for the development of the ESP application and included a selected review of established procedures and instructions. Our examinations included a selective review of the applicant's activities and records relating to surveillance of contractors, such as audits, inspections, and reviews, and of the applicant's assessments pertaining to the acceptability and timeliness of contract implementation of delegated parts of the QA control framework.

Assessment

After the audit, IEHB conducted an assessment of audit findings to ascertain if substantive deviations from NRC QA guidance exist. Our assessment included consideration of the NRR/IEHB review findings relating to the QA program description in the tendered application.

Conclusions

Based on the above assessment, the IEHB determined that there are [are not any] substantive QA controls deviations requiring corrective action prior to final approval of the subject application for an early site permit. We therefore conclude that the QA control framework for the Ajax Electric Company is [is not] consistent with the status of the project and NRC ESP QA guidance. (Add the following *only* if necessary: Areas of the implemented QA program where substantive deviations have been identified and for which appropriate applicant corrective action is required before IEHB can change its present conclusion are identified below.

[List audit findings and their basis for consideration as a substantive finding.]