

NRC INSPECTION MANUAL

CQV

MANUAL CHAPTER 2501

CONSTRUCTION INSPECTION PROGRAM:
EARLY SITE PERMIT (ESP)

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CONSTRUCTION INSPECTION PROGRAM: EARLY SITE PERMIT

2501-01 PURPOSE

To provide inspection policy and guidance for the implementation of the inspection program during licensee preparation and Nuclear Regulatory Commission (NRC) review of Early Site Permit (ESP) applications submitted under 10 CFR Part 52.

2501-02 OBJECTIVES

02.01 To verify that the information in the ESP application meets requirements specified in Subpart A to 10 CFR Part 52.

02.02 To verify effective implementation of the quality assurance (QA) program, as described in the application for an ESP, to provide reasonable assurance of the integrity and reliability of the ESP data or analyses that would affect the performance of safety-related systems, structures, and components (SSCs).

02.03 To provide guidance for the audit of ESP or combined license (COL) geotechnical and foundation activities to verify that data and analyses supporting the ESP or COL application are governed by an adequate QA program.

2501-03 DEFINITIONS

03.01 Audit. A planned and documented activity performed by the staff before the application is docketed to determine, by investigation, examination, or evaluation of objective evidence, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation of the quality assurance (QA) program used in the development of the application.

03.02 Combined License (COL). A combined construction permit and operating license with conditions for a nuclear power facility, issued pursuant to subpart C of 10 CFR Part 52.

03.03 Contractor. Any organization or individual that is under contract to furnish items or services to an applicant. This includes, where appropriate, the terms consultant, vendor, supplier, and other titled sub-tier organizations.

03.04 Early Site Permit (ESP). A Commission approval, issued pursuant to subpart A of 10 CFR Part 52, for a site or sites for one or more nuclear power facilities. Such a permit addresses, as a minimum, site suitability issues, environmental issues, and physical characteristics unique to the site that could pose a significant impediment to the development of emergency plans.

03.05 Inspection. An NRC planned and documented activity performed during the review of the application (once docketed) to determine, by investigation, examination, or evaluation of objective evidence, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and to verify effective implementation of the QA program.

03.06 Nonconformance. A vendor's failure to meet contract requirements related to NRC-regulated activities (e.g., Appendix B to 10 CFR Part 50), where the NRC has not placed requirements directly on the vendor.

03.07 NRC Quality Assurance Guidance. Guidance either developed or endorsed by the NRC - through issuance of regulatory guides, review standards, or national standard documents - that discusses acceptable methods of implementing a QA program consistent with Appendix B to 10 CFR Part 50 requirements. Standard Review Plan (SRP) 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," provides QA guidance for Design Certification reviews.

03.08 Objective Evidence. Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on direct observations, measurements, or tests that can be verified.

03.09 Quality Assurance. QA comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component (SSC) will perform satisfactorily in service. QA includes quality control.

03.10 Quality Assurance Manual. A compilation of quality assurance documents that defines the quality assurance policy and program, describes the method(s) by which the policy will be implemented through procedures and instructions, and identifies the parties responsible for implementation.

03.11 Quality Control (QC). Quality Control (QC) comprises QA actions related to the physical characteristics of an SSC. This provides a means to control the quality of the SSC to applicant-predetermined requirements.

03.12 QA Program/QA Commitments. These terms relate to the description of the QA program, or any part thereof, as required by 10 CFR 52.79(a)(25) in each application for a COL for a nuclear power facility. The description of the QA program must include a discussion of how the applicable requirements of Appendix B have been and will be satisfied, including a discussion of how the quality assurance program will be implemented.

03.13 Safety Evaluation Report. The safety evaluation report (SER) provides the technical, safety, and legal basis for the NRC's disposition of a license request or license amendment request.

03.14 Surveillance. Applicant and contractor activities such as reviews, observations, inspections, and audits to determine if an item or activity conforms to QA Program commitments.

03.15 Tendered Application. As used in this document, an Application that has been submitted but not accepted for docketing.

03.16 Violation. For the purposes of this manual chapter, the failure to comply with any portion of a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification.

2501-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office of New Reactors (NRO). Provides overall direction for the NRC construction inspection program.

- 04.02 Director, Division of Construction, Inspection, and Operational Programs (DCIP).
- a. Directs the implementation of policies, programs, and procedures to inspect applicants, licensees, and other entities subject to NRC jurisdiction.
 - b. Assesses the effectiveness, uniformity, and completeness of implementation of the ESP inspection program.
 - c. Approves changes to the ESP inspection program.
- 04.03 Deputy Regional Administrator for Construction.
- a. Provides program direction for management and implementation of the inspection program elements performed by their regional office.
 - b. Within budget limitations, ensures the regional office staff includes adequate number of inspectors necessary to carry out the portions of the inspection program that are within the regional office's responsibility.
 - c. Directs the implementation of geotechnical and site characterization activities as described in this manual chapter.

2501-05 DISCUSSION

This inspection manual chapter (IMC) will initially be applied when an applicant announces its intent to apply for an ESP and will continue to be applied during the review process until the NRC issues the ESP. The NRC's decision to docket an application will be based, in part, on pre-ESP audits that inform the NRC staff's acceptance reviews. The NRC will implement this IMC to assess the applicant's implementation of its QA program for activities performed prior to and during the ESP application development process. The NRC will also implement this IMC to audit and assess the applicant's performance of site characterization activities in preparation for construction of a nuclear power facility. Where the performance and/or surveillance of activities associated with the ESP phase have been contracted to other organizations, this IMC applies to the organizations conducting the activities for the applicant organization.

2501-06 INSPECTION POLICIES AND GUIDANCE

06.01 Inspection/Audit Emphasis. Audit and inspection emphasis is placed on the applicant's ESP development processes, inspecting design and procurement engineering activities, and inspecting QA program implementation. In addition to verifying the implementation of the applicable Appendix B criteria, inspections will include a review of the applicant's 10 CFR Part 21 procedures.

06.02 Inspection/Audit Plans. Inspection or audit plans are required for all inspections or audits. The lead inspector is responsible for preparation of the plan. The plans will follow the guidance contained in Section 06.03 of this manual chapter.

06.03 General Inspection/Audit Process. For each audit or inspection, the inspector should implement the process described below for pre-inspection/audit activities, onsite inspection/audit activities, and post-inspection/audit activities. The inspection procedures listed in Enclosure 1 provide more specific guidance for onsite inspection/audit activities.

- a. Pre-inspection/audit activities. To facilitate management of inspection resource allocations and tracking of audit and inspection activities, the lead inspector should develop an audit or inspection plan consistent with the guidance described below.

The responsible team leader will develop an audit or inspection plan. The audit or inspection plan will identify the applicant and describe the scope and major areas of emphasis that will be reviewed, evaluated, or assessed. In addition, the audit or inspection plan should identify the team members and the inspection/audit schedule. This plan is to be reviewed and approved by the responsible Branch Chief.

- b. Onsite inspection/audit activities. Entrance and exit meetings with the applicant management or its representative should be scheduled in advance. The lead inspector should hold an entrance meeting with the designated representative who has responsibility for the areas to be inspected. At the entrance meeting, the lead inspector should discuss the inspection or audit scope and other administrative matters, such as interviews with staff and/or document reviews. Whenever possible, the lead inspector should schedule a daily status meeting with the applicant management or its representative to discuss the inspection or audit progress and issues identified.

An exit meeting should be conducted at the conclusion of the audit or inspection. The results of the audit or inspection, including preliminary findings, should be presented emphasizing their impact on safety. The lead inspector should emphasize that preliminary findings are always subject to management review before they are documented in an inspection or audit report. Prior to the exit, the lead inspector should determine whether his/her supervisor should be briefed on the preliminary inspection findings.

- c. Post-inspection/audit activities. Audits reports will be issued as required by IMC-0614, "Documenting 10 CFR Part 52 Construction Audit Activities." Inspection reports will be issued as required by IMC-0612, "Power Reactor Inspection Reports." Issues that cannot be resolved at the time of the audit or inspection will be documented as unresolved items. Potential violations identified through inspection activities will be processed in accordance with the NRC's Enforcement Policy.

06.04 Inspection/Audit of a Previously Submitted Application. The scope of this IMC may be reduced for applications submitted by an applicant who has recently (within the past 36 months) been inspected in accordance with these instructions for a prior application. The reductions in inspection scope will be determined on a case by case basis by agreement between NRO and Region II.

06.05 Inspector Qualification. NRC inspectors will be assigned responsibility for those inspection requirements consistent with their qualifications.

2501-07 TYPES OF INSPECTIONS

07.01 Site Exploration and Data Collection/Analysis Activities. Audits will be conducted to assess the implementation of QA requirements at an early stage in the application development process. Prior to the docketing of the application, and as early as possible after notification of the applicant's intention to submit an ESP or COL application, the designated regional office will coordinate with the respective project manager and DCIP to gather information regarding the applicant's schedule for data collection and related site characterization activities. Site exploration audits should coincide with the performance

of significant geotechnical and site characterization activities conducted at the prospective site. Audits of geotechnical and site characterization activities will be conducted using the guidance contained in IP 45051, "Review of Geotechnical and Site Characterization Activities." These audits will be led by the lead region in cooperation with DCIP and Division of Site and Environment Reviews (DSER).

Audits will place particular emphasis on the applicant's QA program, document control, and methodologies for data collection, analysis, and evaluation. This includes a review of the methodology for data collection, analysis, and evaluation for soil composition, geology, hydrology, and seismology determinations for the foundations of SSCs important to safety.

Additionally, the audit team will review the applicant's oversight of contracted activities to ensure the effective control of all work and the proper implementation of the required elements of the QA program. The audit team will review a suitable sample of in-process documents related to ESP site characterization activities to verify the effective implementation of the applicant and contractor's QA programs. Observations of these activities should determine whether QA program requirements are being adequately implemented as required by the applicant and/or contractor's procedures. Early involvement of NRC staff will facilitate and support prompt identification and resolution of issues, and timely completion of the acceptance review process following submission of the application.

07.02 QA Program Reviews. The QA program described in Chapter 17 of the ESP application will be reviewed according to guidance contained in SRP 17.5. The staff should encourage an early submittal of the applicant's quality assurance topical report (QATR) or their quality assurance program description (QAPD) for staff review and issuance of an SER (provided the QAPD was not previously approved in a SER).

Based on the information provided by the applicant and inspections performed under this IMC, as appropriate, an SER will be issued. The SER documents the NRC approval of the QAPD, if not previously approved in another SER. In addition, the SER will include the inspection results (when applicable) to support the staff's disposition regarding the adequacy of the QAPD implementation for ESP activities.

07.03 Pre-Application Audit. Typically one QA audit is performed to ensure accuracy and completeness of the application in accordance with the requirements of 10 CFR 50.9. Additionally, QA program audits verify that the applicant's QA programs are being effectively implemented to provide reasonable assurance of the integrity and reliability of the ESP data or analyses that would affect the performance of safety-related SSCs. Pre-application QA audits also provide for a review of the applicant's oversight of any contracted activities. The inspectors will review a representative sample of documents prepared by the applicant and its contractors to verify the effective implementation of the applicant's QA programs.

IP 35005, "Quality Assurance Program Audit," will be used before the applicant tenders its ESP application to verify the extent and effectiveness of the applicant's implementation of its QA program. IP 36100, "Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance," will be used to determine if an applicant has established a program and procedures to effectively implement 10 CFR Part 21 and 10 CFR 50.55(e) requirements for reporting defects and failures to comply associated with a substantial safety hazard. These audits will be led by DCIP in cooperation with the lead region.

07.04 Post-Docketing Inspection. The objective of a post-docketing QA program inspection is to provide the staff with reasonable assurance that the QA program has been effectively implemented. IP 35017, "Quality Assurance Implementation Inspection," will be used as guidance for conducting this inspection. After the NRC staff approves the applicant's QA program and issues an SER, the NRC will inspect the

applicant's implementation of its QA Program. This objective is consistent with regulations that govern all stages of the licensing process. Assigned NRC inspectors will verify whether activities affecting quality are conducted under the appropriate provisions of Appendix B. These inspections will be led by DCIP in cooperation with the lead region. Typically one inspection is conducted to verify the implementation of the applicant's QA program and to support the staff's SER input. Follow-up inspections are performed as necessary.

As noted in SRP 17.5, a QA program submitted by an ESP applicant applies to all phases of a facility's life, including design, construction, and operation. Construction and operational QA activities may be addressed in separate QA programs.

2501-08 ENFORCEMENT ACTIONS

Possible enforcement actions associated with a ESP application are not anticipated in the pre-docketing application phase. However, the information submitted with the application will become subject to NRC regulations, including enforcement actions for willful wrongdoing or fraudulent information. During the post-docketing phase, the applicant will be subject to 10 CFR Part 21 and Appendix B requirements and may be subject to enforcement actions, such as notices of violation and nonconformance.

2501-09 REFERENCES

U.S. Code Of Federal Regulations. 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses For Nuclear Power Plants."

U.S. Code of Federal Regulations. 10 CFR Part 50.55, "Conditions of Construction Permits."

U.S. Code of Federal Regulations. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

U.S. Code of Federal Regulations. 10 CFR Part 21, "Reporting of Defects and Noncompliance."

END

Attachments:

1. INSPECTION PROCEDURES
2. REVISION HISTORY

ATTACHMENT 1

Inspection Procedures

Inspection Procedure No.	Inspection Procedure Title
35005	Quality Assurance Program Audit
35017	Quality Assurance Implementation Inspection
36100	Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance
45051	Review of Geotechnical and Site Characterization Activities

ATTACHMENT 2

Revision History for IMC 2501

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment Resolution Accession Number
N/A	05/29/03	Initial issuance	None	N/A	N/A
N/A	04/25/06	Delete requirement for Regional Administrator to send letter to Nuclear Reactor Regulations (NRR) Office Director recommending issuance of ESP	None	N/A	N/A
N/A	10/03/07 CN 07-030	<ol style="list-style-type: none"> 1. Delete procedures for meetings and updated guidance for pre-application audits. 2. Incorporate the new requirements of 10 CFR Part 52 and SRP 17.5 guidance. 3. Researched commitments for 4 years and found none. 	None	N/A	ML072570180