

NRC INSPECTION MANUAL

IQVB

INSPECTION MANUAL CHAPTER 2501

CONSTRUCTION INSPECTION PROGRAM:
EARLY SITE PERMIT (ESP)

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2501-01 PURPOSE

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

01.02 To provide guidance for the inspection, assessment, and documentation of quality assurance (QA) program implementation during geotechnical and site characterization activities (Site Exploration and Data Collection/Analysis) performed by the applicant and its contractors.

2501-02 OBJECTIVES

02.01 To verify that quality processes used in the development of the ESP application are adequately described, and that technical, quality and administrative requirements important to public health and safety are effectively implemented during geotechnical and site characterization activities associated with ESP.

02.02 To verify effective implementation of QA program, as described in the application for an ESP, as a means of providing 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 verify that the applicant and its contractor's ongoing geotechnical and site characterization activities associated with ESP application are being effectively implemented in accordance with applicable 10 CFR Part 50 Appendix B, QA requirements.

2501-03 APPLICABILITY

03.01 General. This inspection manual chapter (IMC) will initially be applied when an applicant tenders an application for an ESP and will continue to be applied during the review process until the NRC issues the ESP. The NRC will implement this IMC to inspect and assess the applicant's implementation of applicable 10 CFR Part 50, Appendix B quality assurance requirements by the applicant or contractor's on behalf of the applicant during the performance of geotechnical and site characterization activities.

2501-04 DEFINITIONS

Definitions of terms used in this inspection program are included in Inspection Manual Chapter 2506, "Construction Reactor Oversight Process General Guidance and Basis Document."

2501-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Director, Office of Nuclear Reactor Regulation (NRR). Provides overall direction for the NRC construction inspection program.

05.02 Director, Division of Reactor Oversight (DRO).

- a. Directs the implementation of policies, programs, and procedures to inspect applicants, licensees, and other entities subject to NRC jurisdiction associated with new reactor construction pursuant to 10 CFR Part 52.
- b. Assesses the effectiveness, uniformity, and completeness of implementation of the ESP inspection program.
- c. Approves changes to the ESP inspection program.

05.03 Region II 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 inspection of geotechnical and site characterization activities by the region inspection staff as described in this manual chapter.

2501-06 REQUIREMENTS

06.01 Inspection Emphasis. Inspection emphasis is placed on following applicable elements of the applicant's programs:

- a. ESP development processes,
- b. Design and procurement engineering activities,
- c. QA program implementation.
- d. Review of the applicant's 10 CFR Part 21 procedures.

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

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

The inspection plan will identify the applicant and describe the scope and major areas of emphasis that will be reviewed, evaluated, or assessed including open unresolved items if applicable. In addition, the inspection plan should identify the team members, team assignments, inspection procedures to be used, logistics, the inspection schedule, and deliverables.

This plan is to be reviewed and approved by the responsible Headquarters or Regional Branch Chief as necessary.

- b. Onsite inspection activities. 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 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 progress and issues identified.

An exit meeting should be conducted at the conclusion of the inspection. The results of the 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 report. Prior to the exit, the lead inspector should brief his/her supervisor if possible, on the preliminary inspection findings.

- c. During the conduct of inspections, the Inspection Staff will also make every reasonable attempt to stop work practices that are unsafe or could lead to an unsafe situation. Additional discussion regarding witnessing of unsafe situations may be found in Section A03.02.05, "Witnessing Unsafe Situations," of IMC-2506, "Construction Reactor Oversight Process General Guidance and Basis Document."
- d. Inspection documentation. Inspection reports regarding the applicant's implementation of its QA program for safety-related activities in support of the staff licensing activities associated with the ESP will be issued as required by IMC-0617, "Vendor and Quality Assurance Implementation Inspection Reports."

Potential violations identified through inspection activities will be processed in accordance with the NRC's Enforcement Policy.

06.03 Inspection 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.

06.04 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. The objective of site exploration and data collection/analysis activities is to provide the staff reasonable assurance that the QA program as applicable to ESP geotechnical activities has been adequately implemented. DRO will not be directly involved in this inspection.

DRO will review of the methodology for data collection, analysis, and evaluation for geology, hydrology, and seismology determinations for the foundations of SSCs important to safety. Inspection of geotechnical and site characterization activities will be conducted using the guidance contained in IP 45052, "Review of Geotechnical and Site Characterization Activities."

Additionally, the team will review the applicant's oversight of contracted activities to ensure the applicant has effective control of all work and the proper implementation of the required elements of the QA program. The 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. These inspections will be led by the host region in cooperation with DRO and technical support, as necessary. Follow-up inspections will be performed as necessary.

07.02 Post-Docketing QA Program 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. 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 to 10 CFR Part 50. Effective implementation of the QA program shall provide reasonable assurance of the integrity and reliability of the ESP data or analysis that would affect the performance of safety-related SSCs.

Typically, one post-docketing QA program inspection will be conducted using the guidance contained in Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection," and to verify the implementation of the applicant's QA program and to support the staff's SER input. These inspections will be led by DRO in cooperation with other technical divisions and the host region, as necessary. Follow-up inspections will be performed as necessary. Significant inspection findings relating to QA implementation should be resolved before the SER for the ESP is issued.

In addition, post-docketing QA program inspection will include a review of the applicant's program associated with 10 CFR Part 21. The inspector will use IP 36100, "Inspection of 10 CFR Part 21 Programs for Reporting Defects and Noncompliance," to verify that the applicant has established appropriate procedures and programs to effectively implement 10 CFR Part 21 requirements for reporting defects and noncompliance.

2501-08 ENFORCEMENT ACTIONS

The NRC Enforcement Policy governs the processes and procedures for the initiation and review of violations of NRC requirements and the NRC Enforcement Manual contains implementation guidance. During the post-docketing phase, the applicant and their contractors performing safety-related activities will be subject to 10 CFR Part 21 and 10 CFR Part 50, Appendix B requirements and may be subject to enforcement actions as deemed appropriate.

2501-09 REFERENCES

U.S. Code of Federal Regulations. 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"

U.S. Code of Federal Regulations. 10 CFR Part 50.55, "Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses"

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"

70 FR 12908, "Use of the Web and ADAMS to Disseminate the Enforcement Policy, Discontinuation of NUREG-1600, and Simplification of the Official Policy Statement Title"

Inspection Manual Chapter 0613, "Documenting 10 CFR Part 52 Construction Inspections"

Inspection Manual Chapter 0617, "Vendor and Quality Assurance Implementation Reports"

Inspection Manual Chapter 2506, "Construction Reactor Oversight Process General Guidance and Basis Document"

NUREG-800 Standard Review Plan, Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit, and New License Applicants"

END

Attachments:

1. Inspection Procedures
2. Revision History for IMC 2501

Attachment 1

Inspection Procedures

Inspection Procedure No.	Inspection Procedure Title
35017	Quality Assurance Implementation Inspection
36100	Inspection of 10 CFR Part 21 Programs for Reporting Defects and Noncompliance
45052	Review of Geotechnical and Site Characterization Activities

Attachment 2

Revision History for IMC 2501

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML031540014 05/29/03 CN 03-018	Initial issuance	N/A	N/A
N/A	ML061090070 04/25/06 CN 06-010	Delete requirement for Regional Administrator to send letter to Nuclear Reactor Regulations (NRR) Office Director recommending issuance of ESP.	N/A	N/A
N/A	ML072490548 10/03/07 CN 07-030	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.	N/A	ML072570180
N/A	ML112620209 06/06/13 CN-13-013	1. Deleted pre-application audits. 2. Conforming changes. 3. Additional references clarifying inclusion of geotechnical and site characterization activities.	N/A	ML13130A176
N/A	ML19319C175 07/02/20 CN 20-029	Revised in accordance with IMC 0040 due to NRR/NRO merger in October 2019. Periodic review completed.	N/A	N/A