

NRC INSPECTION MANUAL

IIPB

MANUAL CHAPTER 2501

NUCLEAR REACTOR INSPECTION PROGRAM EARLY SITE PERMIT

2501-01 PURPOSE

The Early Site Permit (ESP) inspection program establishes guidance for NRC inspection activities directed towards the review of an ESP application and the related applicant activities governed by NRC regulations. The ESP inspection program applies to the applicant and the applicant's contractors, and to all activities related to NRC regulations. The principal regulations for this phase are those described by 10 CFR Part 52 and 10 CFR Part 100. The ESP phase begins when the NRC receives notification of an applicant's intention to apply for an ESP. It continues until the ESP expires or a combined operating license or construction permit is issued (See Figure 1).

Where the performance and/or surveillance of activities associated with the ESP phase have been contracted to other organizations, this program applies to the organizations conducting the activities for the applicant organization.

2501-02 OBJECTIVES

The principal objective of the ESP phase is to verify that the ESP application meets the requirements specified in 10 CFR Part 52 and is of a quality suitable for docketing and approval. Additional objectives are to (1) reduce unnecessary regulatory burden, and optimize the efficiency and effectiveness of docketing, (2) explain to the public the contents of an ESP application and the opportunities for public intervention, (3) explain the NRC licensing process, and (4) ascertain whether the appropriate elements and standards to assure quality are being applied to ESP project activities.

To achieve these objectives, substantial emphasis will be placed on verifying the quality and accuracy of data collected and the analysis and the evaluation of information used in support of the application. Inspections and audits will verify that data and analyses supporting the ESP application are governed by an adequate QA control framework.

2501-03 DEFINITIONS

Definitions of terms used in this inspection program are as follows:

03.01 Audit. An applicant/contractor activity to determine through investigation the adequacy of/and adherence to, established procedures, instructions, specifications, codes, and other applicable contractual and licensing requirements, and the effectiveness of implementation.

03.02 Contractor. Any organization or individual under contract to furnish items or services to an applicant. It includes the terms consultant, vendor, supplier, fabricator, constructor, and subtier levels of these, where appropriate.

03.03 Documentation. Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

03.04 Inspection. An NRC activity consisting of examination, observation or measurements to determine the conformance with requirements and/or standards.

03.05 NRC QA Guidance. Guidance endorsed by NRC through issuance of regulatory guides, review standards, or national standard documents which discuss acceptable methods of implementing controls equivalent in substance to 10 CFR 50, Appendix B. Specifically, Section 17.1.1 of Review Standard (RS)-002, "Processing Early Site Permit Applications," provides QA guidance for early site permit reviews.

03.06 Objective Evidence. Any direct observation or documented statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item or service based on verifiable observations, measurements, or tests.

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

03.08 Quality Assurance Framework. The collection of internal policies, procedures and instructions established by the applicant 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.

03.09 Quality Control. Quality control (QC) comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

03.10 The Tendered/Docketed Application. As used by this instruction, the tendered application consists of the ESP application, 10 CFR 52.17 (a) - (c) general information; 10 CFR 50.33 a - d, information required by 50.34(a)(12) and (b)(10); and to the extent approval of emergency plans is sought under paragraph (b)(2) (ii) of 10 CFR Part 52, the 10 CFR 51.45 and Part 51.50, Environmental Report.

Where the term docketing is used by this instruction it refers to the docketing of the ESP application.

2501-04 RESPONSIBILITIES AND AUTHORITIES

04.01 The Commission has the overall responsibility to make a determination regarding the acceptability of the ESP application. The applicable Regional Administrator has the responsibility to make a recommendation to the Director, Office of Nuclear Reactor Regulation, regarding denial or approval of the ESP application (see Enclosure 2).

04.02 The Director, Division of Inspection and Program Management has the responsibility to review and make a determination regarding the acceptability of the QA program description document if presented with the applicant's application and for ascertaining whether the applicant has established and executed acceptable QA controls.

04.03 The Director, New Reactor Licensing Project Office, has the responsibility to make a determination regarding the acceptability of the technical information in support of the ESP application and to determine whether to docket the application.

2501-05 DISCUSSION

05.01 Pre-Docketing. During the pre-docketing phase the NRC primarily gathers information regarding the quality of site suitability and environmental data collected in support of the application.

Prior to the submittal of the application, and as early as possible after notification of the applicant's intention to submit an ESP application, the NRC will conduct meetings with the applicant to: (1) meet the primary contacts for the various technical disciplines, (2) review the applicant's schedule for collection of data, and related ESP activities, (3) arrange for observation of data collection methodology, (4) arrange for a preliminary walk-down of the prospective site and (5) discuss acceptable QA controls for ESP activities. Additionally, the NRC staff will coordinate schedules with the applicant and gather information in preparation for public meetings, schedule public meetings to introduce the local community to the NRC licensing process, and arrange meetings with state and local officials.

The pre-docketing QA controls inspection, if performed, needs to coincide with the performance of significant site characterization activities and be completed as early as possible before the tendering of an ESP application. The inspection will place particular emphasis on the applicant's QA framework, document control, and methodologies for data collection, analysis, and evaluation. Departures from accepted QA principles or deviations from accepted industry standards may require independent evaluations, requests for additional information, and additional communications with the applicant, thus extending the NRC review and evaluation process. Significant deviations from NRC QA guidance without justification that adversely impact the integrity or reliability of site data and analyses important to safety may result in the denial of the ESP application.

Additionally, the ESP inspection program provides for a review of applicant oversight of contracted activities and inspection of those activities. The direct inspection of contractor work activities may be performed, as necessary, to ensure the effective control of all work and the proper implementation of the required elements of the QA program or equivalent in substance.

05.02 Post-Docketing Review. After an application is tendered, the application will be reviewed according to the guidance contained in Review Standard RS-002. During the post-docketing period (See Figure 1), inspections are conducted to complete the review of the applicant's QA controls and to support testimony for the Atomic Safety and Licensing Board (ASLB) hearing required by 10 CFR 52.21. Based on the information provided by the applicant and the results of the inspections, safety evaluation reports (SER)s will be issued and the ASLB hearing will be conducted prior to making the determination whether to grant the ESP.

05.03 Inspections. Inspections will be accomplished by the regional office having geographical jurisdiction with technical support from NRR. Inspections will be led by the responsible region after coordinating the effort with the responsible NRR Project Manager (PM). Technical support will be provided by various divisions within NRR as requested by the PM. The technical staff will evaluate the applicant's methodologies for data collection using the guidance provided in Review Standard RS-002. Inspections will be consolidated to minimize impact on the applicant. Within five days of the conclusion of the inspection, the NRR technical staff and/or its contractors will forward their findings to the inspection team leader for integration into a trip report.

Site visits and meetings conducted exclusively by the NRR Project Manager or NRR technical staff will be documented in a trip report with the cognizant regional management on distribution.

ESP Phase Inspection Guidance, Enclosure 1 to MC-2501, provides guidance which may be applicable during inspections, audits, or site visits.

05.04 Enforcement. Enforcement actions associated with an ESP application are not anticipated in the pre-docketing phase. However, as stated in Part 52.21, an ESP is a partial construction permit and is therefore subject to all procedural requirements in 10 CFR Part 2 applicable to construction permits. The information submitted with the application will become subject to NRC regulations including enforcement actions for willful wrongdoing or fraudulent information.

05.05 Quality Assurance. The objective of the QA inspection is to ascertain with reasonable assurance that data obtained at the ESP stage that would affect the design or construction of future SSCs important to safety is accurate and reliable. This objective is consistent with the regulations that govern later stages of the licensing process.

Inspectors will determine that ESP activities associated with site safety are controlled by measures "equivalent in substance" to the controls described in Appendix B to 10 CFR Part 50 to provide reasonable assurance that future SSCs important to safety that might be constructed on the site will perform adequately in service. This is because the 10 CFR Part 52 regulations do not require that a Part 50 Appendix B program be implemented in support of ESP applications. However, regulations in 10 CFR 52.39 prohibit revisiting findings made at the ESP absent new information. For example, activities associated with data collection, analysis, and evaluation for soil composition, geology, hydrology, meteorology, and seismology determinations need to be subjected to QA controls, commensurate with the importance of the respective activities to design. Further, information derived from recognized authorities (such as the Census Bureau or the National Oceanic and Atmospheric Administration), should be controlled using processes for maintaining data integrity, traceability, document control, evaluation, analysis, and record storage that are equivalent in substance to the processes and controls described in Appendix B to 10 CFR Part 50 if the information would affect the design and construction of SSCs important to safety.

"Equivalent in substance" means that the applicant's QA controls must provide reasonable assurance of integrity and reliability of data that might affect design or construction of future SSCs important to safety. Appendix B defines a substantive and procedural framework of controls that collectively help provide such assurance, and that framework has been proven through many years of safe nuclear power plant operation. It is not the only method which assures integrity and reliability, however the staff will evaluate quality controls using the criterion that the applicant's controls be equivalent in substance to the controls specified in Appendix B.

Applicants should apply quality controls equivalent in substance to Appendix B to each ESP activity that would impact the design or construction of future SSCs important to safety. The technical staff plans to evaluate in considerable depth information obtained outside such a quality control framework. As a practical matter, the burden on the applicant of demonstrating equivalence will be reduced if the applicant invokes the appropriate Appendix B requirements. In some cases, applicants may elect to submit a QA program description to more efficiently provide the necessary QA control information. Otherwise, it will be necessary for the staff to request information needed to provide reasonable assurance of the integrity and reliability of data that would affect the performance of future SSCs important to safety. 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 as a stand alone substantive conclusion without reference to Appendix B.

- a. Quality Assurance Applicability. The applicable criteria of 10 CFR 50 Appendix B are those criteria which can directly relate to the pedigree or genesis of any safety-related or risk-significant structure, system, or component (SSC). For example, for an ESP application, Appendix B criteria should be applied to the methodology for data collection, analysis, and evaluation for soil composition, geology, hydrology, and seismology determinations for the foundations of SSCs important to safety.

Information submitted with the ESP application that impacts the design and construction of SSCs important to safety is subject to QA controls equivalent in substance to 10 CFR 50, Appendix B. Inspections will be performed on a sampling basis to provide added confidence that the application contents are in conformance with regulations and that information presented in the application is accurate and reliable.

- b. NRC Process Relating to Inspection of QA Program. The NRC process relating to inspection of the QA program implementation and documentation of findings is as follows:
 1. As part of the inspection preparation, the inspectors shall review the applicable elements of the applicant's QA framework.
 2. Findings shall not be formally documented in an inspection report until after conduct of the QA program implementation inspection at the applicant/contractor offices (and at the site, as appropriate).
 3. Significant findings relating to the QA program may be forwarded to NRR technical staff for review and resolution with DIPM/IEHB at any time during the performance of the inspection activity.

05.06 Limited Work Authorization (LWA). If an early site permit contains a site redress plan, the holder of the permit may perform the activities at the site allowed by 10 CFR 50.10(e)(1). A limited work authorization under § 50.10(e) is informally termed LWA-1. Under § 50.10(e)(1), the Director of NRR may authorize site preparation work, installation of temporary construction support facilities, excavation for nuclear and non-nuclear facilities, construction of service facilities and construction of structures, systems and components which do not prevent or mitigate the consequences of postulated accidents. An LWA-1 may be granted only after the ASLB has made all of the National Environmental Policy Act (NEPA) findings required by 10 CFR Part 51 for the issuance of a construction permit and has determined that there is reasonable assurance that the proposed site is a suitable location for a nuclear power reactor.

In each case the LWA-1 will clarify which of the requested activities may be conducted at the site and the conditions that must be met. If the LWA-1 is granted, inspectors will ascertain that special precautions are taken if an existing operating plant is in close proximity as overhead power lines may be impacted by cranes, and earth moving activities may impact flooding of the existing facility.

END

Enclosures:

1. INSPECTION GUIDANCE
2. SAMPLE LETTER
3. EARLY SITE PERMIT TIME-LINE

ENCLOSURE 1

INSPECTION GUIDANCE

INSPECTION
PROCEDURE

INSPECTION GUIDANCE

35002	Early Site Permit Pre-Docketing Quality Assurance Controls Meeting
35004	Pre-Docketing Early Site Permit Quality Assurance Controls Inspection
35006	Post-Docketing Early Site Permit Quality Assurance Controls Inspection
35012	Early Site Permit Quality Assurance Controls Assessment and Conclusion
45051	Geo-Technical/Foundation Activities Procedure Review

ENCLOSURE 2

SAMPLE LETTER

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION XX, Address

Memorandum To: _____, Director
Office of Nuclear Reactor Regulation

FROM: _____,
Regional Administrator

SUBJECT: (Site name) EARLY SITE PERMIT APPLICATION

(XXX) Corporation , by letter dated (XXXXX) , requested an Early Site Permit (ESP) for (XXX) Nuclear Station, Unit(s) (X) in accordance with Title 10 of the Code of Federal Regulations Part 52 . We have completed our inspections in accordance with the guidance contained in Manual Chapter (MC) 2501 and in close coordination with the Office of Nuclear Reactor Regulation. The inspections verified that (XXXX) has implemented programs in conformance with the descriptions contained in (XXXX' s) application.

Additionally, the inspections compared statements in the safety evaluation report with (XXXX's) implementation in the field confirming the accuracy of assumptions used by the Office of Nuclear Reactor Regulation (NRR) to form technical positions. Details of the scope of our inspections and results are contained in the following Inspection Trip Reports (XXX) dated (XXXXX)....

Based on the results of our inspection efforts, we have determined that (Company's) programs and activities related to the ESP at (Company) have been completed in agreement with docketed commitments and regulatory requirements. Within the above inspection scope, we have determined that (Company) has met the applicable criteria for site suitability, emergency preparedness and environmental impact. We, therefore, conclude that (Company) has provided an adequate foundation for the granting of an early site permit.

ENCLOSURE 3

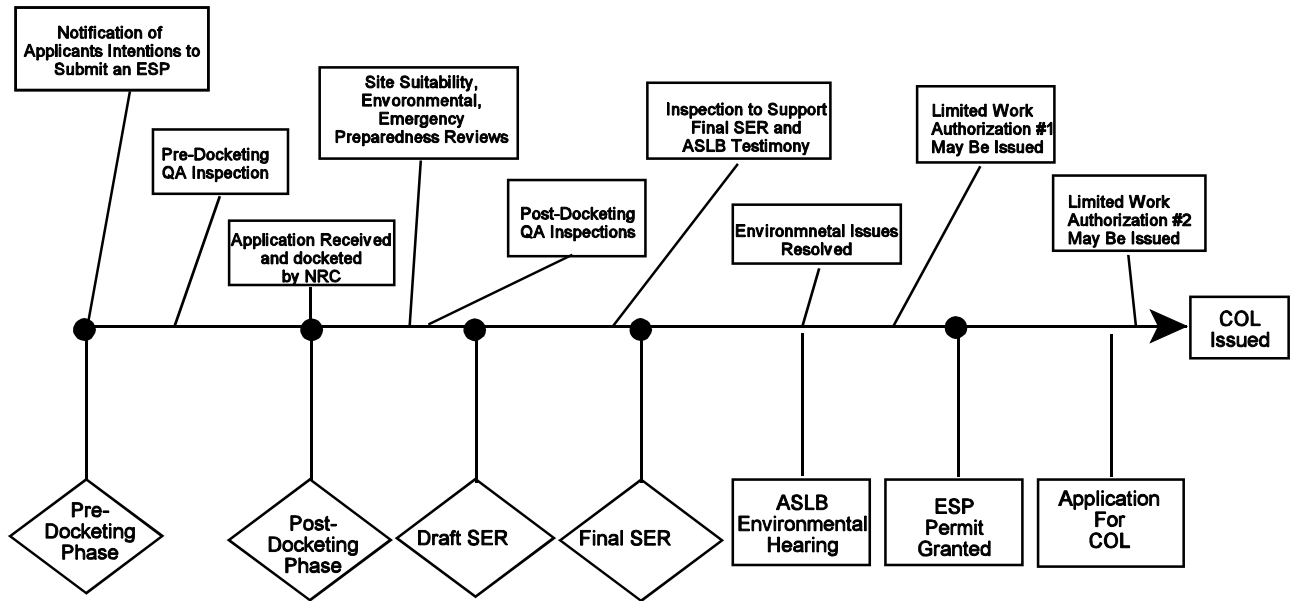


Figure 1