

NRC INSPECTION MANUAL

DRO/IQVB

INSPECTION MANUAL CHAPTER 2501

**INSPECTION ACTIVITIES FOLLOWING ACCEPTANCE OF A DOCKETED APPLICATION
FOR A PERMIT, LICENSE, OR NRC AUTHORIZATION**

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2501-01 PURPOSE

- 01.01 To provide inspection policy and guidance, following the acceptance and docketing, of an application for a limited work authorization (LWA) or construction permit (CP), submitted under Title 10 of the *Code of Federal Regulations* (CFR) Part 50, or an application for an early site permit (ESP), combined license (COL) or manufacturing license (ML), submitted under 10 CFR Part 52.
- 01.02 To provide guidance for the inspection, assessment, and documentation of the implementation of the quality assurance (QA) program during safety-significant pre-construction activities performed by the applicant and its contractors.

2501-02 OBJECTIVES

- 02.01 To verify effective implementation of the QA program, as described in the accepted application, as a means of providing reasonable assurance of the integrity and reliability of the data or analyses that would affect the performance of safety-related (SR) or non-safety-related safety-significant (NSRSS) structures, systems, and components (SSCs).
- 02.02 To verify pre-construction activities are effectively implemented by the applicant and its contractors in accordance with applicable 10 CFR Part 50, Appendix B, QA requirements.
- 02.03 Results from inspections may support the NRC's future ITAAC closure verification.

2501-03 APPLICABILITY

- 03.01 General. This inspection manual chapter (IMC) may be implemented, in whole or in part, after the NRC has accepted and docketed an application for an ESP, LWA, CP, COL, or ML. Inspection under this IMC ends when the NRC issues the applicable permit, authorization, or license.
- 03.02 Staff should not implement this IMC if the level of experience and prior NRC inspections, of the applicant's and its contractor's quality assurance program implementation, provides confidence that further inspection is not necessary to provide reasonable assurance of quality.

2501-04 DEFINITIONS

Definitions of terms used in this inspection program are included in IMC 2506, "Construction Reactor Oversight Process General Guidance and Basis Document." Some definitions are provided below for the reader's convenience.

- 04.01 Applicant. A person or an entity applying for a license, permit, or other form of Commission permission or approval under 10 CFR Part 50 or Part 52, and whose application has been accepted for review by the NRC.

- 04.02 Contractor. Any organization or individual under contract to furnish items or services to an applicant engaging in an NRC-regulated activity. It includes the terms consultant, vendor, supplier, fabricator, constructor, and sub-tier levels of these organizations.
- 04.03 Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC). The inspections, tests, analyses, and acceptance criteria, that if met by the licensee, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, as amended, and the Commission's rules and regulations.
- 04.04 Notice of Nonconformance (NON). A written notice describing the failure of an applicant's contractor to meet commitments that have not been made legally binding requirements by the NRC (e.g., a commitment made in a procurement contract with an applicant as required by 10 CFR Part 50, Appendix B).
- 04.05 Non-safety-related, safety significant (NSRSS) SSCs. SSCs which are not designated as safety-class SSCs, but whose preventive or mitigative function is risk significant or contributes to defense in depth. NSRSS is an umbrella term which encompasses licensing methodology-specific SSC classifications such as Regulatory Treatment of Non-safety Systems (RTNSS) and Non-safety-related with Special Treatment (NSRST).
- 04.06 Pre-Construction Activity. Any activity conducted prior to issuance of an ESP, COL, ML, CP, or LWA by the applicant or contracted suppliers on behalf of the applicant associated with SR or NSRSS components or portions of the proposed facility.
- 04.07 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.
- 04.08 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.
- 04.09 QA Program / QA Commitments. These terms relate to the description of the QA program, or any part thereof, as required by 10 CFR 50.34(a)(7), 52.79(a)(25), and 52.157(f)(17) in each application for a CP, COL, or ML respectively for a nuclear power facility. The description of the QA program must include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been and will be satisfied, including a discussion of how the QA program will be implemented.
- 04.10 Quality Control (QC). 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.
- 04.11 Safety-related structures, systems, and components (SSC).
- a. For light water reactors (LWRs), those structures, systems and components (SSCs) that are relied upon to remain functional during and following design basis events to assure:
 1. The integrity of the reactor coolant pressure boundary; or

2. The capability to shut down the reactor and maintain it in a safe shutdown condition;
or
 3. The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 50.34(a)(1) or § 100.11 of Part 50, as applicable.
- b. For non-LWRs using the licensing methodology described in NEI 18-04, rev 1, safety-related SSCs are those that:
1. Are selected by the designer from the SSCs that are available to perform the required safety functions to mitigate the consequences of design basis events to within the licensing basis event frequency-consequence target, and to mitigate design basis accidents that only rely on the safety-related SSCs to meet the dose limits of 10 CFR 50.34 using conservative assumptions; or
 2. Are selected by the designer and relied on to perform required safety functions to prevent the frequency of beyond design basis events with consequences greater than the 10 CFR 50.34 dose limits from increasing into the design basis events region and beyond the frequency-consequence target.

See NEI 18-04, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," Revision 1, which is endorsed by RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors," for a full explanation of LMP methodology and terms.

- 04.12 Violation. The failure to comply with any portion of a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification.

2501-05 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 50 and Part 52.
- b. Assesses the effectiveness, uniformity, and completeness of implementation of the pre-license phase inspection program.
- c. Approves changes to the pre-license phase inspection program.

2501-06 REQUIREMENTS

06.01 Inspection Emphasis

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

- a. design and procurement engineering activities
- b. QA program implementation
- c. 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 branch chief as necessary.

- b. Onsite inspection activities. The lead inspector should hold an entrance meeting with the designated applicant 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 or the accuracy and completeness of the ESP, LWA, CP, COL, or ML application. 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 A.03.02.05, "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 or non-safety-related safety-significant activities in support of the staff licensing activities will be issued as required by IMC 0617, "Vendor and Quality Assurance Implementation Inspection Reports."
- e. Potential noncompliance identified through inspection activities will be processed in accordance with the NRC's Enforcement Policy.

06.03 Inspector Qualification

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

2501-07 INSPECTION

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 or non-safety-related safety-significant SSCs.

If a QA program inspection is performed (see Section 03.02 of this IMC for applicability guidance), it will be conducted using the guidance contained in Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection," 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/or 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, LWA, CP, COL, or ML is issued.

In addition, the 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 noncompliance with NRC requirements or other applicant commitments. 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

- 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"
- 10 CFR Part 50.55, "Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses"
- 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
- 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"
- IMC 0617, "Vendor and Quality Assurance Implementation Reports"
- IMC 2506, "Construction Reactor Oversight Process General Guidance and Basis Document"
- IMC 2570, "Advanced Reactor Construction Oversight Process General Guidance and Basis Document"
- NEI 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development"
- NUREG-800 Standard Review Plan, Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit, and New License Applicants"
- Regulatory Guide 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors"

END

Attachments:

1. Inspection Procedures
2. Revision History for IMC 2501

Attachment 1: Inspection Procedures

35017	Quality Assurance Implementation Inspection
36100	Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance
36100.01	Inspection of 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance During Construction

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
N/A	ML25114A243 05/01/25 CN 25-010	Major revision that combined the requirements of IMC 2501 and 2502 into the revised IMC 2501. IMC 2501 also now includes both 10 CFR Part 50 and Part 52 pre-licensing activities (ESP, LWA, CP, COL, and ML).	N/A (appropriate personnel will be on concurrence for the revisions)	N/A