NRC INSPECTION MANUAL

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INSPECTION MANUAL CHAPTER 2502

CONSTRUCTION INSPECTION PROGRAM:
PRE-COMBINED LICENSE (PRE-COL) PHASE

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2502-01 PURPOSE

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

01.02 To provide guidance for the inspection, assessment, and documentation of pre-construction activities performed by the applicant and contracted suppliers of the applicant.

2502-02 OBJECTIVES

02.01 To verify that quality processes used in the development of the COL application are adequately described, and that technical, quality, and administrative requirements important to public health and safety are effectively implemented during the design and procurement phases of pre-COL activities.

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

02.03 To verify that the applicant's and contracted suppliers' ongoing pre-construction activities are being effectively implemented in accordance with the applicable 10 CFR Part 50 Appendix B QA requirements. The results of these inspection may support the NRC's future closure verification of ITAAC.

2502-03 APPLICABILITY

03.01 General. This inspection manual chapter (IMC) will initially be applied when an applicant tenders an application for a COL and will continue to be applied during the review process until the NRC issues a COL. The NRC will implement this IMC to inspect and assess the applicant's implementation of its QA program for safety-related activities in support of the COL and to evaluate the implementation of applicable 10 CFR Part 50, Appendix B quality assurance requirements by the applicant or contractor's on behalf of the applicant for pre-construction activities that occur prior to license issuance.

03.02 Applications Referencing an ESP. Violations of the conditions of an ESP identified during assessment or review of design engineering or site preparation activities conducted under IMC 2501, "Construction Inspection Program: Early Site Permit (ESP)," will be subject to enforcement, including notices of violation, civil penalties and orders.

2502-04 DEFINITIONS

04.01 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.

04.02 Contractor. Any organization or individual under contract to furnish items or services to a licensee engaging in an NRC-regulated activity. It includes the terms consultant, vendor,

supplier, fabricator, constructor, and sub-tier levels of these organizations.

04.03 Design Acceptance Criteria (DAC). A set of prescribed limits, parameters, procedures, and attributes upon which the NRC relies, in a limited number of technical areas, in making a final safety determination to support a design certification. DAC are part of the ITAAC inventory for a given design.

04.04 Design Control Document (DCD). A repository of information comprising the Standard Plant Design. The DCD also provides the design-related information to be incorporated by reference into the 10 CFR Part 52 Appendices containing the design certification rules (i.e., Appendices A, B, C and D).

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

04.06 Early Site Permit (ESP). Commission approval, issued under subpart A of Part 52, for a site or sites for one or more nuclear power facilities. An early site permit is a partial construction permit.

04.07 Inspection. (1) An NRC activity consisting of examination, observation, or measurement to determine applicant/licensee/contractor/vendor conformance with requirements and/or standards. (2) Applicant/licensee/contractor/vendor activity consisting of examination, observation, or measurements to determine the conformance of materials, supplies, components, parts, systems, processes or structures to pre-determined quality requirements.

04.08 Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC). Those inspections, tests, analyses, and acceptance criteria identified in the combined license 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.

04.09 Limited Work Authorization (LWA). The authorization provided by the Director of Nuclear Reactor Regulation under 10 CFR 50.10 allowing that person to perform the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of the foundation, including placement of concrete, any of which are for an SSC of the facility for which either a construction permit or combined license is otherwise required.

04.10 Pre-Construction Activity. Any activity conducted prior to issuance of a COL or LWA by the applicant or contracted suppliers on behalf of the applicant associated with a proposed ITAAC for safety-related components or portions of the proposed facility and occurring at other than the final, in-place location at the facility.

04.11 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 COL application reviews.

04.12 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.

04.13 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.

04.14 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.

04.15 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 to 10 CFR Part 50 have been and will be satisfied, including a discussion of how the QA program will be implemented.

04.16 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.

04.17 Safety Evaluation Report. The safety evaluation report (SER) provides the technical, safety, and legal basis for the NRC=s disposition of a license request (i.e., COL, early site permit, and design certification) or license amendment request.

04.18 Safety-related structures, systems and components (SSC). Those structures, systems and components that are relied upon to remain functional during and following design basis events to assure:

a. The integrity of the reactor coolant pressure boundary

b. The capability to shut down the reactor and maintain it in a safe shutdown condition; or

c. 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 this chapter, as applicable.

04.19 Standard Design. Standard design means a design that is sufficiently detailed and complete to support certification in accordance with Subpart B of 10 CFR Part 52 and that is usable for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

04.20 Standard Design Certification. Standard design certification, design certification, or certification means a Commission approval, issued under Subpart B of 10 CFR Part 52, of a final standard design for a nuclear power facility. This design may be referred to as a certified standard design.

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

04.22 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.

2502-05 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 pre-COL inspection program.

c. Approves changes to the pre-COL inspection program.

05.03 Deputy Regional Administrator for Construction.

a. Provides program direction for management and implementation of the inspection program elements performed by the regional office.

b. Within budget limitations, ensures the regional office staff includes an 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 pre-construction activities by the region inspection staff that occur prior to issuance of a license (e.g., COL, LWA).

2502-06 REQUIREMENTS

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

a. COL development process.

b. Design and procurement engineering activities.

c. QA program implementation.

d. Review of 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, provides 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, 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 or the accuracy and completeness of the COL 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 A03.02.05, “Witnessing Unsafe Situations,” of IMC-2506, “Construction Reactor Oversight Process General Guidance and Basis Document.”

d. Inspection documentation.

1. 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 COL will be issued as required by IMC 0617, “Vendor and Quality Assurance Implementation Inspection Reports.”

2. Inspections of pre-construction activities that may support the NRC’s future closure verification of ITAAC will be documented in accordance with IMC 0613, “Documenting 10 CFR Part 52 Construction Inspections”.

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 this manual chapter 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.

2502-07 TYPES OF INSPECTIONS

07.01 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 adequately 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 that SSCs will perform adequately in service.

Typically, one post-docketing QA program inspection will be conducted using the guidance contained in 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 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 COL 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 Parts 21 and 10 CFR 50.55(e) 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.

07.02 Pre-Construction Activity Inspections. The objective of these inspections is to gather information associated with an applicant's implementation of their QA program and oversight of their contractors performing pre-construction activities in support of facility construction.

Inspectors should use IP 35007, "Quality Assurance Implementation During Construction and Pre-Construction Activities," to evaluate the applicant's implementation of applicable 10 CFR Part 50, Appendix B quality assurance requirements for ongoing pre-construction activities performed by the applicant and contracted suppliers to the applicant.

Inspections will focus on pre-construction activities associated with proposed ITAAC that are included in the license application or in the certified design, where applicable. The results of these inspections may support the NRC's future closure verification of ITAAC. Information

gathered during these inspections will be reviewed for relevance to ITAAC closure after issuance of the license.

These inspections will most often be performed at or near the proposed plant site (e.g., co-located site), but may also be performed at other locations where such proposed ITAAC-related activities may be occurring. These inspections shall be conducted in accordance with the process described in Section 06.02 of IMC 2506.

2502-08 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.

2502-09 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.”

IMC 0613, “Documenting 10 CFR Part 52 Construction Inspections.”

IMC 0617, “Vendor and Quality Assurance Implementation Reports.”

IMC 2501, “Construction Inspection Program Early Site Permit (ESP).”

IMC 2506, “Construction Reactor Oversight Process General Guidance and Basis Document.”

END

Attachments:
1. Inspection Procedures
2. Revision History for IMC 2502

Attachment 1 – Inspection Procedures

Inspection Procedure No.	Inspection Procedure Title
35017	Quality Assurance Implementation Inspection Reports
36100	Inspection of 10 CFR Parts 21 and 10 CFR Part 50.55(e) “Programs for Reporting Defects and Noncompliance”
35007	Quality Assurance Implementation During Construction and Pre-Construction Activities

Attachment 2 – Revision History for IMC 2502

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	ML043070008 06/22/05 CN 05-016	Initial Issuance	N/A	N/A
N/A	ML072550206 10/03/07 CN 07-030	Revised to reflect program development and incorporate stakeholder feedback. Researched commitments for 4 years and found none.	N/A	ML072550328
N/A	ML103020140 12/13/10 CN 10-026	1. Delete all pre-COL application audits 2. Delete EDV inspections/audits 3. Added QA Program Review 4. Added Pre-Construction inspection activities 5. Modified definitions to be consistent with IMC-2506	N/A	ML103020145
N/A	ML 19324E320 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