

# **NRC INSPECTION MANUAL**

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MANUAL CHAPTER 2502

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

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## CONSTRUCTION INSPECTION PROGRAM: PRE-COMBINED LICENSE PHASE

### 2502-01 PURPOSE

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

### 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 provide guidance for the early inspection and review of licensee design engineering that was not covered as part of the design certification process, including review of First-of-a-Kind Engineering (FOAKE) items.

### 2502-03 DEFINITIONS

03.01 Audit. For the purposes of this manual chapter, 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 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.

03.05 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).

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

03.07 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.

03.08 FOAKE Inspections. Reviews of the applicant's translation of Tier 1 and Tier 2 certified design information into construction / design documents, including reviews of implementation DAC, changes to Tier 2 information included in the certified design, and site-specific issues.

03.09 Inspection. For the purposes of this manual chapter, 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.

03.10 Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC). Those inspections, tests, analyses, and acceptance criteria identified in the combined license that if met 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, and the Commission's rules and regulations. The ITAAC identified in a combined license referencing a certified design will include the ITAAC defined in the Tier 1 documentation. Site-specific ITAAC, which include emergency planning ITAAC and ITAAC that are not part of the certified design, will also be included in a combined license. ITAAC are conditions of the license and must be met prior to operation.

03.11 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.

03.12 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.

03.13 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.

03.14 Quality Assurance (QA). 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.

03.15 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.

03.16 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.

03.17 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.

03.18 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.

03.19 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.

03.20 Standard Design Certification. Standard design certification, design certification, or certification means a Commission approval, issued pursuant to Subpart B of 10 CFR Part 52, of a standard design for a nuclear power facility. A design so approved may be referred to as a certified standard design.

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

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

03.23 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.

## 2502-04 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 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.

04.03 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 geotechnical and site characterization activities as described in this manual chapter.

## 2502-05 DISCUSSION

05.01 General. This inspection manual chapter (IMC) will initially be applied when an applicant announces its intent to apply for a COL and will continue to be applied during the review process until the NRC decides to issue a COL. The NRC's decision to docket an application will be based on pre-COL audits that support the NRC staff's acceptance reviews. The NRC will implement this IMC to audit and assess the applicant's implementation of its QA and design engineering programs for activities performed prior to a COL application. The NRC will also implement this IMC to audit and assess the applicant's performance of design engineering activities in preparation for construction of a nuclear power facility.

The NRC will perform additional inspections and assessments after docketing the application to determine if the COL application meets the Commission's requirements and regulations and the provisions of the Atomic Energy Act.

05.02 Applications Referencing an ESP. Violations of the conditions of an ESP identified during assessment or review of design engineering or site preparation activities will be subject to enforcement, including notices of violation, civil penalties and orders.

## 2502-06 INSPECTION POLICIES AND GUIDANCE

06.01 Inspection/Audit Emphasis. Audit and 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. Implementation of Appendix B criteria.
- e. Review of 10 CFR Part 21 procedures.
- f. Commercial-grade dedication activities.

06.02 General Inspection/Audit Process. For each audit or inspection, the inspector should implement the process described below for pre-oversight activities, onsite oversight activities, and post-oversight activities. The inspection procedures listed in Attachment A provide more specific guidance for onsite oversight 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 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 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/audited. At the entrance meeting, the lead inspector should discuss the inspection/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/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 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/audit report. Prior to the exit, the lead inspector should determine whether his/her supervisor should be briefed on the preliminary findings.

- c. Post-inspection/audit activities. Audit reports will be issued as required by IMC-0614, "Documenting 10 CFR Part 52 Construction Inspection 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 in accordance with IMC-0614 or IMC-0612. Potential violations identified through inspection activities will be processed in accordance with the NRC's Enforcement Policy.

06.03 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 or audited in accordance with this manual chapter for a prior application. The reductions in inspection scope will be determined on a case by case basis by agreement between NRO and the Regional office.

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 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.

Audits will place particular emphasis on the applicant's QA program implementation related to 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 or COL site characterization activities to verify the effective implementation of the applicant's and contractor's QA programs. Observations of these activities should determine if QA program requirements are being adequately implemented as required by the applicant's and/or contractor's procedures affecting quality. 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 Pre-Application Audit. Typically a pre-application QA audit is performed to ensure accuracy and completeness of the application in accordance with the requirements of 10 CFR 50.9. Additionally, the pre-application audits verify that the applicant's QA programs are being effectively implemented to provide reasonable assurance of the integrity and reliability of the COL data or analyses that would affect the performance of SSCs. The pre-application QA audits also provide for a review of the adequacy 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 submits its COL application to verify the extent and effectiveness of the applicant's implementation of its QA program. The applicant's pre-application QA program will be inspected/audited with particular emphasis on the applicant's QA program implementation, including oversight of contracted activities. 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 region.

07.03 Post-Docketing Inspection. An application for a COL may, but need not, reference a standard design certification and/or an ESP. Attachment A of this IMC lists the inspection activities applicable to a COL application.

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.

After approval, the applicant's implementation of its QA Program will be inspected. Typically one post-docketing QA program inspection will be conducted using the guidance contained in IP 35017, "Quality Assurance Implementation Inspection," to verify the implementation of the applicant's QA program and to support the staff's supplemental SER input. These inspections will be led by DCIP in cooperation with the region. Follow-up inspections will be performed as necessary. Significant inspection findings relating to QA implementation should be resolved before the last supplemental SER for the COL is issued.

The post-docketing QA program inspection also includes a review and evaluation of the COL applicant's design reliability assurance program (D-RAP). NRO will approve the COL applicant's D-RAP before the applicant's 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 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.

07.04 FOAKE Inspections. The objective of the FOAKE inspections is to verify that the design process for a new plant being constructed under 10 CFR Part 52 of each certified design is effectively implemented in accordance with NRC regulations and the design commitments made in the applicable FSAR. See IP 37802, "First-of-a-Kind Design Engineering Inspections," for guidance. The focus of these inspections is on activities not covered previously by the design certification process.

FOAKE inspections will be conducted only when sufficient procurement, construction, and installation specifications, the documentation for closed DAC, deviations to the certified design, and site-specific issues have been completed and are available for inspection. The results of the review of the translation of Tier 1 and Tier 2 certified design information, including site-specific design information not confirmed during the certification process, into lower-tier construction/design documents will be used to assess the applicant's QA and engineering programs. While, from a programmatic standpoint the provisions of this IMC are intended to have been completed and end with the issuance of the COL, FOAKE inspections will likely continue after the issuance of the COL into the construction phase. Other engineering inspections (e.g., for matters subject to DAC) will continue to be conducted in accordance with other IMC provisions after the COL has been issued.

#### 2502-08 ENFORCEMENT ACTIONS

Possible enforcement actions associated with a COL 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 to 10 CFR Part 50 requirements and may be subject to enforcement actions, such as notices of violation and nonconformances.

#### 2502-09 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, 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:

A – Inspection Procedures to Support COL Issuance

B – Revision History

## Attachment A

### Inspection Procedures to Support COL Issuance

INSPECTION PROCEDURES (IPs)	
NUMBER	TITLE and INSPECTION REQUIREMENT
45051	Review of Geotechnical and Site Characterization Activities
35005	Quality Assurance Audit
35017	Quality Assurance Implementation Inspection
37802	First-of-a-Kind Engineering Inspections
36100	Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance

ATTACHMENT B

Revision History for IMC 2502

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
N/A	06/22/05	Initial Issuance	None	N/A	N/A
N/A	10/03/07 CN 07-030	Revised to reflect program development and incorporate stakeholder feedback. Researched commitments for 4 years and found none.	None	N/A	ML072550328