

NRC INSPECTION MANUAL

CQAB

MANUAL CHAPTER 2508

CONSTRUCTION INSPECTION PROGRAM:
DESIGN CERTIFICATION

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2508-01 PURPOSE

01.01 To provide guidance for the review of Design Certification (DC) applications and inspections to support this review activity.

01.02 To provide inspection guidance for activities directed towards the review of a DC application and related applicant activities governed by NRC regulations.

2508-02 OBJECTIVES

02.01 To provide assurance that the application for a DC meets requirements specified in Subpart B to 10 CFR Part 52.

02.02 To verify that quality processes used in the development of the DC 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 DC activities.

02.03 To verify effective implementation of the quality assurance (QA) program, as described in the application for a DC, satisfy the appropriate provisions of Appendix B to 10 CFR Part 50.

02.04 To verify whether the qualification testing activities supporting the application are conducted in accordance with the requirements of Appendix B to 10 CFR Part 50.

2508-03 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."

2508-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office of New Reactors (NRO). The Director provides the overall direction of 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 designs applications pursuant to 10 CFR Part 52.
- b. Assesses the effectiveness, uniformity, and completeness of the implementation of this MC.

05.01 General. This MC applies to the applicant and the applicant's contractors, and to activities related to NRC regulations related to the DC review process. The principal regulations for this phase are those described by Subpart B to 10 CFR Part 52. The DC review phase begins when the NRC receives notification of an applicant's intention to apply for a DC.

Where activities associated with the DC phase have been contracted to other organizations, this program applies to the organizations conducting the activities for the applicant organization.

05.02 QA Program Reviews. The QA program will be reviewed in accordance with the guidance contained in SRP 17.5. The staff should encourage an early submittal of the applicant's quality assurance topical report (QATR) or their quality assurance program description (QAPD) for staff review and issuance of an SER (provided the QAPD was not previously approved in an SER).

Departures from accepted QA process controls or deviations from accepted industry standards may require independent evaluations and additional communications with the applicant. This could extend the NRC review process. Where the QAPD contains significant deviations from NRC QA guidance (SRP 17.5) that could adversely impact the integrity or reliability of the design, the applicant should provide sufficient justification for the staff to address/consider the deviation. Significant deviations from NRC guidance could extend the NRC review process.

Based on the information provided by the applicant, and from audits and inspections performed under this MC, as appropriate, an SER will be issued. The SER documents the NRC approval of the QAPD, if not previously approved in another SER. In addition, as appropriate, the SER includes the inspection results to support the staff's disposition regarding the adequacy of the QAPD implementation.

05.03 Post-Docketing QA Program Inspection. Typically one inspection is conducted to verify the implementation of the applicant's QA program and to support the staff's SER input. Follow-up inspections are performed as necessary.

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 DC activities are conducted under the appropriate provisions of Appendix B to 10 CFR Part 50. Effective implementation of the QA program provides reasonable assurance of the integrity and reliability of the DC data or analyses that would affect the performance of safety related systems, structures, and components.

05.04 Design Qualification Testing Inspection. 10 CFR 52.47(c)(2) requires, in part, that a standard design that differs significantly from light water reactor designs, such as by using passive means to accomplish its safety functions, must demonstrate either through analysis, appropriate test programs, experience, or a combination thereof, the performance of each safety feature. This provision requires that the applicant develop and perform a design certification test program of sufficient scope that includes both separate-effects and integral-

system testing to provide data to assess the computer codes used to analyze plant behavior over a range of normal operating conditions, transient conditions, and specified accident sequences.

In addition, Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 states, in part, that where a test program is used to verify the adequacy of a specific design feature, the design control measures shall include suitable qualification testing of a prototype unit under the most adverse design conditions.

As necessary, and based on the design considerations, one or more design qualification testing inspections are performed. The objective of a design qualification testing inspection is to verify that test activities performed to support the design certification were conducted under the appropriate provisions of Appendix B to 10 CFR Part 50, and the applicant's QA program. Also as part of the inspection, the staff from the appropriate technical discipline will verify that the test program demonstrates the appropriate sequence of events and key phenomena influencing system (or component) behavior required to provide acceptable data to assess computer codes.

05.05 Inspection of Part 21 Program. The DC QA program inspections will include a review of the applicant's program associated with 10 CFR Part 21. This will provide assurance that the applicant has established appropriate procedures and programs to effectively implement 10 CFR Part 21 requirements for reporting defects and noncompliance.

05.06 Inspection Specifics. Inspections will be led by the Quality and Vendor Branches of NRO. Technical support, as needed, will be obtained from NRO technical staff or contractors. Enclosure 1 of this MC contains a list of all the inspection procedures that support DC inspection and audit activities.

2508-06 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. Enforcement actions associated with a DC application are not anticipated in the pre-docketing 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 and their contractors performing safety-related activities 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 nonconformance.

2508-07 INSPECTION REPORTS

Inspection reports will be issued by CQAB as required by IMC-0617, "Vendor and Quality Assurance Implementation Inspection Reports."

2508-08 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, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

U.S. Code of Federal Regulations 10 CFR Part 21, "Requirements for Reporting Defects and Noncompliance"

NUREG 0800, Standard Review Plan, Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants."

IMC 0617, "Vendor and Quality Assurance Implementation Reports."

END

Attachments:

1. Inspection Procedures
2. Revision History

ATTACHMENT 1

INSPECTION GUIDANCE

INSPECTION PROCEDURE NO.	INSPECTION PROCEDURE TITLE
35017	Quality Assurance Implementation Inspection
35034	Design Qualification Testing Inspection
36100	Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance

ATTACHMENT 2

Revision History for IMC 2508

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Accession Number
N/A	10/03/07 CN 07-030	Researched commitments for 4 years and found none. Issued to provide initial guidance for design certification inspections.	N/A	N/A
N/A	ML12209A155 03/08/2013 CN-13-008	Issued to discontinue the use of audits.	N/A	ML12209A151