

NRC INSPECTION MANUAL

IQVB

INSPECTION 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 toward the review of a DC application and related applicant activities governed by NRC regulations.
- 01.03 To provide inspection guidance for activities related to the protection of Safeguards Information (SGI) by design certification applicants/vendors that are required to protect SGI in accordance with an NRC Order, Title 10 of the Code of Federal Regulations (CFR) 73.21 and/or 10 CFR 73.22.

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, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."
- 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.
- 02.05 To verify that information protection systems effectively protect Safeguards Information (SGI), as defined in 10 CFR 73.21 and 10 CFR 73.22, and prevents unauthorized disclosure.

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 Nuclear Reactor Regulation (NRR).

The Director provides the overall direction of the NRC Construction Inspection Program.

04.02 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 designs applications pursuant to 10 CFR Part 52.
- b. Assesses the effectiveness, uniformity, and completeness of the implementation of this inspection manual chapter (IMC).

2508-05 DISCUSSION

05.01 General

This IMC 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.

The SGI protection inspection related portions of this IMC apply to applicants for design certifications and vendors who are required to protect SGI in accordance with 10 CFR Part 73 and applicable orders. Applicants and vendors will be subject to such inspections for as long as the applicant/vendor is required to protect SGI.

05.02 Quality Assurance Program Reviews

The QA program will be reviewed in accordance with the guidance contained in Standard Review Plan (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 a safety evaluation report (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 IMC, 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 10 CFR Part 21 Inspection

The DC QA program inspections will include a review of the applicant's program associated with 10 CFR Part 21, "**Reporting of Defects and Noncompliance.**" 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 Protection of Safeguards Information Inspection

Design certification applicants and vendors will be inspected to verify that their SGI protection program is effective in meeting applicable requirements. Inspections will be performed in accordance with, Inspection Procedure 81811, "Protection of Safeguards Information (SGI) Design Certification Applicants and Vendors." Protection of SGI Inspections will continue to be performed for as long as the applicant/vendor is required to comply with SGI protection requirements. Protection of SGI inspections may be included in regularly scheduled vendor inspections performed in accordance with IMC 2507, "Vendor Inspections."

05.07 Inspection Specifics

Inspections will be led by NRC's Quality Assurance and Vendor Inspection (IQVB) Branch. Technical support, as needed, will be obtained from NSIR technical staff or contractors. Enclosure 1 of this IMC contains a list of all the inspection procedures that support DC inspection activities.

05.08 Witnessing Unsafe Situations

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."

2508-06 ENFORCEMENT ACTIONS

The NRC's Enforcement Policy establishes the general principles governing the NRC's Enforcement Program and specifies a process for implementing the agency's enforcement authority in response to violations of NRC requirements. The NRC's Enforcement Manual provides specific guidance on implementation of the NRC enforcement program. Typically, enforcement actions associated with a DC application are not issued in the pre-docketing phase. However, the information submitted with the application will become subject to NRC regulations, up to and including enforcement actions for wrongdoing and submission of inaccurate and incomplete information. During the post-docketing phase, the applicant and their contractors performing safety-related activities will be subject to the requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50 and may be subject to enforcement actions, such as notices of violation and nonconformance. Activities related to protection of SGI, as delineated in the applicable order issued to the applicant/vendor, are also subject to enforcement actions.

2508-07 INSPECTION REPORTS

Inspection reports will be issued by IQVB 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"

U.S. Code of Federal Regulations 10 CFR Part 73, "Physical Protection of Plants and Materials"

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:

Attachment 1: Inspection Procedures

Attachment 2: Revision History for IMC 2508

Attachment 1: Inspection Guidance

<u>INSPECTION PROCEDURE NO.</u>	<u>INSPECTION PROCEDURE TITLE</u>
35017	Quality Assurance Implementation Inspection
35034	Design Qualification Testing Inspection
36100	Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance
81811	Protection of Safeguards Information (SGI) By Design Certification Applicants and Vendors

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 Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
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
N/A	ML16126A117 09/06/16 CN 16-022	Revised to address protection of SGI inspections for DC applicants and vendors.	N/A	ML16126A113
N/A	ML22097A207 05/03/22 CN 22-009	Periodic review completed. Revised inspection procedure to make minor editorial corrections and include updated references.	N/A	N/A