CONSTRUCTION INSPECTION PROGRAM: DESIGN CERTIFICATION

TABLE OF CONTENTS

2508-01 PURPOSE

This Manual Chapter (MC) provides guidance for the review of Design Certification (DC) applications, and audits and inspections to support this review activity.

This MC establishes audit and 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 the quality assurance (QA) program that is being applied to DC project activities satisfy the appropriate provisions of Appendix B to 10 CFR Part 50.

02.03 To verify, by inspection and audit, that the QA program supporting the DC application is adequately implemented.

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 as follows:

03.01 Audit. 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 QA program used in the development of the application.

03.02 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 subtier organizations.

03.03 Design Qualification Testing. A test to assure that a system and/or a component performs as designed. For example, thermal hydraulic testing provides thermal hydraulic data for computer code validation and simulates the operation of the design safety systems including anticipated accidents conditions.

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

03.05 Inspection. 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 the effectiveness of implementation of the QA program.

03.06 Nonconformance. The failure of a contractor or non-licensee (applicant) to meet a commitment that has not been made a legally binding requirement.

03.07 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. Standard Review Plan (SRP) 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," provides QA guidance for Design Certification reviews.

03.08 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.

03.09 Quality Assurance. 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.

03.10 Quality Assurance Program Description. 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.

03.11 Quality Control. 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 design requirements.

03.12 Safety Evaluation Report. The safety evaluation report (SER) provides the technical, safety, and legal basis for the NRC's disposition of a license request or license amendment request.

03.13 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.

03.14 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.

03.15 Tendered (Docketed) Application. An application that has been submitted but not accepted for docketing.

03.16 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.

2508-04 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 this MC.

b. Assesses the effectiveness, uniformity, and completeness of the implementation of this MC.

2508-05 DISCUSSION

05.01 DC Manual Chapter Scope. 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 Pre-Docketing Audit. Typically one QA audit is performed prior to the docketing of an application to verify that the development of the application is performed in a manner to ensure accuracy and completeness of the application in accordance with the requirements of 10 CFR 50.9. In addition, the regulations in 10 CFR Part 52 require that an Appendix B to 10 CFR Part 50 quality assurance program be implemented during DC quality-related activities. The pre-docketing QA audit provides assurance that a quality assurance program is being adequately implemented to control information that will be submitted as part of a DC application in accordance with the applicant's Appendix B to 10 CFR Part 50 QA program.

The Pre-Docketing QA program audit also provides for a review of the applicant's oversight of any contracted activities. The inspectors will review a representative sample of documents of the applicant and its contractors to provide assurance the quality assurance programs are being adequately implemented.

05.04 Post-Docketing 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.

05.05 Design Qualification Testing Inspection. 10 CFR 52.47(b)(2)(i)(A) 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.

05.06 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.

05.07 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

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 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

Audits reports will be issued by CQV as required by IMC-614, "Documenting 10 CFR Part 52 Construction Audit Activities." Inspection reports will be issued by CQV as required by IMC-0612, "Power Reactor Inspection Reports."

2508-08 REFERENCES

10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"

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"

END

Attachments:

1. Inspection Guidance
2. Revision History

ATTACHMENT 1

INSPECTION GUIDANCE

IP #	INSPECTION GUIDANCE
35005	Quality Assurance Program Audit
35017	Quality Assurance Implementation Inspection
35034	Design Qualification Testing Inspection
36100	Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance

ATTACHMENT 2

Revision History for IMC 2508

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment 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.	None	N/A	N/A