

HLWYM NPEmails

From: Vincent Everett
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To: James Rubenstone
Subject: New Reactor Program Parallel to MC 2300
Attachments: Comparison with New Reactor IMC.pdf; IMC 2501 highlighted.pdf; IMC 2502 highlighted.pdf; IMC 2503 highlighted.pdf; IMC 2507 highlighted.pdf; IMC 2508 highlighted.pdf

Jim

Attached is the new reactor program manual chapters that I reviewed before I started the draft MC 2300 to attempt to have some uniformity between what we were doing and the new reactor program. The highlighted sections were the portions that seemed applicable. It seemed that having a previous template would make it easier to justify what we were doing in our MC 2300. There is not a one-to-one relationship, but you can at least see the similarities.

Vincent

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Comparison with New Reactor IMC.pdf		3186
IMC 2501 highlighted.pdf	63094	
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**APPLICABILITY OF THE NEW REACTOR INSPECTION PROGRAM MANUAL
CHAPTERS TO THE YUCCA MOUNTAIN INSPECTION PROGRAM**

IMC	TITLE	APPLICABLE
2501	Construction Inspection Program: Early Site Permit	yes
2502	Construction Inspection program: Pre-Combined License Phase	yes
2503	Construction Inspection Program: Inspections of Inspections, Tests, Analysis & Acceptance Criteria (ITAAC) Related Work	yes
2504	Construction Inspection Program: Non-ITAAC Work	no
2507	Construction Inspection Program: Vendor Inspections	yes
2508	Construction Inspection Program: Design Certification	yes

NRC INSPECTION MANUAL

CQV

MANUAL CHAPTER 2501

**CONSTRUCTION INSPECTION PROGRAM:
EARLY SITE PERMIT (ESP)**

**CONCEPTS THAT ARE APPLICABLE TO THE YUCCA MOUNTAIN INSPECTION
PROGRAM ARE HIGHLIGHTED**

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CONSTRUCTION INSPECTION PROGRAM: EARLY SITE PERMIT

2501-01 PURPOSE

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

2501-02 OBJECTIVES

02.01 To verify that the information in the ESP application meets requirements specified in Subpart A to 10 CFR Part 52.

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

02.03 To provide guidance for the audit of ESP or combined license (COL) geotechnical and foundation activities to verify that data and analyses supporting the ESP or COL application are governed by an adequate QA program.

2501-03 DEFINITIONS

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 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 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.

03.05 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 to verify effective implementation of the QA program.

03.06 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.

03.07 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 requirements. 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 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.

03.11 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.

03.12 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 have been and will be satisfied, including a discussion of how the quality assurance program will be implemented.

03.13 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.

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

03.15 Tendered Application. As used in this document, 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.

2501-04 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.
 - b. Assesses the effectiveness, uniformity, and completeness of implementation of the ESP inspection program.
 - c. Approves changes to the ESP inspection program.
- 04.03 Deputy Regional Administrator for Construction.
- a. Provides program direction for management and implementation of the inspection program elements performed by their regional office.
 - b. Within budget limitations, ensures the regional office staff includes 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.

2501-05 DISCUSSION

This inspection manual chapter (IMC) will initially be applied when an applicant announces its intent to apply for an ESP and will continue to be applied during the review process until the NRC issues the ESP. The NRC's decision to docket an application will be based, in part, on pre-ESP audits that inform the NRC staff's acceptance reviews. The NRC will implement this IMC to assess the applicant's implementation of its QA program for activities performed prior to and during the ESP application development process. The NRC will also implement this IMC to audit and assess the applicant's performance of site characterization activities in preparation for construction of a nuclear power facility. Where the performance and/or surveillance of activities associated with the ESP phase have been contracted to other organizations, this IMC applies to the organizations conducting the activities for the applicant organization.

2501-06 INSPECTION POLICIES AND GUIDANCE

06.01 Inspection/Audit Emphasis. Audit and inspection emphasis is placed on the applicant's ESP development processes, inspecting design and procurement engineering activities, and inspecting QA program implementation. In addition to verifying the implementation of the applicable Appendix B criteria, inspections will include a review of the applicant's 10 CFR Part 21 procedures.

06.02 Inspection/Audit Plans. Inspection or audit plans are required for all inspections or audits. The lead inspector is responsible for preparation of the plan. The plans will follow the guidance contained in Section 06.03 of this manual chapter.

06.03 General Inspection/Audit Process. For each audit or inspection, the inspector should implement the process described below for pre-inspection/audit activities, onsite inspection/audit activities, and post-inspection/audit activities. The inspection procedures listed in Enclosure 1 provide more specific guidance for onsite inspection/audit 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 responsible team leader will develop an audit or inspection plan. 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/audit 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. At the entrance meeting, the lead inspector should discuss the inspection or 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 or 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. The lead inspector should emphasize that preliminary findings are always subject to management review before they are documented in an inspection or audit report. Prior to the exit, the lead inspector should determine whether his/her supervisor should be briefed on the preliminary inspection findings.

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

06.04 **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 in accordance with these instructions for a prior application. The reductions in inspection scope will be determined on a case by case basis by agreement between NRO and Region II.

06.05 **Inspector Qualification.** NRC inspectors will be assigned responsibility for those inspection requirements consistent with their qualifications.

2501-07 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 and Division of Site and Environment Reviews (DSER).

Audits will place particular emphasis on the applicant's QA program, 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 site characterization activities to verify the effective implementation of the applicant and contractor's QA programs. Observations of these activities should determine whether QA program requirements are being adequately implemented as required by the applicant and/or contractor's procedures. 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 QA Program Reviews. The QA program described in Chapter 17 of the ESP application will be reviewed according to 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 a SER).

Based on the information provided by the applicant 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, the SER will include the inspection results (when applicable) to support the staff's disposition regarding the adequacy of the QAPD implementation for ESP activities.

07.03 Pre-Application Audit. Typically one QA audit is performed to ensure accuracy and completeness of the application in accordance with the requirements of 10 CFR 50.9. Additionally, QA program audits verify that the applicant's QA programs are being effectively implemented to provide reasonable assurance of the integrity and reliability of the ESP data or analyses that would affect the performance of safety-related SSCs. Pre-application QA audits also provide for a review 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 tenders its ESP application to verify the extent and effectiveness of the applicant's implementation of its QA program. 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 lead region.

07.04 Post-Docketing Inspection. The objective of a post-docketing QA program inspection is to provide the staff with reasonable assurance that the QA program has been effectively implemented. IP 35017, "Quality Assurance Implementation Inspection," will be used as guidance for conducting this inspection. After the NRC staff approves the applicant's QA program and issues an SER, the NRC will inspect the applicant's

implementation of its QA Program. 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. These inspections will be led by DCIP in cooperation with the lead region. 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.

As noted in SRP 17.5, a QA program submitted by an ESP applicant applies to all phases of a facility's life, including design, construction, and operation. Construction and operational QA activities may be addressed in separate QA programs.

2501-08 ENFORCEMENT ACTIONS

Possible enforcement actions associated with a ESP 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 requirements and may be subject to enforcement actions, such as notices of violation and nonconformance.

2501-09 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 50.55, "Conditions of Construction Permits."

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:

1. INSPECTION PROCEDURES
2. REVISION HISTORY

ATTACHMENT 1

Inspection Procedures

Inspection Procedure No.	Inspection Procedure Title
35005	Quality Assurance Program Audit
35017	Quality Assurance Implementation Inspection
36100	Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance
45051	Review of Geotechnical and Site Characterization Activities

ATTACHMENT 2

Revision History for IMC 2501

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment Resolution Accession Number
N/A	05/29/03	Initial issuance	None	N/A	N/A
N/A	04/25/06	Delete requirement for Regional Administrator to send letter to Nuclear Reactor Regulations (NRR) Office Director recommending issuance of ESP	None	N/A	N/A
N/A	10/03/07 CN 07-030	<p>1. Delete procedures for meetings and updated guidance for pre-application audits.</p> <p>2. Incorporate the new requirements of 10 CFR Part 52 and SRP 17.5 guidance.</p> <p>3. Researched commitments for 4 years and found none.</p>	None	N/A	ML072570180

NRC INSPECTION MANUAL

CQV

MANUAL CHAPTER 2502

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

PORTIONS OF THIS PROCEDURE THAT SHOULD BE INCORPORATED INTO
MC 2300 THAT ARE NOT IN MC 2501 ARE HIGHLIGHTED

THIS MC INCLUDES INFORMATION ON ENGINEERING/DESIGN

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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.

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.

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

NRC INSPECTION MANUAL

CCIB

MANUAL CHAPTER 2503

CONSTRUCTION INSPECTION PROGRAM:
INSPECTIONS OF INSPECTIONS, TESTS,
ANALYSES, AND ACCEPTANCE CRITERIA (ITAAC)
RELATED WORK

PORTIONS OF THIS PROCEDURE THAT SHOULD BE INCORPORATED INTO
MC 2300 THAT ARE NOT IN MC 2501 ARE HIGHLIGHTED

THIS MC INCLUDES SEVERAL CONCEPTS SUCH AS "FINDING VS MINOR
FINDING," "LONG LEAD TIME ITEMS," AND "PERIODIC REVIEW OF INSPECTION
FINDINGS TO DETERMINE IF THE INSPECTION EFFORT SHOULD BE CHANGED."

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**CONSTRUCTION INSPECTION PROGRAM:
INSPECTIONS, TESTS, ANALYSES, AND ACCEPTANCE CRITERIA
(ITAAC)**

2503-01 PURPOSES

01.01 To specify the policy used for the NRC's inspection of the Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) of a combined license or Limited Work Authorization (LWA).

01.02 To provide guidance for inspections intended to support the Commission's determination, in accordance with 10 CFR 52.103(g), that the acceptance criteria in the combined license have been met.

2503-02 OBJECTIVES

02.01 To provide guidance to inspectors on inspection of ITAAC-related work activities.

02.02 To provide a sufficient basis to support the Commission determination in accordance with 10 CFR 52.103(g) that the acceptance criteria in a combined license have been met.

2503-03 DEFINITIONS

03.01 Construction Activities. Any activity associated with the construction, fabrication, or testing of structures, components, subcomponents, subsystems, or systems either at the construction site or at remote fabrication or testing facilities. Construction activities also include related design and engineering activities including design changes for the structures, systems, and components.

03.02 Construction Inspection Finding. A hardware or programmatic finding that is not material to ITAAC closeout verification. A Construction Finding may result in enforcement actions in accordance with the Enforcement Policy.

03.03 Construction Inspection Program Information Management System (CIPIMS). The computer database that provides the means to document, report, and track all NRC inspection activities and their results.

03.04 Contractor. Any organization under contract for furnishing items or services to a licensee. It includes the terms consultant, vendor, supplier, fabricator, constructor, and subtier levels of these organizations.

03.05 Family of ITAAC. A grouping of ITAAC that are related through similar construction processes, resulting products, and general inspection attributes.

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

03.07 Inspection Assessment. Periodic reviews of inspection findings by NRC management to determine if the current level of inspection effort should change.

03.08 Inspection Sample. Items or groups selected for inspection of one or more inspection characteristics.

03.09 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.

03.10 ITAAC Attributes. A number of common, descriptive characteristics for each ITAAC that can be analyzed and weighted by a methodology that allows the ITAAC to be prioritized for inspection planning.

03.11 ITAAC Closeout. The process by which the licensee affirms that an ITAAC has been satisfactorily completed.

03.12 ITAAC Closeout Verification. The NRC process which evaluates the licensee's affirmation of satisfactory ITAAC completion.

03.13 ITAAC Finding. A finding of such significance that, if not corrected, would prevent the NRC from reaching a positive ITAAC determination. An ITAAC finding may be related to a single ITAAC or a family of ITAAC.

03.14 ITAAC Matrix. An inspection planning tool that identifies groups (i.e., "families") of ITAAC, based upon common characteristics, which facilitate the ITAAC inspection sampling process and provide a consistent model for the inspection of ITAAC at plants of a similar design.

03.15 Minor Findings. Any inspection result that does not affect the successful completion of an ITAAC or a licensee program. These results may include issues related to record keeping; insignificant dimensional, time, calculation, or drawing discrepancies characterized by minor discrepant values referred to in the licensee's Final Safety Analysis Report (FSAR) or design documents; or insignificant procedural errors that have no impact on the quality of design, fabrication, construction or testing.

03.16 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. Quality Assurance includes quality control.

03.17 Tier 1 Material. Tier 1 refers to the portion of the design related information contained in the design control document that is approved and certified by the NRC through the rulemaking process. Tier 1 information includes : Definitions and general provisions; design descriptions; ITAAC; significant site parameters; and significant interface requirements.

03.18 Tier 2 Material. Tier 2 refers to the portion of the design related information contained in the design control document that is approved but not certified by the NRC. Tier 2 information includes : Information required by 10 CFR52.47 with the exception of technical specifications and conceptual design information; Information required for a final safety analysis report under 10 CFR 50.34; supporting information on ITAAC that will be performed to demonstrate that the acceptance criteria have been met; and Combined License (COL) information items which identify certain matters that are addressed by a COL applicant that references a certified design. Tier 1 material is derived from Tier 2 material. Compliance with Tier 2 is required and demonstrates a sufficient but not the only method for complying with Tier 1.

2503-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Office of New Reactors (NRO). The Director, NRO, has responsibility for:

- a. Providing the overall direction of the construction inspection program and directing the development and implementation of policies, programs and procedures for the construction inspection program.
- b. Providing inspector resources to support and augment regional inspector resources assigned to construction projects.
- c. Publishing notices in the Federal Register of the successful completion of ITAAC in accordance with 10 CFR 52.99.
- d. Making the recommendation to the Commission regarding a determination pursuant to 10 CFR 52.103(g) that the acceptance criteria have been successfully completed.

04.02 Region II Office. The Deputy Regional Administrator for Construction has responsibility for:

- a. Supporting the Commission finding required by 10 CFR 52.103(g) by informing the Director, NRO, on the licensee's completion of the ITAAC, the plant's readiness to load fuel, and the overall readiness for operation.

04.03 Region II Construction Inspection Staff. The Region II Construction Inspection Staff (CIS) has responsibility for:

- a. Implementing the construction inspection program and documenting inspection findings.
- b. Providing NRO with the status of inspections related to specific ITAAC.
- c. Coordinating the development of the site inspection plan.
- d. Integrating all of the inspection findings to develop an overall assessment of licensee performance as described in IMC 2505.

04.04 Headquarters Construction Inspection Staff. The Headquarters Construction Inspection Staff (CIS) has responsibility for:

- a. Administering and monitoring the execution of the construction inspection program.
- b. Ensuring the requisite inspection procedures are maintained current and accurate.
- c. Ensuring that the necessary inspection record is maintained to support final NRC determination of satisfactory ITAAC completion.

2503-05 BACKGROUND

05.01 General. When licensing a plant under 10 CFR Part 52, the Commission is required by § 52.97(b)(1) to identify "...within the combined license, the inspections, tests, and analyses; including those applicable to emergency planning that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Atomic Energy Act, and the Commission's rules and regulations."

In addition, § 52.103(g) requires that "... the Commission shall find that the acceptance criteria in the combined license are met" prior to allowing the facility to operate. Successful completion of the ITAAC are the responsibility of the licensee. The NRC will use inspections of construction activities to independently verify that the licensee successfully carries out construction activities and identifies and corrects deficiencies which may have an impact on the ITAAC. The results of the construction inspection program implemented through this manual chapter will form the basis of the staff's recommendation to the Commission's determination, in accordance with 10 CFR 52.103(g), of whether the acceptance criteria have been met.

05.02 ITAAC Inspection Overview. The NRC may begin ITAAC inspection when an applicant begins procurement of long lead time components, such as reactor vessels. Since many of the ITAAC are oriented towards system completion, they may not be completed until construction is nearly complete. Therefore, the staff intends to implement an ITAAC inspection approach which will require NRC inspectors to observe ITAAC-related construction activities as they are performed.

The NRC has developed a framework to prioritize the ITAAC and allow for more efficient

inspections. This framework is structured to integrate complementary inspection activities that evaluate the licensee's control of the construction processes. Central to the NRC's inspection program for construction under 10 CFR Part 52 is the ITAAC Matrix which provides a means for ensuring adequate inspection coverage of ITAAC inspections. The matrix will be populated with the ITAAC applicable for each certified design as described in Appendix B to this manual chapter. Site specific ITAAC will be added to the matrix population once they have been identified.

The approach to ITAAC inspection will require inspectors to evaluate the acceptability of ITAAC-related processes. The NRC will perform sampling-type inspections of ITAAC-related activities to verify that the licensee is performing the activities successfully. The selection of the ITAAC for each design to receive direct inspection will be based on a prioritization process used to determine overall inspection value.

When the licensee notifies the NRC that an ITAAC is complete, they will also identify the bases for the ITAAC completion. NRC reviews of the licensee's ITAAC documentation as well as any NRC inspection history for that ITAAC will determine if the licensee's ITAAC completion letter and its associated bases are satisfactory.

The staff will use the Construction Inspection Program Information Management System (CIPIMS) to link inspection results to the docket, the inspection report, and the specific ITAAC.

2503-06 PROGRAM REQUIREMENTS

06.01 Inspection Requirements. The inspection procedures (IPs) applicable during construction are identified in Appendix A to this manual chapter. The listed IPs will be used by NRC inspectors when conducting inspections of ITAAC-related construction activities.

2503-07 PROGRAM MANAGEMENT

07.01 Inspection Planning. The staff shall develop an inspection plan to verify that ITAAC related construction activities are being successfully performed. This plan shall include as a minimum the baseline inspection requirements for the selected certified reactor design. The plan shall provide the level of detail necessary to determine the general time-frame in which each occurrence of an inspection procedure is to take place.

- a. The licensee's construction schedule shall be used to identify when key activities will be available for inspection.
- b. The overall schedule will incorporate all of the planned inspection activities for the planned period of construction. The Construction Inspection Scheduler (CIS) should review this schedule regularly to adjust it for changes to the licensee's construction schedule. The overall construction inspection schedule will be used for planning of inspection resources (i.e., ensuring the required inspection skills or engineering disciplines are available when required).

07.02 Implementation. The inspection program is intended to provide the framework for managing the inspection effort. When and how often each inspection procedure should be performed during the construction period, and when each inspection procedure occurrence should be performed will be determined during development of the site specific inspection plan.

Inspectors are encouraged to pursue any safety or risk significant concern. However, inspectors must identify the inspection procedure used to perform inspection activities and to accurately record this information and the inspection results so they can be incorporated into CIPIMS.

Regional managers responsible for the construction inspection program shall periodically review inspection results to monitor progress on the inspection plan. Changes to the inspection plan will occur as part of the assessment process as described in IMC 2505 "Periodic Assessment of Construction Inspection Program Results."

07.03 Inspection Results. NRC inspections of ITAAC related work are expected to result in the early identification and resolution of problems, their root causes, and generic implications. All inspection observations and inspection results will be documented in accordance with IMC 0613 "New Reactor Construction Inspection Reports."

a. Categories of ITAAC Inspection Results. Because of their potential for affecting the NRC's verification of successful ITAAC completion, inspection findings will be categorized to reflect their impact on ITAAC. The documentation requirements for the different types of inspection results are described in IMC 0613, Construction Inspection Reports. Listed below are the categories into which inspection findings will be placed.

1. ITAAC Finding - A finding in which the NRC has determined that an ITAAC has not or will not be met if the deficiency is not corrected. Resolution of an ITAAC finding will require the licensee to provide a determination of the extent to which the condition may exist. The issue will be assigned an NRC tracking number in CIPIMS that will be tied to the related ITAAC. Followup inspections and reviews will monitor and document licensee corrective actions until closure. Any followup reviews and the basis for closing an ITAAC finding must be documented in an inspection report to ensure a complete history of the issue in the public record. An ITAAC determination submitted by a licensee for a specific ITAAC will not be accepted by the NRC for closure if an ITAAC finding remains open against that ITAAC.
2. Construction Inspection Finding - A hardware or programmatic finding that is not material to ITAAC closeout verification. A Construction Finding may result in enforcement actions in accordance with the Enforcement Policy.
3. Minor Finding - Findings that would not affect the licensee's ability to meet the ITAAC. These include minor record keeping issues, insignificant dimensional, time, calculation, or drawing discrepancies, or insignificant procedural errors that have no impact on the quality of design, fabrication, erecting or testing. Findings in this category are expected to be resolved

successfully by the licensee through the corrective action program.

- b. Assessment of Inspection Results. NRC will periodically review inspection results to determine if the current level of inspection effort should be changed. The review of inspection results will focus on two factors: (1) the implementation of specific construction activities as documented in the inspection history and (2) the implementation of the licensee's quality assurance program. This approach will assure that any deficiencies that have been identified by the licensee or NRC have been adequately addressed by the licensee's QA program and have resulted in effective corrective actions. The NRC's confidence in the licensee's construction activities is directly related to confidence in the quality assurance program. This process will be further defined in IMC 2505.

07.04 ITAAC Determinations. The licensee will notify the NRC when an ITAAC has been successfully completed. The NRC will review each ITAAC completion basis for adequacy and accuracy. The NRC's determination of successful ITAAC completion will be based on a combination of inspection results, technical staff reviews, and a review of the information submitted by the licensee. The inspection history may reflect any or all of the following: direct inspection related to the specific ITAAC; inspection results from direct inspection of similar ITAAC within an ITAAC family; and inspection results from direct inspection of processes related to that specific ITAAC. The NRC will publish in *Federal Register* notices the successful completion of inspections, tests, and analyses, as required by 10 CFR 52.99.

07.05 Enforcement. During the construction period, the agency will process identified violations of NRC regulations and conditions of the COL in accordance with the CIP process and the Commission's Enforcement Policy, NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

END

Appendix A: IMC-2503 Inspection Procedures
Appendix B: The ITAAC Matrix
Appendix C: Revision History for IMC 2503

APPENDIX A: IMC-2503

INSPECTION PROCEDURES

- IP 65001 - ITAAC Inspections
 - 65001.01 - Foundations and Buildings
 - 65001.02 - Structural Concrete
 - 65001.03 - Piping
 - 65001.04 - Pipe Supports & Restraints
 - 65001.05 - RPV & Internals
 - 65001.06 - Mechanical Components
 - 65001.07 - Valves
 - 65001.08 - Electrical Components & Systems
 - 65001.09 - Electrical Cable
 - 65001.10 - I&C Components & Systems
 - 65001.11 - Containment Integrity & Penetrations
 - 65001.12 - HVAC
 - 65001.13 - Equipment Handling & Fuel Racks
 - 65001.14 - Complex Systems with Multiple Components
 - 65001.15 - Fire Protection
 - 65001.16 - Engineering
 - 65001.17 - Security
 - 65001.18 - Emergency Planning
 - 65001.19 - Radiation Protection
 - 65001.A - As Built Inspection
 - 65001.B - Welding
 - 65001.C - Construction Testing
 - 65001.D - Operational Testing
 - 65001.E - Qualification Criteria
 - 65001.F - Design/ Fabrication Requirements

APPENDIX B: The ITAAC Matrix

BACKGROUND: The goal of inspections conducted under IMC-2503 is to verify licensee compliance with all 10 CFR Part 52 ITAAC requirements, as well as other relevant NRC regulations, using an integrated inspection and review strategy.

The ITAAC inspection philosophy contained in IMC-2503 recognizes that several ITAAC are expected to be closely related, thereby providing the NRC with the opportunity to evaluate a family of ITAAC based upon an examination of some representative ITAAC within the family. Such an inspection approach would allow for the efficient use of NRC inspection resources for evaluation of the construction processes that result in the ITAAC completion.

OBJECTIVE: A framework was developed by the NRC to manage ITAAC inspections, while recognizing the need for a sampling-inspection approach. This framework was structured to integrate inspection activities that evaluate the licensee's control of the construction processes into the NRC inspection program. Central to the NRC's CIP for construction under 10 CFR Part 52 is a tool that provides a coherent approach to the coverage and completion of the ITAAC related inspections. This tool is called the ITAAC Matrix and is shown in Figure 1.

OVERVIEW: The ITAAC Matrix provides a means for assigning each ITAAC into a matrix block referred to as an ITAAC family. Each family represents a combination of ITAAC characteristics related to the successful ITAAC completion.

The IPs for the 19 Matrix rows provide guidance on the inspection of specific technical disciplines, while the IPs for the six Matrix columns discuss those inspection criteria that crosscut disciplinary boundaries. The 25 IPs developed to address all Matrix categories provide a template for ITAAC inspections, as well as inspection of the licensee's control of the construction processes. This facilitates the process of inspecting the selected sample of ITAAC, but also ensures adequate coverage of all construction disciplines. For example, all ITAAC within a specific plant design that discuss instrumentation and control (I&C) components and systems and specific as-built inspection criteria would be binned in the matrix block formed at the intersection of row (10) and column (A).

POPULATING THE ITAAC MATRIX: Each ITAAC for a specific design is evaluated and assigned to the appropriate family by selecting the appropriate combination of row and column. Site specific ITAAC will also be added to the population once they have been identified.

- a. An NRC expert panel reviews all the ITAAC for each design. An expert panel will generally consist of a minimum of three NRC personnel with some combination of expertise in plant construction, reactor risk, and project licensing, including some relevant plant design and ITAAC experience.
- b. The expert panel will review each of the ITAAC and will place it in one of the

families of the ITAAC Matrix.

- c. Once the expert panel determines where in the Matrix each of the ITAAC for a particular design should be placed, all facilities constructed with that particular design will use that ITAAC Matrix.

This use of a single ITAAC Matrix format provides a consistent framework for developing the inspection programs for each of the different reactors that are licensed and built under 10 CFR Part 52. This also ensures consistency in the inspection program within any specific design.

Figure 1: THE ITAAC MATRIX

	A)As-Built Insp	B) Welding	C)Const Testing	D) Opn Testing	E)Qual Criteria	F)Design /Fab Req
01)Foundations & Buildings	A01	B01	C01	D01	E01	F01
02)Struc Conc	A02	B02	C02	D02	E02	F02
03)Piping	A03	B03	C03	D03	E03	F03
04)Pipe Spt & Restraints	A04	B04	C04	D04	E04	F04
05)RPV & Int'l's	A05	B05	C05	D05	E05	F05
06)Mech Comp	A06	B06	C06	D06	E06	F06
07)Valves	A07	B07	C07	D07	E07	F07
08)Elec Comp & Systems	A08	B08	C08	D08	E08	F08
09)Elec Cable	A09	B09	C09	D09	E09	F09
10)I&C Comp & Systems	A10	B10	C10	D10	E10	F10
11)Containment Integrity & Pen's	A11	B11	C11	D11	E11	F11
12)HVAC	A12	B12	C12	D12	E12	F12
13)Eqp Handle & Fuel Racks	A13	B13	C13	D13	E13	F13
14)Complex Sys w/ Multi-Comp	A14	B14	C14	D14	E14	F14
15)Fire Prot	A15	B15	C15	D15	E15	F15
16)Engineering	A16	B16	C16	D16	E16	F16
17)Security	A17	B17	C17	D17	E17	F17
18)EP	A18	B18	C18	D18	E18	F18
19) Rad Prot	A19	B19	C19	D19	E19	F19

- Column Categories [A thru F]: Interdisciplinary NRC inspection activities that represent common ITAAC attributes. An NRC inspection procedure (IP) will correspond to each column category.

- Row Categories [1 thru 19]: Construction processes & resulting products (e.g., SSC) that relate to a unique discipline, with an IP corresponding to each row category.

NOTES:

Column Classification

[A] “As-Built Inspection” comprises the functional/physical arrangement series of ITAAC, to include checks for location, alignment, dimensions, sizing, and measurements, and may include functional checks, unless related to testing (which would be covered by [C] or [D]) or a design report/analysis (which would be covered by [F]). Simple calculations (e.g., a screen area or tank volume) that can be made from field measurements or sizing estimates would be covered here based upon the dimensional checks; however, more complex calculations, even if field measurements are involved, would better be categorized in [F]. If a single ITAAC involves both as-built information, like a physical or dimensional check, and other criteria, like those for an operational test [D] or design analyses/calculations [F], the [D] or [F] categories, as applicable, would take preference over this as-built [A] category. Also, checking that a meter or display is located properly (e.g., is on the Main Control Board) would be categorized here [A], while reading the meter or retrieving data from the display as part of an operational test would better be categorized in [D].

[B] “Welding” comprises those ITAAC which address any welding process, whether code referenced (e.g., ASME piping) or oriented to other processes (e.g., structural steel or electrical supports). This category also includes those ITAAC which address or provide criteria for weld quality, e.g. the requirements for the nondestructive examination (NDE) of welds. Additionally, activities and programs related to the welding process (e.g., welder training, testing, and certification; weld procedure qualification; NDE personnel and procedure qualification; other weld testing activities) are all included in this welding [B] category.

[C] “Construction Testing” includes specific ITAAC tests that are associated with the quality of component fabrication and construction activities, to include quality acceptance tests (e.g., concrete testing or simulated signal testing to confirm Class 1E division boundaries), baseline data checks (e.g., PSI), and field-work completion testing (e.g., “hydro’s”) or any other similar construction testing activities. In-process field testing of individual pieces of equipment would be covered here, while the construction-complete, pre-operational test phases leading to integrated system testing would better be categorized in [D]. However, the testing (e.g., “type tests”) of equipment for “qualification” in a harsh environment (EQ) or in analyzing seismic response, as well as for other like programmatic “qualification criteria”, should be covered by [E], as described in note (E) below.

[D] “Operational Testing” involves testing activities that check component and system function by measuring operational parameters (e.g., flow requirements) and/or validating operational performance acceptance criteria (e.g., component actuation with signal inputs or similar “pre-op” testing). Such tests might be performed on a single component, an individual system, or a complex, integrated system. Similarly, as with “Construction Testing” above, “type tests” and equipment “qualification” should be covered by [E].

[E] “Qualification Criteria” includes seismic qualification, environmental qualification (EQ) and other ITAAC qualification programs and any related program attributes that are oriented toward broad design criteria versus the specific test parameters of [C] or [D]. The characteristics of such programs as the Design Reliability Assurance Program (DRAP)

might be considered here, which would include any Design Acceptance Criteria (DAC) associated with a particular facility design.

[F] “Design/Fabrication Requirements” cover those ITAAC that refer to Code (e.g., ASME) requirements for the fabrication of material and components or discuss the adequacy of design by reference to analyses, calculations, bounding condition checks, functional assessments, engineering evaluations and other design reports. However, if “Welding” is the primary fabrication process, this is better categorized in [B]. If construction or operational “Testing” result in design parameters/measurements, this is better categorized in [C] or [D]. Also, if the design analyses involve programmatic “Qualification Criteria” (e.g., seismic), this would be better categorized in [E]. Where a report exists, or the functional capabilities of the system/components are analyzed, to confirm compliance with general Code requirements versus specific test results or programmatic qualification criteria, it should be covered here under [F].

Row Classification

(01) “Foundations & Buildings” include geo-technical (e.g., rock) investigation, civil surveying, elevation grading, pre-construction preparations (e.g., “mudmats”) and site layout, including the arrangement of buildings and structures; except that the Containment, as a separate “Building”, is covered by line (11) while its “Foundation” is covered here with all site foundations. This category also includes the building framework, like the structural steel and bolting materials. However, any ITAAC discussing the details of construction of the buildings that are more specifically defined by other Matrix rows will be classified by that process [i.e., “Structural Concrete” (02) for concrete buildings, “Mechanical Components” (06) for large metal tanks, or “Engineering” (16) for generic design criteria (e.g., seismic) of buildings, like the nuclear island].

(02) “Structural Concrete” includes all the materials (e.g., cement and rebar) and processes (e.g., concrete batch mixing and delivery) that result in a steel reinforced concrete placement, as well as embedments, anchors, anchorages, water barriers that are installed before or after the concrete placement, and structural grout. Any items that are installed in the formwork (for example, anchor bolts that are embedded in the concrete when placed) are covered by this line item, while items that are subsequently attached to finished concrete are covered by other functional categories; for example, concrete expansion anchors, which are known to provide piping support or electrical raceway support, are covered under lines (04) and (09) respectively. For work on placed and finished concrete, where the ultimate function is unknown (e.g., expansion anchors for general supports), such activities are covered here under (02).

(03) “Piping” includes all piping, whether safety-related or not, and covers all ASME classes including the reactor coolant pressure boundary, as well as piping referenced in other codes (e.g., B31.1). ITAAC that describe systems that deliver fluid flow through piping as the major function, as well as the pressure boundary function (e.g., the pressure rating verified by hydrostatic testing) of such systems, are best categorized here. However, if the system functions and test acceptance criteria are more complex, involving diverse component interactions, the ITAAC might better fit (14) for “Complex Systems w/ Multiple Components”.

(04) “Pipe Supports & Restraints” apply to all classes of piping and all types of supports (e.g., snubbers, struts, anchors, guides) and pipe whip restraints. The seismic adequacy of piping systems would likely be applied here in (04). However, if the ITAAC focuses on the seismic qualification of a unique component (e.g., a pump) instead of the piping system, “Mechanical Components” (06) would be most appropriate line for categorization.

(05) “Reactor Pressure Vessel (RPV) & Internals” While the RPV may be considered a mechanical component or part of a fluid-flow system, it is uniquely covered here, along with the reactor internals. However, any instrumentation internal to the RPV is best categorized on the I&C line (10).

(06) “Mechanical Components” include all classes (ASME or non-safety) of equipment (e.g., pumps, heat exchangers, strainers, etc.), but not “Valves” (07) and not “HVAC” (12). It also includes any mechanical equipment support that is unique (e.g., a steel pedestal) to the component, rather than part of the building structure [e.g., concrete pads with anchor bolts that are part of “Structural Concrete” (02)]. Storage tanks that are fabricated metal components would fit here (06), but concrete tanks with only a liner, may best fit under “Structural Concrete” (02).

(07) “Valves”, regardless of the type of operator (e.g., motor, hydraulic, air, squib, etc.), are considered here as a separate category of mechanical components because of the unique nature in the way they are described in the ITAAC. This category covers all valves, including check valves and any other valves of a similar self-actuating nature. Also, any valve functions related to containment isolation are covered in line (11), “Containment Integrity & Penetrations”.

(08) “Electrical Components & Systems” include all electrical equipment (e.g., diesel generators) and supporting distribution components (e.g., switchgear), except for the cables. Because of their unique nature, containment electrical penetration assemblies are included here instead of line (11).

(09) “Electrical Cable” involves all cable and includes the raceways (e.g., conduit, cable tray) in which it is run and the raceway supports (e.g., “unistrut”), unless they are part of the building structural steel (01) or pipe supports (04).

(10) “I&C Components & Systems” include sensing instrumentation and actuation control equipment, including the system hardware (e.g., signal process cabinets) and logic process devices, as well as the related signal initiation, control and annunciation checks, e.g., including those for the Main Control Board (MCB). Displays on the MCB and the retrieval of the information from the MCB windows or other panels and cabinets in the main control room (MCR) would be covered here. However, low-voltage instrument cable is covered under (09), “Electrical Cable”, with all other cable.

(11) “Containment Integrity & Penetrations” involve the Containment structure and boundary, including all aspects of the containment isolation function. Therefore, any containment isolation check (e.g., a valve closure) or integrity criteria (e.g., hatch leakage) are covered here, instead of line (07) for valves or line (06) for mechanical components. However, the containment concrete material and placement is covered by “Structural Concrete” (02) and the electrical penetration assemblies are considered “Electrical

Components” (08).

(12) “Heating, Ventilating & Air Conditioning” [HVAC] involves air distribution and environmental control systems from a functional standpoint, thereby including all mechanical, electrical, and I&C equipment that is directly related to the HVAC function or system performance.

(13) “Equipment Handling and Fuel Racks” includes the components involved with equipment handling and movement (e.g., polar crane), fuel movement (e.g, fuel bridges) both inside and outside of containment, and the spent fuel storage racks and related equipment. The fuel itself is not covered here, but rather in line (05) as an “internal” component.

(14) “Complex Systems with Multiple-Components” is intended to cover categories that discuss attributes that cross disciplinary boundaries, for example electrical, I&C, and valve response are all connected to the same ITAAC. This would also cover any ITAAC that refer to Tables of equipment, that would fit multiple lines of the Matrix if the components were evaluated separately; for example, a Table that lists valves, mechanical components, and I&C components. This category should be used when the nature of the ITAAC does not lend itself to clear placement in one of the other categories. However, even for complex systems, where the ITAAC focus is specific (e.g., the pressure boundary function of an integrated piping system), the matrix category (in this example line (03) for piping) that best fits the focal point of the ITAAC should be selected.

(15) “Fire Protection” includes all related material, equipment, systems, processes, and programs.

(16) “Engineering” is a separate line to distinguish it as a “process” separate from the construction activities that result in the SSC and products on the other lines. If design criteria (e.g., flooding analyses) are the dominant focus of an ITAAC (e.g., building room boundaries) “engineering” would apply. Similarly, for design issues (e.g., seismic) and more subjective areas (e.g., human reliability analysis) that cross disciplinary boundaries, are “engineering” oriented, and difficult to categorize on any other line, the most applicable categorization may fit here under line (16).

(17) “Security” and (18) “Emergency Planning” (EP) are separate lines to cover the systems, processes, and programs related to these activities.

(19) “Radiological Protection” includes not only all radiation protection (RP) components and RP system functions, but also those processes and programs related to RP, similar to the way fire protection and security systems and programs fit under lines (15) and (17)

respectively. An ITAAC that refers generally to the EP function, which might include radiological protection, is better categorized under line (18); while a more direct reference to RP equipment functionality and the programs that support the use of RP data would fit here under line (19).

APPENDIX C

Revision History For IMC 2503

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
N/A	04/25/06	Initial Issuance	None	N/A	N/A
N/A	10/03/07	Researched commitments for 4 years and found none. Revised to reflect program development and incorporate stakeholder feedback.	None	N/A	N/A

NRC INSPECTION MANUAL

CQV

MANUAL CHAPTER **2507**

CONSTRUCTION INSPECTION PROGRAM: VENDOR INSPECTIONS

**PORTIONS OF THIS PROCEDURE THAT SHOULD BE INCORPORATED INTO
MC 2300 THAT ARE NOT IN MC 2501 ARE HIGHLIGHTED**

THIS MC INCLUDES THE CONCEPT OF VENDOR INSPECTIONS

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CONSTRUCTION INSPECTION PROGRAM: VENDOR INSPECTIONS

2507-01 PURPOSE

01.01 To establish the inspection program for vendors providing safety-related materials, equipment, and services in support of new reactor construction.

01.02 To provide requirements and guidance to NRC inspectors for conducting inspections at vendor facilities.

2507-02 OBJECTIVES

02.01 To verify effective implementation of vendor quality assurance programs as a means of assuring the quality of materials, equipment, and services supplied to the commercial nuclear industry.

02.02 To verify effective implementation of commercial-grade dedication programs for safety-related materials, equipment, and services.

02.03 To assure that vendors have an effective system for reporting defects under 10 CFR Part 21.

02.04 To conduct inspections at vendor facilities to help support the Commission determination that the acceptance criteria in a combined license have been met in accordance with 10 CFR 52.99 and 10 CFR 52.103(g).

02.05 To obtain sufficient information through inspection activities at vendor facilities to assure that root causes of reported vendor related problems are being identified and suitable corrective actions are developed and implemented.

02.06 To assure that follow-up and resolution of allegations, 10 CFR Part 21 or 10 CFR Part 50.55(e) reports, and licensee event reports (LERs) assigned to the Quality and Vendor Branch (CQV) are accomplished in a timely manner.

02.07 To assure that fraudulently marketed products are traced to their source and that licensees are informed so that the fraudulent products can be removed from use or possible use.

02.08 To provide input to the NRC operating experience program of instances involving substandard, suspected counterfeit, or fraudulently marketed vendor products and to gather information in order to provide timely information to licensees and other users.

2507-03 DEFINITIONS

03.01 Announced Inspection. The licensee/vendor or any member of the licensee/vendor organization is notified by the lead inspector or any member of the NRC staff that an inspection is to be conducted. The announcement may be made by a written communication, telephone call, or other communication informing any member of the licensee/vendor organization that an inspection may or will take place at a specific time or date.

03.02 Basic Component. A structure, system, component, or part thereof that affects its safety function necessary to assure:

- The integrity of the reactor coolant pressure boundary;
- The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in 10 CFR 50.34(a)(1), 10 CFR 50.67(b)(2), or 10 CFR 100.11, as applicable.

Basic components are items designed and manufactured under a QA program complying with Appendix B to 10 CFR Part 50, or commercial-grade items which have successfully completed the dedication process.

In all cases, a basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

03.03 Counterfeit or Fraudulently Marketed Items. Items that are deliberately manufactured or altered in such a way as to misrepresent the actual quality of the item with intent to defraud or deceive the purchaser.

03.04 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 rules and regulations.

03.05 ITAAC Family. A grouping of ITAAC that are related through similar construction processes, resulting products, and general inspection attributes.

03.06 Nonconformance. A vendor's or certificate holder'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 or certificate holder.

03.07 Quality Assurance Manual. A compilation of quality assurance documents that define the quality assurance policy and program, describe the method(s) by which the policy will be implemented through procedures and instructions, and identifies the parties responsible for implementation.

03.08 Reactive Vendor Inspection. Inspections performed for the purpose of obtaining additional information and/or verifying adequate corrective actions on reported problems

or deficiencies involving vendor supplied products or services. Reactive inspections are typically performed in response to a specific problem identified by any group within the NRC (e.g., including headquarters, the regional offices), or in response to allegations or other identified problems (e.g., 10 CFR Part 21 or 10 CFR 50.55(e) reports) from outside sources.

03.09 Routine Vendor Inspection. Inspections performed to verify effective implementation of a facility's QA program used to furnish basic components to the nuclear industry.

03.10 Supplier. For the purposes of this manual chapter, any organization that supplies basic components to a vendor, applicant, or holder of a 10 CFR Part 52 license.

03.11 Unannounced Inspection. The vendor or any member of the vendor organization is not notified by the inspector or any member of the NRC staff until the inspector arrives at the vendor's facility or at the site where the inspection is to be conducted.

03.12 Unresolved Item. Any inspection finding that requires more information in order to determine that it is an acceptable item or whether a violation or nonconformance may exist.

03.13 Vendor. For the purposes of this manual chapter, any company or organization that provides products such as material, equipment, components, or services to be used in an NRC-licensed facility or activity. In certain cases the vendor may be an NRC licensee (e.g., a nuclear fuel fabricator) or the product may have NRC certificates (e.g., a transportation cask).

03.14 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.

2507-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office of New Reactors (NRO). Provides overall direction for the NRC vendor inspection program.

04.02 Director, Division of Construction, Inspection, and Operational Programs (DCIP).

- a. Directs the implementation of policies, programs, and procedures for inspecting vendors, applicants, licensees, and other entities.
- b. Assesses the effectiveness, uniformity, and completeness of implementation of the vendor inspection program.
- c. Approves changes to the vendor inspection program.

2507-05 DISCUSSION

The NRO Quality and Vendor branches (CQV) are responsible for implementing the construction vendor inspection program at facilities where basic components are designed, manufactured, or stored. Routine and reactive inspections are conducted to verify that the vendor QA programs are implemented and comply with the applicable regulatory requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

This manual chapter provides NRC guidance for inspection and assessment of vendor QA programs in support of new reactor licensing and construction activities. Specifically, this chapter defines the vendor inspection program for the following activities:

- Inspections of vendor QA program implementation during design and procurement activities in support of an application for a combined license (COL). This encompasses ITAAC-related activities associated with vendors, such as inspection of offsite fabrication, modular construction techniques, and fabrication of long-lead components.
- Inspections to assess whether the vendor QA programs address specific processes such as commercial-grade dedication practices, vendor/licensee and vendor/applicant oversight, and reporting of defects and noncompliance associated with safety-related components or services utilized in a nuclear power plant in accordance with 10 CFR Part 21.
- Inspections to verify that root cause analyses of reported defects and failures to comply are being identified and that suitable corrective actions are developed and implemented.
- Provide input to the NRC operating experience program in order to provide timely information to the nuclear industry of potential issues that are safety significant and with generic implications. These issues could include substandard, suspected counterfeit, or fraudulently marketed vendor products.

2507-06 INSPECTION POLICIES AND GUIDANCE

06.01 Vendor Selection. The selection of vendors for inspection is based on several factors, that include:

- The significance to safety of the equipment or service provided,
- Verification of inspections, tests, analyses, and acceptance criteria (ITAAC) in support of onsite construction activities,
- Input from the technical staff necessary to support completion of design certification (DC) and combined license (COL) reviews,
- The frequency and significance to safety of problems identified with vendor-supplied materials, equipment, or services, including third-party auditing organizations,

- The number of licensees affected by the problem identified, the performance history of a vendor, and
- Other information received by CQV from allegations, Part 21 reports, 50.55(e) reports, Licensee Event Reports (LERs), and other NRC organizations.

The results of past inspections, event evaluations, and inspector and management reviews should be used to schedule and determine the focus of planned inspections at each vendor facility.

06.02 Inspection Emphasis. Inspection emphasis is placed on manufacturing processes employed by vendors during the design, fabrication, and testing of basic components. The inspectors will ensure that the vendor's quality processes meet applicable industry codes, standards, and regulatory requirements.

In addition to verifying the implementation of the Appendix B criteria described above, vendor inspections will include the review of the vendor's 10 CFR Part 21 or Part 50.55(e) procedures and, when applicable, activities performed as part of commercial-grade dedication.

To support ITAAC verification and closure, inspectors will focus on components related to a certified design ITAAC and will verify the necessary critical attributes to provide input into the ITAAC closure process.

06.03 Inspection Plans. Inspection plans are required for all inspections. The lead inspector is responsible for preparation of the inspection plan. Inspection plans will follow the guidance contained in Section 06.06 of this manual chapter.

06.04 Development of Generic Communications. The CQV will prepare input to the Construction Inspection and Allegation Branch in NRO for the development of generic communications (bulletins, information notices, generic letters, or regulatory information summaries) to alert the nuclear industry and others of vendor-related product/service deficiencies.

06.05 Inspection Contractor Support. In the past, vendor inspections have used contractor support as one method for increasing the technical expert resources available to the NRC for carrying out its inspection responsibilities. Such contractor augmentations have proven to be extremely helpful for these headquarters-based inspection efforts. Like all NRC team inspections, contractor-supported team inspections are led by an NRC team leader having inspection authority and responsibility. There is no delegation of NRC inspection authority or responsibilities to a contractor.

06.06 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 Enclosure 1 provide more specific guidance for onsite inspection activities.

- Pre-inspection activities.** To facilitate management of inspection resource allocations and tracking of inspection activities, the lead inspector should develop

facility-specific inspection plans consistent with the guidance described below.

The responsible team leader will develop an inspection plan. The inspection plan will identify the vendor facility, describe the scope and major areas of emphasis that will be reviewed, evaluated, or assessed. In addition, the inspection plan should identify the inspection type, team members, and the inspection schedule. This plan is to be reviewed and approved by the responsible Branch chief. For inspections involving allegations, inspection plans shall be controlled at all times by the inspection team.

Inspections will be typically announced 30 calendar days in advance. The lead inspector will contact the vendor representative (preferably the QA Manager), announce the upcoming inspection, and discuss the inspection schedule. It may be appropriate to inform the vendor as to the purpose, estimated duration, and the number of NRC inspectors expected to take part in the inspection. The specific areas to be covered should also be described if this will facilitate and be consistent with the objectives of the inspection. For inspections involving allegations, the lead inspector shall not disclose that the inspection is in response to an allegation.

The inspectors should review the vendor's recent inspection and enforcement history (if available), any outstanding open items, third-party audit report if available, and any events (e.g., §50.72 reports, Part 21 notifications) reported by the vendor.

- b. Onsite inspection activities. Entrance and exit meetings with vendor personnel should be scheduled in advance to minimize the impact on other vendor activities. The lead inspector should hold an entrance meeting with the senior vendor representative (preferably the facility's QA Manager) who has responsibility for the areas to be inspected. At the entrance meeting, the lead inspector should discuss the inspection scope with vendor management and other administrative matters, such as the observation of facility operations, interviews with staff, and/or document reviews. Whenever possible, the lead inspector should schedule a daily status meeting with vendor management to discuss the inspection progress and issued identified.

An exit meeting should be conducted with vendor management at the conclusion of the inspection. The results of the inspection, including preliminary findings, should be presented emphasizing their impact on safety. 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 determine whether his/her supervisor should be briefed on the preliminary inspection findings.

- c. Post-inspection activities. Inspection findings/observations will be documented in accordance with IMC-0612, "Power Reactor Inspection Reports." Inspection issues that cannot be resolved at the time of the inspection will be documented as unresolved items in accordance with IMC-0612.

2507-07 TYPES OF INSPECTIONS

The following types of inspections are performed by the Quality and Vendor Branch. Enclosure 1 lists the inspection procedures that are applicable to the vendor inspection program as described in this manual chapter.

07.01 Routine Inspections. The inspectors will review the vendor's QA program and verify effective implementation of QA controls for activities related to the basic component being provided. The inspectors will also verify that the QA program provides controls for reporting of defects and noncompliance. For vendors performing dedication of commercial-grade items, the inspectors will verify that the facility has implemented an effective commercial-grade dedication program. In addition, the inspectors will verify the vendor's capability to assure the quality of basic components procured by licensees or applicants. Typically one inspection is conducted to verify implementation of the vendor's QA controls. Follow-up inspection are performed as necessary.

07.02 Reactive Inspections. The inspectors will verify that vendors of basic components have developed and implemented adequate procedures to evaluate and correct conditions adverse to quality. Reactive inspections are conducted in response to allegations, previous inspection findings, reports in accordance with Part 21 and/or 50.55(e), and other information sources indicating the possibility that NRC requirements are not being met. Typically one inspection is conducted to verify implementation of the vendor's QA controls. Follow-up inspection are performed as necessary.

07.03 Third-Party Audit Oversight. The NRC staff will provide oversight of third-party audit activities (e.g., Nuclear Procurement Issues Committee (NUPIC)) on a periodic basis. This includes participation in third-party audit organization meetings related to vendor performance. The purpose of NRC oversight of third-party audit organizations is to verify the effective implementation of the audit process to ensure that the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B are satisfied. These audits are conducted twice a year by the Quality and Vendor branches.

2507-08 ENFORCEMENT ACTIONS

Potential violations identified through inspection activities will be processed in accordance with the NRC's Enforcement Policy, NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

2507-09 REFERENCES

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

U.S. Code of Federal Regulations. 10 CFR Part 50.55, "Conditions of Construction Permits."

U.S. Code of Federal Regulations. 10 CFR Part 50, Appendix B, "Quality Assurance

Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.”

ASME NQA-1-1994, “Quality Assurance Program Requirements for Nuclear Facilities.”

END

Attachments:

1. Inspection Procedures
2. Revision History

ATTACHMENT 1

INSPECTION PROCEDURES

Inspection Procedure No.	Inspection Procedure Title	Procedure Applicability: Routine (R) or As Needed (N)
VENDOR INSPECTION PROCEDURES		
43002	Routine Inspections of Nuclear Vendors	R
43003	Reactive Inspections of Nuclear Vendors	N
QUALITY ASSURANCE INSPECTION PROCEDURES		
36100	Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance	R
43004	Inspection of Commercial-Grade Dedication Programs	N

ATTACHMENT 2

Revision History for IMC 2507

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	Initial issuance to establish guidance for 10 CFR Part 52 vendor inspections Researched commitments for 4 years and found none.	None	N/A	N/A

CONSTRUCTION INSPECTION PROGRAM:
DESIGN CERTIFICATION

PORTIONS OF THIS PROCEDURE THAT SHOULD BE INCORPORATED INTO
MC 2300 THAT ARE NOT IN MC 2501 ARE HIGHLIGHTED

THIS MC INCLUDES THE CONCEPTS OF QUALIFICATION TESTING OF PROTO-
TYPES WHICH WOULD BE APPLICABLE TO DOE EXPERIMENTS SUCH AS THE
ALLOY 22 LONG TERM TESTING, ETC

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ATTACHMENT 1 Inspection Guidance A1-1

ATTACHMENT 2 Revision History A2-1

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