

DESIGN CERTIFICATION TESTING INSPECTION

PROGRAM APPLICABILITY: IMC 2508

35034-01 INSPECTION OBJECTIVE

To verify that testing activities, performed in support of design certification, are conducted in accordance with the applicable provisions of Appendix B to 10 CFR Part 50 and the applicable quality assurance (QA) program.

This procedure may be supplemented by Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection."

35034-02 BACKGROUND

10 CFR 50.43(e) requires, in part, that a reactor design that differs significantly from light-water reactor designs that were licensed before 1997, or uses simplified, inherent, passive or other innovative means to accomplish safety functions, must demonstrate satisfactory performance of each safety feature through analysis, appropriate test programs, experience, or combination thereof. When testing is used for satisfying this requirement, the applicant must develop and conduct a design certification test program of sufficient scope that includes separate-effects and integral-system testing to provide data for assessing the adequacy of computer codes used to analyze plant response over a range of operating and transient conditions, and certain accident scenarios.

Design certification testing provides reasonable assurance that design features of **structure, systems, or components (SSCs) described in the design certification application (DCA)** perform as designed under postulated service conditions. Design certification tests also provide thermal-hydraulic data for validation of computer codes and simulate the operation of a safety system or design feature under the design conditions. Design certification testing is typically conducted with scaled or full-size models, or **representative components** with additional features to simulate integral system performance.

35034-03 INSPECTION REQUIREMENTS

The inspector will verify that the applicable (applicant and/or contractor) quality assurance (**QA**) program and controls for the design certification test program are adequate for the testing to be conducted and effectively implemented. The inspection will, as a minimum, cover the following areas:

- a. Test Control and Configuration Management

- b. Control of Measuring and Test Equipment
- c. QA Records
- d. Personnel Qualification

However, inspection activities within this area should consider all applicable elements of Appendix B to 10 CFR Part 50.

35034-04 INSPECTION GUIDANCE

Review the implementation of QA criteria applicable to design certification testing. The inspection will typically address the following QA program elements:

04.01 Test Control and Configuration Management.

- a. Test Program

General Guidance.

1. Verify that a documented test program effectively demonstrates that an SSC meets the design specifications and will perform reliably in service.
2. Verify that the test plan fully implements the test specifications specified by the design authority.
 - (a) Verify that DCA provisions and design specifications are correctly translated into test requirements.
 - (b) Verify the adequacy of the test configuration with respect to support of the test program.
3. Verify that the test program describes program responsibilities and authorities, including personnel augmenting test program staff during performance of the tests.
4. Verify that the design certification test plan describes the scope, pre-testing activities and responsibilities, and data acquisition requirements.
5. Verify that technical information crossing organizational interfaces is accurate and controlled. Determine that there are clearly defined lines of authority and communication within and among the applicant testing organization and contractor organizations for changes, notifications, reporting, approvals, and stop work.

Specific Guidance.

1. Review the test program description to verify that it clearly and comprehensively describes the processes necessary to accomplish stated test program objectives

and provides the controls necessary for successful performance of the test(s) and functionality of test equipment.

2. Review the design certification test plan to verify that it adequately controls the translation of technical information and contract specifications into test parameters that can be monitored and controlled across the range of interest. Review the configuration controls necessary for performance of the test; verify that important dimensions and physical attributes of the design features to be tested and critical aspects of the test facility conform to the design specifications.
3. Review organizational description, responsibilities, and authority for the test facility staff and support personnel, particularly those positions responsible for conduct of testing and data reduction. Specifically, review test procedures, test criteria, and test requirements with respect to defined responsibilities and oversight by test management and technical and QA personnel.
4. Review a sample of planned test runs to verify that they clearly describe the purpose and objectives of the test, test prerequisites, instrumentation, test sequence and test instrumentation and data acquisition hardware and software. Verify that test responsibilities and the data to be collected as the basis for establishing the design certification testing are clearly defined. Review test facility prerequisites necessary to commence the test. Review a sample of completed test records for compliance with the QA plan and operating procedures; representative records would include test logs, instrument diagrams, and correspondence related to approval of test documentation and software, personnel training and qualification records.
5. Review procedures controlling the flow of technical and QA information across organizational interfaces. Review the integrity and effectiveness of record systems and databases for controlling this information. Typical records would include customer correspondence imposing technical requirements or changes thereto, changes in organizational responsibilities, resolution of test anomalies through appropriate design and procedural changes, actions taken in connection with any nonconformances noted during testing, including justification for acceptance of testing deviations, and review, concurrence, and approval of test documents and revisions.

Test Plan and Procedures.

General Guidance.

1. Verify that the test plan and procedures provide adequate description of pre-testing, testing and post-testing activities.
2. Verify the adequate implementation of test plan and procedures, including a walkdown of the test setup and observation of testing (if practical).

Specific Guidance.

1. Review the test plan and selected procedures to confirm the adequacy of test objectives, QA requirements, facility description and control, data acquisition and

analysis, initial conditions, prerequisites, instructions, acceptance criteria, and post-test activities.

2. Conduct a walkdown of the test setup to verify that the test of the representative SSC is performed under appropriate environmental conditions that will demonstrate the performance of the actual SSC for its service application as described in the DCA and design specifications. Evaluate the differences between the design certification test and the service application described in the design specifications to verify that the test results will demonstrate the design feature(s) of the SSC in accordance with 10 CFR 50.43(e).
3. Confirm adequate implementation of the test plan and procedures by witnessing design certification testing. This inspection should be coordinated with the applicant to allow observation of the design certification testing by the inspectors. If direct observation of the design certification testing is not possible, review test documentation or other test related activities that are occurring. Specifically, the inspector should confirm that the following test plan elements and procedures have been satisfied, verified, and recorded:
 - (a) Test parameters and initial conditions
 - (b) Test acceptance criteria
 - (c) All test prerequisites
 - (d) Test facility environmental conditions
 - (e) Formal test procedure revision
 - (f) Mandatory hold points and QA verification were completed
 - (g) Test anomalies (unanticipated events and conditions) and their disposition
 - (h) Test instrumentation range, accuracy, and uncertainty were appropriate for the test
 - (i) Test instrumentation calibration was current
 - (j) Test procedure sequence was followed, or deviations were adequately evaluated and documented.

b. Configuration Management

General Guidance.

1. Verify that an appropriate configuration control program has been developed and implemented to process test configuration design changes and modifications.
2. Verify that test facility configuration controls are adequate to support design certification testing for the contracted component or design feature.

3. Verify that **test configuration** instrumentation and components are correctly identified and called out in as-built drawings and test procedures.
4. Verify that the change process for **modifications** to the test configuration is adequate.
5. Verify that administrative controls have been established for controlling temporary modifications to the test facility or procedures.
6. Verify that controls have been established for documenting test failures or deviations that occur during the conduct of design certification tests.
7. Verify the adequate implementation of controls for re-work, modification, and/or repair activities.

Specific Guidance.

1. Review and confirm the adequacy of the process and procedures for changes and modifications to the test facility or equipment. The inspector should confirm that the following elements of configuration control have been implemented:
 - (a) Test facility description
 - (b) Instrumentation list and description
 - (c) Line diagrams for process and test instrumentation and piping (air, hydraulic, mechanical) - P&ID
 - (d) Master equipment list
 - (e) Dimensional inspection report
 - (f) Control log/database for changes to the test **configuration**
 - (g) Record of field changes, and requests for engineering changes
2. Review selected documents (such as drawings, sketches, and procedures) for adequate implementation of verification, labeling, and approval process for the testing of the component or design feature.
3. Review a sample of test instrumentation that was altered as part of the modifications to confirm that the adequacy of the range, type, and accuracy of new instrumentation is consistent with as-built drawings and procedures.
4. Select a substantive modification and perform a walkdown of the test facility to verify that:
 - (a) "As-built" modification matches the design documents.
 - (b) Applicable test facility procedures were updated.

- (c) Responsible test facility personnel were trained.
5. The inspector should ensure that measures have been provided for temporary changes to drawings pending formal issuance. Where temporary mark-ups are used, the inspector should ensure that the drawing is legible and clear so that they are effectively implemented by test personnel.
 6. Review the controls established for the reporting and disposition of non-conforming test results by reviewing a sample of nonconformance/deviation reports to determine that:
 - (a) Records adequately document current status of nonconformances and deviations.
 - (b) Records are legible, complete, and provide objective evidence and that reports are promptly reviewed by qualified personnel for adequacy and completeness, disposition, and prioritization.
 - (c) Records are routinely processed through established channels for resolution of the immediate issue, as well as for evaluation of the impact on test results.
 - (d) Records are properly identified, stored, and retrievable in a reasonable timeframe.
 - (e) Nonconformance reports include the status of corrective action or resolution.
 - (f) Resolution of nonconformances is appropriate and demonstrates good engineering practice.
 7. Review a sample of records to verify that controls for re-work, modification, and/or repair activities are being adequately implemented. The sample may include logs, marked-up drawings, tags, re-work order, purchase order to contractor for rework/modification activity, re-work order documenting work performed, records of re-performed tests to **demonstrate the capability** of the modified SSC **for design certification testing** and the assessment report documenting review and approval of retests by design organizations.

c. Test Results and Data Reduction

General Guidance.

1. Verify that suitable QA requirements are being implemented in the data collection process.
2. Verify that process and functional responsibilities are established for effective evaluation of test results.

3. Verify that the test results are evaluated to demonstrate that the SSC performance satisfies the service application described in the DCA and design specifications.
4. Verify that controls are implemented for test deficiencies and design changes based on the test results.
5. Verify that supplemental testing to demonstrate SSC performance following design changes based on initial test results is acceptable.

Specific Guidance.

1. Review the test facility's QA plan and controls applicable to data collection (log taking and software). Assess the completeness of the selected QA plan requirements with regard to traceable, verifiable data and with regard to documenting the accuracy of instruments used to collect data. Review design documents for the data acquisition system and assess the implementation of the QA plan with regard to the data acquisition system's design, modification and programming.
2. The process should provide for the following:
 - (a) Test data are reduced to a format facilitating design certification of the component or design feature.
 - (b) Test results are compared with the specified performance criteria.
 - (c) Test deficiencies are clearly identified, and appropriate corrective action has been proposed, reviewed and completed.
 - (d) Evaluations were reviewed and approved by responsible test engineer/management and submitted to the design organization for final approval.
 - (e) Design changes based on test results are controlled and evaluated to demonstrate that the design specifications are satisfied.
 - (f) Supplemental testing of an SSC that has received design modifications based on initial test results is conducted in a controlled manner with an evaluation of the SSC performance to demonstrate that service application as described in the DCA and design specifications is satisfied.

04.02 Control of Measuring and Test Equipment (M&TE).

General Guidance.

- a. Verify the calibration standards are traceable to a recognized standard.
- b. Verify that procedures are established and controlled to assure that M&TE is controlled, calibrated, and maintained at prescribed intervals or prior to use.

- c. Verify that measures are established to assure that the type, range and accuracy of M&TE conform to established requirements.
- d. Verify that measures are in place for the control and disposition of M&TE found to be out of calibration and provide for documented evaluation of the acceptability of previous inspection or test results involving the equipment.

Specific Guidance.

- a. Verify that the calibration of M&TE is traceable to a nationally recognized standard administered by the National Institutes of Standards and Technology (NIST). If the test facility is located in a foreign country, verify that calibration of MT&E is traceable to a standard recognized by the appropriate government ministry in the country responsible for administering calibration standards.
- b. Review the test facility calibration program and implementing procedures for the control of M&TE to confirm compliance with Criterion XII to 10 CFR Part 50, Appendix B. Select and review calibration records for a sample of test instrumentation for a particular test for compliance with test and procedural requirements.
- c. Review the instrumentation used for the test(s) to verify that calibration is current. Review the instrumentation range, accuracy and uncertainty for adequacy of their use for the design certification test(s).
- d. Review a sample of evaluation records documenting out-of-tolerance conditions for compliance to procedural requirements. Review a sample of test facility calibration records in issue logs and test data sheets for procedural compliance.

04.03 QA Records.

General Guidance.

- a. Verify that QA requirements provide for assignment of record responsibilities, retention periods and storage conditions.
- b. Verify that sufficient records are generated to document activities affecting quality, such as the results of reviews, inspections, tests, audits, process monitoring, materials analyses and records for qualification for personnel, procedures, and equipment.
- c. Verify that QA records are retrievable, legible, adequate, and are adequately protected. Records should refer to markings, identification tags, or other means of identifying critical components.
- d. Verify that appropriate provisions have been established to maintain electronic media records including monitoring for degradation.

Specific Guidance.

- a. Review applicable portions of test facility QA program and supplemental QA procedures to verify that responsibilities for control of record storage, transfer and retention, retention periods and authority to dispose records have been assigned. Review the

facility record retention policies and procedures.

- b. Review a representative sample of test program records and verify that controls have been adequately implemented.
- c. Select a sample of completed records to verify that information supporting the records is available, accurate, identifiable, and complete and that records are traceable to the test for which the record was generated.
- d. Review records retention program to ensure that there is a process in place to monitor potential degradation of records maintained on electronic media and that provisions have been established to migrate degraded records without loss of technical content.

04.04 Personnel Qualification.

General Requirements.

- a. Verify that training programs have been established and implemented for the indoctrination and training of personnel performing test activities to assure that proficiency was achieved and maintained.
- b. Verify that qualification records document any certifications required by industry and contract requirements and have been periodically evaluated, reviewed, and approved in accordance with QA program requirements.
- c. Verify that training of test facility personnel was conducted and documented to familiarize personnel with facility hardware and software, equipment operation, test plans and procedures, and test specifications.

Specific Guidance.

- a. Review the indoctrination and training records to assure that the training program was been established. Review a sample of qualification records for guidance to qualify personnel involved in quality related activities.
- b. Review a sample of training records to verify that personnel have received and maintained qualification standards as described in the program and required by industry and contract requirements. Verify that training records have been periodically evaluated, reviewed, and approved in accordance with QA program requirements.
- c. Review training plans and a sample of training records to verify that both reflect the information in accordance with the QA plan. Verify that the personnel received and maintained the appropriate training related to test facility hardware and software, equipment operation, test plans and procedures, and test specifications.

35034-05 RESOURCE ESTIMATE

The resource estimate for this inspection procedure is 240 hours of direct inspection effort.

35034-06 REFERENCES

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

10 CFR Part 50.43, "Additional Standards and Provisions Affecting Class 103 Licenses and Certifications for Commercial Power."

American Society of Mechanical Engineers (ASME), Quality Assurance Program for Nuclear Facilities, NQA-1, 1994 Edition, in particular the basic and supplementary requirements for test control (Section 11).

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

END

Attachment 1: Revision History Sheet for IP 35034

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Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
NA	ML082140148 01/27/10 CN 10-003	<p>Researched commitments for 4 years and found none,</p> <p>IP 35034 is issued to verify that testing activities, performed in support of design certification, are conducted in accordance with the applicable provisions of Appendix B to 10 CFR Part 50 and the applicable quality assurance (QA) program.</p>	Not Applicable (N/A)	N/A
	ML19350C675 03/23/20 CN 20-017	Updated to incorporate additional guidance based on implementation of IP 35034.	N/A	N/A