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## INSPECTION PROCEDURE 40600

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### LICENSEE PROGRAM FOR INSPECTIONS, TESTS, ANALYSES, AND ACCEPTANCE CRITERIA (ITAAC) MANAGEMENT

PROGRAM APPLICABILITY: 2504

#### 40600-01 INSPECTION OBJECTIVES

01.01 To verify that programmatic controls have been established to govern ITAAC closure.

01.02 To verify that the licensee's ITAAC process for preparing and approving closure letters is adequate and conforms to the applicable requirements of 10 CFR Part 50, Appendix B.

01.03 To verify that the licensee has implemented the ITAAC closure letter program in accordance with approved procedures and instructions.

01.04 To verify that the licensee has implemented an ITAAC maintenance program to ensure that structures, systems, and components continue to meet the acceptance criteria described in the ITAAC closure letters until the Commission finding described in 10 CFR 52.103(g) is made.

#### 40600-02 INSPECTION REQUIREMENTS AND GUIDANCE

##### General Guidance.

10 CFR 52.80 requires that the combined license application contain the proposed inspections, tests, and analyses that the licensee shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the combined license, the provisions of the Atomic Energy Act, and the Commission's rules and regulations.

10 CFR 52.99 requires that licensees shall notify the NRC that prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria have been met. The notification must contain sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria have been met. The Nuclear Energy Institute (NEI) issued NEI 08-01, "Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52," to provide guidance to the industry on processes and documentation acceptable to NRC to achieve ITAAC closure. The NRC staff endorsed the

methodologies described in NEI 08-01 in Regulatory Guide (RG) 1.215, "Guidance for ITAAC Closure under 10 CFR Part 52."

This inspection is intended to confirm that the ITAAC closure process, as documented in the ITAAC closure letters submitted to the NRC, is adequately controlled by procedures. Direct inspection of ITAAC will be performed using IMC-2503 and IP 65001 and its sub-tier procedures. As part of these inspection provisions, a sample of ITAAC will be reviewed to verify that the licensee's ITAAC closure controls have been properly implemented and the resulting closure letters accurately reflect the record of completion of the subject ITAAC.

10 CFR 52.79(a)(25) requires that the licensee's COL application include a description of the quality assurance (QA) program. The description must include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been and will be satisfied and how the QA program will be implemented. The QA requirements of Appendix B to Part 50 apply to all safety-related activities being conducted by the licensee during the design, construction, and operations phase, including those safety-related activities performed to satisfy ITAAC. However, there are ITAAC activities that are not safety-related, but play a significant role in the verification and design integrity of the as-built facility. NEI 08-01, Section 3.2.1.2 includes guidance to licensees on this topic. Specifically, it notes that "[b]ecause ITAAC have special regulatory significance under Part 52, licensees should document ITAAC closure under their QAP." This means that even if an ITAAC is for a non-safety SSC, the closure package and notification letter will be controlled by the QAP for those licensees that choose to implement NEI 08-01.

02.01 Programmatic Controls for ITAAC Closure. This section should be implemented as early as is reasonable in the construction of the facility to determine if the licensee's ITAAC closure and records controls processes would support accurate and verifiable closure letters to be submitted to the NRC in accordance with 10 CFR 52.99.

Inspection Requirement. Review the program established by the licensee to control specific construction and tracking activities that relate to the completion of the ITAAC. Assess ITAAC documentation and related construction records controls. Specifically evaluate the licensee processes that satisfy the regulatory requirements of 10 CFR 52.99.

Inspection Guidance. The inspector should review the current revision of NEI 08-01, as endorsed by NRC in RG 1.215. The programmatic controls for ITAAC completion, documentation, records verification, quality assurance, and notification should be assessed with respect to the following governing provisions:

- a. 10 CFR 52.99 ("Inspection during construction") requirements, which describes the regulatory process for ITAAC performance and successful completion.
- b. A Quality Assurance Program (QAP) that complies with 10 CFR Part 50, Appendix B requirements. Licensees are expected to perform ITAAC closure activities in accordance with approved QAP controls and procedures

- c. Specific Combined License (COL) requirements that may modify and/or augment the ITAAC established pursuant to the standard design certification for that design.
- d. Appropriate Corrective Action Program (CAP) controls that specifically address the effectiveness of corrective measures associated with NRC "ITAAC-Related Construction Findings" and "ITAAC Findings," as well as any internal licensee nonconformance or deficiency reports that can impact ITAAC acceptability.
- e. Other applicable regulatory requirements related to the ITAAC provisions delineated in 10 CFR Part 52; as well as, but not limited to, 10 CFR Part 50 (e.g., 50.9, 50.55a, and, in particular, 50.55(e)).

02.02 Implementation of ITAAC Closure Letter Controls. This section should be implemented when the licensee has submitted a sufficient number of ITAAC closure letters to the NRC to establish a reasonable track record of compliance with 10 CFR 52.99. To the extent practicable, Section 02.02 should be performed simultaneously with Section 02.03.

Inspection Requirement. Review the detailed process established by the licensee for the generation, validation, and submittal of ITAAC closure letters to the NRC. Assess the framework provided for organization, division of responsibilities, quality assurance, and final authority, as set forth in the licensee's approved procedures and instructions.

Inspection Guidance. The inspector should review NEI 08-01, as endorsed by NRC in RG 1.215, and particularly the NEI 08-01 Appendices D and E, to view acceptable examples of ITAAC closure letters. As directly applicable to the licensee and facility being inspected, the inspector should evaluate the principles underlying the basis for the verifiability of the licensee's ITAAC closure packages. The inspector should confirm that controls have been established that provide reasonable assurance that the ITAAC have been successfully performed and the acceptance criteria have been met and are being maintained. The following attributes may be checked to assist in this assessment:

- a. An approved procedural and controlled QA process is used to document ITAAC closure.
- b. The ITAAC closure process is supported by verifiable documents and traceable records that confirm ITAAC were satisfactorily closed.
- c. The contents of ITAAC closure letters are consistent with the examples in NEI 08-01 Appendices D and E and the ITAAC closure packages support the letter conclusions. Appendix D provides multiple examples of ITAAC closure letters of sufficient detail required by 10 CFR 52.99 to document closure of ITAAC of varying degrees of complexity. Appendix E provides examples of licensee letters notifying NRC of uncompleted ITAAC 225 days prior to initial fuel load. These letters typically will also provide a closure plan and status for each ITAAC listed in the letter.

- d. The licensee's QA organization has a well defined role in the ITAAC verification and closure process.
- e. ITAAC issues identified by either the licensee or the NRC are closely tracked and resolved.
- f. Oversight and organizational responsibilities for preparation and approval of the ITAAC closure letters have been established.
- g. Qualification requirements and training activities have been established for the separate groups and individuals involved with preparation, verification, approval, and audit activities for both ITAAC closure packages and closure letters.
- h. Interface controls among the various independent licensee groups involved with the ITAAC closure process have been defined.

02.03 Implementation of ITAAC Closure Controls. This section should be implemented after the licensee has submitted a sufficient number of ITAAC closure letters to the NRC to enable the inspector to review representative samples of various letter types from different disciplines. To the extent practicable, Section 02.03 should be performed simultaneously with Section 02.02.

Inspection Requirement. Select a sample of several "targeted" and "non-targeted" ITAAC closure letters for verification that the licensee has implemented its approved ITAAC closure program in accordance with the approved procedures and instructions.

Note that the "targeted" ITAAC have been subject to independent, direct NRC inspection, but the "non-targeted" ITAAC may have received no NRC inspection, thus relying upon the licensee's program of controls and submitted closure letters to demonstrate that the ITAAC are complete. See IMC-2503 and IP 65001 for further explanation of the ITAAC sample inspection program and related terminology.

For the selected sample of both "targeted" and "non-targeted" ITAAC, review the closeout packages and supporting documentation to confirm that evidence is available to substantiate ITAAC acceptability and closure. As necessary, verify that ITAAC closure documentation is traceable to QA records that are retrievable.

Inspection Guidance. The inspector should verify the following types of process controls, QA activities, and record checks with respect to the sampled ITAAC, their closure letters and the referenced supporting documentation:

- a. Evidence that all ITAAC sub-tier construction activities have been adequately controlled and tracked from the start of any related construction to the submittal of the closure letter to the NRC.
- b. An ITAAC determination basis that supports ITAAC closure and provides evidence of management oversight of the ITAAC during construction.

- c. Verification of quality control (QC) involvement, where applicable (e.g., hold points), and the appropriate QA review and audit activities.
- d. Review of the status of all “ITAAC-Related Construction Findings” and confirmation of consistency between the NRC Construction Inspection Program Information Management System (CIPIMS) and the corresponding licensee results. [Note that in the case where an “ITAAC Finding” may have been identified with respect to a previous ITAAC closure letter, a more complete review may be in order.]
- e. Record of adequate corrective actions for any internal licensee findings and adequate resolution for any unresolved quality issues related to a specific ITAAC.\*
- f. As applicable to 10 CFR 50, Appendix B requirements, evidence of the conduct of root cause analyses and extent-of-condition reviews for any significant conditions adverse to quality related to ITAAC completion.\*
- g. Retrievable records that support appropriate ITAAC quality and verifiable ITAAC completion, with some examples of the types of such records listed as follows:
  - 1. Test reports and supported test procedure number
  - 2. Vendor or test facility reports
  - 3. Construction work planning/sequence documents
  - 4. QC inspection records
  - 5. QA audit reports
  - 6. Procurement documents
  - 7. Fabrication records for components, equipment, or modules
  - 8. Receipt inspection records
  - 9. Certified material test reports
  - 10. Certificates of compliance
  - 11. Registered professional engineer approval of design documents
  - 12. Code design reports and data reports
  - 13. Design analyses and reconciliation reports
  - 14. Installation records and special process “travelers”

15. As-built inspections and/or walkdowns
  16. Nonconformance and deviation reports – resolved and closed
  17. Personnel qualification and training records
  18. Self-assessment results
- h. ITAAC Closure Package documents that support the referenced ITAAC closure and are consistent with the appropriate records and activities noted above.

Note: Corrective Action Program inspections are not integral to or part of the conduct of this IP. However, as noted above (\*), certain licensee corrective action activities and records may impact the acceptable closure of any ITAAC. Where efficiencies can be gained, coordination of this IP with NRC corrective action inspections that could be focused on ITAAC would be beneficial.

02.04 ITAAC Maintenance Controls. Section 02.04 should be implemented when the licensee has closed any ITAAC items to verify that it is maintaining the integrity of completed ITAAC.

Inspection Requirement. Review the detailed process established by the licensee for maintaining structures, systems, and components such that they could continue to meet the acceptance criteria described in the ITAAC closure letters. Assess the framework provided for organization, division of responsibilities, quality assurance, and final authority, as set forth in the licensee's approved procedures and instructions.

Inspection Guidance. The inspector should review NEI 08-01, as endorsed by NRC, particularly Section 8.1, as well as Reg Guide 1.215, to view acceptable methods of maintaining the integrity of completed ITAAC. The inspector should also consider reviewing supplemental ITAAC closure letters, ITAAC component replacement summary letters, and the final licensee notification that all ITAAC are complete.

Additional guidance for review of licensee programs and processes that address ITAAC maintenance will be issued after the NRC staff reaches resolution on this topic.

#### 40600-03 RESOURCE ESTIMATE

The inspection in Section 02.01 should be conducted by one inspector over a one-week period. The inspection in Section 02.02 should be conducted by one inspector over a one-week period. The inspection in Sections 02.03 should be conducted by two inspectors over two separate week-long periods, scheduled for the first inspection to be timely (when a sufficient number of ITAAC closure letters are available for inspection) and, for the second inspection, to be comprehensive (when a substantial number of ITAAC letters have been submitted and all disciplines are represented). The inspection in Section 02.04 should be conducted by one inspector over a one-week period. The resource estimate for this inspection procedure is approximately 280 hours of direct

inspection effort. Sections of this inspection procedure may be repeated as necessary if multiple ITAAC findings are identified.

#### 40600-04 REFERENCES

10 CFR Part 50, Domestic Licensing of Production and Utilization Facilities

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

10 CFR Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants

Inspection Manual Chapter (IMC) 2503, Construction Inspection Program: Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

IMC 2504, Construction Inspection Program: Inspection of Construction and Operational Programs

Inspection Procedure (IP) 35007, Quality Assurance Program Implementation during Construction

IP 65001, Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) Related Work

Regulatory Guide 1.215, Guidance for ITAAC Closure Under 10 CFR Part 52

Nuclear Energy Institute (NEI) Document NEI 08-01, "Industry Guideline for the ITAAC Closure Process under 10 CFR 52," Revision 3, January 2009 (ADAMS Accession No. ML090270415)

#### 40600-05 PROCEDURE COMPLETION

The goal of the inspections conducted in Sections 2.02, 2.03, and 2.04 is to review 10 packages; if fewer than 10 packages are available, then all available packages should be reviewed. However, if fewer packages than these goals are reviewed, but the inspectors feel that the quality of the packages is high and there are no significant findings, the intent of this Inspection Procedure has been met.

This procedure is complete upon satisfactory inspection results verifying that an ITAAC management program exists that adequately implements and documents the successful completion and maintenance of ITAAC. The inspection must demonstrate that the program results in accurate and verifiable ITAAC closure letters upon which the staff can make a reasonable assurance determination that the ITAAC have been met.

END

Attachment 1 - Revision History for IP 40600

ATTACHMENT 1  
Revision History for IP 40600

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment Resolution Accession Number
N/A	03/17/10 CN 10-009	<p>Initial issue to support inspections of construction programs described in IMC 2504, Construction Inspection Program: Inspection of Construction and Operational Programs.</p> <p>Completed 4 year search of historical CNs and found no commitments related to this Inspection Procedure.</p>	None	N/A	N/A