NRC INSPECTION MANUAL

INSPECTION PROCEDURE 40600

LICENSEE PROGRAM FOR MANAGING INSPECTIONS, TESTS, ANALYSES, AND ACCEPTANCE CRITERIA (ITAAC) CLOSURE

PROGRAM APPLICABILITY: IMC 2504 App A

40600-01 INSPECTION OBJECTIVES

01.01 To verify that the licensee has established programmatic controls to manage inspections, tests, analyses, and acceptance criteria (ITAAC) closure and ITAAC maintenance activities.

01.02 To verify that the licensee develops notifications on ITAAC in accordance with approved procedures. To verify that notifications accurately reflect ITAAC completion as supported by verifiable documents and traceable records.

01.03 To verify that the licensee is effectively implementing ITAAC maintenance to maintain the basis and conclusions of the accepted ITAAC closure notifications (ICNs). To verify that the licensee submits ITAAC post-closure notifications (IPCNs) when required.

40600-02 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance.

Inspectors should implement the standalone inspection in Section 02.01 early in construction (e.g., prior to any ITAAC notifications being submitted):

- to verify that the licensee has developed and implemented the required controls and procedures necessary to manage and track ITAAC completion,
- to determine if the licensee's ITAAC closure and records controls processes would support accurate and verifiable ITAAC notifications, and
- to determine if the controls and procedures are sufficient to maintain the validity of the ITAAC acceptance criteria until the title 10 of the *Code of Federal Regulations* (10 CFR) 52.103(g) finding is made.

Inspectors should conduct the inspections in Sections 02.02 and 02.03 together. Inspectors may also conduct each of them periodically to focus on one aspect (i.e., verification of the ITAAC notifications or implementation of ITAAC maintenance requirements). Staff should conduct the first inspection under these two sections as soon as enough ICNs have been submitted to establish a reasonable track record of compliance with 10 CFR 52.99(c)(1) and (c)(2). Conduct additional inspections approximately midway through construction and again toward the end of construction. The resident inspectors may perform inspection samples periodically, during other planned inspections, or as a substitute if other inspections have been delayed due to schedule changes.

10 CFR 52.99(c)(1) requires that licensees shall notify the NRC that prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met. An ICN is submitted when an ITAAC has been completed by the licensee. The ICN must contain sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are 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 completion. 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."

10 CFR 52.99(c)(2) requires that licensees notify the NRC of significant issues or events that materially affect a closed ITAAC. The ITAAC Post-Closure Notification reports this event, as well as its resolution. RG 1.215 includes reporting thresholds for which 10 CFR 52.99(c)(2) notifications are required. The thresholds eliminate the need for constantly notifying the NRC on less than significant events that are corrected on previously closed ITAAC and provides the licensee a means to perform preventive maintenance and corrective actions on structures, systems, or components (SSCs) material to an ITAAC without having to submit an IPCN.

10 CFR 52.99(c)(3) requires licensees to report the planned method to complete any ITAAC for which an ICN has not been submitted by 225 days before scheduled fuel load. These notifications are primarily to provide the public with information on planned ITAAC completion methodologies in advance of the deadlines for filing for an ITAAC hearing opportunity.

The last notification required under 10 CFR 52.99(c) is (c)(4), the All ITAAC Complete Notification. This notification is submitted to the NRC upon a licensee's completion of all ITAAC in a combined license and confirms that all acceptance criteria are "met" in preparation for the 10 CFR 52.103(g) finding.

With exception of verifying that the licensee's program contains adequate instructions to meet the requirements of 10 CFR 52.99(c)(3) and (c)(4) and to develop the required uncompleted ITAAC notifications (UINs) and All ITAAC Complete Notification, review of UINs and the All ITAAC Complete Notification is excluded from this procedure.

10 CFR 52.79(a)(25) requires that the licensee's combined license 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 10 CFR 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 3.1.2 includes guidance to licensees on this topic. Specifically, it notes that "[b]ecause ITAAC have special regulatory significance under 10 CFR Part 52, licensees should document ITAAC closure under their QAP." This means that even if an ITAAC is for a non-safety SSC, the completion package and subsequent notifications on ITAAC will be controlled by the QAP.

02.01 <u>Programmatic Controls for ITAAC Closure</u>: The purpose of this inspection is to verify the licensee has developed and implemented an ITAAC program that has the required processes, controls, and procedures in place to:

- manage and track ITAAC completion throughout construction,
- develop, maintain, and store verifiable and traceable completed records for ITAAC closure,
- prepare ITAAC notifications with sufficient information pursuant to 10 CFR 52.99(c),
- maintain the validity of the ITAAC acceptance criteria until the 10 CFR 52.103(g) finding is made, and
- provide adequate ITAAC training to personnel commensurate with their ITAAC responsibilities.

Inspection Requirement: Review the processes and procedures that control specific construction and tracking activities that relate to the completion of the ITAAC. Review the detailed process for the generation, validation, and submittal of ITAAC notifications to the NRC. Review the licensee's ITAAC training requirements. Assess ITAAC documentation and related construction records controls and the framework provided for organization, division of responsibilities, quality assurance, and final authority, as set forth in the licensee's approved procedures and instructions. Specifically evaluate the licensee's processes and procedures that satisfy the regulatory requirements of 10 CFR 52.99(c)(1) through (c)(4). Verify that the licensee documents ITAAC closure under its QAP.

Inspection Guidance: The inspector should review the latest revision of RG 1.215 and the associated endorsed revision of NEI 08-01, and particularly the NEI 08-01 Appendices, to view acceptable examples of notifications on ITAAC. 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 completion 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 also being maintained.

- 1. The programmatic controls for ITAAC completion, documentation, records verification, quality assurance, and notification should be assessed with respect to the following:
 - a. 10 CFR 52.99 ("Inspection during construction") requirements, which describes the regulatory process for ITAAC performance and successful completion.
 - b. Appropriate screening and corrective action program (CAP) controls that specifically address the effectiveness of corrective measures associated with NRC "ITAAC Findings" and "ITAAC-Related" vendor findings, as well as any internal licensee nonconformance, deviation or deficiency reports that can impact completed ITAAC acceptability.
 - c. 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)).

- d. An approved procedural and controlled QA process is used to document ITAAC closure and maintenance.
- e. The ITAAC closure process is supported by verifiable completion packages that include documents and traceable records that confirm ITAAC were satisfactorily closed.
- f. Sufficient instructions exist to ensure the contents of notifications on ITAAC are consistent with the examples in the NEI 08-01 appendices, and that the ITAAC completion packages will support the conclusions of successful completion. NEI 08-01, Appendix D, provides numerous examples of ICNs of sufficient detail required by 10 CFR 52.99(c)(1) to document closure of ITAAC of varying degrees of complexity. Appendix E provides examples of licensee letters notifying the NRC of uncompleted ITAAC 225 days prior to initial fuel load (i.e., Uncompleted ITAAC Notifications). Appendix I provides examples of ITAAC Post-Closure Notifications that would be required if an event materially alters the basis for determining that an ITAAC was completed. Appendix F provides a template for the All ITAAC Complete Notification.
- g. The licensee's QA organization provides appropriate support to feedback into the ITAAC closure and maintenance process.
- h. ITAAC issues identified by either the licensee or the NRC are closely tracked and resolved.
- i. Oversight and organizational responsibilities for preparation and approval of the notifications on ITAAC have been established.
- j. Interface controls among the various independent licensee groups involved with the ITAAC closure process have been defined.
- k. Qualification requirements and training activities have been established for the groups and individuals involved with preparation, performance, approval, and audit activities for ITAAC completion packages, ICNs, and other notifications on ITAAC.
- I. General ITAAC training requirements for craft personnel provides a basic understanding of ITAAC.
- 2. Review the licensee's processes and procedures established to maintain the validity of the ITAAC determination basis and conclusions for the completed ITAAC. The ITAAC maintenance period is the period between the submission of an ICN pursuant to 10 CFR 52.99(c)(1) and an affirmative 10 CFR 52.103(g) finding. While this section focuses mainly on SSCs, it also applies to the maintenance of emergency preparedness ITAAC, security ITAAC, and other ITAAC that may not be related to a specific SSC. Verify the licensee has established ITAAC maintenance requirements in programs such as:
 - QA Program
 - Maintenance Program

- Corrective Action Program
- Design and Configuration Control Program
 - a. Verify the maintenance program includes elements that ensure maintenance activities are screened for impact on completed ITAAC. That after the preventive or corrective maintenance activities are completed, post-work verification activities are performed, as appropriate, to ensure the affected ITAAC continue to meet the acceptance criteria.
 - b. Verify the corrective action program includes elements that ensure identified deficiencies, nonconformances, and deviations are screened for impact on ITAAC. That items that affect ITAAC are specifically flagged, tracked, corrected and documented in the appropriate ITAAC completion packages.
 - c. Verify the design and configuration control program includes elements that ensure all design changes are screened for impact on ITAAC, including an assessment to confirm affected ITAAC would still be valid, that SSCs associated with that ITAAC continue to meet their design commitment and the associated ITAAC acceptance criteria. In particular, the design and configuration control program should include an assessment and evaluation that confirms that any completed ITAAC potentially affected by a proposed change is still valid and assures the functionality originally intended.
 - d. Verify the activities performed under these programs in regard to ITAAC maintenance include updating the ITAAC completion package as appropriate.
 - e. In all instances of ITAAC maintenance, verify the licensee considers whether an ITAAC Post-Closure Notification is required pursuant to 10 CFR 52.99(c)(2) and the following thresholds from RG 1.215:
 - Material Error or Omission—Is there a material error or omission in the original ICN?
 - Postwork Verification (PWV)—Will the PWV use a significantly different approach than the original performance of the inspection, test, or analysis as described in the original ICN?
 - Engineering Changes—Will an engineering change be made that materially alters the determination that the acceptance criteria are met?
 - Additional Items to Be Verified—Will there be additional items that need to be verified through the ITAAC?
 - Complete and Valid ITAAC Representation—Will any other licensee activities materially alter the ITAAC determination basis?

An acceptable licensee approach to maintaining ITAAC provides the NRC with confidence that the acceptance criteria continue to be met at the conclusion of construction when a determination under 10 CFR 52.103(g) is made. An ITAAC Post-Closure Notification made on an event after applying these reporting thresholds should summarize the event and its resolution similar to the level of detail expected for an ICN. For events that do not reach these reporting thresholds, ITAAC Post-Closure notifications would not be required.

02.02 <u>ITAAC Closure and Post-Closure Notifications:</u> The purpose of this inspection is to verify that the ITAAC notifications are developed in accordance with approved procedures and that the resulting notifications accurately reflect ITAAC completion as supported by verifiable documents and traceable records.

Inspection Requirement. Select a sample of 10 to 20 ICNs, as well as any associated ITAAC Post-Closure Notifications, for verification that the licensee has implemented its approved ITAAC closure program in accordance with the approved procedures. Note that the "targeted" ITAAC have been subject to independent, direct NRC inspection, therefore it is preferable most of the inspection sample be selected from the non-targeted ITAAC. For the selected samples, review the completion packages and supporting documentation to confirm that evidence is available to substantiate ITAAC performance acceptability and closure. As necessary, verify that ITAAC closure documentation is traceable to QA records that are retrievable.

<u>Inspection Guidance</u>. The inspector should verify the following types of process controls, QA activities, and record checks with respect to the sampled ITAAC, their notifications, and the referenced supporting documentation. The level of technical review for this inspection should be commensurate with the complexity of the ITAAC. A completion package that is 1,000 pages long will require far more depth than a completion package that is only a few pages long. NRC staff subject matter experts can lend technical assistance on what elements should be reviewed to confirm that the ITAAC is met.

- a. Evidence that ITAAC sub-tier construction activities have been adequately controlled and tracked from the start of any related construction. An example would be construction records supporting the pouring of a pump foundation for an ITAAC on pump installation.
- b. Evidence of management oversight of performing the ITAAC. An example of this would be a sub-contractor conducting ITAAC closure testing that was not performed correctly and seeing where the licensee, who maintains overall responsibility for ITAAC closure, entered this in a corrective action program, re- performed the test, and adequately verified ITAAC closure through the corrective measure. The focus here is not on the quality of the corrective action program, but rather the existence of an oversight measure where necessary.
- c. Verification of quality control (QC) involvement, where applicable, and the appropriate QA review and audit activities. An example of this might be QA hold-points associated with an ASME Code installation of a component whose acceptance criteria is "Installed per ASME Code." Records of the hold-points, or documentation supporting equivalent/compensatory measures, would be appropriate to review for this verification.

- d. Review of the status of all "ITAAC Findings" and confirmation of consistency between the NRC Construction Inspection Program Information Management System (CIPIMS) and the corresponding licensee results. Additional review may be required if an "ITAAC Finding" was identified for a previous ICN or ITAAC Post-Closure Notification.
- 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 Part 50, Appendix B requirements, evidence of the conduct of 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 performance quality and verifiable ITAAC completion, with some examples of the types of such records listed as follows:

ITAAC Completion Packages

- 1. Test reports and supported test procedure number
- 2. QC inspection records
- 3. Vendor or test facility reports
- 4. Construction work planning/sequence documents
- 5. Procurement documents
- 6. Fabrication records for components, equipment, or modules
- 7. Receipt inspection records
- 8. Certified material test reports
- 9. Certificates of compliance
- 10. Registered professional engineer approval of design documents
- 11. Code design reports and data reports
- 12. Design analyses and reconciliation reports
- 13. Installation records and special process "travelers"
- 14. As-built inspections and/or walkdowns
- 15. Disposition of Nonconformance and deviation reports
- 16. Records regarding ITAAC maintenance activities, including preventive maintenance, minor corrective actions, component replacement, and associated retesting (see Section 02.04 of this IP)

ITAAC Closure Process Documentation

- 1. Personnel qualification and training records
- 2. QA audit reports
- 3. ITAAC closure process self-assessment results
- h. ITAAC Completion Package documents that support the referenced ITAAC closure and are consistent with the appropriate records and activities noted above.

02.03 <u>ITAAC Maintenance Controls</u>. The purpose of this inspection is to verify the licensee effectively implements ITAAC maintenance requirements pursuant to 10 CFR 52.99(c)(2) and its established procedures and processes to maintain the determination basis and conclusions of previously closed ITAAC and when necessary has submitted an IPCN.

Inspection Requirement. Select 4 to 8 samples of completed maintenance activities; 5 to 10 condition reports, nonconformances, or deviations; 2 to 4 design changes; and other activities that potentially could impact an ITAAC. Verify the licensee followed its procedures for screening and documenting each item's potential impact on ITAAC. Evaluate the conclusion for each item and the actions taken to maintain a closed ITAAC's determination basis and conclusion (i.e., inspections, tests, and analyses (ITA) and acceptance criteria (AC)). Verify if an IPCN was required and submitted.

<u>Inspection Guidance</u>. The inspector should review RG 1.215 and NEI 08-01, particularly Appendix H, to view examples when an ITAAC maintenance threshold "is" and "is not" crossed.

40600-03 RESOURCE ESTIMATE

The resource estimate for this inspection procedure is approximately 360 hours of direct inspection effort. Additional hours may be expended, and sections of this inspection procedure may be repeated if inspectors identify multiple ITAAC findings.

The inspection in Section 02.01 should be conducted by one inspector over a one-week period (i.e., 40 hours). As previously stated, 02.01 should be performed as a stand-alone inspection early in the construction period, before ICNs are received. After the initial program inspection, it or specific aspects of it may be repeated, if necessary, during subsequent inspections pursuant to Sections 02.02 or 02.03.

The inspections in Sections 02.02 and 02.03 should be implemented together. They may also be conducted individually to focus on one aspect (e.g., verification of the ITAAC notifications or implementation of ITAAC maintenance requirements). One inspector should conduct the first inspection of these two sections over a one-week period as soon as enough ICNs have been submitted to establish a reasonable track record of compliance with 10 CFR 52.99(c)(1) and (c)(2) (i.e., 40 hours). Two additional inspections should be conducted throughout construction, approximately midway through construction and again toward the end of construction. Each of these subsequent inspections should be conducted by two inspectors over a one-week period (i.e., 80 hours each). Inspection samples per Sections 02.02 and or

02.03 may also be performed on a periodic basis by the resident staff or during other planned inspections when the planned inspection activity has been delayed due to schedule changes (i.e., 80 hours available).

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 and Pre-Construction Activities

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"

40600-05 PROCEDURE COMPLETION

The goal of the inspections conducted in Sections 2.02 and 2.03 is to review 10 to 20 ITAAC completion packages; 4 to 8 maintenance packages; 5 to 10 condition reports, nonconformances, or deviations; and 2 to 4 design changes per inspection; 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.

Additionally, inspectors may have the opportunity to review samples of the licensee's ITAAC Post-Closure Notifications as part of their sample. If no ITAAC Post-Closure Notifications are available, inspectors may conduct a follow-on inspection to verify the quality of these notifications.

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 notifications on ITAAC upon which the staff can make a reasonable assurance determination that the ITAAC have been successfully completed and that the acceptance criteria are met.

END

Attachment: Revision History for IP 40600

Attachment 1 - Revision History for IP 40600

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non- Public Information)
N/A	ML072530607 03/17/10 CN 10-009	Initial issue to support inspections of construction programs described in IMC 2504, Construction Inspection Program: Inspection of Construction and Operational Programs. Completed 4 year search of historical CNs and found no commitments related to this Inspection Procedure.	None	N/A
	ML14183B422 07/28/14 CN 14-017	Incorporates editorial changes to standardize "closure" and "completion" and add examples of various areas of review. Also includes updates due to 10 CFR 52.99 reporting requirements, current developments in ITAAC maintenance, and terminology changes.	None	ML14183B423
	ML20136A308 05/29/20 CN 20-025	Incorporates editorial changes and clarifications, consolidates inspection activities, and moves ITAAC maintenance programmatic inspection activities to section 02.01.	None	ML20136A348