

NRC INSPECTION MANUAL

NRO/IGCB

INSPECTION PROCEDURE 40600

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

PROGRAM APPLICABILITY: 2504

40600-01 INSPECTION OBJECTIVES

- 01.01 To verify that programmatic controls have been established to **manage inspections, tests, analyses, and acceptance criteria (ITAAC)** closure.
- 01.02 To verify that the licensee's process for preparing and approving **notifications on ITAAC** is adequate and conforms to the applicable requirements of **the licensee's quality assurance program (QAP)**.
- 01.03 To verify that the licensee has implemented the **notifications on ITAAC** program in accordance with approved procedures and instructions.
- 01.04 To verify that the licensee has implemented an ITAAC maintenance **process** to ensure that the acceptance criteria **continue to be met** until the finding described in **Title 10 of the Code of Federal Regulations (CFR) Part 52, Section 103(g)**, 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.

Pursuant to 10 CFR 52.99, licensees are required to submit notifications on ITAAC for use by staff to verify ITAAC completion. The notifications also provide the public with information regarding the completion of the ITAAC.

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 ITAAC Closure Notification (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." These two documents are periodically updated to include current information, and the latest revision of RG 1.215 should be referenced to determine which revision of NEI 08-01 is the latest to be endorsed.

10 CFR 52.99(c)(2) requires that licensees notify the NRC of issues or events that materially affect a closed ITAAC. The 10 CFR 52.99(c)(2) 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 minor corrective actions on structures, systems, or components (SSCs) material to an ITAAC without having to resubmit an ICN.

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

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 remain "met" in preparation for the 10 CFR 52.103(g) finding.

Throughout this Inspection Procedure (IP), the term "notifications on ITAAC" is meant to include these four types of notifications, 10 CFR 52.99(c)(1), (c)(2), (c)(3), and (c)(4), unless otherwise specified as only one of these four.

Sections of this IP associate 10 CFR 52.99(c)(1) and (c)(2) together. This is due to the potential for a 10 CFR 52.99(c)(2) notification to be submitted after the (c)(1) notification. Submittal of the ITAAC Post-Closure Notification could occur right after an ICN. This IP is written to reflect this possibility, but an ITAAC Post-Closure Notification will still have an ITAAC maintenance threshold tripped before it is required.

This IP is intended to confirm that the ITAAC closure process, as documented in each notification on ITAAC submitted to the NRC, is adequately controlled by procedures. As part of these inspection provisions, a sample of ITAAC will be reviewed to verify that the licensee's ITAAC closure and ITAAC maintenance controls have been properly implemented and the resulting notifications on ITAAC accurately reflect the record of completion and maintenance of the subject ITAAC.

10 CFR 52.79(a)(25) requires that the licensee's **combined license (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 3.1.2 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 **completion** package and **subsequent notifications on ITAAC** 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 **ICNs** to be submitted to the NRC in accordance with 10 CFR 52.99(c)(1). **For any unit under construction, 02.01 can be performed as a stand-alone inspection early in the construction period (i.e, prior to any ITAAC notifications being submitted). However, after the first IP 40600 inspection, all four sections – 02.01, 02.02, 02.03 and 02.04 – should be performed simultaneously each time the IP 40600 inspection is performed. Once an ICN is submitted, ITAAC Post-Closure Notification procedures and ITAAC maintenance procedures must be in place.**

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(c)(1).

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 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 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 Findings," as well as any internal licensee nonconformance or deficiency reports that can impact **completed** 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 Controls for notifications on ITAAC. This section should be implemented when the licensee has submitted a sufficient number of **ICNs and/or ITAAC Post-Closure Notifications** to the NRC to establish a reasonable track record of compliance with 10 CFR 52.99(c)(1) and (c)(2). 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 **notifications on ITAAC** 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, 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. 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 **and maintenance**.
- b. The ITAAC closure process is supported by verifiable documents and traceable records that confirm ITAAC were satisfactorily closed.
- c. The contents of **notifications on ITAAC** are consistent with the examples in **the** NEI 08-01 **appendices**, and **that** the ITAAC **completion** packages support the conclusions of **successful completion**. 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**). These **notifications should** provide a closure plan for each ITAAC listed in the **notification**. 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**.
- d. The licensee's QA organization **provides appropriate support to feedback into** the ITAAC closure **and maintenance** 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 **notifications on ITAAC** have been established.
- g. 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**.
- 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 **ICNs, and potentially ITAAC Post-Closure Notifications**, to the NRC to enable the inspector to review representative samples of various **ICNs and ITAAC Post-Closure Notifications** 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 **ICNs of both “targeted” and “non-targeted” ITAAC , 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 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 **ICNs and ITAAC Post-Closure Notifications** to demonstrate that the ITAAC are complete, **and that the acceptance criteria remain “met”**. 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 **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.

Inspection Guidance. 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. An ITAAC determination basis that supports ITAAC closure, and **when applicable**, provides 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 zz.zzz". 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. [Note that in the case where an "ITAAC Finding" may have been identified with respect to a previous **ICN or ITAAC Post-Closure Notification**, 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 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.

02.04 ITAAC Maintenance Controls. Section 02.04 should be implemented when the licensee has closed an ITAAC **in order** 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 **would** continue to meet the acceptance criteria. 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 **the** NRC, as well as RG 1.215, to view acceptable **licensee programs that include elements** of maintaining the integrity of completed ITAAC. **These programs are discussed further in this section.** The inspector should also consider reviewing **partial ICNs (if any), ITAAC Post-Closure Notifications, Uncompleted ITAAC Notifications, and the All ITAAC Complete Notification (if applicable).** **Due to the late completion times for the Uncompleted ITAAC Notifications and the All ITAAC Complete Notification for a unit under construction, reviews of these notifications may not be**

realistic, in which case the licensee's procedures for developing these notifications could be reviewed in lieu during a final IP40600 inspection.

Following the completion of an ITAAC, the licensee must maintain the validity of the acceptance criteria of the completed ITAAC. The ITAAC maintenance period for a completed ITAAC 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. 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.

The inspector should check for ITAAC maintenance provisions in licensee's programs such as:

1. QA Program - NEI 08-01 states the following about the QA program as it applies to ITAAC maintenance: "[The] QAP requirements governing licensee procurement, fabrication, construction, inspection and test activities for SSCs covered by ITAAC are specified in accordance with the safety classification and/or safety significance of the SSCs involved. ITAAC encompass SSCs of varying safety significance and safety classification, including safety-related and non-safety-related SSCs. Because ITAAC have special regulatory significance under Part 52, licensees should document ITAAC closure and ITAAC Maintenance under their Quality Assurance Program."
2. Maintenance Program – The Maintenance Program should include elements that ensure that the acceptance criteria of closed ITAAC continue to be met after ITAAC completion and any associated maintenance to that completed ITAAC. Maintenance activities should be screened for any impacts on a completed ITAAC and also ITAAC not immediately associated with the maintenance activity. After any preventive maintenance activities are completed, post-work verification should be performed as appropriate to maintain the validity of completed ITAAC.
3. Corrective Action Program – The Corrective Action Program should identify and track the resolution of any ITAAC-related deficiencies to ensure that the ITAAC acceptance criteria continue to be met. These should be screened for impact on associated ITAAC. Conditions material to ITAAC should be specifically flagged, and should be corrected and documented.
4. Design and Configuration Control Program - The Design and Configuration Control Program should ensure that any changes do not affect completed or uncompleted ITAAC, and also ensure that ITAAC acceptance criteria continue to be met for ITAAC that have been successfully completed. Design changes should be screened for impact on ITAAC, including an assessment to confirm that any affected ITAAC would still be valid and that SSCs associated with that ITAAC continue to meet their design commitment.

ITAAC maintenance provisions should include licensee plans and programs to ensure that activities affecting successfully completed ITAAC do not invalidate the conclusion that the acceptance criteria are met. In particular, the design and configuration control program should include an assessment and evaluation that confirms that any ITAAC potentially affected by a proposed change is still valid and assures the functionality originally intended. While this IP

focuses mainly on the construction and installation of SSCs, this section also applies to the maintenance of emergency preparedness, security ITAAC, and other ITAAC that may not be related to a specific SSC.

Activities performed under these programs in regard to ITAAC maintenance should include updating the ITAAC completion package as appropriate. In all instances of ITAAC maintenance, the licensee needs to consider whether an ITAAC Post-Closure Notification is required pursuant to 10 CFR 52.99(c)(2). The following list from RG 1.215 includes thresholds for determining when a licensee should notify the NRC of new information material to an ITAAC that it has discovered after the submission of an ICN:

- **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 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 or an Uncompleted ITAAC Notification. For events that do not reach these reporting thresholds, ITAAC Post-Closure notifications would not be required. Examples may include like-for-like component replacements, minor corrective actions, or preventive maintenance activities.

40600-03 RESOURCE ESTIMATE

The inspection in Section 02.01 should be conducted by one inspector over a one-week period. As previously stated, 02.01 can be performed as a stand-alone inspection early in the construction period. After the first inspection, 02.02, 02.03 and 02.04 should be performed simultaneously each time the IP40600 inspection is performed.

After an initial 02.01 inspection, it may be repeated for subsequent inspections that include 02.02, 02.03 and 02.04. The inspections in Sections 02.01, 02.02, and 02.04 should be conducted by one inspector over a one-week period for each. The inspection in Section 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 notifications on ITAAC are available for inspection) and, for the second inspection, to be comprehensive (when a substantial number of notifications on ITAAC have been submitted and all disciplines are represented).

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 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, 2.03, and 2.04 is to review 10 **ITAAC completion** 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.

Additionally, inspectors may have the opportunity to review samples of the licensee's ITAAC Post-Closure Notifications and Uncompleted ITAAC Notifications as part of their sample. If no ITAAC Post-Closure Notifications or Uncompleted ITAAC Notifications are available, inspectors may deem it necessary to conduct a follow-on inspection at a later date 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 and Feedback Resolution Accession Number
N/A	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