

RULEMAKING ISSUE
(Affirmation)

February 23, 2012

SECY-12-0030

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: FINAL RULE: REQUIREMENTS FOR MAINTENANCE OF
INSPECTIONS, TESTS, ANALYSES, AND ACCEPTANCE CRITERIA
(RIN 3150-AI77)

PURPOSE:

To obtain the Commission's approval to publish in the *Federal Register* (FR) a final rule that amends the requirements relating to verification of nuclear power plant construction activities through inspections, tests, analyses, and acceptance criteria (ITAAC) under a combined license.

SUMMARY:

The U.S. Nuclear Regulatory Commission (NRC) staff seeks Commission approval of proposed amendments to the regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 52.99, "Inspection during construction," related to verification of nuclear power plant construction activities through ITAAC under a combined license under Part 52. Specifically, the staff proposes new provisions that apply after a licensee has completed an ITAAC verification and submitted an ITAAC closure letter under § 52.99(c)(1). The new provisions would require licensees to (1) report new information materially altering the basis for determining that a prescribed inspection, test, or analysis was performed as required, or finding that a prescribed acceptance criterion is met and (2) notify the NRC of the completion of all ITAAC activities.

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In addition, the final rule contains changes to the following regulations in order to make the rule language consistent with statutory language of the Atomic Energy Act of 1954, as amended (AEA), and to more clearly describe possible ways in which a presiding officer decision may lead to a Commission decision on acceptance criteria:

- 10 CFR 2.340, “Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits, and licenses,” and
- 10 CFR 52.99 “Inspection during construction.”

The *Federal Register* notice of final rulemaking will also announce the issuance of RG 1.215.

BACKGROUND:

When the Commission first issued 10 CFR Part 52, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors” (54 FR 15372; April 18, 1989), it included 10 CFR 52.99 to make it clear that the inspection carried out during construction under a combined license would be based on ITAAC proposed by the applicant, approved by the staff, and incorporated in the combined license. At that time, the Commission clearly stated that, although 10 CFR 52.99 envisioned a “sign-as-you-go” process in which the NRC staff would sign off on inspection units and notice of the staff’s sign-off would be published in the FR, the Commission itself would make no findings on construction until it was complete. Thereafter, the Energy Policy Act of 1992 amended Sections 185 and 189 of the AEA to address combined licenses and ITAAC.

In 2007, the Commission revised Part 52 to enhance the NRC’s regulatory effectiveness and efficiency in implementing its licensing and approval processes (72 FR 49352; August 28, 2007). In that revision, the NRC amended 10 CFR 52.99 to require licensees to notify the NRC that the prescribed inspections, tests, and analyses in the ITAAC have been completed and that the acceptance criteria have been met. The revision also requires that these notifications contain sufficient information to demonstrate that the prescribed inspections, tests, or analyses have been performed and that the prescribed acceptance criteria have been met. The NRC added this requirement to ensure that combined license applicants and holders were aware of the following: (1) that it was the licensee’s burden to demonstrate compliance with the ITAAC, and (2) that the NRC expected the notification of ITAAC completion to contain more information than just a simple statement that the licensee believes the ITAAC had been completed and the acceptance criteria met.

The notifications currently required by 10 CFR 52.99(c)(1) perform two functions, as discussed in the supplementary information for the 2007 final rule amending 10 CFR Part 52 (72 FR 49352, 49450 (second column); August 28, 2007). First, the notifications alert the NRC to the licensee’s completion of the ITAAC¹ and ensure that the NRC has sufficient information to complete all of the activities necessary for the Commission to find whether all of the ITAAC acceptance criteria have been or will be met before initial operation (the “will be met” finding is relevant to any hearing on ITAAC under 10 CFR 52.103, “Operation under a combined license”). Secondly, the notifications ensure that interested persons will have access to

¹ In this discussion, the phrases “completion of the ITAAC” and “ITAAC completion” mean that the licensee has determined that (1) the prescribed inspections, tests, or analyses were performed and (2) the prescribed acceptance criteria are met.

information on both completed and uncompleted ITAAC at a level of detail sufficient to address the AEA Section 189a(1)(B) threshold for requesting a hearing on acceptance criteria.

After completing the 2007 rulemaking, the staff began developing guidance on the ITAAC closure process and the requirements under 10 CFR 52.99. In October 2009, the NRC issued regulatory guidance for implementing the revised 10 CFR 52.99 in Regulatory Guide (RG) 1.215, "Guidance for ITAAC Closure under 10 CFR Part 52." This RG endorsed guidance developed by the Nuclear Energy Institute (NEI) in NEI 08-01, "Industry Guideline for the ITAAC Closure Process under 10 CFR Part 52," Revision 3, issued January 2009 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML090270415).

After considering information presented by industry representatives in a series of public meetings, the staff realized that the various provisions in Part 52 left some additional implementation issues unaddressed. In particular, the staff determined that the combined license holder should provide additional notifications to the NRC following the notification of ITAAC completion currently required by 10 CFR 52.99(c)(1). The staff refers to the time after this ITAAC closure notification but before the date the Commission makes the finding under 10 CFR 52.103(g), as the "ITAAC maintenance period."

Since mid-2008, the staff has held numerous public meetings that have discussed the topic of ITAAC maintenance. In SECY-09-0119, "Staff Progress in Resolving Issues Associated with Inspections, Tests, Analyses, and Acceptance Criteria," dated August 26, 2009, the staff informed the Commission of its progress in resolving issues concerning ITAAC maintenance and reporting, including the threshold for notification of events that may result in the acceptance criteria of successfully completed ITAAC no longer being satisfied. That paper described new types of notifications that licensees may make to the NRC to address instances in which licensee activities affect previously completed ITAAC after the licensee submits an ITAAC closure letter to the NRC. In the paper, the staff stated its intention to propose that the Commission supplement 10 CFR Part 52 in order to include additional notification requirements to address ITAAC maintenance. The staff reiterated its plans to propose rulemaking on ITAAC maintenance in a September 22, 2009, Commission meeting on this topic.

More recently, the staff held two public meetings in March 2010 to discuss a draft proposed rule that it had made available to the public in February 2010. In developing the proposed rule, the staff considered feedback from external stakeholders during those meetings. In addition, NEI submitted written comments on the staff's plans to amend 10 CFR 52.99 in a letter dated April 29, 2010 (ADAMS Accession No. ML101300103), reiterating many of the comments made by NEI representatives in the March 2010 public meetings. The staff responded to NEI on June 21, 2010 (ADAMS Accession No. ML101590526) requesting that NEI resubmit those written comments from its letter that NEI believes are applicable to the published proposed rule. The staff addressed NEI's comments as part of the NRC's response to comments it received on the proposed rule.

In parallel with the discussions on the draft proposed rule, NEI revised its ITAAC closure guidance in NEI 08-01 to address the topic of ITAAC maintenance. On July 16, 2010, NEI submitted Revision 4 of NEI 08-01 for NRC review and endorsement (ADAMS Accession No. ML102010076). The staff has reviewed this latest revision of NEI 08-01 and issued a draft revision to RG 1.215 (DG-1250) (ADAMS Accession No. ML102530401) for public comment, endorsing NEI 08-01 and providing necessary clarifications.

As stated in the Commission's staff requirements memorandum (SRM) for SECY-11-0032, dated October 11, 2011, the staff considered how the concept of cumulative effects of regulation in the rulemaking process may apply to this rule. This rule is not expected to result in any cumulative effects in implementation because the rule's requirements apply during construction only and do not affect combined license issuance. In addition, prospective licensees that are subject to the new requirements will have significant exposure to them well before the time the requirements become effective and, therefore, have adequate time to determine how to implement the rule. Finally, the issues involving ITAAC maintenance are fundamental to the process for making the Commission's finding under 10 CFR 52.103(g), so the staff does not have latitude in determining the implementation period of the rule. Therefore, the staff concludes that no additional action to address the concept of cumulative effects of regulation is necessary.

DISCUSSION:

The final rule amendment includes the following new notifications after ITAAC closure:

- ITAAC post-closure notification
- All ITAAC complete notification

In general, the reasons for these proposed new notifications are analogous to the reasons presented in the 2007 rulemaking for the existing 10 CFR 52.99(c) notifications: (1) to ensure that the NRC has sufficient information, in light of new information developed or identified after the ITAAC closure notification under 10 CFR 52.99(c)(1), to complete all of the activities necessary for the Commission to make a finding on ITAAC, and (2) to ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189a(1)(B) threshold for requesting a hearing. The following sections of this paper describe each of the proposed notification and documentation requirements in this rulemaking and the bases for each of the proposed requirements.

(1) ITAAC Post-closure Notification

The first new notification in the final rule is the ITAAC post-closure notification under 10 CFR 52.99(c)(2). When making the 10 CFR 52.103(g) finding, the Commission must have information sufficient to determine that the relevant acceptance criteria are met despite new information that materially altered the basis for (1) determining that a prescribed inspection, test, or analysis was performed as required or (2) a finding that a prescribed acceptance criterion is met (the "ITAAC determination basis"). The licensee's statement of the issue and bases for resolving the issue, discussion of any action taken, and a list of the key licensee documents supporting the resolution and its implementation will assist the NRC in making its independent evaluation of the issue. Apart from the NRC's use of the information, the staff also believes that making this information available to the public is necessary to ensure that interested persons will have sufficient information to review when preparing a request for a hearing under 10 CFR 52.103, comparable to the information provided under 10 CFR 52.99(c)(1), as described in the statements of consideration for the 10 CFR Part 52 rulemaking (72 FR 49352; August 28, 2007).

Accordingly, under 10 CFR 52.99(c)(2), the licensee is required to submit a resolution notification to the NRC in the form of an ITAAC post-closure notification. This ITAAC

post-closure notification, described in 10 CFR 52.99(c)(2), requires the licensee to submit a written notification of the resolution of the circumstances that materially altered the existing ITAAC determination basis. The ITAAC post-closure notification must contain sufficient information to demonstrate that, notwithstanding the new information of a materially altered ITAAC determination basis, the prescribed inspections, tests, or analyses have been performed as required and the prescribed acceptance criteria are met. The ITAAC post-closure notifications should explain the need for the supplemental notification, outline the resolution of the issue, and confirm that the ITAAC acceptance criteria continue to be met. The ITAAC post-closure notifications must include a level of detail similar to the level of information required in initial ITAAC closure notifications under 10 CFR 52.99(c)(1).

The staff proposes that the NRC's receipt of the notification under 10 CFR 52.99(c)(2) be published in the FR, at least until the last date for submission of requests for a hearing, under 10 CFR 52.99(e)(1). In addition, the staff proposes that the 10 CFR 52.99(c)(2) notification be available for public review under 10 CFR 52.99(e)(2). These requirements help ensure public availability and accessibility of important information on ITAAC closure.

Events that affect completed ITAAC could involve activities that include, but are not limited to, maintenance and engineering programs or design changes. The staff expects that licensees will carry out these activities under established programs to maintain ITAAC conclusions and that no supplemental notification will be necessary in most instances. The NRC can have confidence that prior ITAAC conclusions are maintained, as long as the ITAAC determination bases established by the original ITAAC closure letter are not materially altered. If the ITAAC determination bases are not materially altered, licensee activities will remain below the notification threshold of 10 CFR 52.99(c)(2). If the ITAAC determination bases are materially altered, then the licensee is required to document resolution of the issue in the ITAAC post-closure notification under 10 CFR 52.99(c)(2).

(2) All ITAAC Complete Notification

The second new notification in the final rule is the all ITAAC complete notification under 10 CFR 52.99(c)(4). The purpose of this notification is to facilitate the required Commission finding under 10 CFR 52.103(g) that the acceptance criteria in the combined license are met. After or concurrent with the last ITAAC closure letter required by 10 CFR 52.99(c)(1) or (c)(2), the licensee would be required to notify the NRC that all ITAAC are complete. At the time the licensee submits the all ITAAC complete notification, the staff would expect that all activities requiring ITAAC post-closure notifications have been completed and that the associated ITAAC determination bases have been updated.

The staff recognizes that construction and operational readiness activities will continue even after the licensee submits the all ITAAC complete notification under 10 CFR 52.99(c)(4), and that these activities could result in new information that may materially alter the bases for a finding on acceptance criteria under 10 CFR 52.103(g). However, the staff understands that prospective licensees expect to complete the last ITAAC very close to the scheduled date for fuel load, and it expects the Commission to make the 10 CFR 52.103(g) finding on acceptance criteria shortly thereafter. The NRC's ITAAC closure notification regulatory process is structured so that the Commission is able to make a timely 10 CFR 52.103(g) finding that meets all applicable legal standards and has been developed through a process that promotes public confidence. In addition, while not addressed by the rule, industry guidance in NEI 08-01,

Revision 4, provides that licensees should expeditiously evaluate new information to determine whether the threshold for ITAAC post-closure notifications is exceeded, and, if so, “the licensee should notify the NRC within 24 hours of such a determination.”

(3) Additional Conforming Changes to 10 CFR 52.99

The final rule also contains several editorial changes to 10 CFR 52.99(b), (c)(1), (c)(2), and (d)(1). In all of these cases, the rule replaces the phrase “acceptance criteria have been met” with the phrase “acceptance criteria are met” for consistency with Section 185b of the AEA and the wording of the requirement in 10 CFR 52.103(g) on the Commission’s ITAAC finding. In addition, the staff is proposing an editorial change to 10 CFR 52.99(d)(2) to replace the phrase “ITAAC has been met” with the phrase “prescribed acceptance criteria are met” for consistency with the wording in 10 CFR 52.99(d)(1).

(4) Conforming Changes to 10 CFR 2.340

The final rule contains an associated correction to the language in 10 CFR 2.340(j). The NRC substantially revised 10 CFR 2.340 as part of the 2007 10 CFR Part 52 rulemaking to set forth (among other things) the circumstances under which the Commission may make a finding on acceptance criteria under Section 185b of the AEA and 10 CFR 52.103(g). The staff’s interactions with external stakeholders on ITAAC identified an error in the language of this section. The introductory language of 10 CFR 2.340(j) incorrectly describes the Commission’s finding under 10 CFR 52.103(g) as a finding that the acceptance criteria in a combined license “have been, or will be met.” This phrase actually describes the finding that a presiding officer makes only with respect to contested matters involving ITAAC in a hearing under 10 CFR 52.103. The presiding officer’s finding does not negate the need for the Commission (or appropriate office director, if the Commission chooses to delegate this authority) to make the overall finding on acceptance criteria as required by Section 185b of the AEA and 10 CFR 52.103(g). Accordingly, the rule contains a correcting change to 10 CFR 2.340(j) to accurately describe the Commission’s finding under 10 CFR 52.103(g) as a finding that the acceptance criteria “are met.”

In addition to correcting this error, the staff proposes to expand the language of 10 CFR 2.340(j) to (1) more clearly distinguish among adjudicatory findings on contentions (contested matters) with respect to ITAAC and the overall Commission finding on acceptance criteria under Section 185b of the AEA and 10 CFR 52.103(g) and (2) describe in more detail what findings on ITAAC must be made, depending on whether there are contested ITAAC.

(5) Changes to Proposed Rule Language, 10 CFR 52.99(e)

The draft final rule includes rule text that is substantially similar to the proposed rule with one language change to Section 52.99(e)(2) to clarify NRC notices to the public. The one language change made to the section, “NRC inspection, publication of notices, and availability of licensee notifications,” is to replace the language “The NRC shall make publicly available the licensee notifications under paragraphs (c)(1) through (4) of this section no later than the date of publication of the notice of intended operations required by 10 CFR 52.103(a)” with: “The NRC shall, no later than the date of publication of the notice of intended operation required by 10 CFR 52.103(a), make publicly available those licensee notifications under paragraph (c) of this section that have been submitted to the NRC at least seven (7) days before that notice.”

The NRC will make public all paragraph (c) ITAAC notifications that were submitted to the NRC at least 7 days before the date of publication of the notice of intended operation required by 10 CFR 52.103(a) which is, at a minimum, 180 days before the date scheduled for initial loading of fuel. A licensee could submit ITAAC notifications required by paragraph (c) later than the date of publication of the notice of intended operation required by 10 CFR 52.103(a). The NRC will continue to make these later notifications publicly available pursuant to the first sentence of 10 CFR 52.99(e)(2).

PUBLIC COMMENTS:

The NRC received one public comment submission from one industry organization, the Nuclear Energy Institute (ADAMS Accession No. ML11208C708). The comment submission contained 11 comments, consisting of 2 general comments and 9 specific comments. All comments and their resolution are discussed in the *Federal Register* Notice (FRN)(Enclosure 1).

The first general comment (Comment 1, p.1) on the proposed rule, Section 52.99, NEI requested including language contained within Section IX.B.1 of the design certification rules (DCR) concerning the focus of the ITAAC finding by the NRC. Referencing the Supplementary Information accompanying the ABWR design certification rule (62 FR 25813), NEI requested that the proposed 52.99(e)(1) be revised to state, "... the NRC staff's determination ~~of the successful completion of~~ that inspections, tests, and analyses contained in the license have been successfully completed and, based solely thereon, that the prescribed acceptance criteria are met." The NRC does not agree with this general comment. The change that NEI proposed is not within the scope of the ITAAC Maintenance rulemaking, as it does not address the issues of ITAAC maintenance (including public awareness of significant changes to the bases of licensee notifications under § 52.99). In addition, NEI proposed this change as part of a set of changes in their comment submission on the 2006 proposed Part 52 rule (ML011100405). In the 2007 rulemaking revising Part 52, the NRC declined to make the NEI-proposed change. See 72 FR 49352, 49385 (August 28, 2007). NEI does not present any new arguments that the staff believes should result in a change to the Commission's 2007 position rejecting the NEI proposal. No changes to the final rule language were made as a result of this comment.

The second general comment (Comment 11, p. 4) addressed the need to ensure that the NRC adequately considered the effect of 10 CFR 52.103(c). Under 10 CFR 52.103(c), the Commission may allow a period of interim operation pending completion of a hearing granted on one or more ITAAC, provided there is reasonable assurance of adequate protection to the public health and safety during the period of interim operation. The NRC staff disagrees with the comment because the relationship between § 52.103(c) and (g) is outside the scope of this rulemaking, and Section 189b(1)(B)(iii) of the AEA clearly provides the Commission with authority to allow interim operation during a pending hearing on acceptance criteria. The NRC staff will provide the Commission with a paper addressing issues associated with an interim operation finding during the pendency of hearings at a later time.

The nine specific comments received on the proposed rule contained recommendations for changes to the supplementary information to correctly reflect common terminology between the rule supplementary information, the associated RG 1.215 and the industry guidance contained within Revision 4 of NEI 08-01 (ADAMS Accession No. ML102010051). These nine specific comments focused on the supplementary information section; therefore no changes to the final

rule language were made as a result of these comments. Eight of the nine comments resulted in clarifications in the supplementary information section.

RECOMMENDATIONS:

The staff recommends that the Commission do the following:

- (1) Approve for publication in the *Federal Register* the enclosed notice of final rulemaking (Enclosure 1).
- (2) Certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b). This certification is included in the enclosed *Federal Register* notice.
- (3) Note the following:
 - a. The *Federal Register* notice of final rulemaking will announce the staff's issuance of the final RG 1.215 for use.
 - b. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act (5 U.S.C. 605(b)).
 - c. The staff has determined that this action is not a "major rule," as defined in the Congressional Review Act of 1996 (5 U.S.C. 804(2)), and has confirmed this determination with the Office of Management and Budget. The staff will inform the appropriate Congressional and Government Accountability Office contacts.
 - d. The appropriate Congressional committees will be informed.
 - e. The Office of Public Affairs will issue a press release when the final rulemaking is filed with the Office of the Federal Register.

RESOURCES:

It is estimated that 0.8 full time equivalent (FTE) is needed to complete this rulemaking activity and this estimate was included in the FY 2012 Budget.

Office	Product Line	Product	FY 2012 Resources \$/FTE
NRO	Rulemaking	Rulemaking	0.5
OGC	Rulemaking	Corporate Rulemaking	0.1
OIS	Rulemaking	Rulemaking	0.1
ADM	Rulemaking	Corporate Rulemaking	0.1
Total:			0.8

If additional resources are required beyond FY 2013, they will be addressed through the Planning, Budget, and Performance Management process.

COORDINATION:

The staff briefed the Advisory Committee on Reactor Safeguards on this final rule on December 1, 2011, and received the Committee's recommendation for approval by letter on December 8, 2011 (ADAMS Accession No. ML11350A104). The OGC has no legal objection to this SECY paper, the draft final FRN, and supporting rulemaking documents. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

/RA by Martin J. Virgilio for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. [Federal Register Notice](#)
2. [Final Regulatory Analysis](#)
3. [Supporting Statement](#)

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2 and 52

RIN 3150-AI77

NRC-2010-0012

**Requirements for Maintenance of Inspections,
Tests, Analyses, and Acceptance Criteria**

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule and regulatory guide, issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations related to verification of nuclear power plant construction activities through inspections, tests, analyses, and acceptance criteria (ITAAC) under a combined license, and issuing a revision to Regulatory Guide (RG) 1.215 “Guidance for ITAAC Closure Under 10 CFR Part 52.” The final rule contains new provisions that apply after a licensee has completed an ITAAC and submitted an ITAAC closure notification. The new provisions require licensees to report new information materially altering the basis for determining that inspections, tests, or analyses were performed as required, or that acceptance criteria are met, and to notify the NRC of the completion of all ITAAC activities. In addition, the NRC is including editorial corrections to existing language in the NRC’s regulations to make that language consistent with language in the Atomic Energy Act of 1954, as amended (AEA). RG 1.215 describes a method that the staff of the NRC considers acceptable for use in satisfying the requirements for documenting the completion of ITAAC.

EFFECTIVE DATE: [insert date 30 days after publication in the *Federal Register*].

ADDRESSES: You can access publicly available documents related to this document using the following methods:

- **NRC's Public Document Room (PDR):** The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** Publicly available documents created or received at the NRC are available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.
- **Federal Rulemaking Web site:** Public comments and supporting materials related to this final rule can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2010-0012. Address questions and concerns regarding NRC dockets to Carol Gallagher; telephone at 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Mr. Earl R. Libby, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001; telephone: 301-415-0522; e-mail: Earl.Libby@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Comments on the Proposed Rule and Regulatory Guide
 - A. Overview of Public Comments
 - B. Comments on the Proposed Rule
 - C. Comments on the Draft Regulatory Guide DG-1250/RG 1.215

- III. Discussion
 - A. Licensee Programs That Maintain ITAAC Conclusions
 - B. Additional ITAAC Notifications
 - C. Conforming Changes to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.340
- IV. Section-by-Section Analysis
- V. Availability of Regulatory Guidance
- VI. Availability of Documents
- VII. Plain Language Writing
- VIII. Agreement State Compatibility
- IX. Voluntary Consensus Standards
- X. Environmental Impact – Categorical Exclusion
- XI. Paperwork Reduction Act Statement
- XII. Public Protection Notification
- XIII. Regulatory Analysis
- XIV. Regulatory Flexibility Act Certification
- XV. Backfitting and Issue Finality
- XVI. Congressional Review Act

I. Background

The Commission first issued Title 10 part 52, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors” on April 18, 1989 (54 FR 15372). Section 52.99, “Inspection during construction,” was included to make it clear that the NRC’s inspection carried out during construction under a combined license would be based on ITAAC proposed by the applicant, approved by the NRC staff, and incorporated in the combined license. At that time, the Commission made it clear that, although 10 CFR 52.99 envisioned a “sign-as-you-go” process in which the NRC staff would sign off on inspection units and notice of

the staff's sign-off would be published in the *Federal Register*, the Commission itself would make no findings with respect to construction until construction was complete. (See 54 FR 15372; April 18, 1989; at 15383 (second column)).

On August 28, 2007 (72 FR 49352), the Commission revised Title 10 of the *Code of Federal Regulations* part 52 to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and approval processes. In that revision, the NRC amended 10 CFR 52.99 to require licensees to notify the NRC that the prescribed inspections, tests, or analyses in the ITAAC have been completed and that the acceptance criteria have been met. The revision also requires that these notifications contain sufficient information to demonstrate that the prescribed inspections, tests, or analyses have been performed and that the prescribed acceptance criteria have been met. The statement of considerations for the 2007 rule indicated that this requirement would ensure that combined license applicants and holders were aware that it was the licensee's burden to demonstrate compliance with the ITAAC, and that the notification of ITAAC completion will contain more information than just a simple statement that the licensee believes the ITAAC had been completed and the acceptance criteria met.

Under Section 185b of the AEA and 10 CFR 52.97(b), a combined license for a nuclear power plant (a "facility") must contain those ITAAC that are "necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with" the license, the AEA, and the NRC regulations. Following issuance of the combined license, Section 185b of the AEA and 10 CFR 52.99(e) require that the Commission "ensure that the prescribed inspections, tests, and analyses are performed." Finally, before operation of the facility, Section 185b of the AEA and 10 CFR 52.103(g) require that the Commission find that the "prescribed acceptance criteria *are met*" (emphasis added). This Commission finding will not occur until construction is complete, near the scheduled date for initial fuel load.

As currently required by 10 CFR 52.99(c)(1), the licensee must submit ITAAC closure notifications containing “sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the associated acceptance criteria have been met.” These notifications perform two functions. First, they alert the NRC to the licensee’s completion of the ITAAC¹ and ensure that the NRC has sufficient information to complete all of the activities necessary for the Commission to determine whether all of the ITAAC acceptance criteria have been or will be met (the “will be met” finding is relevant to any hearing on ITAAC under 10 CFR 52.103) before initial operation. Second, they ensure that interested persons will have access to information on both completed and uncompleted ITAAC at a level of detail sufficient to address the AEA Section 189a(1)(B) threshold for requesting a hearing on acceptance criteria. See 72 FR 49352; August 28, 2007, at 49450 (second column).

After completing the 2007 rulemaking, the NRC began developing guidance on the ITAAC closure process and the requirements under 10 CFR 52.99. In October 2009, the NRC issued regulatory guidance for the implementation of the revised 10 CFR 52.99 in Regulatory Guide (RG) 1.215, “Guidance for ITAAC Closure under 10 CFR Part 52.” This RG endorsed guidance developed by the Nuclear Energy Institute (NEI) in NEI 08-01, “Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52,” Revision 3, issued January 2009 (ADAMS Accession No. ML090270415).

After considering information presented by industry representatives in a series of public meetings, the NRC realized that some additional implementation issues were left unaddressed by the various provisions in 10 CFR part 52. In particular, the NRC determined that the combined license holder should provide additional notifications to the NRC following the

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notification of ITAAC completion currently required by 10 CFR 52.99(c)(1). The NRC refers to the time after this ITAAC closure notification, but before the date the Commission makes the finding under 10 CFR 52.103(g), as the ITAAC maintenance period. Most recently, the NRC held two public meetings in March 2010 to discuss draft proposed rule text that it made available to the public in February 2010. The NRC considered feedback given from external stakeholders during those meetings in its development of this final rule. Finally, in March 2010, the NRC issued Inspection Procedure 40600, "Licensee Program for ITAAC Management," which provides guidance to verify licensees have implemented ITAAC maintenance programs to ensure that structures, systems, and components continue to meet the ITAAC acceptance criteria until the Commission makes the finding under 10 CFR 52.103(g) allowing operation.

II. Comments on the Proposed Rule and Regulatory Guide

A. Overview of Public Comments

The NRC published a proposed rule on the Requirements for Maintenance of Inspections, Tests, Analyses and Acceptance Criteria in the *Federal Register* on May 13, 2011 (76 FR 27925). The period for submitting comments on the proposed ITAAC Maintenance rule closed on July 27, 2011. The associated draft regulatory guide for the proposed rule, Regulatory Guide (RG) 1.215 "Guidance for ITAAC Closure under 10 CFR part 52" (DG-1250) was also published in the *Federal Register* on May 13, 2011 (76 FR 27924). The period for submitting comments on the draft guidance closed on July 25, 2011.

Types of Comments

The NRC received 1 public comment submission on the proposed rule containing 11 comments from 1 industry organization, the Nuclear Energy Institute (NEI) (ADAMS Accession No. ML11208C708). The NRC received one public comment submission, from NEI, containing twenty-two comments on the regulatory guide (ADAMS Accession No. ML11209C487). Comments on the proposed rule are discussed separately from the comments on the draft

regulatory guide.

B. Comments on the Proposed Rule

There were two types of comments on the proposed rule:

1. Comments that were general in nature to the proposed rule language.
2. Comments that were specific in nature to the proposed rule supplementary information.

The NEI submission contained two general comments on the proposed rule and nine specific comments on the proposed rule supplementary information. The NRC has carefully considered the public comments received during the comment period and is adopting a final rule that is substantially similar to the proposed rule with one change to § 52.99(e)(2). NEI generally supported the approach and objective of the proposed rule and the associated regulatory guidance.

Comment Identification Format

All comments are identified uniquely by using the formation [Comment X, p. Y] where [Comment X] represents the sequential comment number and [p. Y] represents the comment submission page number.

1. General Comments Regarding the Proposed Rule Language

Comment: Section 52.99(e)(1) should be revised to state, "... the NRC staff's determination ~~of the successful completion of that~~ inspections, tests, and analyses contained in the license have been successfully completed and, based solely thereon, that the prescribed acceptance criteria are met." (Comment 1, p.1)

NRC Response: The NRC does not agree with this comment. The change that NEI proposes is not within the scope of this rulemaking, as it does not address the issues of ITAAC maintenance (including public awareness of significant changes to the bases of licensee notifications under § 52.99). In addition, NEI proposed this change as part of a set of changes in

their comment submission on the 2006 proposed part 52 rule (ML011100405). In the 2007 rulemaking revising Part 52, the NRC declined to make the NEI-proposed change. See 72 FR 49352, 49385 (August 28, 2007). NEI does not present any new arguments that would cause the NRC to change its 2007 position rejecting the NEI proposal. No changes to the final rule language were made as a result of this comment.

Comment: The NRC should clarify in the final rule the relationship between paragraphs (c) and (g) of § 52.103, to account for the possibility of interim operation. (Comment 11, p.4)

NRC Response: The NRC disagrees with the comment because the relationship between § 52.103(c) and (g) is outside the scope of this rulemaking, and Section 189b(1)(B)(iii) of the AEA clearly provides the Commission with authority to allow interim operation during a pending hearing on acceptance criteria. The NRC may address the subject of interim operation at a later time. No change was made to the final rule language as a result of this comment.

2. Specific Comments Regarding the Proposed Rule Supplementary Information

The nine specific comments received on the proposed rule contained recommendations for changes to the supplementary information to correctly reflect common terminology between the rule supplementary information, the associated RG 1.215 and the industry guidance contained within Revision 4 of NEI 08-01 (ADAMS Accession No. ML102010051). These nine specific comments all addressed discussion in the statement of considerations (SOC) (the “Supplementary Information” section of the *Federal Register* notice of proposed rulemaking); therefore no changes to the final rule language were made as a result of these comments. The SOC for the final rule reflects the NRC consideration of these nine comments.

Comment: The phrase “ITAAC closure package” should be replaced with the phrase “ITAAC completion package” in Section III. A, 3d bullet (76 FR 27927) so that the SOC uses terminology which is consistent with that in the associated draft regulatory guide and industry guidance. (Comment 2, p.2)

NRC Response: The NRC agrees with the comment. The SOC for the final rule uses the phrase, "ITAAC completion package."

Comment: Delete the second sentence in Section III.B paragraph beginning "When making..." to maintain a consistent description of the content of 52.99(c)(1) notifications in the associated draft regulatory guide and industry guidance. (Comment 3, p.2)

NRC Response: The NRC agrees with the comment. The SOC for the final rule deleted the sentence "The licensee's summary statement of the basis for resolving the issue which is the subject of the notification, a discussion of any action taken, and a list of the key licensee documents supporting the resolution and its implementation, would assist the NRC in making its independent evaluation of the issue" to agree with the Regulatory Guide 1.215 and the industry guidance contained within Revision 4 of NEI 08-01.

Comment: Add the term "maintenance" to the list of permissible activities that may be in progress at the time of the 10 CFR 52.103(g) finding. (Comment 4, p.2)

NRC Response: The NRC agrees with the comment because it reflects the intent of the rule and the guidance. The SOC for the final rule added the term "maintenance" to the activities that are allowable during the time of the Commission's 10 CFR 52.103(g) finding if the programs credited with maintaining the validity of completed ITAAC guide those activities and the activities are not so significant as to exceed a threshold for reporting.

Comment: Delete "The NRC understands that the nuclear power industry believes..." in Section III.B First paragraph under heading "ITAAC Closure Documentation" because the language is unnecessary. (Comment 5, p.2)

NRC Response: The NRC agrees with the comment because the language is unnecessary. The SOC for the final rule deleted the phrase "The NRC understands that the nuclear power industry believes..." from the sentence.

Comment: Revise Section III.C, as follows for clarity. "In both cases, if the presiding

officer's decision resolves the contention favorably finds that the contested acceptance criteria have been met, ..." (Comment 6, p.3)

NRC Response: The NRC agrees that the sentence should be revised for clarity, but the SOC will use the phrase "have been or will be met" to reflect both types of possible presiding officer findings. The SOC for the final rule was changed to "In both cases, if the presiding officer finds that the contested acceptance criteria have been or will be met, this does not obviate the need for the Commission to make the required finding under Section 185b of the AEA and 10 CFR 52.103(g) that the acceptance criteria are met." This change is consistent with similar language in Section IV of the supplementary information section.

Comment: Add the phrase "... on contested acceptance criteria." to clarify what decision by the presiding officer the paragraph is referencing. (Comment 7, p.3)

NRC Response: The NRC agrees with the comment. The final rule SOC now reads as follows: "The phrase "otherwise able to make" conveys the NRC's determination that the Commission's process for supporting a Commission finding on uncontested acceptance criteria is unrelated to and unaffected by the timing of the presiding officer's initial decision on contested acceptance criteria."

Comment: Replace the term "must" with the term "should" to reflect that ITAAC Maintenance documentation and recordkeeping is an expectation and not a requirement. (Comment 8, p.3)

NRC Response: The NRC agrees with the comment. The final rule SOC uses the term "should" to reflect expectations regarding documentation and recordkeeping in support of ITAAC post-closure notifications. However, as explained below, regulatory provisions such as 10 CFR Part 50 require the preparation and retention of records supporting the vast majority of ITAAC processes, including the activities supporting the notifications that are required by this final rule.

Comment: The comment requested the addition of a sentence stating the NRC

proposed no changes to Section IV, Subsection on § 52.99(d). (Comment 9, p.3)

NRC Response: The NRC does not agree with this comment. The first sentence of § 52.99(d)(1) contains the following change. “In the event that an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria ~~has been~~ are met, the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable.” In addition, 52.99(d)(2) was also changed as follows: “In the event that an activity is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria ~~has been~~ are met, the licensee may take corrective action to successfully complete that ITAAC or request a license amendment under 10 CFR 52.98(f).”

Comment: Delete the phrase “and detailed” when referring to licensee notifications required by § 52.99(c) for consistency with Section IV.B (Comment 10, p.4)

NRC Response: The NRC agrees with this comment. In the final rule SOC the phrase “and detailed” was deleted. The sentence now reads “In general, the NRC expects to make the paragraph (c) notifications available shortly after the NRC has received the notifications and concluded that they are complete.” The accompanying detail necessary for the ITAAC notifications under paragraph (c) is developed in regulatory guidance, RG 1.215. This change is consistent with the last paragraph in Section III.B of the supplementary information.

C. Comments on the Draft Regulatory Guide DG-1250/RG 1.215

The NRC published the draft regulatory guide for the proposed rule, Regulatory Guide (RG) 1.215 “Guidance for ITAAC Closure under 10 CFR part 52” (DG-1250) in the *Federal Register* on May 13, 2011 (76 FR 27924). The period for submitting comments on the draft guidance closed on July 25, 2011.

The NRC received 1 public comment submission on the regulatory guide containing 25 comments from 1 industry organization, NEI (ADAMS Accession No. ML11209C487). The NRC's responses to the public comments are contained in "Response to Public Comments on Draft Regulatory Guide DG-1250, (proposed revision 1 of RG 1.215) "Guidance for ITAAC Closure Under 10 CFR Part 52" (ADAMS Accession No. ML11284A006).

III. Discussion

The NRC is requiring the following new notifications with respect to ITAAC closure:

- ITAAC post-closure notification, and
- All ITAAC complete notification.

In general, the reasons for these new notifications are analogous to the reasons presented in the 2007 rulemaking for the existing 10 CFR 52.99(c) notifications: 1) to ensure that the NRC has sufficient information, in light of new information developed or identified after the ITAAC closure notification under 10 CFR 52.99(c)(1), to complete all of the activities necessary for the NRC to make a determination on ITAAC; and 2) to ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189a(1)(B) threshold for requesting a hearing. After evaluating the various means of ensuring that the Commission has sufficient information to make a determination on ITAAC, and that interested persons have access to sufficient ITAAC information, the NRC has provided a rule augmented by guidance. The details of timing and content of the new notifications are captured in guidance that was issued for public comment simultaneously with the proposed rule, as discussed in more detail in Section V, "Availability of Regulatory Guidance," of this document. The NRC believes that this approach allows more flexibility to adjust the guidance based on lessons learned during early implementation of the ITAAC process under the first combined licenses. Based upon the NRC's experience with the overall NRC oversight and verification of ITAAC, the notification provisions of the rule, the ITAAC hearing process, and the

process for making the 10 CFR 52.103(g) finding, the NRC may revise and supplement the final guidance on the timing and content of notifications. The NRC notes that it would not rely solely on the existence of this rulemaking as a primary basis for the 10 CFR 52.103(g) finding. Rather, the NRC would use a holistic review using results from the NRC's construction inspection program and ITAAC closure review process as primary factors supporting a conclusion that the acceptance criteria in the combined license are met.

Each of the notification requirements in this rulemaking and the basis for each of the requirements, are described in Section III.B, "Additional ITAAC Notifications," of this document. The NRC also included several editorial changes to 10 CFR 52.99 in paragraphs (b), (c)(1), final (c)(3) (former (c)(2)), and (d)(1). In all of these cases, the NRC is replacing the phrase "acceptance criteria have been met" with the phrase "acceptance criteria are met" for consistency with the wording of the requirement in 10 CFR 52.103(g) on the Commission's ITAAC finding, which is derived directly from wording in the AEA. In addition, the NRC changed 10 CFR 52.99(d)(2) to replace the phrase "ITAAC has been met" with the phrase "prescribed acceptance criteria are met" for consistency with the wording in 10 CFR 52.99(d)(1).

A. Licensee Programs That Maintain ITAAC Conclusions

One essential element in ensuring the maintenance of successfully completed ITAAC involves the use of established licensee programs such as the Quality Assurance Program, Problem Identification and Resolution Program, Maintenance/Construction Program, and Design and Configuration Management Program. Each program credited with supporting the maintenance of completed ITAAC should contain attributes that maintain the validity of the ITAAC determination basis. These program attributes include the following:

- Licensee screening of activities and events for impact on ITAAC,
- Licensee determination of whether supplemental ITAAC notification is required, and

- Licensee supplementation of the ITAAC completion package as appropriate to demonstrate that the acceptance criteria continue to be met.

The NRC expects these programs to be fully implemented and effective before the licensee takes credit for them as an appropriate means of supporting ITAAC maintenance. These programs will be subject to NRC inspection.

B. Additional ITAAC Notifications

ITAAC Post-Closure Notification

The first new notification is contained in 10 CFR 52.99(c)(2), “ITAAC post-closure notifications,” and would be required following the licensee’s ITAAC closure notifications under 10 CFR 52.99(c)(1) until the Commission makes the finding under 10 CFR 52.103(g). This provision in 10 CFR 52.99(c)(2) would require the licensee to provide the NRC with timely notification of new information materially altering the basis for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met (referred to as the *ITAAC determination basis*).

The licensee is responsible for maintaining the validity of the ITAAC conclusions after completion of the ITAAC. If the ITAAC determination basis is materially altered, the licensee is expected to notify the NRC. Through public workshops and stakeholder interaction, the NRC developed thresholds to identify when activities would materially alter the basis for determining that a prescribed inspection, test, or analysis was performed as required, or finding that a prescribed acceptance criterion is met. One obvious case is that a notification under paragraph (c)(2) is required to correct a material error or omission in the original ITAAC closure notification. The materially altered determination is further developed in RG 1.215 and the industry guidance NEI 08-01 Revision 4.

Section 52.6, “Completeness and accuracy of information,” paragraph (a), requires that information provided to the Commission by a licensee be complete and accurate in all material

respects. However, it might be the case that the original closure notification was complete and accurate when sent, but subsequent events materially alter the ITAAC determination basis. Also, a material error or omission might not be discovered until after the ITAAC closure notification is sent. It is possible that new information materially altering the ITAAC determination basis would not rise to the reporting threshold under 10 CFR 52.6(b). As required by 10 CFR 52.6(b), licensees must notify the Commission of information identified by the licensee as having, for the regulated activity, a significant implication for public health and safety or the common defense and security. Given the primary purpose of ITAAC—to verify that the plant has been constructed and will be operated in compliance with the approved design—the NRC believes that it cannot rely on the provisions in 10 CFR 52.6 for licensee reporting of new information materially altering the ITAAC determination basis. The reasons for this conclusion are as follows:

1. Material errors and omissions in ITAAC closure notifications, relevant to the accuracy and completeness of the documented basis for the Commission’s finding on ITAAC, may nonetheless be determined in isolation by a licensee as not having a significant implication for public health and safety or common defense and security.

2. A Commission finding of compliance with acceptance criteria in the ITAAC at the time of the finding is required, under Section 185b of the AEA, in order for the combined license holder to commence operation.

3. The addition of specific reporting requirements addressing information relevant and material to the ITAAC finding ensures that the NRC will get the necessary reports as a matter of regulatory requirement and allows the NRC to determine the timing and content of these reports so that they serve the regulatory needs of the NRC.

Therefore, the NRC intends that these issues will be reported under 10 CFR 52.99(c)(2). In addition to the reporting of material errors and omissions, the NRC has identified other

circumstances in which reporting under this provision would be required (i.e., reporting thresholds). These reporting thresholds are described in more detail in Section IV, “Section-by-Section Analysis,” of this document.

When making the 10 CFR 52.103(g) finding, the NRC must have sufficient information to determine that the relevant acceptance criteria are met despite the new information prompting the notification under paragraph (c)(2). Apart from the NRC’s use of the information, the NRC also believes that public availability of such information is necessary to ensure that interested persons will have sufficient information to review when preparing a request for a hearing under 10 CFR 52.103, comparable to the information provided under paragraph (c)(1), as described in the Statement of Consideration for the 2007 part 52 rulemaking. See August 28, 2007; 72 FR 49352, at 49384 (second and third columns). Accordingly, the NRC requires that after a licensee identifies new information materially altering the ITAAC determination basis, the licensee must then submit what is essentially a “resolution” notification to the NRC in the form of an ITAAC post-closure notification. The ITAAC post-closure notification, described in paragraph (c)(2), requires the licensee to submit a written notification of the resolution of the circumstances surrounding the identification of new information materially altering the ITAAC determination basis. The ITAAC post-closure notification must contain sufficient information demonstrating that, notwithstanding the information that prompted notification, the prescribed inspections, tests, and analyses have been performed as required and the prescribed acceptance criteria are met. The ITAAC post-closure notifications should explain the need for the notification, outline the resolution of the issue, and confirm that the ITAAC acceptance criteria continue to be met. The ITAAC post-closure notifications must include a level of detail similar to the level of information required in initial ITAAC closure notifications under 10 CFR 52.99(c)(1).

Section 52.99(c)(2) states that licensees must make the notification “in a timely manner.” Further discussion of what the NRC considers “timely” can be found in the NRC guidance being

issued simultaneously with this final rule, as discussed in more detail in Section V, “Availability of Regulatory Guidance,” of this document.

The NRC provides that the notification be available for public review under paragraph (e)(2). This helps ensure public availability and accessibility of important information on ITAAC closure. Further explanation of the basis for the availability requirement is presented under the discussion on 10 CFR 52.99(e)(2) in Section IV, “Section-by-Section Analysis,” of this document.

Events that affect completed ITAAC could involve activities that include, but are not limited to, maintenance and engineering programs, or design changes. The NRC expects that licensees will carry out these activities under established programs to maintain ITAAC conclusions and that no post-closure notification will be necessary in most instances. The NRC can have confidence that prior ITAAC conclusions are maintained, as long as the ITAAC determination basis established by the original ITAAC closure notification is not materially altered. If the ITAAC determination basis is not materially altered, then licensee activities will remain below the notification threshold of 10 CFR 52.99(c)(2). If the ITAAC determination basis is materially altered, then the licensee is required to notify the NRC under 10 CFR 52.99(c)(2).

Although the NRC is requiring that licensees notify the NRC of information materially altering the ITAAC determination basis only after the licensee has evaluated and resolved the issue prompting the notification, the NRC encourages licensees to communicate with the NRC early in its evaluation process. The purpose of this early communication would be to alert the NRC staff to the fact that additional activities may be scheduled that affect a structure, system, or component (including physical security hardware) or program element for which one or more ITAAC have been closed. This will allow the NRC inspection staff to discuss the licensee’s plans for resolving the issue to determine if the staff wants to observe any of the upcoming activities

for the purpose of making a future staff determination about whether the acceptance criteria for those ITAAC continue to be met.

All ITAAC Complete Notification

Another notification that the NRC is requiring is the “all ITAAC complete” notification under 10 CFR 52.99(c)(4). The purpose of this notification is to facilitate the required Commission finding under 10 CFR 52.103(g) that the acceptance criteria in the combined license are met. After or concurrent with the last ITAAC closure notification required by 10 CFR 52.99(c)(1), the licensee is required to notify the NRC that all ITAAC are complete. When the licensee submits the all ITAAC complete notification, the NRC would expect that all activities requiring ITAAC post-closure notifications have been completed and that the associated ITAAC determination bases have been updated.

To support the Commission’s finding under 10 CFR 52.103(g) that the acceptance criteria in the combined license are met, the NRC staff will, if and when appropriate, send a recommendation to the Commission to make a finding that all of the specified acceptance criteria are met. The staff will consider that all acceptance criteria “are met” if both of the following conditions hold:

- All ITAAC were verified to be met at one time, and
- The licensee provides confidence, in part through the notifications in 10 CFR 52.99(c), that the ITAAC determination basis have been maintained and the ITAAC acceptance criteria continue to be met; and the NRC has no reasonable information to the contrary.

This approach will allow licensees to have ITAAC-related structures, systems, or components, or security or emergency preparedness related hardware, undergoing maintenance or certain other activities at the time of the 10 CFR 52.103(g) finding, if the programs credited with maintaining the validity of completed ITAAC guide those activities and

the activities are not so significant as to exceed a threshold for reporting. If a reporting threshold has been exceeded, then the NRC would need to evaluate the licensee's ITAAC post-closure notification to determine whether the ITAAC continue to be met. Reporting thresholds are discussed in more detail in Section IV, "Section-by-Section Analysis," of this document.

ITAAC Closure Documentation

This final rule does not contain specific ITAAC documentation and record retention requirements. Consistent with regulatory provisions such as 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," licensees are expected to prepare and retain records supporting the vast majority of ITAAC processes, including the activities supporting the notifications that are required by this final rule. Accordingly, the NRC has not included specific documentation and record retention requirements in this final rule. If the NRC inspections disclose substantial issues with licensees' records on ITAAC maintenance, the NRC will revisit the need for explicit documentation and record retention requirements on ITAAC maintenance.

NRC inspection, publication of notices, and availability of licensee notifications

Section 52.99(e)(1) requires that the NRC publish in the *Federal Register* the NRC staff's determination of the successful completion of inspections, tests, and analyses, at appropriate intervals until the last date for submission of requests for hearing under 10 CFR 52.103(a). Section 52.99(e)(2) currently provides that the NRC shall make publicly available the licensee notifications under current paragraphs (c)(1) and (c)(2). The NRC has revised paragraph (e)(2) to cover all notifications under 10 CFR 52.99(c). In general, the NRC expects to make the paragraph (c) notifications available shortly after the NRC has received the notifications and concluded that they are complete. Furthermore, by the date of the *Federal Register* notice of intended operation and opportunity to request a hearing on whether

acceptance criteria are met (under 10 CFR 52.103(a)), the NRC will make available the licensee notifications under paragraphs (c)(1), (c)(2), and (c)(3) that it has received to date.

C. Conforming Changes to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.340

The 2007 10 CFR part 52 rulemaking amended 10 CFR 2.340, “Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits, and licenses,” to clarify, among other things, the scope of the presiding officer’s decision in various kinds of NRC proceedings, and remove the requirement for direct Commission involvement in all production and utilization facility licensing proceedings.

Section 2.340(j) was intended to address these matters in connection with the Commission finding on acceptance criteria and any associated hearing under 10 CFR 52.103. In the course of developing this final rule, the NRC determined that 10 CFR 2.340(j) contains several inconsistencies with the statutory language in Section 185b of the AEA, and could more clearly describe possible ways in which a presiding officer decision may lead to a Commission decision on acceptance criteria. The changes, together with the basis for the changes, are described in the following paragraphs.

Section 2.340(j) currently states that the Commission makes a finding under 10 CFR 52.103(g) that acceptance criteria “have been or will be met.” This is incorrect; the Commission’s finding under 10 CFR 52.103(g) is that the acceptance criteria “are met,” which is the statutory requirement under Section 185b of the AEA. To correct this error, the NRC has amended the introductory language of 10 CFR 2.340(j) to use the correct phrase, “acceptance criteria ... are met”

In addition, 10 CFR 2.340(j), as currently written, does not distinguish among the various circumstances in a contested proceeding where a presiding officer’s decision (that acceptance criteria have been met, or will be met) is followed by the overall finding under 10 CFR 52.103(g) that acceptance criteria *are* met (as required by Section 185.(b) of the AEA). It is not clear from

the current language of 2.340(j) that the presiding officer's initial decision on a contention that acceptance criteria have been met or will be met, does not obviate the need for the Commission (or the appropriate Director) to make the required finding (under Section 185b of the AEA and 10 CFR 52.103(g)) that the acceptance criteria *are met*. To illustrate this point by counter example, the presiding officer could make, in the initial decision, a "predictive finding" that acceptance criteria "will be met." Thereafter, the combined license holder would complete the prescribed inspection, test and/or analysis and inform the NRC under § 52.99 that the acceptance criteria have been met. Nonetheless, the Commission (or the appropriate Director) may determine – based on, *inter alia*, information submitted to the NRC under 10 CFR 52.99 after the hearing record had closed and the presiding officer's initial decision on the contention is made – that the presiding officer's "predictive finding" was not borne out by events and that the acceptance criteria *are not met*. To clarify some of the possible paths that the Commission (or appropriate Director) could follow (after the presiding officer's initial decision) in making a finding that acceptance criteria *are met*, the NRC is revising the language of paragraph (j), thereby making clear that the presiding officer's decision on a contested matter is separate from the overall Commission finding under Section 185b and 10 CFR 52.103(g) that acceptance criteria *are met*.

IV. Section-by-Section Analysis

The primary changes on ITAAC maintenance by the NRC in this rulemaking are to 10 CFR 52.99. The changes to 10 CFR 2.340 are corrections.

Section 2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits and licenses.

Section 2.340(j) Issuance of finding on acceptance criteria under 10 CFR 52.103.

Paragraph (j) was amended to allow the Commission (or the appropriate NRC Office Director) in a contested proceeding to make the finding under 10 CFR 52.103(g) that the

acceptance criteria in a combined license are met, under certain circumstances that are delineated in greater detail in paragraphs (j)(1) through (4). This compares with the current rule, which contains only two paragraphs (j)(1) and (2). The matters covered by paragraph (j)(1) of the current rule are described with greater clarity in paragraphs (j)(1) through (3).

Paragraph (j)(1) clarifies that the Commission may not make the overall 10 CFR 52.103(g) finding unless it is otherwise able to find that all uncontested acceptance criteria (i.e., “acceptance criteria not within the scope of the initial decision of the presiding officer”) are met. The phrase “otherwise able to make” conveys the NRC’s determination that the Commission’s process for supporting a Commission finding on uncontested acceptance criteria is unrelated to and unaffected by the timing of the presiding officer’s initial decision on contested acceptance criteria.

Paragraph (j)(2) clarifies that a presiding officer’s initial decision, which finds that acceptance criteria have been met, is a necessary, but not sufficient prerequisite for the Commission to make a finding that the contested acceptance criteria (i.e., the criteria which are the subject of the presiding officer’s initial decision) are met. The Commission must thereafter— even if the presiding officer’s initial decision finds that the contested acceptance criteria have been met— be able to make a finding that the contested criteria are met after considering: 1) Information submitted in the licensee notifications pursuant to 10 CFR 52.99, and 2) the NRC staff’s findings with respect to these notifications, to issue the overall 10 CFR 52.103 finding. By using the word “thereafter,” the NRC intends to emphasize that the Commission would not make a finding that contested acceptance criteria are met in advance of the presiding officer’s initial decision on those acceptance criteria.

Paragraph (j)(3) expresses the same concept as paragraph (j)(2), but as applied to findings that acceptance criteria will be met. Thus, even if a presiding officer’s initial decision finds that the contested acceptance criteria will be met, the Commission must thereafter be able

to make a finding that the contested criteria are met after considering: (1) Information submitted in an ITAAC closure notification pursuant to 10 CFR 52.99(c)(1); 2) information submitted in the licensee notifications pursuant to 10 CFR 52.99(c)(2) and (c)(4); and 3) the NRC staff's findings with respect to such notifications, to issue the overall 10 CFR 52.103 finding.

Paragraph (j)(4) is the same as the existing provision in 10 CFR 2.340(j)(2). This paragraph provides that the Commission may make the 10 CFR 52.103(g) finding notwithstanding the pendency of a petition for reconsideration under 10 CFR 2.345, a petition for review under 10 CFR 2.341, a motion for a stay under 10 CFR 2.342, or a petition under 10 CFR 2.206.

The NRC notes that 10 CFR 2.340(j) is not intended to be an exhaustive "roadmap" to a possible 10 CFR 52.103(g) finding that acceptance criteria are met. For example, this provision does not directly address what must occur for the Commission to make a 10 CFR 52.103(g) finding where the presiding officer finds, with respect to a contention, that acceptance criteria have not been or will not be met. The NRC also notes that this provision applies only to contested proceedings. If there is no hearing under 10 CFR 52.103 or if the hearing ends without a presiding officer's initial decision on the merits (e.g., a withdrawal of the sole party in a proceeding), then 10 CFR 2.340(j) does not govern the process by which the Commission (or the appropriate staff Office Director) makes the 10 CFR 52.103(g) finding.

Section 52.99 Inspection during construction; ITAAC schedules and notifications; NRC notices.

Although the NRC is not making changes to every paragraph under 10 CFR 52.99, for simplicity, this rulemaking would replace the section in its entirety. Therefore, the NRC is providing a section-by-section discussion for every paragraph in 10 CFR 52.99. For those paragraphs where little or no change is being proposed, the NRC is repeating the section-by-section discussion from the 2007 major revision to 10 CFR part 52 with editorial and conforming changes, as appropriate.

The purpose of this section is to present the requirements to support the NRC's inspections during construction, including requirements for ITAAC schedules and notifications and for NRC notices of ITAAC closure. The title of this section was changed from *Inspection during construction* to *Inspections during construction; ITAAC schedules and notifications; NRC Notices* to reflect the contents of this section.

Section 52.99(a) Licensee schedule for completing inspections, tests, or analyses.

The NRC is not making any changes to 52.99(a). Paragraph (a) requires that the licensee submit to the NRC, no later than 1 year after issuance of the combined license or at the start of construction as defined at 10 CFR 50.10, whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. This provision also requires the licensee to submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, licensees must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under § 52.99(c)(1). The information provided by the licensee will be used by the NRC in developing the NRC's inspection activities and activities necessary to support the Commission's finding whether all of the ITAAC are met prior to the licensee's scheduled date for fuel load. Even in the case where there were no changes to a licensee's ITAAC schedule during an update cycle, the NRC expects the licensee to notify the NRC that there have been no changes to the schedule.

Section 52.99(b) Licensee and applicant conduct of activities subject to ITAAC.

The NRC is making an editorial change to the last sentence of § 52.99(b) to replace the words "have been met" with "are met" for consistency with the requirements of Section 185b of the AEA, as implemented in 10 CFR 52.103(g). The purpose of the requirement in 10 CFR 52.99(b) is to clarify that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee may proceed at its own risk with design,

procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC are met.

Section 52.99(c) Licensee notifications.

Section 52.99(c)(1) ITAAC closure notification and § 52.99(c)(3) Uncompleted ITAAC notification.

The NRC has made editorial changes in § 52.99(c)(1) to replace the words “have been met” with “are met.” Section 52.99(c)(1) requires the licensee to notify the NRC that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met. Section 52.99(c)(1) further requires that the notification contain sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met.

The NRC has renumbered current § 52.99(c)(2) as paragraph (c)(3). In addition, the NRC has made an editorial change to the last sentence in final § 52.99(c)(3) (former 10 CFR 52.99(c)(2)) to replace the words “have been met” with “are met.” Section 52.99(c)(3) requires that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee shall notify the NRC that the prescribed inspections, tests, or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation (consistent with the AEA Section 185b requirement that the Commission, “prior to operation,” find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the prescribed inspections, tests, or analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met.

Section 52.99(c) ensures that: 1) the NRC has sufficient information to complete all of the activities necessary for the Commission to make a finding as to whether all of the ITAAC are met prior to initial operation, and 2) interested persons will have access to information on both completed and uncompleted ITAAC at a level of detail sufficient to address the AEA

Section 189a(1)(B) threshold for requesting a hearing on acceptance criteria. It is the licensee's burden to demonstrate compliance with the ITAAC, and the NRC expects the information submitted under paragraph (c)(1) to contain more than just a simple statement that the licensee believes the ITAAC has been completed and the acceptance criteria met. The NRC would expect the notification to be sufficiently complete and detailed so that a reasonable person could understand the basis for the licensee's representation that the inspections, tests, and analyses have been successfully completed and the acceptance criteria are met. The term "sufficient information" would require, at a minimum, a summary description of the basis for the licensee's conclusion that the inspections, tests, or analyses have been performed and that the prescribed acceptance criteria are met.

Furthermore, with respect to uncompleted ITAAC, it is the licensee's burden to demonstrate that it will comply with the ITAAC, and the NRC would expect the information that the licensee submits under proposed paragraph (c)(3) to be sufficiently detailed so that the NRC staff can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC are met, once the licensee notifies the NRC that those ITAAC have been successfully completed and their acceptance criteria met. The term "sufficient information" requires, at a minimum, a summary description of the basis for the licensee's conclusion that the inspections, tests, or analyses will be performed and that the prescribed acceptance criteria will be met. In addition, "sufficient information" includes, but is not limited to, a description of the specific procedures and analytical methods to be used for

performing the inspections, tests, and analyses and determining that the acceptance criteria are met.

The NRC notes that, even though it did not include a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date, the NRC staff will require some period of time to perform its review of the last ITAAC once the licensee submits its notification that the ITAAC has been successfully completed and the acceptance criteria met. In addition, the Commission itself will require some period of time to perform its review of the staff's conclusions regarding all of the ITAAC and the staff's recommendations regarding the Commission finding under 10 CFR 52.103(g).

Section 52.99(c)(2) ITAAC post-closure notifications.

The NRC has added a new paragraph (c)(2) that would require the licensee to notify the NRC, in a timely manner, of new information that materially alters the basis for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met. The notification must contain sufficient information to demonstrate that, notwithstanding the new information, the prescribed inspections, test, or analyses have been performed as required, and the prescribed acceptance criteria are met. Fundamentally, those circumstances requiring notification under proposed paragraph (c)(2) fall into the following two categories:

- The information presented or referenced in the original 10 CFR 52.99(c)(1) notification is insufficient, either because it omits material information, or because the information is materially erroneous or incorrect, and the licensee discovers or determines there is a material omission or error after filing the original 10 CFR 52.99(c)(1) notification.
- The information presented or referenced in the original 10 CFR 52.99(c)(1) notification was complete (i.e., not omitting material information) and accurate (i.e., not materially erroneous), but there is new material information with respect to the subject of the original 10 CFR 52.99(c)(1) notification.

The term “materially altering” refers to situations in which there is information not contained in the 10 CFR 52.99(c)(1) notification that “has a natural tendency or capability to influence an agency decision maker” in either determining whether the prescribed inspection, test, or analysis was performed as required, or finding that the prescribed acceptance criterion is met. See Final Rule; Completeness and Accuracy of Information, December 31, 1987; 52 FR 49362, at 49363. Applying this concept in the context of 10 CFR 52.99(c), information for which notification would be required under paragraph (c)(2) is that information which, considered by itself or when considered in connection with information previously submitted or referenced by the licensee in a paragraph (c)(1) notification, relates to information which is necessary for any of the following:

- The licensee to assert that the prescribed inspections, test, and analyses have been performed and the acceptance criteria are met;
- The NRC staff to determine if (and provide a recommendation to the Commission as to whether) the prescribed inspections, tests, and analyses were performed and the acceptance criteria are met; or
- The Commission to find that the acceptance criteria are met, as required by Section 185b of the AEA and 10 CFR 52.103(g).

The term “new” information falls into three categories:

- New information (i.e., a “discovery” or new determination identified after the 10 CFR 52.99(c)(1) notification) about the accuracy of material information provided in, referenced by, or necessary to support representations made in that notification.
- New information (i.e., a “discovery” or new determination identified after the 10 CFR 52.99(c)(1) notification) that previously existing information should have been, but was not provided in the notification or referenced in the supporting documentation (i.e., an omission of material information).

- Information on a “new” event or circumstance (i.e., an event or circumstance occurring after the 10 CFR 52.99(c)(1) notification) that materially affects the accuracy or completeness of the basis – as reported or relied upon in the 52.99(c)(1) notification – for the licensee’s representation that the acceptance criteria are met.

Applying these concepts, the NRC believes that the circumstances for which reporting under this provision would be required include:

- *Material Error or Omission* - Is there a material error or omission in the original ITAAC closure notification?
- *Post Work 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 ITAAC notification?
- *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?

Additional guidance on implementing these reporting thresholds is contained in the revision to RG 1.215, being issued simultaneously with this final rule. This guidance is discussed further in Section V, “Availability of Regulatory Guidance,” of this document.

Paragraph (c)(2) would require the licensee to submit an ITAAC post-closure notification documenting the resolution of the circumstances surrounding the identification of new material information. By “resolution,” the NRC means: 1) the completion of the licensee’s technical evaluation of the issue and the determination as to whether the prescribed inspection, test, or analysis was performed as required; 2) licensee completion of any necessary corrective or

supplemental actions; 3) licensee documentation of the issue and any necessary corrective or supplemental actions in order to bring the ITAAC determination basis up to date; and 4) ultimate licensee determination about whether the affected acceptance criteria continue to be met.

The information provided in the notification should be at a level of detail comparable to the ITAAC closure notification under paragraph (c)(1). The dual purposes of the proposed paragraph (c)(2) notification, as described in Section III.B, "Additional ITAAC Notifications," of this document, are comparable to the purposes of the ITAAC closure notification in paragraph (c)(1). Thus, the NRC believes that the considerations for the content of the ITAAC closure notification, as discussed in the final 2007 10 CFR part 52 rule, apply to the paragraph (c)(2) notifications. See 72 FR 49450; August 28, 2007 (second column). Thus, it is the licensee's burden to demonstrate compliance with the ITAAC, taking into account any new information that materially alters the determination that a prescribed inspection, test, or analysis was performed as required or that a prescribed acceptance criterion is met. The NRC expects the paragraph (c)(2) notification to contain more than just a simple statement that the licensee has concluded, despite the material new information, that the prescribed inspection, test, or analysis was performed as required and that a prescribed acceptance criterion is met. The NRC expects the notification to be sufficiently complete and detailed such that a reasonable person could understand the basis for the licensee's determination in the paragraph (c)(2) notification. The term "sufficient information" is comparable to the meaning given to that term in paragraph (c)(1), and requires, at a minimum, a summary description of the basis for the licensee's determination. In addition, "sufficient information" includes, but is not limited to, a description of the specific procedures and analytical methods used or relied upon to develop or support the licensee's determination. The paragraph (c)(2) notification must be in writing, and the records on which it is based should be retained by the licensee to support possible NRC inspection. Licensees should use the same process for submitting ITAAC post-closure notifications as would be used to

submit initial ITAAC closure notifications. The NRC is issuing guidance on implementation of the requirements in proposed paragraph (c)(2), including the level of detail necessary to comply with the requirements of paragraph (c)(2), as discussed in Section V, “Availability of Regulatory Guidance,” of this document.

Section 52.99(c)(4) All ITAAC Complete Notification.

The NRC has added a new paragraph (c)(4) which requires the licensee to notify the NRC that all ITAAC are complete (All ITAAC Complete Notification). When the licensee submits the all ITAAC complete notification, the NRC expects that all activities requiring ITAAC post-closure letters have been completed, that the associated ITAAC determination basis have been updated, and that all required notifications under paragraph (c)(2) have been made.

Section 52.99(d) Licensee determination of non-compliance with ITAAC.

The NRC has made editorial changes in § 52.99(d)(1) to replace the words “have been met” with, “are met” and in § 52.99(d)(2) to replace the phrase “ITAAC has been met” with the phrase “prescribed acceptance criteria are met.” Paragraph (d) states the options that a licensee will have in the event that it is determined that any of the acceptance criteria in the ITAAC are not met. If an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the ITAAC are met, then the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by an application for a license amendment under 10 CFR 52.98(f). The NRC will consider and take action on the request for exemption and the license amendment application together as an integrated NRC action.

Also, if an activity that is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance

criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under 10 CFR 52.98(f).

Section 52.99(e) NRC inspection, publication of notices, and availability of licensee notifications.

The final rule is substantially the same as the proposed rule with one change to § 52.99(e)(2) to clarify NRC notices to the public. The one language change made to the section, “NRC inspection, publication of notices, and availability of licensee notifications,” is to replace the language “The NRC shall make publicly available the licensee notifications under paragraphs (c)(1) through (4) of this section no later than the date of publication of the notice of intended operations required by 10 CFR 52.103(a)” with:

“The NRC shall, no later than the date of publication of the notice of intended operation required by 10 CFR 52.103(a), make publicly available those licensee notifications under paragraph (c) of this section that have been submitted to the NRC at least seven (7) days before that notice.”

The NRC will make public all paragraph (c) ITAAC notifications that were submitted to the NRC at least seven days before the date of publication of the notice of intended operation required by 10 CFR 52.103(a) which is, at a minimum, 180 days before the date scheduled for initial loading of fuel. The NRC recognizes that the licensee could submit ITAAC notifications required by paragraph (c) later than the date of publication of the notice of intended operation required by 10 CFR 52.103(a).

V. Availability of Regulatory Guidance

Concurrent with this final rule, the NRC is issuing Revision 1 to RG 1.215 “Guidance for ITAAC Closure Under 10 CFR Part 52.” Revision 1 of RG 1.215 was issued in draft form for public comment with a temporary identification as Draft Regulatory Guide, DG-1250 (76 FR 27924, May 13, 2011). This guidance series was developed to describe and make available to the public information such as methods that are acceptable to the NRC staff for implementing

specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

In Revision 1 of RG 1.215, the NRC is endorsing Revision 4 to the existing industry ITAAC closure guidance in NEI 08-01, submitted to the NRC for endorsement on July 16, 2010 (Package ADAMS Accession No. ML102010076). The revised guidance is intended to provide an acceptable method by which licensees can implement the new requirements in this final rulemaking.

The proposed final rule requirements for ITAAC maintenance and the draft RG 1.215 were presented to the Advisory Committee on Reactor Safeguards (ACRS) on December 01, 2011 (ADAMS Accession No. ML11342A075). The ACRS conclusion and recommendations were that: 1) The proposed ITAAC rule, "Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria," meets the goal of ensuring maintenance of ITAAC validity and should be approved. 2) The approach in RG 1.215, Revision 1, for closing and maintaining ITAAC should be revised to include an assessment that ensures a change does not introduce unintended consequences. The assessment should also include an evaluation that confirms the original inspections, tests, and analyses and their acceptance criteria are still valid and assures the functionality originally intended. 3) After revision, RG 1.215, Revision 1, should be issued. The NRC agrees to clarify RG 1.215 and the following paragraph is included in Section B, where the requirements of NEI 08-01, section 8 are discussed. "The design and configuration control program should include an assessment and evaluation that confirms that the ITAAC potentially affected by a proposed change are still valid and assures the functionality originally intended."

VI. Availability of Documents

The NRC is making the documents identified below available to interested persons

through one or more of the following methods as indicated. To access documents related to this action, see the ADDRESSES section of this document.

Document	PDR	Web	ADAMS
SECY-XX-XXXX, "Final Rule: Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria (RIN 3150-AI77)"	X	X	ML113390369
Regulatory Analysis for Final Rule - Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria, January 2012	X	X	ML120100062
Regulatory Analysis for Proposed Rule - Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria, February 2011	X	X	ML110040395
ACRS Letter, Proposed Requirements for ITAAC (Inspections, Tests, Analyses, and Acceptance Criteria) Maintenance and Draft Final Regulatory Guide 1.215, "Guidance for ITAAC Closure Under 10 CFR Part 52	X	X	ML11342A075
Staff Requirements Memorandum for SECY-10-0117, "Proposed Rule: Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria (RIN 3150-AI77)," February 4, 2011	X	X	ML110350185
SECY-10-0117, "Proposed Rule: Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria (RIN 3150-AI77)"	X	X	ML101440146
ITAAC Proposed Rule <i>Federal Register</i> Notice	X	X	ML101440177
Regulatory Analysis for Proposed Rule re ITAAC, May 2010			ML101440359
SECY-09-0119, "Staff Progress in Resolving Issues Associated with Inspections, Tests, Analyses and Acceptance Criteria," August 26, 2009	X	X	ML091980372 (Package)
SRM-M090922, "Staff Requirements - Periodic Briefing on New Reactor Issues - Progress in Resolving Issues Associated with Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC), 9:30 A.M., Tuesday, September 22, 2009, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open To Public Attendance)," October 16, 2009	X	X	ML092890658
Inspection Procedure 40600, "Licensee Program for ITAAC Management"	X	X	ML072530607
Regulatory Guide 1.215, "Guidance for ITAAC Closure Under 10 CFR Part 52," Revision 1, January, 2012	X	X	ML112580018
Regulatory Guide 1.215, "Guidance for ITAAC Closure Under 10 CFR Part 52," Revision 0, October 31, 2009	X	X	ML091480076
NEI Comments on ITAAC Maintenance Proposed Rule	X	X	ML11208C708
NEI Comments on DG-1250 Guidance for ITAAC Closure	X	X	ML11209C487

Document	PDR	Web	ADAMS
Staff Responses to Public Comments on DG-1250			ML11284A006
NEI 08-01, "Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52," Revision 3, January 2009	X	X	ML090270415
NEI 08-01, "Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52," Revision 4	X	X	ML102010076 (Package) ML102010051
NEI Comments on NRC Plans to Amend Regulations Related to ITAAC Maintenance	X	X	ML101300103
Russell Bell Ltr. RE: Response to Nuclear Energy Institute on NRC Plans to Amend Regulations Related to ITAAC Maintenance	X	X	ML101590526
Draft Regulatory Guide DG-1250 (Proposed Revision 1 of Regulatory Guide 1.215), "Guidance for ITAAC Closure Under 10 CFR Part 52"	X	X	ML102530401
NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, September 2004	X	X	ML042820192

VII. Plain Language Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices appropriate to the subject or field and the intended audience. The NRC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

VIII. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement States Programs," approved by the Commission on June 20, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this rule is classified as compatibility "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of 10 CFR. Although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a

mechanism that is consistent with the particular State's administrative procedure laws.

Category "NRC" regulations do not confer regulatory authority on the State.

IX. Voluntary Consensus Standard

The National Technology Transfer and Advancement Act of 1995, Public Law 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. The requirements in this rulemaking address procedural and information collection and reporting requirements necessary to support the NRC's regulatory activities on combined licenses under 10 CFR part 52, and to facilitate the NRC's conduct of hearings on ITAAC which may be held under Section 189 of the AEA. These requirements do not establish standards or substantive requirements with which combined license holders must comply. Thus, this rulemaking does not constitute establishment of a standard containing generally applicable requirements falling within the purview of the National Technology Transfer and Advancement Act and the implementing guidance issued by the Office of Management and Budget (OMB).

X. Environmental Impact – Categorical Exclusion

The NRC has determined that these amendments fall within the types of actions described as categorical exclusions under 10 CFR 51.22(c)(2) and (c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.

XI. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0151.

The burden to the public for these information collections is estimated to average 22

hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0151), Office of Management and Budget, Washington, DC 20503. You may also e-mail comments to [Chad S Whiteman@omb.eop.gov](mailto:Chad_S_Whiteman@omb.eop.gov) or comment by telephone at (202) 395-4718.

XII. Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XIII. Regulatory Analysis

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The regulatory analysis is in ADAMS under Accession No. ML120100062.

The regulatory analysis may also be viewed and downloaded electronically via the Federal rulemaking Web site at <http://www.regulations.gov> by searching on Docket ID NRC-2010-0012.

The regulatory analysis examines the benefits and costs of the final rule requirements.

The key findings of the analysis are as follows:

- *Total Cost to Industry.* The final rule would result in additional reporting and recordkeeping costs for the industry. The total annual cost for the rule is \$244,800. The total

present value of the costs is estimated at \$940,000 (using a 7-percent discount rate) and \$1,021,000 (using a 3-percent discount rate) over the next 20 years.

- *Annual Impact to the Economy.* Under the Congressional Review Act of 1996 and as a result of consultations with the Office of Information and Regulatory Affairs of the Office of Management and Budget, the NRC has determined that these actions are not major rules. This determination is based on the estimated one-time costs (expected to occur within the first year) of implementing this action for the total industry is not to exceed \$111,350.

- *Value of Benefits Not Reflected Above.* The cost figures shown above do not reflect the value of the benefits of the proposed rule. These benefits are evaluated qualitatively in Section 3.1 of the regulatory analysis. This regulatory analysis concluded the costs of the rule are justified in view of the qualitative benefits.

- *Costs to NRC.* The NRC would incur costs to review and process licensee responses to the proposed reporting requirements. The total annual costs are approximately \$293,760. The NRC will incur one-time costs for developing the infrastructure to process the new notifications, developing guidance, and training NRC staff on the proposed requirements estimated to be \$49,920.

- *Decision Rationale.* Although the NRC did not quantify the benefits of this rule, the staff did qualitatively examine benefits and concluded that the rule would provide enhanced regulatory effectiveness and efficiency and enhanced openness of the regulatory process. The sum total of the requirements in the proposed rule would be to establish reporting of issues affecting closed ITAAC

XIV. Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of

nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XV. Backfitting and Issue Finality

The NRC has determined that neither the backfit rule, 10 CFR 50.109, nor any of the finality provisions in 10 CFR part 52, apply to this final rule. Therefore, a backfit analysis is not required because the proposed ITAAC maintenance rule does not contain any provisions that would impose backfitting as defined in the backfit rule, nor does it contain provisions that are inconsistent with the finality provisions applicable to applicants for or holders of combined licenses in 10 CFR part 52.

The final rule applies only to holders of combined licenses. The backfitting provisions in 10 CFR 50.109 and the finality provisions in Subpart C of 10 CFR part 52 protect holders of combined licenses (with the exception discussed further in this document). Subpart C of 10 CFR part 52 contains issue finality provisions which protect combined license applicants, but that protection extends only to issue resolution of matters resolved in referenced early site permits, standard design certifications, standard design approvals, or manufactured reactors. This rule does not alter issue resolution associated with referenced early site permits, standard design certifications, standard design approvals, or manufactured reactors. Instead, this final rule addresses requirements concerning the collection and reporting of information to the NRC to support the Commission's finding that ITAAC are met, and the conduct of hearings addressing whether prescribed inspections tests and analyses have been or will be performed and whether the prescribed acceptance criteria have been or will be met. Neither the backfit rule nor the issue finality provisions of 10 CFR part 52 apply to information collection and reporting requirements.

To the extent that the rule revises these information collection and reporting requirements for future combined licenses, these requirements do not constitute backfitting or are otherwise inconsistent with the finality provisions in 10 CFR part 52, for the additional reason that the ITAAC Maintenance Rule's requirements are prospective in nature and effect. Neither the backfit rule nor the issue finality provisions in 10 CFR part 52 were intended to apply to every NRC action, which substantially changes the obligations of future licensees under 10 CFR part 52. Accordingly, the NRC has not prepared a backfit analysis or other evaluation for this final rule.

XVI. Congressional Review Act

Under the Congressional Review Act of 1996, the NRC has determined that these actions are not major rules and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalties, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 2 and 52.

PART 2 -- RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

1. The authority citation for part 2 continues to read as follows:

AUTHORITY: Secs.161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat.1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552; sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97-425, 96 Stat. 2213, as amended (42 U.S.C. 10143(f)); sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871).

Sections 2.102, 2.103, 2.104, 2.105, 2.321 also issued under secs. 102, 103, 104, 105, 183i, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948-951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Section 2.205(j) also issued under Pub. L. 101-410, 104 Stat. 90, as amended by section 3100(s), Pub. L. 104-134, 110 Stat. 1321-373 (28 U.S.C. 2461 note). Subpart C also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Section 2.301 also issued under 5 U.S.C. 554. Sections 2.343, 2.346, 2.712 also issued under 5 U.S.C. 557. Section 2.340 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.390 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853, as

amended (42 U.S.C. 4332). Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553, and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart M also issued under sec. 184 (42 U.S.C. 2234) and sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart N also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91-550, 84 Stat. 1473 (42 U.S.C. 2135).

2. In § 2.340, revise paragraph (j) to read as follows:

§2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits and licenses.

* * * * *

(j) *Issuance of finding on acceptance criteria under 10 CFR 52.103.* The Commission, the Director of the Office of New Reactors, or the Director of the Office of Nuclear Reactor Regulation, as appropriate, shall make the finding under 10 CFR 52.103(g) that acceptance criteria in a combined license are met within 10 days from the date of the presiding officer's initial decision:

(1) If the Commission or the appropriate director is otherwise able to make the finding under 10 CFR 52.103(g) that the prescribed acceptance criteria are met for those acceptance criteria not within the scope of the initial decision of the presiding officer;

(2) If the presiding officer's initial decision—with respect to contentions that the prescribed acceptance criteria have not been met—finds that those acceptance criteria have been met, and the Commission or the appropriate director thereafter is able to make the finding that those acceptance criteria are met;

(3) If the presiding officer's initial decision—with respect to contentions that the

prescribed acceptance criteria will not be met—finds that those acceptance criteria will be met, and the Commission or the appropriate director thereafter is able to make the finding that those acceptance criteria are met; and

(4) Notwithstanding the pendency of a petition for reconsideration under 10 CFR 2.345, a petition for review under 10 CFR 2.341, or a motion for stay under 10 CFR 2.342, or the filing of a petition under 10 CFR 2.206.

* * * * *

PART 52 - LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

3. The authority citation for part 52 continues to read as follows:

AUTHORITY: Secs. 103, 104, 161, 182, 183, 185, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2235, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005), secs. 147 and 149 of the Atomic Energy Act.

4. Revise § 52.99 to read as follows:

§52.99 Inspection during construction; ITAAC schedules and notifications; NRC notices.

(a) *Licensee schedule for completing inspections, tests, or analyses.* The licensee shall submit to the NRC, no later than 1 year after issuance of the combined license or at the start of construction as defined at 10 CFR 50.10(a), whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. The licensee shall submit updates to the ITAAC schedules every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, the licensee shall submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under paragraph (c)(1) of this section.

(b) *Licensee and applicant conduct of activities subject to ITAAC.* With respect to activities subject to an ITAAC, an applicant for a combined license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any one of the prescribed acceptance criteria are met.

(c) *Licensee notifications.*

(1) *ITAAC closure notification.* The licensee shall notify the NRC that prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are 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 are met.

(2) *ITAAC post-closure notifications.* Following the licensee's ITAAC closure notifications under paragraph (c)(1) of this section until the Commission makes the finding under 10 CFR 52.103(g), the licensee shall notify the NRC, in a timely manner, of new information that materially alters the basis for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met. The notification must contain sufficient information to demonstrate that, notwithstanding the new information, the prescribed inspections, tests, or analyses have been performed as required, and the prescribed acceptance criteria are met.

(3) *Uncompleted ITAAC notification.* If the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee shall notify the NRC that the prescribed inspections, tests, or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation. The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must

provide sufficient information to demonstrate that the prescribed inspections, tests, or analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the prescribed inspections, tests, and analyses and determining that the prescribed acceptance criteria are met.

(4) *All ITAAC complete notification.* The licensee shall notify the NRC that all ITAAC are complete.

(d) *Licensee determination of non-compliance with ITAAC.*

(1) In the event that an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under 10 CFR 52.98(f).

(2) In the event that an activity is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under 10 CFR 52.98(f).

(e) *NRC inspection, publication of notices, and availability of licensee notifications.* The NRC shall ensure that the prescribed inspections, tests, and analyses in the ITAAC are performed.

(1) At appropriate intervals until the last date for submission of requests for hearing under 10 CFR 52.103(a), the NRC shall publish notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(2) The NRC shall make publicly available the licensee notifications under paragraph (c)

of this section. The NRC shall, no later than the date of publication of the notice of intended operation required by 10 CFR 52.103(a), make publicly available those licensee notifications under paragraph (c) of this section that have been submitted to the NRC at least seven (7) days before that notice.

Dated at Rockville, Maryland, this day of 2012.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission

Regulatory Analysis for Final Rule - Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria

**U.S. Nuclear Regulatory Commission
January 2012**



EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations related to verification of nuclear power plant construction activities through inspections, tests, analyses, and acceptance criteria (ITAAC) under a combined license. Specifically, the NRC will require new provisions that apply after a combined license holder (licensee) has completed an ITAAC and submitted an ITAAC closure notification. The new provisions require licensees to 1) report new information materially altering the basis for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met, and 2) to notify the NRC of completion of all ITAAC activities. This regulatory analysis focuses on these regulatory provisions.

In addition, the NRC is making editorial corrections to existing language in the NRC's rules of practice and procedure, in order to make it consistent with language in the Atomic Energy Act of 1954, as amended (AEA) regarding the Commission's findings on inspections, tests, analyses and acceptance criteria for combined licenses, and to clarify the relationship between an adjudicatory hearing on a combined license and the issuance of that combined license. Inasmuch as these changes are not regulatory in nature and address procedural matters for which the NRC typically does not perform detailed regulatory analysis, this regulatory analysis does not address these latter corrections and changes.

The analysis presented in this document examines the benefits and costs of the final regulatory requirements. The key findings of the analysis are as follows:

- *Total Cost to Industry.* The final rule will result in additional reporting and recordkeeping costs for the industry. The total annual cost for the rule is \$244,800. The total present value of the costs is estimated at \$940,000 (using a 7-percent discount rate) and \$1,021,000 (using a 3-percent discount rate) over the next 20 years.
- *Annual Impact to the Economy.* Under the Congressional Review Act of 1996 and as a result of consultations with the Office of Information and Regulatory Affairs of the Office of Management and Budget, the NRC has determined that this action is a non-major rule. This determination is based on the estimated one-time costs (expected to occur within the first year) of implementing this action for the total industry is not to exceed \$111,350.
- *Value of Benefits Not Reflected Above.* The cost figures shown above do not reflect the value of the benefits of this rule. These benefits are evaluated qualitatively in Section 3.1. This regulatory analysis concluded the costs of the rule are justified in view of the qualitative benefits.
- *Costs to NRC.* The NRC will incur costs to review and process licensee responses to the reporting requirements. The total annual costs are approximately \$293,760. The NRC will incur one-time costs for developing the infrastructure to process the new notifications, developing guidance, and training NRC staff on the requirements estimated to be \$49,920.

- *Decision Rationale.* Although the NRC did not quantify the benefits of this rule, the staff did qualitatively examine benefits and concluded that the rule will provide enhanced regulatory effectiveness and efficiency, and enhanced openness of the regulatory process. The requirements in this rule will establish minimum NRC requirements governing the reporting of issues affecting ITAAC which the licensee has previously reported to the NRC as “closed,” until the NRC makes the 10 CFR 52.103(g) finding that the specified acceptance criteria are satisfied. The amendments will affect NRC licensees who have received a combined license and who have begun construction.

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ACRONYMS AND ABBREVIATIONS

AEA	Atomic Energy Act of 1954, as amended
ADAMS	NRC's Agencywide Documents Access and Management System
CFR	<i>Code of Federal Regulations</i>
FR	<i>Federal Register</i>
ITAAC	Inspections, Tests, Analyses, and Acceptance Criteria
NEI	Nuclear Energy Institute
NRC	Nuclear Regulatory Commission
NUREG/BR	Nuclear Regulatory Commission/Brochure
RG	Regulatory Guide

1. INTRODUCTION

The NRC is amending Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 2 and 52 to specify additional requirements for reporting of inspections, tests, analyses, and acceptance criteria (ITAAC) activities. The NRC regulations in 10 CFR 52.99 require NRC licensees to provide an ITAAC closure letter once a licensee has successfully completed a required inspection, test, or analysis and determined that the associated acceptance criteria are met. This rulemaking amends these regulations to identify other occasions where a notification of activities affecting closed ITAAC will be required. This regulatory analysis focuses on these regulatory provisions.

The rule also corrects existing language in 10 CFR 52.99 for consistency with other sections in 10 CFR Part 52 and with language in the Atomic Energy Act of 1954, as amended (AEA). Finally, this rulemaking will amend 10 CFR 2.340(j) to make it consistent with language in the AEA regarding the Commission's findings on inspections, tests, analyses and acceptance criteria for combined licenses, and to clarify the relationship between an adjudicatory hearing on a combined license and the issuance of that combined license. Inasmuch as these changes are not regulatory in nature and address procedural matters for which the NRC typically does not perform detailed regulatory analysis, this regulatory analysis does not address these corrections and changes.

This regulatory analysis was prepared in accordance with the Regulatory Analysis Guidelines (RA Guidelines) of the NRC, NUREG/BR-0058, Revision 4, September 2004. This regulatory analysis evaluates the consequences associated with the "Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria" final rule. This document presents background material, rulemaking objectives, alternatives, input assumptions, and analysis of the consequences of the rule language. The regulatory analysis consists of two parts. The first is an aggregate analysis of the rule. The second part is a screening review for disaggregation to identify any individual provisions whose costs are disproportionate to the potential benefits.

The remainder of this introduction is divided into two sections. Section 1.1 states the problem and the objective of the rulemaking. Section 1.2 provides background information and Section 2 identifies the alternatives evaluated in this rulemaking. Section 3 describes the analysis method and input assumptions, Section 4 describes the results, Section 5 discusses the decision rationale, Section 6 implements the preferred alternative, and Section 7 lists the references used in this Regulatory Analysis.

1.1 Statement of the Problem

As the NRC developed its processes for verification of nuclear power plant construction activities through ITAAC under a combined license, it became clear that there were a number of implementation issues left unaddressed by the existing provisions in 10 CFR Part 52. In particular, the NRC believes that additional notifications should be provided to the NRC by the combined license holder following the notification of ITAAC completion currently required by 10 CFR 52.99(c)(1). In general, the reasons for these new notifications are to ensure that the NRC has sufficient information, in light of new information developed or identified after ITAAC completion and NRC notification, to complete all of the activities necessary for the Commission to make a determination on ITAAC, and to ensure that interested persons have access to

information on ITAAC at a level of detail sufficient to address the AEA Section 189.a(1)(B) threshold for requesting a hearing. Therefore, the NRC developed new provisions that apply after a licensee has completed an ITAAC and submitted an ITAAC closure letter.

1.2. Background

1.2.1 Current Regulatory Framework

In 54 FR 15371 (April 18, 1989), the Commission adopted 10 CFR 52.99, "Inspection during construction," to clearly reflect that inspections (carried out during construction under a combined license) would be based on ITAAC proposed by the applicant, approved by the staff, and incorporated in the combined license. At that time, the Commission made it clear that it would make no findings with respect to construction until the construction was complete. Nonetheless, 10 CFR 52.99 envisioned a "sign-as-you-go" process, whereby NRC staff signed-off on inspection units and notice of the staff's sign-off would be published in the *Federal Register*.

In 2007, the Commission revised Part 52 (72 FR 49351; August 28, 2007) to, among other things, enhance the NRC's ITAAC processes. In that revision, the NRC amended 10 CFR 52.99 to require licensees to notify the NRC that the prescribed inspections, tests, and analyses in the ITAAC were complete and that the acceptance criteria were met. The revision also required that notifications sufficiently demonstrate that the prescribed inspections, tests, and analyses were performed and the prescribed acceptance criteria were met. The statement of considerations for the 2007 rule indicated that this requirement would ensure that combined license applicants and holders were aware that it was the licensee's burden to demonstrate compliance with the ITAAC, and that the notification of ITAAC completion will contain more information than just a simple statement that the licensee believes the ITAAC had been completed and the acceptance criteria met.

Under Section 185.b of the AEA and 10 CFR 52.97(b), a combined license for a nuclear power plant must contain ITAAC that are "necessary and sufficient to reasonably assure that the facility was constructed and will operate in conformity with" the license, the AEA, and NRC regulations. Following issuance of the combined license, Section 185.b of the AEA and 10 CFR 52.99(e) require that the Commission "ensure that the prescribed inspections, tests, and analyses are performed." Finally, before operation of the facility, Section 185.b and 10 CFR 52.103(g) require that the Commission find that the "prescribed acceptance criteria are met." This Commission finding will not occur until construction is complete, near the date for scheduled initial fuel load.

As currently required by 10 CFR 52.99(c)(1), the licensee must submit ITAAC closure letters containing "sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the associated acceptance criteria have been met." These notification letters perform two functions: 1) They alert the NRC to the licensee's ITAAC completion and ensure that the NRC has sufficient information to complete all of the necessary activities for the Commission to make a determination as to whether all of the ITAAC have been or will be met (the latter is relevant to any hearing on ITAAC under 10 CFR 52.103) before initial operation; and 2) They ensure that interested persons have access to completed and uncompleted ITAAC information at a level of detail sufficient to address the AEA Section

189.a(1)(B) threshold for requesting a hearing on acceptance criteria (72 FR 49352; August 28, 2007, at 49450 (second column)).

Following the 2007 rulemaking, the NRC began to develop ITAAC closure process guidance on the requirements under 10 CFR 52.99. In October 2009, the NRC issued regulatory guidance for the implementation of the revised 10 CFR 52.99 in Regulatory Guide (RG) 1.215, "Guidance for ITAAC Closure Under 10 CFR Part 52," which endorsed guidance developed by the Nuclear Energy Institute (NEI) in NEI 08-01, "Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52," Revision 3, issued January 2009 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML090270415).

The NRC realized (after a series of public meetings) that a number of additional implementation issues were left unaddressed by various provisions found in 10 CFR Part 52. In particular, the NRC believes that additional notifications should be provided to the NRC by the combined license holder following the notification of ITAAC completion currently required by 10 CFR 52.99(c)(1).

1.2.2 Regulatory Objectives

The NRC's objectives for the rulemaking which are the subject of this regulatory analysis, are to: 1) establish a new provision requiring licensees to report new information that materially alters the bases for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met; and 2) establish a new provision to requires licensees to notify the NRC when all ITAAC activities are complete.

2. IDENTIFICATION OF ALTERNATIVE APPROACHES

The following discussion describes the two regulatory options being considered, with additional analysis presented in Section 3.

2.1 Alternative 1: No-Action

Under Option 1, the No-action alternative, the NRC would not amend the current regulations regarding additional ITAAC notifications. The NRC would continue to work with industry to develop regulatory guidance to achieve the NRC's goals. This option would avoid certain costs imposed by the rule. However, taking no action would not necessarily ensure that the NRC has sufficient information, in light of new information developed or identified after ITAAC completion, to do the following: 1) complete all of the activities necessary for the Commission to make a determination on ITAAC, as required by the AEA, and 2) ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the threshold for requesting a hearing. The success of the no-action alternative is contingent upon: (i) industry agreement to develop guidance which achieves the NRC's goals, and (ii) voluntary industry action in the future to provide, in a timely fashion, information on ITAAC consistent with that industry-developed guidance. The baseline of the analysis is Option 1, the No-action alternative, for which there is no cost.

2.2 Alternative 2: Amend Regulations to Add ITAAC Notification Requirements

Under this option, the NRC would amend its regulations in 10 CFR Part 52 related to verification of nuclear power plant construction activities through ITAAC under a combined license. These changes amend 10 CFR 52.99(c) to: 1) require licensee reporting of new information that materially alters the bases for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met; and 2) require licensee notification of completion of all ITAAC activities.

This alternative would be consistent with the NRC's organizational excellence objectives of ensuring that its actions are efficient, effective, realistic, and timely. The rulemaking alternative is more efficient and effective than relying on voluntary actions by licensees to notify the NRC of these events. It would also be consistent with the NRC's openness strategy. This alternative, through the rulemaking process, would provide for fair, timely, and meaningful stakeholder involvement in the NRC's development of its ITAAC closure process.

The NRC has estimated the benefits and costs of this alternative, as described in Sections 3 and 4 of this regulatory analysis. The NRC has pursued Alternative 2 for the reasons discussed in Section 5.

3. ESTIMATION AND EVALUATION OF VALUES AND IMPACTS

3.1 Identification of Affected Attributes

This section describes the analysis of private and public sector factors that the rule is expected to affect. The analysis is conducted to identify and evaluate the benefits (values) and costs (impacts) of the two regulatory options, using the list of potential attributes provided in Chapter 5 of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," dated January 1997, and in Chapter 4 of NUREG/BR-0058, Rev. 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated September 2004. The evaluation considered each attribute listed in Chapter 5. The basis for selecting those attributes is presented below. Section 3.1 identifies the attributes expected to be affected by the rulemaking. Section 3.2 describes how the values and impacts have been analyzed. Finally, Section 3.3 presents the detailed results of the projected values and impacts.

Affected attributes include the following:

- *Industry Implementation* --The regulatory action will result in the need for combined license holders to read the amended regulations and develop procedures for processing notifications required by the new provisions.
- *Industry Operation* -- The regulatory action will require combined license holders to: 1) report new information materially altering the bases for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met and 2) notify the NRC of completion of all ITAAC activities.
- *NRC Implementation* --The NRC will incur costs to develop rule guidance, develop the infrastructure to process the new notifications, and develop and conduct NRC staff training on the new requirements.

- *NRC Operation* -- Under the regulatory actions, the NRC will incur costs to review licensee responses to the new reporting requirements of the rule.
- *Improvements in Knowledge* --The regulatory action will improve the NRC's knowledge of activities affecting closed ITAAC at facilities under construction.
- *Regulatory Efficiency* -- The regulatory action will improve regulatory efficiency by ensuring that the NRC has sufficient, timely information, in light of new information developed or identified after ITAAC completion and NRC notification, to 1) complete all of the activities necessary for the Commission to make a determination on ITAAC, and 2) ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189.a(1)(B) threshold for requesting a hearing.
- *General Public* -- The regulatory action will improve the general public's ability to participate effectively in the licensing process by ensuring that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189a(1)(B) threshold for requesting a hearing.

Attributes that are *not* expected to be affected by the rulemaking options include the following:

- Occupational Health (Routine)
- Occupational Health (Accident)
- Public Health (Routine)
- Public Health (Accident)
- Off-site Property
- On-site Property
- Environmental Considerations
- Antitrust Considerations
- Other Government
- Safeguards and Security Considerations

3.2 Analytical Methodology

This section describes the methodology used to analyze the consequences associated with the rule. The values (benefits) include any desirable changes in the affected attributes. The impacts (costs) include any undesirable changes in affected attributes.

The NRC collected input assumptions using data and information from the following sources: NRC workgroups and staff experience; NRC databases; and reports and documents.

As described in Section 3.1, the attributes expected to be affected include the following:

- Industry Implementation
- Industry Operation
- NRC Implementation
- NRC Operation
- Improvements in Knowledge

- Regulatory Efficiency
- General Public

This analysis relies on a qualitative evaluation for several of the affected attributes (e.g., improvements in knowledge, regulatory efficiency, and general public) due to difficulty in quantifying the impact of the current rulemaking. The remaining attributes (industry implementation, industry operation, NRC implementation, and NRC operation) are evaluated quantitatively. The analysis proceeds quantitatively for these attributes and makes assumptions as discussed in Section 3.2.1.

In accordance with Office of Management and Budget guidance and NUREG/BR-0058, Rev. 4, the results of the analysis are presented using both 3 percent and 7 percent real discount rates.

3.2.1 Data and Assumptions

3.2.1.1 Affected Entities

Licensees

This regulatory action will affect combined license holders who have begun ITAAC closure activities. The NRC estimates that this will affect 17 licensees over the next 20 years, based on the published schedules for combined license applications currently under NRC review.

NRC

NRC costs for implementing this regulation will be incurred primarily by the Office of New Reactors.

3.2.1.2 Other Data and Attributes

- Assumed labor rate for NRC staff is \$120 per hour and for licensee personnel is \$100 per hour.
- Ongoing costs of operation related to the rule are assumed to begin in 2012, and are modeled on an annual cost basis. Ongoing costs related to the No-Action Alternative are zero because no new requirements are imposed for this alternative.
- The analysis calculated cost and savings over a 4-year construction timeframe, with each year's costs or savings discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 4.
- For the analysis, annual costs have been multiplied by 1.2 to capture inflationary cost increases incurred by the 17 licensees constructing over a 20 year staggered time-frame.
- For the analysis, the NRC conservatively assumed that all 17 combined license applications currently under active review will be approved and issued in 2012.

In addition, the NRC assumed that each combined license holder will begin construction upon issuance of the combined license and that construction will span a period of 4 years. The NRC also assumed that each licensee will submit 6 ITAAC post-closure notifications per year of construction.

3.3 Detailed Results

This section presents a detailed estimate of the values and impacts for the rulemaking (Option 2). Some values and impacts are addressed qualitatively for reasons discussed in Section 3.2. These results are summarized in Table 3.

Option 1: No-action

By definition, this option does not result in any values or impacts.

Option 2: Amend Regulations to Add ITAAC Notification and Recordkeeping Requirements

Industry Implementation

Impact: Read the amended regulations.

- One time incremental effort of 1.5 hours per licensee.

Impact: Develop procedures for processing notifications required by the new provisions.

- One time incremental effort of 56 hours per licensee.

Industry Operation

Impact: Report new information materially altering the ITAAC determination basis.

- Effort of 20 hours per licensee for each ITAAC post-closure letter under 10 CFR 52.99(c)(2).

Impact: Submit All ITAAC Complete Letter under 10 CFR 52.99(c)(4).

- Effort of 8 hours per licensee.

NRC Implementation

Impact: Develop rule guidance:

- One time incremental effort of 140 hours to develop new guidance or revise existing guidance.

Impact: Develop infrastructure to process ITAAC post-closure notifications and All ITAAC Complete notifications:

- One time incremental effort of 112 hours of labor.

Impact: Develop and conduct NRC staff training on new requirements.

- One time incremental effort of 28 hours.

NRC Operation

Impact: Review and process ITAAC post-closure notifications under 10 CFR 52.99(c)(2):

- Incremental effort of 20 hours per report.

Impact: Review and process All ITAAC Complete notification under 10 CFR 52.99(c)(4)

- Incremental effort of 8 hours per report to collect, review, and process.

Table 3
Quantitative Results
Value (+) or Impact (-)

	One-time Implementation Costs	*Annual Operating Costs
Industry Costs	-\$111,350	-\$244,800
NRC Costs	-\$49,920	-\$293,760
Total	-\$161,270	-\$538,560

*Annual Operating costs have been factored by 1.2 to account for inflation over the 20 year construction period that the 17 licensees will be constructing plants.

4. PRESENTATION OF RESULTS

4.1 Values and Impacts

This section presents results of values and impacts (i.e., costs) that are expected to be derived from the rule. To the extent that the affected attributes could be analyzed quantitatively, the net effect of each alternative has been calculated and is presented below. However, some values and impacts could be evaluated only on a qualitative basis.

The results of the value-impact analysis are summarized in Tables 4-1 and 4-2. Table 4-3 provides the cost comparison for the two alternatives. The Rulemaking Alternative will result in additional costs when compared to the No-Action Alternative. The quantitative impact for the Rulemaking Alternative is estimated to cost between \$1,985,000 and \$2,163,000 (7-percent and 3-percent discount rate, respectively). Costs are shared nearly equally by industry and the NRC.

TABLE 4-1

Summary of Benefits/Savings and Costs/Burdens

Net Monetary Savings (or Costs) – Total Present Value in millions	Non-Monetary Benefits/Costs
<p>Alternative 1: No Action</p> <p>Industry: \$0</p> <p>NRC: \$0</p>	<p><u>Qualitative Benefits:</u> None.</p> <p><u>Qualitative Costs:</u> Regulatory Efficiency: Regulatory efficiency will be reduced by not providing the most efficient timely ITAAC completion notifications.</p> <p>General Public: The general public’s ability to participate effectively in the licensing process could be reduced because taking no action will not ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189.a(1)(B) threshold for requesting a hearing.</p>
<p>Alternative 2: Rulemaking</p> <p>Industry: (\$1.02) using a 3% discount rate (\$0.94) using a 7% discount rate</p> <p>NRC: (\$1.14) using a 3% discount rate (\$1.04) using a 7% discount rate</p>	<p><u>Qualitative Benefits:</u> Improvements in Knowledge: Increase knowledge of closed ITAAC at facilities under construction.</p> <p>Regulatory Efficiency: Improve regulatory efficiency by ensuring that the NRC has sufficient, timely information, in light of new information developed or identified after ITAAC completion and NRC notification.</p> <p>General Public: Improve the general public’s ability to participate effectively in the licensing process.</p> <p><u>Qualitative Costs:</u> None.</p>

Table 4-2 presents the net impact of the rule. A negative value below is a cost. A positive number is a savings.

Table 4-2: Net Impact of Alternatives 1 and 2

Regulatory Alternative	Total at 3% discount rate (\$)	Total 7% discount rate (\$)
1. No-Action	\$0	\$0
2. Rulemaking	-\$2,163,000	-\$1,985,000

*Annual costs were factored by 1.20 for inflationary considerations (see attributes section for further information).

There are no “new” substantial costs to industry associated with the No-Action Alternative. No changes will be made to the regulation.

There are no quantifiable values (i.e. benefits) associated with the rule. The qualitative values of the rule are associated with improved regulatory efficiency by ensuring that the NRC has sufficient, timely information, in light of new information developed or identified after ITAAC completion and NRC notification, to complete all of the activities necessary for the Commission to make a determination on ITAAC, and to ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189.a(1)(B) threshold for requesting a hearing. This has a beneficial effect on the attributes of improvements in knowledge, regulatory efficiency, and general public.

Table 4-3 shows the estimated costs by attribute.

Table 4-3: Estimated Values and Impacts by Attribute

Attribute	Alternative 2: Rulemaking Total Cost (million \$)	
	3% Discount	7% Discount
Industry Implementation	(0.10)	(0.10)
Industry Operation	(0.92)	(0.84)
NRC Implementation	(0.03)	(0.03)
NRC Operation	(1.11)	(1.01)
Total	(2.16)	(1.98)

Note: Total may differ from sum of values due to rounding.

5. DECISION RATIONALE

NRC's current regulations in 10 CFR 52.99 require licensees to notify the NRC that the prescribed inspections, tests, and analyses in the ITAAC were complete and that the acceptance criteria were met. As the NRC developed its processes for verification of nuclear power plant construction activities through ITAAC under a combined license, it became clear that there were a number of implementation issues left unaddressed by the existing provisions in 10 CFR Part 52. In particular, the NRC believes that additional notifications should be provided to the NRC by the combined license holder following the notification of ITAAC completion currently required by 10 CFR 52.99(c)(1). In general, the reasons for these new notifications are to ensure that the NRC has sufficient information, in light of new information developed or identified after ITAAC completion and NRC notification, to complete all of the activities necessary for the Commission to make a determination on ITAAC, and to ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189a(1)(B) threshold for requesting a hearing. Therefore, the NRC developed

new provisions that apply after a licensee has completed an ITAAC and submitted an ITAAC closure letter.

5.1 Aggregate Analysis

Two alternatives were evaluated in this Regulatory Analysis. Alternative 1, the No-Action Alternative, would maintain the regulations as currently written and the NRC would continue to work with industry to develop regulatory guidance to achieve the NRC's goals. This option would avoid certain costs that the rule would impose. However, taking no action would not ensure that the NRC has sufficient information, in light of new information developed or identified after ITAAC completion, to complete all of the activities necessary for the Commission to make a determination on ITAAC, as required by the AEA, and to ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the threshold for requesting a hearing.

Alternative 2, the Rulemaking Alternative, would amend NRC regulations to amend 10 CFR 52.99(c)(2) to: 1) require licensee reporting of new information that materially alters the bases for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met; 2) require licensee notification of completion of all ITAAC activities, and 3) make corrections to existing language in 10 CFR 2.340 and 52.99 to be consistent with other sections in 10 CFR Part 52 and with language in the AEA. Alternative 2 would improve regulatory efficiency by ensuring that the NRC has sufficient, timely information, in light of new information developed or identified after ITAAC completion and NRC notification, to complete all of the activities necessary for the Commission to make a determination on ITAAC, and ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189a(1)(B) threshold for requesting a hearing. Therefore, the Rulemaking Alternative is the preferred approach.

5.2 Disaggregation Analysis

The NRC has prepared an analysis of the impact of the changes (Appendix A) that identifies each provision affected by the rulemaking and determines its contribution to the overall cost of this rule. The NRC has determined that each individual requirement is needed for the regulatory initiative to resolve the problems and concerns and meet the stated objectives that are the focus of the regulatory initiative, as illustrated in Table 5-1 below. The NRC also performed an analysis to identify any individual provision that could impose cost disproportionate to the benefits attributable to each provision. The NRC has concluded that there are no provisions whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could mask the impact of this rulemaking.

Table 5-1: Disaggregation Analysis

Rule Objectives	52.99(c)(2)	52.99(c)(4)
	ITAAC post-closure notification	All ITAAC Complete notification
NRC has sufficient information for ITAAC finding	X	X
Interested persons have timely access to new ITAAC information to support a hearing on acceptance criteria	X	

6. IMPLEMENTATION

The staff recommends that the final rule be effective 30 days after publication in the *Federal Register*. The industry has proactively been revising their own guidance document to recommend many of the actions that would be imposed by this final rule.

7. REFERENCES

NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 4.

NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook, Final Report," Office of Nuclear Regulatory Research, January 1997.

SECY-09-0119, "Staff Progress in Resolving Issues Associated with Inspections, Tests, Analyses and Acceptance Criteria," August 26, 2009.

SRM-M090922 - "Staff Requirements - Periodic Briefing on New Reactor Issues - Progress in Resolving Issues Associated with Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC), 9:30 A.M., Tuesday, September 22, 2009," October 16, 2009.

Regulatory Guide 1.215, "Guidance for ITAAC Closure Under 10 CFR Part 52," Revision 0, October 31, 2009.

NEI 08-01, "Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52," Revision 3, January 2009."

Appendix: Analysis Details

52.99(c)(2) ITAAC Post-Closure Notification

The revisions will require the licensee to submit an Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) post-closure notification to report new information that materially alters the bases for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met. The information provided in the notification should be at a level of detail comparable to the ITAAC closure notification under paragraph (c)(1). The dual purposes of paragraph (c)(2) notification are 1) to ensure that the U.S. Nuclear Regulatory Commission (NRC) has sufficient information, in light of new information developed or identified after the ITAAC closure notification under Title 10 of the *Code of Federal Regulations* (10 CFR) 52.99(c)(1), to complete all of the activities necessary for the Commission to make a determination on ITAAC, and 2) to ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the Atomic Energy Act of 1954, as amended (AEA) Section 189a(1)(B) threshold for requesting a hearing.

NRC Costs to Review/Process ITAAC Post-Closure Notifications

Cost of NRC Staff Time	\$120
Hours of NRC Staff Time	x 20
Average Annual No. of ITAAC per Licensee	x 6
Number of Licensees	x <u>17</u>
Total Annual ITAAC Post-Closure Notification Costs	(\$244,800)
Years to Complete Plant Construction	x 4
Inflationary Ratio to Account for 20 Year Construction Period	x <u>1.2</u>
TOTAL NRC REVIEW/PROCESS COSTS	(\$1,175,040)

Licensee Costs ITAAC Post-Closure Notifications

Cost of Licensee Staff Time	\$100
Hours of Industry Staff Time	x 20
Average Annual No. of ITAAC per Licensee	x 6
Number of Licensees	x <u>17</u>
Total Annual ITAAC Post-Closure Notification Costs	(\$204,000)
Years to Complete Plant Construction	x 4
Inflationary Ratio to Account for 20 Year Construction Period	x <u>1.2</u>
TOTAL LICENSEE ITAAC POST-CLOSURE NOTIFICATIONS COSTS	(\$979,200)

*NRC One-Time Costs – Developing
Guidance*

Cost of NRC Staff Time	\$120
Hours of NRC Staff Time	x <u>120</u>
Total NRC One-Time Costs for Developing Guidance	(\$14,400)

*NRC On- Time Costs – Develop
Processing Infrastructure*

Cost of NRC Staff Time	\$120
Hours of NRC Staff Time	x <u>96</u>
Total NRC One-Time Costs for Develop Processing Infrastructure	(\$11,520)

*NRC One-Time Costs – Conducting
Staff Training*

Cost of NRC Staff Time	\$120
Hours of NRC Staff Time	x <u>24</u>
Total NRC One-Time Costs for Conducting Staff Training	(\$2,880)

*Licensee One-Time Costs – Developing
Processing Procedures*

Cost of Industry Staff Time	\$100
Number of Licensees	x 17
Hours of Industry Staff Time	x <u>48</u>
Total Industry One-Time Costs for Developing Processing Procedures	(\$81,600)

52.99(c)(4) All ITAAC Complete Notification

The revisions require licensees to notify the NRC that all ITAAC are complete. At the time the licensee submits the all ITAAC complete notification, the NRC expects that all activities requiring ITAAC post-closure letters have been completed, that the associated ITAAC determination bases have been updated, and that all required notifications under paragraph 52.99(c)(2) have been made.

*NRC One-Time Cost to Review/Process
All ITAAC Complete Notification*

Cost of NRC Staff Time	\$120
Hours of NRC Staff Time	x 8
Number of Licensees	x <u>17</u>
TOTAL NRC REVIEW/PROCESS COSTS	(\$16,320)

Licensee One-Time Cost for All ITAAC Complete Notification

Cost of Industry Staff Time	\$100
Hours of Industry Staff Time	x 8
Number of Licensees	x <u>17</u>
ALL ITAAC COMPLETE NOTIFICATION COSTS	(\$13,600)

*NRC One-Time Costs – Developing
Guidance*

Cost of NRC Staff Time	\$120
Hours of NRC Staff Time	x <u>20</u>
Total NRC One-Time Costs for Developing Guidance	(\$2,400)

NRC One-Time Costs – Develop Processing Infrastructure

Cost of NRC Staff Time	\$120
Hours of NRC Staff Time	x <u>16</u>
Total NRC One-Time Costs for Develop Processing Infrastructure	(\$1,920)

*NRC One-Time Costs – Conducting
Staff Training*

Cost of NRC Staff Time	\$120
Hours of NRC Staff Time	x <u>4</u>
Total NRC One-Time Costs for Conducting Staff Training	(\$480)

*Licensee One-Time Costs – Developing
Processing Procedures*

Cost of Industry Staff Time	\$100
Number of Licensees	x 17
Hours of Industry Staff Time	x <u>8</u>
Total Industry One-Time Costs for Developing Processing Procedures	(\$13,600)

SUPPORTING STATEMENT FOR FINAL RULE
10 CFR PARTS 2 AND 52
REQUIREMENTS FOR MAINTENANCE OF INSPECTIONS, TESTS, ANALYSES, AND
ACCEPTANCE CRITERIA
(RIN 3150-A177)
(3150-0151)

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations related to verification of nuclear power plant construction activities through inspections, tests, analyses, and acceptance criteria (ITAAC) under a combined license. The final rule contains new provisions that apply after a licensee has completed an ITAAC and submitted an ITAAC closure notification. The new provisions require licensees to report new information materially altering the basis for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met, and to notify the NRC of completion of all ITAAC activities.

A. JUSTIFICATION

The Commission first issued Title 10 of the *Code of Federal Regulations* (10 CFR), Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," on April 18, 1989 (54 FR 15371). Section 52.99, "Inspection during construction," was included to make it clear that the NRC's inspection carried out during construction under a combined license would be based on ITAAC proposed by the applicant, approved by the NRC staff, and incorporated in the combined license. On August 28, 2007 (72 FR 49351), the Commission revised 10 CFR Part 52 to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and approval processes. Under Section 185.b of the Atomic Energy Act (AEA) of 1954, as amended and 10 CFR 52.97(b), a combined license for a nuclear power plant (a "facility") must contain those ITAAC that are "necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with" the license, the AEA, and NRC regulations. Following issuance of the combined license, Section 189.b of the AEA and 10 CFR 52.99(e) require that the Commission "ensure that the prescribed inspections, tests, and analyses are performed." Finally, before operation of the facility, Section 189.b and 10 CFR 52.103(g) require that the Commission find that the "prescribed acceptance criteria *are met*" (emphasis added). This Commission finding will not occur until construction is complete, near the date for scheduled initial fuel load. After considering information presented by industry representatives in a series of public meetings, the NRC realized that some additional implementation issues were left unaddressed by the various provisions in 10 CFR Part 52. In particular, the NRC determined that the combined license holder should provide additional notifications to the NRC following the notification of ITAAC completion currently required by 10 CFR 52.99(c)(1). The NRC refers to the time after this ITAAC closure notification, but before the date the Commission makes the finding under 10 CFR 52.103(g), as the ITAAC maintenance period. In addition, the NRC is including editorial corrections to existing language in the NRC's regulations to correct and clarify ambiguous language and make it consistent with language in the AEA.

The NRC is seeking clearance with respect to the changes to 10 CFR Parts 2 and 52 related to the maintenance of the inspection, tests, analyses, and acceptance criteria (ITAAC). The new provisions ensure that the NRC has sufficient information to complete all of the activities necessary for the Commission to make a determination on ITAAC, and ensure that interested

persons have access to information on ITAAC at a level of detail sufficient to address the AEA threshold for requesting a hearing.

1. Need for and Practical Utility of the Collection of Information

The reasons for the reporting and recordkeeping requirements are to ensure that the NRC has sufficient information to review and make a determination that the inspection, test and analysis were performed and the acceptance criteria are met prior to the facility's operation.

10 CFR Part 52.99(c)(2)

New paragraph (c)(2) requires the licensee to submit an ITAAC post-closure notification documenting the resolution of the issue which prompted the notification. By "resolution," the NRC means: (1) the completion of the licensee's technical evaluation of the issue and the determination as to whether the prescribed inspection, test or analyses was performed as required; (2) licensee completion of any necessary corrective or supplemental actions; (3) licensee documentation of the issue and any necessary corrective or supplemental actions in order to bring the ITAAC determination bases up to date; and (4) ultimate licensee determination about whether the affected acceptance criteria continue to be met.

10 CFR Part 52.99(c)(4)

New paragraph (c)(4) would require licensees to notify the NRC that all ITAAC are complete (All ITAAC Complete notification). When the licensee submits the All ITAAC Complete notification, the NRC would expect all activities requiring ITAAC post-closure notifications have been completed, the associated ITAAC determination bases have been updated, and all required notifications under paragraphs (c)(3) have been made. The purpose of the "All ITAAC Complete notification" is to facilitate the required Commission finding under 10 CFR 52.103(g) that the acceptance criteria in the combined license are met.

2. Agency Use of the Information

The reasons for these reporting and recordkeeping requirements are to ensure that the NRC has sufficient information, in light of new information developed or identified after the ITAAC closure notification under 10 CFR 52.99(c)(1), to complete all of the activities necessary for the Commission to make a determination on ITAAC, and to ensure that interested persons have access to information on ITAAC at a level of detail sufficient to address the AEA Section 189.a(1)(B) threshold for requesting a hearing.

The NRC added a new paragraph, 52.99(c)(2), to require the licensee notify the NRC, in a timely manner, of new information that materially alters the bases for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met. The notification must contain sufficient information to demonstrate that, notwithstanding the new information,

the prescribed inspections, tests, or analyses have been performed as required, and the prescribed acceptance criteria are met. Apart from the NRC's use of the information, the NRC also believes that public availability of such information is necessary to ensure that interested persons will have sufficient information to review when preparing a request for a hearing under 10 CFR 52.103, comparable to the information provided under 10 CFR 52.99(c)(1).

The NRC added a new paragraph, 52.99(c)(4), to require the licensee notify the NRC that all ITAAC are complete. When the licensee submits the All ITAAC Complete Notification, the NRC would expect all activities requiring ITAAC post-closure notifications letters have been completed, the associated ITAAC determination bases have been updated, and all required notifications under 52.99(c)(2) have been made. Following this notification, the NRC staff would prepare its recommendation to the Commission in support of the 10 CFR 52.103(g) finding that would allow operation.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use new automated information technology when it could be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58792), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. It is estimated that 100 percent of the applications will be submitted electronically.

4. Effort to Identify Duplication and Use of Similar Information

There is no duplication of requirements and this information is not available from any source other than the licensees involved. The information required by the NRC in the ITAAC records concerning the licensee performance of inspections, tests, and analyses during nuclear power plant construction does not duplicate other Federal information collection requirements. The NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

The information collection required by this regulation will not be a burden on small business because only large companies have the technical and financial resources to support the large capital investment required to construct these nuclear power plants. Therefore, small businesses will not be seeking a combined license made available by 10 CFR Part 52. No small entities are expected to be impacted by the final rule.

6. Consequences to Federal Program Activities if the Collection is Not Conducted or is Conducted Less Frequently

The information required by the addition of 10 CFR Part 52.99(c)(2), is collected and evaluated during new reactor construction whenever a licensee determines that it has new information materially altering the basis for a prior ITAAC determination. Without this collection of information, the NRC will not have a sufficient technical basis for evaluation whether the licensee has maintained ITAAC from the time of its completion until the time of the Commission's 10 CFR 52.103(g) finding.

The information required by the addition of 10 CFR Part 52.99(c)(4) is collected and evaluated once during new reactor construction when the licensee determines that all ITAAC are complete. Without this collection of information the NRC will not have sufficient technical basis to complete all of the activities necessary for the Commission to make a determination on ITAAC in accordance with 10 CFR 52.103(g).

The NRC cannot collect the information any less frequently than provided in this rule or it will compromise its ability to (1) evaluate the licensee's maintenance of the inspections, tests, analyses and acceptance criteria during nuclear plant construction and (2) provide the NRC sufficient information to complete all of the activities necessary for the Commission to make a determination on ITAAC in compliance with 10 CFR 52.103(g).

7. Circumstances Which Justify Variation from Office of Management and Budget Guidelines

None

8. Consultation Outside the NRC

An opportunity to comment on the proposed rule's information collection requirements was published in the *Federal Register* on May 13, 2011 (76 FR 27925). A total of one comment letter was received on the proposed rule, which is summarized below. The OMB commented on the information collection for the proposed rule as a comment and file. The 1 comment letter received contained 11 comments consisting of 2 general comments on the proposed rule and 9 specific comments on the proposed rule supplementary information. The commenter was generally supportive of the proposed rule and associated regulatory guide. There were no changes from the proposed rule language to the final rule language based on the comments received. The final rule *Federal Register* notice discusses the comments resolution.

9. Payments or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

Information identified as proprietary or confidential will be handled and protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). If the applicant includes any sensitive information in its reports, it will only be available to those NRC staff that are authorized and have a need-to-know. Certain information designated as Safeguards Information (SGI) is prohibited from public disclosure in accordance with the provisions of the AEA of 1954, as amended, Chapter 12, Section 147, or designated as classified national security information, in accordance with Executive Order 12958.

11. Justification for Sensitive Questions

Not applicable.

12. Estimate of Annualized Burden and Burden Hour Cost

The information required by 10 CFR 52.99(c)(2) is collected only when events or licensee activities exceed a certain reporting threshold (i.e., when those activities produce information that materially alters the ITAAC determination basis). The information that would be required by 10 CFR 52.99(c)(4) is collected once from each licensee, when all ITAAC have been completed.

The final rule will increase the reporting burden for combined license holders. The reporting burden for the final rule is calculated for each combined license applicant that is expected to be issued a license during this 3-year OMB clearance period.

For the analyses, the NRC assumed that all combined license applications currently under active review would be approved and issued on their current published schedules. In addition, the NRC assumed that each combined license holder would begin construction upon issuance of the combined license and that construction would span a period of 4 years. The NRC also assumed that each licensee would have events that exceeded the reporting thresholds 6 times per year of construction.

Based on these assumptions, the NRC determined that there would be 2 respondents in year one, 9 respondents in year two, and 11 respondents in year three, for an average of 7.33 respondents per year that would report information under the proposed requirements.

For the requirements in proposed 10 CFR 52.99(c)(2), the NRC estimates six reports per licensee per year of construction. The NRC estimates 20 hours per response would be required. In addition, the NRC estimates a one-time licensee burden of 48 hours for each licensee to develop reporting procedures.

For the requirements in proposed 10 CFR 52.99(c)(4), there would be one response per licensee. The NRC estimates 8 hours per response would be required. In addition, the NRC estimates a one-time licensee burden of 8 hours

for each licensee to develop reporting procedures. The NRC expects no burden from this requirement because there will not be any licensees who will complete all ITAAC during the 3-year clearance period.

Total Burden and Burden Hour Cost

The burden for the annualized reporting burden is given in Tables 1 and 2. The total annualized burden for all information collections is 1,056 hours, broken down as follows:

- 176 hours¹ for one-time reporting burden
- 880 hours for annual reporting burden

The annual estimated cost for the collection is \$288,288 (1,056 hours x \$273/hr).

13. Estimate of Other Additional Cost

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the recordkeeping storage cost has been estimated to be equal to .0004 percent of the recordkeeping burden. Therefore, the annual recordkeeping storage cost for this collection is estimated to be \$0.00 (0 recordkeeping hours x \$273 x .0004).

14. Estimated Annualized Cost to the Federal Government

This section calculates the estimated cost to the government over the 3-year OMB clearance period covered by this analysis. The NRC will incur costs to review licensee responses to the new reporting requirements of the final rule. In addition, the NRC will incur one-time costs to develop rule guidance and the infrastructure to process the new notifications, and conduct NRC staff training on the new requirements.

10 CFR 52.99(c)(2)

The NRC estimates that it will spend 20 hours per report processing and reviewing reports that would be required by proposed 10 CFR 52.99(c)(2). The NRC assumed that each licensee would have events that exceeded this reporting threshold six times per year of construction. Finally, the NRC estimates one-time costs for developing guidance (120 hours), developing the infrastructure to process the reports (96 hours), and to conduct staff training for the new requirements (24 hours).

¹ Each one-time burden in these analyses has been annualized (divided by 3 to represent the annual total over the 3 year clearance period).

10 CFR 52.99(c)(4)

The NRC estimates that it will spend 8 hours per report processing and reviewing reports that would be required by proposed 10 CFR 52.99(c)(4). Each licensee would be required to submit this report one time. Finally, the NRC estimates one-time costs for developing guidance (20 hours), developing the infrastructure to process the reports (16 hours), and to conduct staff training for the new requirements (4 hours).

Total Government Burden and Burden Hour Cost

The costs for the one-time and annualized government burden are given in Tables 3 and 4. The total annualized government burden for all information collections is 1,029 hours, broken down as follows:

- 93 hours for one-time burden
- 936 hours for annual burden

The total annual cost to the Federal government is \$280,917 (1,029 hours x \$273/hr). These costs are fully recovered by fee assessments to NRC applicants pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Change in Burden or Cost

All of the burden for this information collection will be new burden which will be added to 10 CFR Part 52 and the total is 1,056 hours annually. This final rule would increase the annual burden for 10 CFR Part 52 from 204,075 hours to 205,131 hours by requiring licensees to report new information materially altering the basis for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met, and to notify the NRC of completion of all ITAAC activities.

16. Publication for Statistical Use

The collected information is not published for statistical use.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the *Code of Federal Regulations* to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable. Statistical methods are not used in this collection of information.

TABLE 1
ANNUAL REPORTING BURDEN, 10 CFR PART 52.99(c)
MAINTENANCE OF INSPECTIONS, TESTS, ANALYSES AND ACCEPTANCE CRITERIA
RULE

Section	No. of Respondents	Responses per Respondent	Total No. of Responses	Burden Hours per Response	Total Annual Reporting Burden (Hrs)
52.99(c)(2)	7.3	6	44	20	880
52.99(c)(4)	0	1	0	8	0
TOTAL	7.3	6	44	20	880

TABLE 2
ONE-TIME REPORTING BURDEN, 10 CFR PART 52.99(c) (ANNUALIZED)²
MAINTENANCE OF INSPECTIONS, TESTS, ANALYSES AND ACCEPTANCE CRITERIA
RULE

Section	No. Of Respondents ³	Annualized One-Time Burden per Respondent (\$)	Total Annual Reporting Burden (Hrs)
52.99(c)(2)	11	16	176
52.99(c)(4)	0	2.67	0
TOTAL	11	18.67	176

TOTAL BURDEN HOURS: 1,056 hours
 TOTAL BURDEN HOUR COST: \$288,288 (1,056 hours x \$273/hr)
 ANNUAL RESPONDENTS: 7.33 respondents (2 in year 1 + 9 in year 2 + 11 in year 3)
 RESPONSES: 48 responses (44 annual responses plus 3.66 annualized one-time responses)

² Burden hour estimates on all one-time burden tables have been annualized (divided by 3) to reflect annual burden during the 3-year clearance period. For example, 10 CFR 52.99(c)(2) imposes a one-time burden of 48 hours, which has been annualized to 16 hours (48 hours / 3 = 16) on Table 2.

³ Estimates of the number of respondents on all one-time burden tables represent the total number of respondents who will complete each one-time requirement. The average annual number of respondents is still 7.33 (2 in year one, 9 in year two, and 11 in year three).

TABLE 3
ONE-TIME GOVERNMENT BURDEN, 10 CFR PART 52 (ANNUALIZED)
MAINTENANCE OF INSPECTIONS, TESTS, ANALYSES AND ACCEPTANCE CRITERIA
RULE

Section	Annualized One-Time Burden Hours
10 CFR 52.99(c)(2)-guidance	40
10 CFR 52.99(c)(2)- infrastructure	32
10 CFR 52.99(c)(2)-training	8
10 CFR 52.99(c)(4)-guidance	7
10 CFR 52.99(c)(4)- infrastructure	5
10 CFR 52.99(c)(4)-training	1
TOTAL	93

TABLE 4
ANNUAL GOVERNMENT BURDEN, 10 CFR PART 52
MAINTENANCE OF INSPECTIONS, TESTS, ANALYSES AND ACCEPTANCE CRITERIA
RULE

Section	No. of Licensees Reporting	Reports or Inspections per Licensee	Total No. of Reports or Inspections	Burden Hours per Report or Inspection	Total Annual Burden (Hrs)
10 CFR 52.99(c)(2)	7.33	6	44	20	880
10 CFR 52.99(c)(4)	7.33	1	7	8	56
TOTAL	7.33	7	51	28	936

TOTAL GOVERNMENT BURDEN HOURS: 1,029 hours (936 annual hours + 93
 annualized one-time hours)

TOTAL GOVERNMENT BURDEN HOUR COST: \$280,917 (1,029 hrs x \$273/hr)