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To:
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Description:
NRC public meeting on the ITAAC Demonstration Project and new NRC
Inspection Manual Chapter 2502 (PROJECT 689)

Assigned To:
DIRS

Contact:
CASE, MICHAEL J

Special Instructions:
Letter for signature to Michael Case.



NUCLEAR ENERGY INSTITUTE

Adrian P. Heymer
SENIOR DIRECTOR, NEW PLANT DEPLOYMENT
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April 4, 2006

Mr. Michael J. Case
Director, Division of Inspection and Regional Support
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

PROJECT 689

Dear Mr. Case:

This letter is a follow-up to the discussions in a March 6, 2006, NRC public meeting on the ITAAC Demonstration Project and new NRC Inspection Manual Chapter 2502, *Construction Inspection Program (CIP): Pre-Combined License (COL) Phase*.

Enclosure 1 provides industry lessons learned to date from the ITAAC Demonstration Project. These are slightly revised from the set that we discussed in our March 6 meeting. These lessons learned are provided as input to the information paper(s) being prepared for the Commission regarding construction inspection program implementation. Enclosure 2 provides industry comments on IMC-2502 and some of its supporting procedures. Key points from the enclosures concerning IMC-2502 and the ongoing ITAAC Demonstration Project are summarized below.

IMC-2502

We have one significant comment on IMC-2502 concerning the description of the relationship between first-of-a-kind engineering (FOAKE) and the NRC decision to issue a COL. FOAKE is the detailed engineering that translates the certified and approved design information into lower tier construction and design documentation that supports plant construction and equipment procurement.

Completion of FOAKE is not required for the issuance of a combined license (COL). An applicant may decide to complete all or a portion of FOAKE for reasons of construction efficiency and business advantage, but doing so is not a regulatory requirement. For example, all of the prospective COL applicants – for business case and project efficiency reasons – are working on a portion of the Design Acceptance Criteria (DAC) for instrumentation and control (I&C) systems and the main control room.



Mr. Michael J. Case
U.S. Nuclear Regulatory Commission
April 4, 2006
Page 2

Section 05.08 of IMC-2502 states FOAKE inspections will be scheduled and conducted so that results can "be available as input to the NRC staff recommendations for issuance of the COL." Appendix B, Section 4.b says that results from both phases of envisioned FOAKE inspections would be considered "in the determination of whether to issue a COL." FOAKE inspections will occur only after sufficient information is available for audit. For some COL projects, especially for the first-of-class I&C design, this may not be until after the SER or COL is issued.

Part 52 requires COL applicants referencing a design certification to provide certain site-specific design information, including required interfaces with the approved standard design. Part 52 does not require COL applications to include additional design detail regarding systems, structures and components (SSC) within the design certification scope.

There was significant discussion in the first NRC workshop on draft Regulatory Guide DG-1145, *COL Applications for Nuclear Power Plants (LWR Edition)*, on the level of design information needed for COL versus the FOAKE needed to construct the plant and procure equipment. We request that the NRC staff take steps to assure that future DG-1145 guidance and associated workshop discussions reflect that FOAKE is not required for COL and that NRC inspection of FOAKE may occur after the COL is issued. In addition, this important point should be clarified in the upcoming Commission papers.

Recommendations for clarifying IMC-2502, including a proposed definition for FOAKE, are provided in Enclosure 2.

ITAAC Demonstration Project

The upcoming SECY papers provide the opportunity to update the Commission on at least two important ongoing issues related to the CIP and ITAAC verification. Both are addressed in the lessons learned in Enclosure 1.

The first is our deepening level of common understanding regarding the documentation to be relied upon to conclude that an ITAAC has been satisfied – the so-called ITAAC determination bases (IDB) – including the distinction between IDB and underlying Quality Assurance Program documentation. We believe we have made important progress in this area. We fully support the NRC staff's idea to further examine the IDB for representative types of ITAAC and to hold a workshop in the second half of this year to discuss these examples in detail.

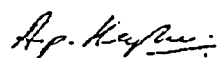
The second issue is the industry expectation that licensee quality assurance, corrective action, configuration control and maintenance programs will be relied upon to maintain SSCs after ITAAC are completed. As we have discussed with the staff, properly implemented maintenance and modification work on SSCs previously verified via ITAAC – including post work testing and/or analysis that demonstrates

Mr. Michael J. Case
U.S. Nuclear Regulatory Commission
April 4, 2006
Page 3

that acceptance criteria continue to be met – should have no effect on the completed status of affected ITAAC with respect to the Commission's Section 52.103(g) finding. We understand that the NRC staff will address this issue in a forthcoming SECY paper.

We appreciate the constructive series of interactions we have had since our joint ITAAC Demonstration Project began in early 2004. The common understandings that are being established are building confidence in Part 52 and the ITAAC process. If you have any questions concerning this letter or the enclosures, please contact me (202) 739-8094; aph@nei.org or Russ Bell (202) 739-8087; rjb@nei.org.

Sincerely,



Adrian P. Heymer

Enclosures

c: Dr. William D. Beckner, NRC
Ms. Mary Ann Ashley, NRC
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**Industry Lessons Learned from the
Industry – NRC ITAAC Demonstration Project (Phases 1 & 2)**

Throughout the performance of the phase 1 and phase 2 of the ITAAC Demonstration Project, the industry has been building a list of relevant lessons learned that could be applied to the overall CIPIMS/ITAAC verification process. Our resulting list for both phases is provided here for consideration by the NRC staff:

1. Construction schedule information at a summary level (Level 3) should be readily available to NRC and be current within a day or two. This information will not include fabrication schedule information. Fabrication schedule information can be provided to the NRC for specific items upon request to support inspection planning.
2. The industry considers that construction schedule information is business sensitive and proprietary. The licensee will be responsible for making the schedule available to the NRC and for justifying why construction schedule information should be withheld pursuant to 10 CFR 2.390, "Public inspections, exemptions, requests for withholding."

If NRR, using LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure," determines that the construction schedule information is proprietary, that determination will remain in place for the life of the construction project. [Reference NRC memo, Ashley to Richards, dated 6/3/04.]
3. There are a variety of acceptable ways for electronic information transfer between NRC and the COL holder. The specific mechanism will be determined at time of need but will be compatible with CIPIMS.
4. The NRC can perform Construction Inspection activities as it wishes. These activities include: inspection of fabrication and construction activities on site and at offsite facilities, review of requested vendor and contractor documentation and data, or review of the COL holder's Quality Assurance Records.
5. The NRC shall verify that the ITAAC referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met [ref. Section IX.B.1 of the design certification rules].
6. Repackaging or submittal of the licensee's QA Records will not be required to support licensee notification of ITAAC completion. QA Records will be available for audit. (QAR as defined in 10 CFR Part 50, Appendix B, or equivalent.)

7. Documentation to support Construction Inspection will be established and controlled in accordance with importance to safety and the COL holder's Quality Assurance Program. This includes: fabrication, procurement, installation, test, acceptance of sub-tier QA Programs, recordkeeping, etc.
8. ITAAC Determination Bases are those documents on which is based the licensee's determination that one or more ITAAC are satisfied.
9. ITAAC determinations will be submitted to support each individual ITAAC segment for which there is a specific acceptance criterion. ITAAC determinations will be submitted to NRC in ITAAC completion letters. ITAAC completion letters may cover multiple ITAAC determinations.
10. NRC acceptance of the licensee's ITAAC determination will occur for each individual ITAAC segment for which there is a specific acceptance criterion. Section 52.99 notices will be issued periodically by NRC and may cover multiple ITAAC.
11. ITAAC completion letters should be submitted to NRC under oath and affirmation, but may include information that is provided for information only. In particular, ITAAC completion letters should identify – for information only – ITAAC Determination Bases (IDB) documents and where they may be examined to help focus and expedite NRC ITAAC verification.
12. NRC Headquarters staff are expected to be tasked with processing the licensee determination letters and issuing the Federal Register Notices required by 10 CFR 52.99. It is expected that the NRC will inspect the process used by the licensee to generate the closeout letter and that the level of review of the licensee letters, ITAAC Determination Bases (IDB) and any supporting information would be determined, at least in part, by the NRC's level of confidence with the process. Also, the level of review will be governed by the NRC's inspection history related to the specific ITAAC (and similar ITAAC and other NRC inspections), the nature of the ITAAC, and related factors.
13. In public meetings, the industry has discussed several examples of IDB with the NRC staff. In a November 21, 2005, letter to NEI, the NRC provided its perspective on what should be included in the IDB documentation list. As we discussed on March 6, in a few cases the requested IDB documentation list is beyond that which the industry envisions. For example, the NRC letter correctly states the principle that "IDB should directly correspond to the acceptance criteria;" however, the letter identifies receipt inspection records as an example of potential IDB documentation. We would consider receipt inspection records as part of underlying QAP information, not as IDB. We expect that follow-up interactions related to IDB will assure there is a common understanding of the

distinction between IDB information versus underlying Quality Assurance records.

14. IDB documents will not be submitted to the NRC unless they are required in connection with a hearing granted under Section 52.103(c). The NRC may choose to examine licensee IDB documents on site, as well as additional licensee records, as part of the ITAAC verification process. Consistent with current practice, licensee construction, installation and testing documentation (drawings, calculations, test procedures, etc.) will not be submitted to the NRC.
15. ITAAC are a key subset of the normal construction, inspection and test activities performed by the licensee under its Quality Assurance Program (QAP). While related, there are important distinctions between ITAAC and the QAP that should be recognized and preserved in COL implementation and NRC inspection guidance:
 - QAP – Continuous licensee process for assuring that 1) design, construction and testing activities, including ITAAC inspections, tests and analyses, are performed in accordance with the license, NRC regulations and applicable codes and standards, and 2) that SSCs will perform their intended functions
 - ITAAC – ITAAC address the acceptability of the “end point” of specific design and construction sequences, while the QAP provides more broadly for the day-to-day evaluation of design and construction processes. ITAAC verification – NRC process for confirming that the licensee has completed specified ITAAC inspections, tests and analyses and that associated acceptance criteria have been met
16. a) Issues identified during the inspection process that call into question the ability of the licensee to meet the ITAAC acceptance criteria would be called an “ITAAC open item.” ITAAC Open Items and the specific ITAAC to which they pertain should be clearly documented in NRC inspection reports. Inspection reports may also document other issues of lesser significance or unrelated to ITAAC that would not prevent the staff from finding that the ITAAC had been met. ITAAC Open Items would need to be closed by the NRC in an inspection report before the NRC would find that an ITAAC had been successfully met. ITAAC Open Items and other inspection findings will be resolved via the licensee’s corrective action program.
- b) It is expected that licensees will review ITAAC Open Items prior to sending in ITAAC determination letters. Licensees should be able to determine that ITAAC Open Items pertaining to the ITAAC have been closed or provide basis for concluding that the ITAAC is met despite the continued existence of one or more ITAAC Open Items. Remaining ITAAC Open Items (i.e., those found not to preclude a conclusion that acceptance criteria are met) would continue to be

resolved via the licensee's corrective action program.

c) It is expected that ITAAC Open Items (inspection findings potentially material to a conclusion that an acceptance criteria has been met) will be rare compared to routine NRC inspection findings on overall construction processes and QAP implementation. NRC procedures will establish criteria for consistent identification of ITAAC Open Items, and require management review and approval before inclusion in an NRC inspection report.

17. The licensee's QA, configuration control, and corrective action programs will be relied upon to maintain the condition of the SSC consistent with specified acceptance criteria following completion of the ITAAC.

- After an ITAAC is completed, SSCs may be taken out of service for normal or corrective maintenance, or to implement design changes, in accordance with established licensee procedures and processes. It is the responsibility of the licensee to maintain the validity of the ITAAC using controlled and approved processes and procedures. The licensee is responsible for evaluating any work performed after an ITAAC determination has been made to ensure that the acceptance criteria continue to be met. This evaluation may be based on post-work testing, engineering analysis, or a combination of both testing and analysis.
- If, following maintenance or modification work, an SSC previously verified as part of an ITAAC cannot be restored in a manner that satisfies the ITAAC, the licensee must notify the NRC and seek exemption from the ITAAC in accordance with Section 52.97(b)(2)(i).
- Licensees will maintain records of work affecting SSCs previously verified as part of an ITAAC in accordance with approved maintenance and configuration management processes. NRC inspectors may refer to the corrective actions log and similar licensee records to determine the status of SSCs following the completion of ITAAC.

18. A completed ITAAC would be withdrawn and re-verified only if the IDB in which the licensee's determination was based is determined to be incorrect or invalid. Properly implemented maintenance, corrective action and/or design changes following completion and verification of ITAAC do not alter the completed status of the ITAAC and do not affect the basis for the Commission Section 52.103(g) finding.

19. Some design certification ITAAC are identified as applicable to the "First-Plant-Only" or "First-Three-Plants-Only." Each COL applicant must address all ITAAC in a referenced design certification; however, for ITAAC applicable to only the first, or first three, plants of a given design, subsequent applicants may reference the ITAAC closure from a previous project and request those ITAAC to be considered resolved in for purposes of additional COL proceedings.

20. Some ITAAC acceptance criteria include tolerances. In the event of an out-of-tolerance situation that cannot be otherwise resolved, the licensee would need to request and be granted an exemption from the specified acceptance criterion.
21. COL applicants wishing to minimize time-to-market may initiate fabrication of long lead components and modules before the COL is issued and perhaps even prior to submitting the COL application. This is allowed under the regulations and acceptable to the NRC staff. The staff has emphasized the importance that COL applicants communicate as early as possible plans and schedules for early fabrication activities so that NRC inspectors have the opportunity to perform associated inspections.
22. Some ITAAC acceptance criteria take the form of "A report exists and concludes that ..." In some cases, this refers to a well-known report such as an ASME Code report. In other cases, the "report" may consist of a document or set of documents that demonstrate that the acceptance criterion has been met. More discussion is needed on this type of the IDB. This should be the topic of additional NRC-industry interactions.

**Industry Comments on
IMC 2502: Construction Inspection Program – Pre-Combined License Phase**

1. We suggest that Section 03, "Definitions," include an explanation of the term "first-of-a-kind engineering." Consider the following:

First-of-a-kind (FOAK) Engineering FOAK Engineering is the detailed engineering that translates the certified and approved design information into lower tier construction and design documentation. The FOAK Engineering products were generally not inspected in support of design certification.

2. Appendix B (Section B.4.b) indicates that the FOAK engineering inspections will be initiated approximately one year before the COL might be issued. It would be more appropriate to say that FOAKE inspections would begin as described in the base text of Section 05.08 of this inspection manual chapter: "...when sufficient procurement, construction, and installation specifications have been completed and are available for auditing." This timing would be mutually agreed upon between the applicant and the NRC. For projects geared to minimize time to market, FOAKE inspections could begin prior to COLA, while for other projects, meaningful FOAKE may not be available for inspection until after the SER or COL is issued.

Section 05.08 states FOAK engineering inspections will be scheduled and conducted so that results can "be available as input to the NRC staff recommendations for issuance of the COL." Appendix B, Section 4.b says that results from both Phase 1 and Phase 2 FOAKE inspections would be considered "in the determination of whether to issue a COL." As indicated in comment (2) above, FOAKE inspections will occur only after sufficient information is available for audit, and for some COL projects, this may not be until after the SER and/or COL is issued. The option to defer FOAKE until after the COL is issued is permitted under NRC regulations. The NRC guidance should be clarified as follows:

"Completion of FOAKE and associated NRC inspections is not a prerequisite for issuance of a COL. However, if the COL applicant performs significant FOAKE prior to issuance of the SER (e.g., completion of specific Design Acceptance Criteria (DAC)), the NRC may conduct FOAKE inspections, and the results of those inspections may be considered when issuing the COL. For example, the NRC may determine and identify in the license that specific DAC elements have been satisfactorily completed. If FOAKE inspections are not performed prior to COL issuance, the NRC will perform those inspections after the license is issued as the necessary information is completed and made available by the licensee."

3. Section B.4, item (3) in Appendix B for FOAK inspections directs that "risk information" be considered when selecting the systems to be inspected. Item (1) of the same guidance suggests that the sample include systems that are "essential to plant safety." For clarity, we recommend that the entry in item (1) be replaced with "essential to plant safety or highly risk significant," and that item (3) be replaced with, "A discussion of sampling and risk-informing construction inspection activities is included in Appendix C to NUREG-1789." This would make item (1) more consistent with Section 03.01a(1) of IF 37802.

4. Section B.4, item (4) suggests that the FOAK inspection include an evaluation for "...programmatic questions or significant Tier1 – Tier 2 interrelationships...which could affect design information flow..." Tier 1 – Tier 2 interrelationships are not explained in any more detail elsewhere in the document and "programmatic questions" are not defined. This section should clarify via use of examples what is meant by "Tier1 – Tier 2 interrelationships" and "programmatic questions".
5. As described in NUREG-1789, FOAKE inspections are part of NRC engineering design verification activities, which also include assessment of the applicant's design change process. Satisfactory outcome of engineering design verification inspections will mark a significant milestone for both the NRC and the applicant, signaling confidence in the applicant's processes for translating high-level design certification information into lower tier design, construction and procurement implementation information. We understand and expect that the results of FOAKE inspections will be identified in one or more NRC inspection reports. In addition, due to the significance of the milestone, we recommend that the NRC CIP also include plans for issuing a conspicuous finding upon satisfactory completion of engineering design verification inspections. We understand that after making such a conclusion early in the project, the NRC may continue to spot check the applicant's design engineering processes to assure continued effective implementation.

IP 37802: First-of-a-Kind Engineering Inspections

6. The following discussion is included in Section 03.02:

"In some instances, the design may not be complete and design documentation will not be available. In this case, ensure that there is a DAC which will verify the appropriate design item at a later date. If there is no DAC to inspect or verify this item, ensure that the engineering contractor, equipment vendor or the licensee has a commitment to inspect and verify this item, and report the results of that inspection to the NRC inspection team responsible for that item."

This section needs to be amended and clarified. The design acceptance criteria (DAC) applicable to a given design have been limited to a select few technical areas, and these will have been previously identified in the FSAR. In this instance the reference to "DAC" is confusing. There may be items not related to a DAC that warrant follow-up inspection at a later time when sufficient information is available. We recommend the procedure be revised to reflect the intent as described in Appendix B, Section 4.b of IMC-2502. There it says that "design areas that were not ready for inspection during Phase 1 [of the FOAKE inspection], but which were deemed significant enough to warrant some level of review and verification" should be flagged for inspection in Phase 2.

IP 35100: Review of QA Manual

7. It is suggested that, for clarity, the terms in IP 35100 and IMC 2502 be reviewed for consistency in their usage. The title of IP 35100 is "Review of QA Manual;" however, Appendix A of IMC 2502 anticipates that IP 35100 would be titled, "Implementation of Quality Assurance (QA) Program Described in Final Safety Analysis Report (FSAR)." IMC 2502 notes (05.05.a) that the review of the QA Manual is the responsibility of NRR, an activity performed in accordance with the Standard Review Plan. However, 03a. of IP 35100 states, "If the inspector, during review of the QA manual, considers the QA

program (as described) to be deficient, the matter should be referred to NRR for resolution.”

8. Also, we recommend that the timing of the proposed inspections and the assumed status of the plant construction associated with this inspection be outlined in the IP.

IP 35005: Pre-Docketing Combined License Quality Assurance Controls Inspection

9. The Specific Guidance subsection of Section 03 identifies that sampling techniques will be used during the examination of design and procurement activities. It would be beneficial for the guidance to direct the sample to emphasize risk-significant activities.

IP 35017: Post-Docketing Development of the Quality Assurance Program for Design and Procurement Activities, and

IP 35021: Post-Docketing Implementation of Quality Assurance Activities Related to Design, Procurement, and Construction

10. IMC 2502 notes (Table A.1) that IP35017 may be implemented both after docketing and after the Draft SER. However, the General Guidance of Section 35017-03 only references the period just after docketing. We believe that the intent was that the period just after the draft SER would be addressed by IP35021. This should be clarified in Table A.1 of IMC 2502 in the entries for the two IPs.

IP 35020: Applicant's Surveillance of Contractor Quality Assurance Activities

11. The objectives of this procedure, as described in 35020-01, are much more generally stated than in the guidance of 35020-03. The first section should be clarified so as to indicate that this procedure addresses follow-on inspections to address previously identified deficiencies or concerns.

IP 36100: 10 CFR Parts 21 and 50.55(e) Programs, Reporting Defects and Noncompliance

12. Inspection Procedure 36100 states in Section 03, General Guidance, that the procedure "...is not intended to be applied to vendors." However, Table A.4 from the Inspection Manual Chapter 2502 appears to apply IP 36100 to "...any consultant or vendor tied to 10 CFR 21 thru the Applicant..."

IP 80210: Environmental Protection – Initial and Periodic Inspections

13. The phrase "...just before or just after receipt of application to review site" in Table A.1 of IMC-2502 is not clear. We suggest that the clearer wording from paragraph 03.01a of IP 80210 be used: "...no later than three months after the notification that (1) site preparation activities will begin, or (2) either a CP or COL application is being prepared for a site for which an ESP has previously been issued."
14. Somewhat related to the previous comment, we suggest that for clarity the first sentence in Section 02.01 be revised along the following lines: "For sites at which multiple units are to be added, the management meeting in 02.01a, below, should normally only be required prior to construction for the first unit."