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Rules and Directives  
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Dr. Ronald L. Simard  
Senior Director, Business  
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Business Operations Division

July 31, 2001

Mr. Joseph M. Sebrosky  
Project Manager  
U.S. Nuclear Regulatory Commission  
Mail Stop O-11 F1  
One White Flint North  
11555 Rockville Pike  
Rockville, MD 20852

66 FR 33178

6/25/01

(2)

Subject: *Federal Register* Notice 66 FR 33178, June 25, 2001, Request for Public  
Comment regarding Inspections, Test, Analyses, and Acceptance  
Criteria (ITAAC)

Dear Mr. Sebrosky:

The Nuclear Energy Institute (NEI)<sup>1</sup> is submitting these comments on behalf of the nuclear energy industry in response to the subject *Federal Register* notice. We appreciate the NRC's efforts to obtain a range of stakeholder perspectives on the scope of inspections, tests, analyses and acceptance criteria (ITAAC) to be required in Part 52 combined licenses.

In a letter to Chairman Meserve dated May 14, 2001, NEI requested early Commission resolution of the specific issue identified in the FRN, namely, whether or not combined licenses must include ITAAC on operational programs. The NEI letter and the attached "White Paper on the Scope of Combined License ITAAC" strongly recommend that the Commission adopt as a matter of policy the interpretation that Part 52 does not require so-called "programmatic ITAAC" to be included in combined licenses. Our May 14 letter is enclosed, and we request that

<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plants designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

Template = ADM-013

E-RIDS = ADM-03

Call = J. Sebrosky (SMS3)

Mr. Joseph M. Sebrosky  
U.S. Nuclear Regulatory Commission  
July 31, 2001  
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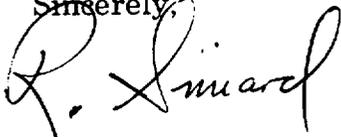
the NRC consider this recommendation and underlying bases contained therein as the industry's response to the subject FRN.

As discussed with the Commission in a July 19 briefing, we believe the record on this issue is more than sufficient to support a policy determination by the Commission, and we urge the NRC to resolve the issue as soon as possible. The resolution of this will affect the ongoing development of guidance on ITAAC verification and COL application contents.

Most importantly, it will also be a factor in near term business decisions, including the assessment of licensing risk, associated with new nuclear plant projects.

We look forward to continued interactions with the NRC staff to help provide future licensees and NRC reviewers with the clarity and predictability needed to implement Part 52 effectively.

Sincerely,

A handwritten signature in cursive script, appearing to read "R. Simard".

Ron Simard

Enclosure



NUCLEAR ENERGY INSTITUTE

**Marvin S. Fertel**  
Senior Vice President  
Business Operations

May 14, 2001

The Honorable Richard A. Meserve  
Chairman  
U.S. Nuclear Regulatory Commission  
Mail Stop 016 C1  
Washington, D.C. 20555-0001

Dear Chairman Meserve:

We appreciate the Commission's efforts to ensure timely identification of policy issues that may impede or complicate near term Part 52 license applications. One such policy issue is whether combined license (COL) applications should contain inspections, tests, analyses and acceptance criteria (ITAAC) on operational programs such as security, training, and radiation protection. We believe they should not.

In SECY-00-0092, the NRC staff interprets the 1992 Energy Policy Act and Part 52 to require that COLs contain ITAAC on operational programs. Our longstanding interpretation of these requirements is that COL ITAAC may and should be focused on verifying the proper construction of the plant and that ITAAC on operational programs are not required. Our strong preference for this view is based on the underlying intent and objectives of Congress and Part 52 as well as important policy considerations, including continued reliance on the existing NRC inspection and oversight activities.

It is not the one-time verification of ITAAC on operational programs that will provide the NRC with reasonable assurance that the facility will be operated as licensed. The inclusion of programmatic ITAAC would be little more than a checklist of program elements and thus would do little in verifying a licensee's ongoing ability to implement such programs. Rather, it is continued compliance with operational program requirements and the ongoing NRC oversight of licensee performance that provides this reasonable assurance.

The Honorable Richard A. Meserve  
May 14, 2001  
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Given the comprehensiveness and demonstrated effectiveness of the NRC inspection and enforcement processes, programmatic ITAAC would be largely duplicative of existing NRC oversight and thus needlessly consume NRC and licensee resources, both in their development and in their implementation during plant construction.

The attached paper summarizes our position. Discussions with the Office of General Counsel have established that ours is an equally valid legal interpretation of the language in question. What remains is a policy decision by the Commission on the need—or lack of need—for programmatic ITAAC in COLs.

We ask that the Commission make the policy decision now that COL ITAAC on programs are not necessary. We ask for early resolution of this issue to allow licensees, the NRC and other stakeholders to be clear on how key Part 52 requirements on the scope of COL ITAAC are to be met. A Commission decision on this issue will also allow for appropriate allocation of limited resources available for addressing a range of important Part 52 process issues and Part 50 requirements that are currently being addressed in anticipation of new plant license applications.

We would be pleased to further discuss this important matter with the Commission should you desire.

Sincerely,

*Original Signed By:*

Marvin S. Fertel

c: The Honorable Nils J. Diaz  
The Honorable Greta J. Dicus  
The Honorable Edward McGaffigan, Jr.  
The Honorable Jeffrey S. Merrifield  
Dr. William D. Travers

# White Paper on the Scope of Combined License ITAAC

## ISSUE

Section 185.b. of the Atomic Energy Act requires in pertinent part, that the Commission conclude, based on inspections, tests, analyses and acceptance criteria (ITAAC), that a facility licensed under 10 CFR Part 52 has been constructed and *will be operated* in conformity with the license, NRC regulations, and the Atomic Energy Act. The NRC staff has concluded that the Atomic Energy Act, as amended by the Energy Policy Act of 1992, requires that ITTAC be developed for each “programmatically” activity as a condition precedent for the NRC to be able to issue a combined operating license pursuant 10 CFR 52.97(a).

The question is “is the NRC’s staff’s interpretation of the statutory requirement the only reasonable interpretation and, if not, does a different interpretation make more sense from a policy perspective?”

## Background

Subtitle C of Title XXIX of the Energy Policy Act of 1992 states that the purposes of those amendments to the Atomic Energy Act are to require the Secretary [of Energy] to carry out civilian nuclear programs in a way that would lead toward the commercial availability of advanced nuclear reactor technologies and to authorize activities to further the timely availability of advanced nuclear reactor technologies. Specific program goals were enumerated for the Secretary of Energy and the NRC “to encourage the deployment of advanced nuclear reactor technologies that, to the maximum extent practicable, are cost-effective, exhibit enhanced safety features, and facilitate the design, licensing, construction and operation using a standardized design.” In addition to those specific requirements to encourage the development of advanced reactor designs, the statute evidences a strong encouragement for such projects to go forward (e.g., for the Secretary to determine “how the Federal Government can most effectively cooperate with the private sector in the accomplishment of the goals set forth”).

With that as backdrop, the statute also amended Section 185 of the Atomic Energy Act and explicitly authorized the Commission to be able to grant a combined construction and operating license prior to the construction of an advanced reactor. In order to issue that combined license, the NRC must determine, after holding a public hearing, that the license applicant had identified and incorporated in the license application the inspections, tests, and analyses – including those applicable to emergency planning – that the licensee must perform, and the acceptance criteria that must be met, to ensure that the completed facility will operate safely.

## ANALYSIS

### Statutory Provisions

The Energy Policy Act of 1992 contains two statutory provisions whose interpretation is critical to the resolution of this issue. First, in the new Section 185.b., the statute provides that the Commission shall issue a combined license if the application contains sufficient information to support a Commission determination that “there is reasonable assurance that the facility *will be constructed and will operate* in conformity with the license, . . . .” (emphasis added).

Further on, the statute requires that the Commission identify “the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility *has been constructed and will be operated* in conformity with the license, . . . .” (emphasis added).

In contrast, Section 185.a., which relates to the traditional licensing approach used under Part 50, contains similar wording associated with the required Commission finding, except that the required NRC finding is that “the facility authorized has been constructed and *will operate* in conformity . . . .” (emphasis added).

Thus, a critical question is whether the difference in the choice of words between Section 185.a. and 185.b. portends a Congressional intent that ITAAC must be established on all matters that would underlie a Commission determination of “necessary and sufficient to provide reasonable assurance,” including all required programs related to satisfactory facility operation. Of note in this regard is that analogous determinations made under Part 50 rely on the NRC’s oversight programs, including inspection and enforcement, to provide the NRC with necessary assurance of licensee performance. The NRC staff has interpreted the addition of the verb “be,” and the inclusion of the requirement for ITAAC applicable to emergency planning, as indications of Congressional intent that ITAAC are required on all required operational programs as well as on key attributes of the constructed facility.

A related question is whether the reference in Section 185.b. relating to an explicit requirement for ITAAC applicable to emergency planning signifies a Congressional endorsement of programmatic ITAAC in general, or merely a requirement that ITAAC be established on that matter.

### Congressional Intent

The intent of Congress with respect to the purpose of ITAAC is directly addressed in the U.S. Senate Energy and Natural Resources Committee Report associated with the passage of the Energy Policy Act of 1992. The Report states that the purpose of

ITAAC is to “enhance certainty for the utility building the plant by spelling out before construction begins what conditions the *completed plant* must satisfy in order to operate.” (emphasis added). The Report further states that ITAAC will “provide NRC regulators objective safety standards (i.e., acceptance criteria) with which to measure the *constructed plant* in deciding whether the plant is safe to operate.” (emphasis added). This language supports a statutory interpretation that ITAAC are intended to assure that the plant was constructed as designed. That is, that the critical attributes of the design, as approved by the NRC through the issuance of the COL, were properly constructed, the demonstration of which was the satisfaction of the acceptance criteria associated with the design.

These passages from the legislative history provide support for an interpretation that ITAAC are intended to demonstrate that the design approved by the NRC was properly constructed (i.e., that the ITAAC are intended to focus on “hardware”). Absent any commentary on the issue in the legislative history, the inclusion of the requirement for ITAAC for emergency planning is not dispositive either way. It is not unreasonable to assume, therefore, that the Congressional intent was formed by experiences in Part 50 operating license proceedings where emergency planning became a pivotal issue (e.g., Shoreham, Seabrook). As a result, the inclusion of emergency planning ITAAC most likely was an expression of interest in ensuring that fundamental decisions of site suitability for emergency planning purposes were resolved at the COL stage.

### Regulatory Interpretation

Although not dispositive, the NRC’s regulations in Part 52 are consistent with an interpretation of Section 185.b. that ITAAC are intended to verify construction of the physical facility.

For example, 10 CFR 52.47(a)(vi) states that the design certification ITAAC must be sufficient to provide reasonable assurance that “a *plant* which references the *design* is *built* and will *operate* in accordance with the design certification.” (emphasis added). Further, 10 CFR 52.79(c) states that the COL ITAAC must include ITAAC, including certified design ITAAC as applicable, and which are necessary and sufficient to provide reasonable assurance that “the *facility* has been *constructed* and *will operate* in conformity with the combined license, the provisions of the Atomic Energy Act, and the NRC’s regulations.” (emphasis added). 10 CFR 52.97(b)(1) states that the COL ITAAC must be “necessary and sufficient to provide reasonable assurance that the *facility* has been *constructed* and *will be operated* in conformity with a license, the provisions of the Atomic Energy Act, and the NRC’s rules and regulations.” (emphasis added).

These provisions of Part 52, and a statutory interpretation focused on the physical attributes of the plant as constructed (i.e., the hardware), are completely consistent with the Commission’s Statement of Considerations that accompanied the final

rule. Importantly, the Commission stated that the finding that must be made post-construction, and prior to operation, is “whether *construction* has been completed in accord with the terms of the combined license, and the final rule so provides.”

Both the regulatory language used by the NRC, and the underlying intent described by the Commission in the Statement of Considerations for the final Part 52 rule, are consistent with an interpretation of the ITAAC being focused on whether the facility was properly constructed (i.e., on the “hardware”).

The NRC staff, placing primary emphasis on the words *will be operated* in 10 CFR 52.97(b), has concluded that ITAAC thus are required for operational programs (so-called “programmatic ITAAC”). The industry, however, places emphasis on the words of both 10 CFR 52.79(c) and 10 CFR 52.97(b) “that the facility has been constructed and will . . . .” Given the statements indicating the intent of Congress and the Commission, the industry interprets Section 185.b that ITAAC are not required for operational programs, but rather are intended to be hardware-focused. This would also include developing ITAAC for emergency planning, as required by the Energy Policy Act of 1992, that would be similarly hardware-oriented.

#### Regulatory Bases for Required Commission Findings If There Are No Programmatic ITAAC

It is to be expected that the types of inspections and reviews conducted by the NRC for a plant licensed under Part 52 will be similar to the ongoing inspections and reviews conducted for a plant licensed under Part 50, with the addition of verifying compliance with ITAAC to demonstrate that the facility was constructed in accordance with the approved design. In fact, Part 52 explicitly recognizes the applicability of Part 50 (and other sections of Title 10) to a plant licensed through the Part 52 licensing process (e.g., 10 CFR 52.83 states that “all provisions of 10 CFR Part 50 and its appendices applicable to holders of construction permits for nuclear power reactors apply to holders of combined licenses issued under this subpart”).

The NRC retains plenary Part 50 authority to take enforcement action as necessary to ensure the adequacy of all licensee activities, including those associated with programs (e.g., 10 CFR 50.100 authorizes the NRC to issue enforcement orders to nuclear plants for violations of NRC regulations, including revocation, suspension, modification of a license or a construction permit for, *inter alia*, “failure to construct or operate a facility in accordance with the terms of the construction permit or license . . . or for a violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, permit, or order of the Commission”). This is consistent with the Congressional intent as evidenced in the Senate Energy and Natural Resources Committee Report associated with the passage of the Energy Policy Act of 1992: “The NRC should have the power and responsibility to block operation of the plant until *any* non-compliance has been corrected. The NRC

retains all of its existing authority under Sections 186 and 187 of the Atomic Energy Act to modify, suspend and revoke any license in order to protect public health and safety.” (emphasis added).

Importantly, 10 CFR 52.79(b) requires a COL applicant to include operational program descriptions in its FSAR consistent with the requirements of 10 CFR 50.34. Furthermore, other NRC regulations contain detailed programmatic requirements. Examples include radiation protection programs required under Part 20, the access authorization program in Part 73, and fitness for duty programs in Part 26. Attachment A is a partial listing of those programs.

The program descriptions included in COL applications are expected to be analogous to those contained in updated FSARs for operating plants. This information must be approved by the NRC, and will be subject to the formal COL hearing process prior to the granting of a COL. The proper implementation of those programs will be subject to the NRC’s well-established inspection and other oversight review functions.

Finally, the NRC has other explicit methods for assuring the adequacy of programs prior to issuance of the authorization to commence operation under 10 CFR 52.103. For example, the technical specifications typically contain a number of programmatic requirements. These include surveillance requirements, a delineation of the licensee’s organizational structure and responsibilities, staffing qualifications, effluent controls, radiation protection programs, and various other specific programs. The NRC has unquestioned authority to ensure compliance with technical specification requirements, regardless of whether a plant was licensed under Part 52 or Part 50.

Given the effectiveness of the normal (i.e., non-ITAAC) NRC oversight processes, developing ITAAC on required operational programs would not add value to the licensing process. There would be no increase in assurance of licensee performance by providing ITAAC in programmatic areas over that provided by NRC oversight and enforcement of required compliance with the license and NRC regulations. Programmatic ITAAC would be largely duplicative of existing NRC requirements and thus needlessly consume NRC and licensee resources, both in their development and in their implementation during plant construction.

In summary, the NRC does not have to rely on the development and implementation of programmatic ITAAC to ensure the adequacy of operational programs. The NRC will review all appropriate operational programs prior to granting a COL to ensure their acceptability, which would then be subject to the formal hearing process, and verified through the NRC’s ongoing routine inspections during the construction and operations phase after a COL has been issued. Finally, both a plant’s technical specifications (which are required to include those matters which are “of controlling importance to safety”) and the NRC’s regulations

regarding the implementation of programs outside Part 52 provide the NRC with sufficient means to ensure the adequacy of specific programmatic activities.

Under Part 52, the NRC retains its authority under Section 186 of the Atomic Energy Act and 10 CFR 50.100 to take enforcement action for any violation of the COL, FSAR, or any other regulations, including the suspension or revocation of the COL if necessary. Further, any member of the public may raise a question concerning a licensee's proper implementation of its commitments in the FSAR, its technical specifications, or its compliance with NRC regulations through the 10 CFR 2.206 process. Although the 10 CFR 2.206 process will not necessarily result in a hearing as might otherwise be obtained under 10 CFR 52.103, neither must an individual or organization raising an issue satisfy the very strict criteria established in 10 CFR 52.103 for their issue to be considered by the Commission.

### Additional Policy Considerations

In making its policy decision regarding the appropriate interpretation of the Atomic Energy Act, the Energy Policy Act, and the underlying Congressional intent regarding whether programmatic ITAAC are to be developed, a separate issue appropriate for Commission consideration is whether programmatic ITAAC will lend themselves to objective determinations which are critical to achieving the goal of Part 52 to have a predictable and stable licensing process. As stated in the Statements of Consideration accompanying the 1989 final Part 52 rule, the Commission stated that it did not believe that "every finding the Commission must make before operation begins under a combined license will necessarily always be based on wholly self-implementing acceptance criteria." Indeed, the Commission postulated that "trying to assure that the test, inspections and related acceptance criteria in the combined license are wholly self-implementing may well only succeed in introducing inordinate delays into the hearing on the application for a combined license."

It also deserves emphasis that the U.S. Senate Energy and Natural Resources Committee Report associated with the passage of the Energy Policy Act of 1992 stated that ITAAC should "provide NRC regulators *objective* safety standards (i.e., acceptance criteria) with which to measure the constructed plant in deciding whether the plant is safe to operate." (emphasis added). Given the time and effort required to develop objective, mutually acceptable ITAAC for the design certification rules, and notwithstanding the best efforts by both the NRC staff and the industry, implementation of programmatic ITAAC and the development of objective acceptance criteria may be very difficult and time consuming to achieve. And doing so without undermining the overarching goal of a predictable and stable licensing process may be impossible.

## Conclusion

The Energy Policy Act, its legislative history, and indeed the Commission's own statements of intent, support an interpretation that programmatic ITAAC are not necessary for the Commission to be able to make the findings required under Part 52 for both issuance of the COL and authorization of operation under 10 CFR 52.103. Indeed, the fundamental principle underlying Part 52 was to establish a predictable process with as many issues resolved as possible at the COL application stage and with as few issues remaining as possible when construction is complete and operation is ready to begin. It is not the one-time verification of ITAAC on operational programs that will provide the NRC with reasonable assurance that the facility will be operated as licensed. The inclusion of programmatic ITAAC would be little more than a checklist of program elements and thus would do little in verifying a licensee's ongoing ability to implement such program elements. Rather, it is continued compliance with operational program requirements and the ongoing NRC oversight of licensee performance that provides this reasonable assurance. The goal is to make it possible to resolve safety and environmental issues before plants are built, rather than after, thus eliminating the unpredictability and instability that is emblematic of the Part 50 licensing process.

The interpretation advocated in this paper of the ITAAC provisions of Part 52 is as valid, if not more so, as that put forward by the NRC staff, and only this "hardware-focused" interpretation promotes the workability and efficiency of the new licensing process and avoids burdening licensees and the already complex ITAAC process with unnecessary additional requirements. Accordingly, the Commission should support an interpretation of the Atomic Energy Act, and the NRC's implementing regulations, consistent with ITAAC being developed and implemented for the sole purpose of verifying that the facility design, as approved by the Commission and incorporated in the COL, was properly constructed.

## Operational Programs

- § Emergency Plan (10 CFR 50.54(q), 10 CFR 50.47, 10 CFR 50 Appendix E)
- § Security Plan (10 CFR 50.54 (p), 10 CFR 73 Appendix C)
- § Quality Assurance Program (10 CFR 50.54(a), 10 CFR 50 Appendix B)
- § Fire Protection Program (10 CFR 50.48, 10 CFR 50 Appendix R)
- § Radiation Protection Program (10 CFR 20, 10 CFR 50 Appendix I)
- § Access Authorization Program (10 CFR 73.56)
- § Fitness for Duty Program (10 CFR 26)
- § Training Program (10 CFR 50.120)
- § Licensed Operator Program (10 CFR 50.54 (h) thru (m), 10 CFR 55)
- § Reportability Program (10 CFR 21, 10 CFR 50.72 & 50.73)
- § ISI /IST program (10 CFR 50.55a (f) and (g))
- § Maintenance Rule Program (10 CFR 50.65)
- § Containment Leak Rate Test Program (10 CFR 50.54(o), 10 CFR 50 Appendix J)
- § Equipment Qualification Program (10 CFR 50.49)