

September 11, 2002

COMMISSION VOTING RECORD

DECISION ITEM: SECY-02-0067

TITLE: INSPECTIONS, TESTS, ANALYSES, AND  
ACCEPTANCE CRITERIA (ITAAC) FOR  
OPERATIONAL PROGRAMS (PROGRAMMATIC  
ITAAC)

The Commission (with Commissioners Dicus and Merrifield agreeing; Chairman Meserve and Commissioner Diaz agreeing in part and disagreeing in part; and Commissioner McGaffigan disagreeing) acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of September 11, 2002.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

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Annette L. Vietti-Cook  
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve  
Commissioner Dicus  
Commissioner Diaz  
Commissioner McGaffigan  
OGC  
EDO  
PDR

VOTING SUMMARY - SECY-02-0067

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X	X				7/22/02
COMR. DICUS	X					5/24/02
COMR. DIAZ	X	X				6/27/02
COMR. McGAFFIGAN		X				7/30/02
COMR. MERRIFIELD	X					8/15/02

COMMENT RESOLUTION

In their vote sheets, Commissioners Dicus and Merrifield approved; Chairman Meserve and Commissioner Diaz approved in part and disapproved in part; and Commissioner McGaffigan disapproved the staff's recommendation. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on September 11, 2002.

## Commissioner Comments on SECY-02-0067

### Chairman Meserve

SECY-02-0067 presents a question concerning inspections, tests, analyses and acceptance criteria (ITAAC) in the application of Part 52 of our regulations. The revised licensing framework established by Part 52 allows the issuance of combined licenses (COLs) to authorize both the construction and operation of a power reactor. Through the application of ITAAC, the NRC determines whether fuel loading of the completed reactor may occur. 10 C.F.R. § 52.103. Because the COL is issued before construction, there is an obvious need to verify through ITAAC that construction has been accomplished properly. The relevant regulatory provision governing ITAAC provides:

The Commission shall identify within the combined license 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, the provisions of the Atomic Energy Act, and the Commission's rules and regulations.

10 C.F.R. § 52.97(b)(1). The issue that is presented for Commission review relates to the scope of the ITAAC -- namely, whether the ITAAC may encompass operational programs.

Staff argues that the ITAAC could cover a wide range of operational programs, suggesting the ITAAC might encompass emergency planning, quality assurance, radiation protection, fitness for duty, operator licensing, containment leak rate tests, inservice inspection and testing, physical security, fire protection, access authorization, training, reportability, and equipment qualification. SECY-02-0067, Att. 1 at 13. Industry representatives, by contrast, assert that such programmatic ITAAC should not be included at all, but rather that ITAAC should be limited to construction issues (other than emergency planning).<sup>1</sup>

The issue has provoked extensive comment and concern.<sup>2</sup> The reason derives from the

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<sup>1</sup> Section 185b. of the Atomic Energy Act explicitly provides that ITAAC should encompass emergency planning. This reference to emergency planning presumably relates to Congressional concern with emergency planning at Shoreham and Seabrook at the time of enactment. See, e.g., 138 Cong. Rec. S1142, 1153 (daily ed. Feb. 6, 1992). Thus, the precise issue presented to the Commission is whether ITAAC should encompass programs other than emergency planning.

<sup>2</sup> In response to a Federal Register notice seeking comment on the need for and scope of programmatic ITAAC, the staff received 13 comment letters -- 10 from industry, 2 from the Illinois Department of Nuclear Safety, and 1 from a public interest group. See SECY-02-0067, at 3. The Commission has received subsequent letters from the Nuclear Energy Institute, and others. See e.g. Letter to R.A. Meserve from M. C. Kray, Exelon (June 3, 2002); Letter to R.A. Meserve from E.S. Grecheck, Dominion (May 30, 2002); Letter to R.A. Meserve from K. Hughley, Entergy (May 24, 2002); Letter to R.A. Meserve from M. S. Fertel, Nuclear Energy Institute (May

important role of ITAAC in the regulatory scheme. One of the primary purposes of the Part 52 was to provide early resolution of issues, with the aim that the bulk of the issues should be resolved at the hearing on the issuance of a COL. But not all issues may be resolvable at that time. Most obviously, issues relating to whether the facility has been constructed in accordance with the licensed design can only be resolved during and after construction. Part 52 ties any post-construction hearing to the ITAAC; it provides the opportunity for a hearing, under certain circumstances, only if one or more of the acceptance criteria have not been met. 10 C.F.R. § 52.103(b). Thus, if the ITAAC are broad, the opportunity for a hearing, with possible resultant delay or denial of operation, is expanded. In addition, programmatic ITAAC may be seen to be particularly problematic in this respect because of concern that the acceptance criteria for programs may be more subjective than those relating to construction, opening the opportunity for more dispute as to whether the acceptance criteria have been adequately satisfied. Accordingly, licensees understandably seek to narrow the scope of the ITAAC in order to minimize the risk attendant to disputes over satisfaction of the ITAAC.<sup>3</sup>

The determination of the appropriate scope of the ITAAC requires a careful examination of the legislative and regulatory history surrounding the provision. Staff argues that programmatic ITAAC are envisioned by section 185b. of the Atomic Energy Act. The section provides:

After holding a public hearing under section 189a.(1)(A), the Commission shall issue to the applicant a combined construction and operating license if the application contains sufficient information to support the issuance of a combined license and the Commission determines that there is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of this Act, and the Commission's rules and regulations. The Commission shall identify within the combined license 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, the provisions of this Act, and the Commission's rules and regulations.

42 U.S.C. § 2235b. Staff points to the second sentence in arguing that the acceptance criteria should demonstrate not only that the facility "has been constructed," but also that it "will be operated" in conformity with the license, the provisions of the Act, and the Commission's rules and regulations. Thus, in the staff's view, the inclusion of operational programs in the ITAAC is clearly contemplated by the statute.

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13, 2002). The matter was also discussed at the Commission meeting on May 29, 2002.

<sup>3</sup> The scope of the ITAAC also affects the relationship between the staff and the licensee. Because at the time of the verification of acceptance criteria a licensee is under considerably financial pressure to commence operation, the staff has significant leverage through ITAAC in bringing about modification of licensee programs. At this point the licensee bears the burden of demonstrating compliance with the acceptance criteria. See 10 C.F.R. § 52.97. By contrast, if the staff must exercise its enforcement authority to ensure that various programs are adequate, the burden is on the staff to demonstrate that such action is necessary. See 10 C.F.R. § 2.732.

In my view, however, the statutory provision does not serve to resolve the issue that is before the Commission. As shown by the first sentence, section 185b. envisions that the standard to govern the issuance of a COL is a requirement that “the facility will be constructed and will operate in conformity with the license, the provisions of this Act, and the Commission’s rules and regulations.” The reference to construction and operations in the second sentence governing the acceptance criteria is simply a repetition of the overall standard that must be satisfied through the licensing process; that is, the cumulative effect of the COL and the ITAAC should serve to provide the necessary assurance of full conformity to legal standards. Viewed in this light, the second sentence does not necessarily by itself define the scope of the ITAAC. Indeed, the logic of the staff’s argument might lead to the conclusion that the ITAAC must encompass everything that bears on providing reasonable assurance that construction and operations are in conformity with the license, the Act, and the Commission’s regulations. This arguably could encompass the NRC’s entire regulatory program. But, as will be seen, the ITAAC were clearly intended to be very limited. I thus conclude that the Commission is not subject to a legal constraint that would bar the narrowing of ITAAC in ways that the Commission believes are appropriate, so long as the narrowing nonetheless ensures that the licensing process as a whole provides the necessary assurance of conformity with the license, the provisions of the Act, and the Commission’s rules and regulations.

An examination of the history surrounding the promulgation of Part 52 and the subsequent Congressional actions in the Energy Policy Act of 1992 is helpful in revealing the scope of the ITAAC. As noted above, the ITAAC are intimately related to the right to a hearing and thus the Commission’s observations with respect to hearings are illuminating with respect to the intended scope of ITAAC. In promulgating Part 52, the Commission observed that the “simple aim” of the rulemaking was “for the standardization of nuclear power plants and more generally the early resolution of safety and environmental issues in licensing proceedings.” 54 Fed. Reg. 15372, 15373 (1989). The Commission explained that its intent was to “make it possible to resolve safety and environmental issues before plants are built, rather than after.” Id.

The Commission thus addressed the question of whether there should be any hearings at all after construction. DOE had argued that the Commission should rely on an exception to the requirement for a hearing in the Administrative Procedure Act for an agency decision that rests “solely on inspections, tests, or elections.” 5 U.S.C. §554(a)(3); see 54 Fed. Reg. at 15380. The Commission rejected this argument because “not every finding that the Commission must make before operations begins under a combined licensee will necessarily always be based on wholly self-implementing acceptance criteria and therefore encompassed within the APA exception.” Id. But the Commission stated that it had the intention through the rule to “adopt[ ] an approach within the bounds of our legal authority which sets reasonable limits on any post-construction hearing.” Id.

The Commission then provided some revealing guidance on the scope of any post-construction hearing:

[U]nder section 185 of the Atomic Energy Act, the Commission must find, prior to facility operation, that the facility has been constructed and will operate in conformity with the application and the rules and regulations of the Commission. This statutory finding, in the context of Subpart C of this rule, translates into two separate but related regulatory findings: that compliance with the acceptance criteria in the combined license will provide reasonable assurance that the facility has been constructed and will operate in

accordance with the Commission's requirements, and that the acceptance criteria have in fact been satisfied. The former finding will be made prior to issuance of the combined license, and will necessarily be the subject of any combined license hearing under section 189a of the Act.

Id. On the specific subject of a post-construction hearing, the Commission stated:

The latter finding [i.e., conformance with the acceptance criteria] cannot by its nature be made until later, after construction is substantially complete, and therefore cannot by its nature be the subject of any hearing prior to issuance of the combined license. Thus, to the extent that an opportunity for hearing should be afforded prior to operation, it should be confined to the single issue that cannot have been litigated earlier -- whether the acceptance criteria are satisfied.

Id. (emphasis added). Thus, the Commission clearly intended to limit post-construction hearings, and by implication ITAAC, to those matters that by their nature could not be resolved until after construction.

Other observations by the Commission reinforce the conclusion that any post-construction hearing, and thus the ITAAC, should be narrowly confined. The Commission observed:

There have to be substantial limits on the issues that can be raised after construction. A licensing proceeding without any uncertainty in result may be a sham, but the bulk of the uncertainty should be addressed and resolved prior to, not after construction. Part 52 does not remove uncertainty, it simply reallocates it to the beginning of the licensing process.

Id. at 15381.

The subsequent history reinforces the point. The rule was reviewed by the D.C. Circuit, which initially concluded that the Commission had exceeded its authority in restricting post-construction hearings.<sup>4</sup> Nuclear Information and Resource Service v. NRC, 918 F.2d 189, 190 (D.C. Cir. 1990). The court subsequently reviewed the matter en banc and its ruling clearly shows the court's understanding that the intended scope of any such hearings was to be extraordinarily narrow. In describing the scope of a post-construction hearing, the court observed:

After construction is complete, the Commission -- having approved the design and site, and having approved the match between the design and site -- treats every licensing issue as finally resolved, save whether the plant as actually built meets the specifications established by the acceptance criteria. . . . Part 52's post-construction procedures limit the NRC's role to determining whether the plant was constructed as its license required; it is not to revisit issues settled at prior stages in the regulatory process, but to rely on the hearings held and findings made at those stages.

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<sup>4</sup> Specifically, the court found that the hearing requirement was not satisfied by requiring an interested party to file a petition under 10 C.F.R. § 2.206 if it were to seek to modify the terms and conditions of the COL. 918 F.2d at 194-96.

Nuclear Information Resource Service v. NRC, 969 F.2d 1169, 1172 (D.C. Cir. 1992)(emphasis added). The court found that this narrowing did not violate the law.

In the interval before the en banc ruling, Congress initiated action to provide an unambiguous statutory foundation for the Commission's action in promulgating Part 52, ultimately enacting section 185b., quoted above. The relevant Senate Report described the statutory purpose as follows:

The Committee believes that requiring resolution of all important safety issues and establishing the licensing criteria against which the plant will be judged in the combined license before construction begins will have several major benefits. First, it will enhance public participation by airing all safety issues first, before the license is issued and the plant is built . . . . Second it will 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. No longer will the rules be made up after the game is played. Finally, it will provide the NRC regulators objective safety standards with which to measure the constructed plant in deciding whether the plant is safe to operate.

S. Rep. No. 102-72, 102d Cong., 1st Sess. 293 (1991) (Committee Report).<sup>5</sup> Achieving the purpose sought by Congress would argue for sharply confining ITAAC, thereby eliminating the uncertainty that would attend broad post-construction hearings.

I conclude from a review of the regulatory and legislative history that the ITAAC were intended to be very narrow. They should encompass only those matters that, by their nature, cannot be resolved prior to construction. As a result, I conclude that the ITAAC should not sweep so broadly as the staff has proposed. In fact, it appears that most of the operational areas in which the staff has proposed ITAAC are ones that can and should be resolved at the time of the issuance of the COL. If ITAAC were to encompass a wide spectrum of operational programs, the whole purpose of Part 52 would be substantially undermined.

On the other hand, the history does not unambiguously support the position of licensees that ITAAC must necessarily be confined to the verification that construction conforms to the design (and emergency planning). The history shows that ITAAC should be limited to matters that cannot be verified until after construction, not that a sharp distinction must be drawn between hardware and programmatic topics. Although I would expect that most ITAAC would relate to verification that construction conforms to the approved design, I cannot foreclose the possibility that there may be some operational programs that are so intimately connected with construction that ITAAC are necessary. For example, the resolution of adequacy of security programs might depend on review of the plant as constructed so as to ensure that any vulnerabilities have been appropriately addressed and resolved. The fire protection program might also require a post-construction ITAAC. Because the NRC has yet to have any experience in the actual application of ITAAC, I am not yet prepared to dismiss the possibility that programmatic ITAAC may be necessary in some very limited areas. The issue of the scope of ITAAC should be revisited after the staff has had some experience with them. In the interim, consistent with the underlying

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<sup>5</sup> Because the Senate intended to provide a statutory foundation for Part 52 as promulgated by the Commission, the regulatory history surrounding of Part 52 illuminates the Congressional purpose in enacting Section 185b. Id. at 291-92.

purpose of Part 52, applicants and staff should seek to limit any programmatic ITAAC.

There are two final points that bear emphasis. First, my conclusion that ITAAC should be narrowly confined is not intended in any fashion to prevent a full public hearing on material issues. Rather, it is my expectation that there will be an opportunity for a hearing on all such matters, but that such a hearing should occur at the COL stage, except for limited matters that cannot by their nature be resolved then. See Nuclear Information and Resource Service v. NRC, 969 F.2d at 1174 (“Under Part 52, parties are uncontestably permitted their day in court on every material issues at some point in the licensing process.”). This places a burden on the applicants and the staff to ensure that the application provides the necessary detail to enable the resolution of nearly all issues at the COL hearing.

Second, the fact that ITAAC are limited does not in any fashion constrain the staff’s right and obligation through its inspection and enforcement program to ensure both during construction and thereafter that the facility provides adequate protection of the public health and safety and the environment. If there are issues that are detected by the staff after the COL is issued that are not covered by ITAAC, the staff has full power to ensure that those issues are appropriately addressed.<sup>6</sup>

#### Commissioner Dicus

In supporting the staff’s position that there can be programmatic ITAACs, I offer the following comments to clarify what I believe are the implications of that position and the proper framework for considering what specific programmatic ITAACs are necessary in individual situations.

When moving from a two stage licensing process to a single stage licensing process, one of the overall goals of the Commission was to provide predictability so that licensee’s would have assurance that, if they built a facility as specified in the license and set up operations in accordance with the license, they would be able to operate the facility. By the same token, intervenors had expressed concerns with underlying pressures to grant an operating license to a facility after many millions of dollars had been spent on construction. Through the single stage licensing process it was expected that intervenors who had concerns about basic issues (i.e. is effective emergency planning possible at the proposed site) would not face the prospect of having to litigate such issues after the licensee had constructed the facility. Nowhere did the Commission state that the intention was to render immune to public hearings those issues that, in the traditional two-stage licensing process, were previously subject to public scrutiny and requests for

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<sup>6</sup> The staff has asserted that under section 52.103(g) the Commission’s ability to prohibit fuel load after construction is completely tied to ITAAC. SECY-02-0067, Att. 1 at 7,9. But Section 52.103(g) does not by its terms impose any constraint on enforcement powers. Indeed, Congress clearly contemplated that the Commission’s broad enforcement authority would be unaffected by the new process. Committee Report at 294. Thus, if the staff finds through inspections that the licensee’s programs do not provide adequate protection of public health and safety, the staff should take appropriate enforcement action to prohibit or delay fuel load pending appropriate corrective action. It is appropriate to note in this connection that the industry concedes that the staff retains this power. Letter to R. A. Meserve from M. S. Fertel, Nuclear Energy Institute, Att. 1 at 7 (May 13, 2002).

a hearing. Rather, the intent was to have hearings on and resolve such issues, to the maximum extent possible, earlier in the process before issuance of the COL. Further, the development of ITAACs, and resolution of their acceptability through the COL hearing process, was designed to minimize the likelihood of hearings just prior to operations on issues where final acceptability will not be determined until a time closer to the NRC's determination on whether to authorize operations. While some may want to point to comments of Commissioners that may or may not have been focused on this tie to traditional operating license hearing issues, the Statement of Considerations for the original adoption of Part 52, as approved by the Commission, could not have been clearer. There the Commission stated:

...the Commission has stuck to the simple aim in this rulemaking of providing procedures for the standardization of nuclear power plants and more generally for the early resolution of safety and environmental issues in licensing proceedings...

... The Commission's intent with this rulemaking is only to have a sensible and stable procedural framework in place for the consideration of future designs, and to make it possible to resolve safety and environmental issues before plants are built rather than after...

...The rule does not prevent the public from **participating in the resolution of any operating license issue**. It simply moves **the bulk of the issues** up front in the licensing process to the ...combined license part of the process.

54 FR 15372 (4/18/89) (emphasis added)

Two things are obvious from these statements. First, interested members of the public were not supposed to be denied the opportunity to address the same issues that had historically been address in operating licensing hearings. Thus, operational issues would be considered. More importantly, the comment that "the bulk of the issues" would be dealt with up front clearly demonstrates that all issues related to traditional operating licenses would not be resolved prior to the COL issuance. There would be some issues on which the public had participated in the operating license phase of the traditional two stage reactor licensing process that, under Part 52, would not be resolved until after construction. It was recognized that at the pre-construction stage it was unlikely that as much detail would be available concerning construction and operations as was traditionally available for operating license reviews and hearings. Here is where the concept of ITAACs enters the picture. It was intended that ITAACs provide, to the extent practicable, objective criteria for judging the acceptability of construction and the readiness for operations. Hearings were still possible prior to operation concerning compliance with the ITAACs, but the more objective the ITAAC the less likely there would be any dispute over whether the ITAAC was met. It was well recognized from the beginning, however, that all issues might not be resolved at the COL stage to a level that would eliminate post construction hearings under the Administrative Procedures Act (APA) exemption for agency decisions based solely on "inspections, tests, or elections". The Commission stated in adopting Part 52:

...However, not every finding the Commission must make before operation begins under a combined license will necessarily always

be based on wholly self-implementing acceptance criteria and, therefore, encompassed in the APA exception...Indeed, trying to assure that tests, inspections and related acceptance criteria in the combined license are wholly self-implementing may well only succeed in introducing inordinate delay into the hearing on the application for the combined license...

...A licensing proceeding without any uncertainty in result may be a sham, but the bulk of uncertainty should be addressed and resolved prior to, not after, construction.

The final rule makes issues of conformity with the terms of the combined license part of any post-construction hearing, unless those issues are excepted from adjudication by the APA exception for findings based solely on the results of tests and inspections.

54 FR 15372 (4/18/89)

With that understanding one can readily see that the purpose of ITAACs is most closely related to the generic question “What actions are so fundamental to finding that the plant was built and will operate safely that the NRC must verify the licensee has appropriately completed those actions **before** operations can be authorized by the NRC?” Since ITAACs are the method chosen in Part 52 by which the Commission can measure whether the plant “has been constructed and will operate in conformity with the combined license, the provisions of the Atomic Energy Act, and the NRC’s regulations”, the ITAACs, by definition, relate to verifications and findings that must be made prior to operation and not to the ongoing license and regulatory requirements that will be subject to the inspection and enforcement program throughout the life of the facility. The Commission’s explanations in adopting Part 52 never focused on a dichotomy between construction issues and operational issues. The focus was always on issues generally being resolved as early as possible, while recognizing there would be issues that could not be resolved prior to issuance of the COL.

The above framework does not mean that every aspect of an operational program will be in an ITAAC. Thus, for example, there may be an ITAAC concerning verification of completion of an emergency planning exercise prior to operation along with examination of any changes made to the plan as a result of the exercise, but there will also be continuing regulatory requirements (in the license or in the regulations) that call for ongoing emergency planning exercises. The successful completion of the ITAAC-related exercise may be subject to pre-operational verification and, potentially, a hearing. The continuing obligation for periodic exercises and maintaining emergency preparedness will be subject to verification throughout the life of the facility through the inspection and enforcement program. As can be seen, some aspects of operational programs will have an ITAAC, while other aspects do not. Additionally, there may be some areas concerning compliance with regulatory requirements where it appears there is complete agreement between the staff and licensees (and where no ITAAC is developed), that become areas where the staff subsequently finds, prior to operations, that the license is not in compliance with the regulations or its license conditions. As will be discussed below, NRC’s enforcement regime is robust enough and flexible enough to address these situations.

As can be seen in the portions of the Statements of Consideration quoted above, it was always

recognized that some ITAACs would be more objective than others. It may well be there are programs and operational details that cannot be developed prior to issuance of the COL, or for which the expense of developing the detailed program is viewed as prohibitive by licensees. In those instances the ITAACs developed may be more subjective than, for example, those related to specific construction criteria. If the staff finds such a general, subjective ITAAC unacceptable it can ask for alternative, more specific and/or objective criteria. By the same token intervenors can, assuming they meet the criteria for requesting and admission to a hearing, also challenge the sufficiency of the proposed ITAAC. On the other hand, the licensee which proposes a more subjective ITAAC may have increased risk of a hearing being granted related to compliance with the ITAAC prior to authorization of operations.

As the Commission noted in adopting Part 52, a licensee may not be able to provide sufficient self-implementing criteria for every aspect of NRC's requirements to avoid a second hearing under the APA exception. The licensee can balance costs and difficulties in developing more objective ITAACs against the costs and difficulties of addressing such issues later in the process. A key point, however, is that absent significant new information there will only be one hearing on a given issue. Intervenors, staff, and the licensee are all bound by the decision at the COL stage that the ITAACs are the acceptable standards for determining the adequacy of construction and the readiness for operations. Whether those standards are objective or subjective, only questions of compliance, not the adequacy of the standards, are subject to challenge after the plant is built. This protection of previously reviewed acceptance criteria is what achieves the predictability that was one of the Commission's stated goals in adopting Part 52.

No system is perfect, but the COL system was designed to ensure that issues and concerns about building and operating nuclear power plants could be addressed in a manner that did not waste the resources of the staff, the public, the intervenors and the licensee. Opportunities were included in the system for input from all concerned as to what would be looked at before the COL was issued and what could or must await verification closer to operations. While some have proposed that all programmatic ITAACs are unnecessary because the inspection and enforcement process can address such issues by relying on regulatory requirements instead of ITAACs, such a position overstates the case and ignores the fact that findings on the adequacy of certain programs must be made before the plant is authorized to operate. While many aspects of an operational program are of a continuing nature subject to inspection and enforcement (and should appear, therefore, as a requirement somewhere other than an ITAAC), other aspects of an operational program do require verification prior to authorizing operations and would be appropriate for an ITAAC. The error in the underlying argument is the implicit belief that the acceptability of programmatic ITAACs is an all or nothing proposition. Thus, we return to the question I posed earlier as the correct focus for ITAACs. Whether it is construction related, design related, programmatic, or related to any other regulatory requirement, the correct question to ask is "What actions are so fundamental to finding that the plant was built and will operate safely that the NRC must verify the licensee has appropriately completed those actions **before** operations can be authorized by the NRC?" The ITAACs may vary in objectivity and detail, but the question of what ITAACs are needed starts with this question.

Finally, I turn to the question of issues arising prior to operations for which there is no ITAAC. These may arise because the staff did not believe the requirement in question was significant enough to require verification before operations are authorized or when a disagreement in interpretation of a requirement develops after the COL is issued. It has been said by some that the staff may not be able to deny authorization to operate if the ITAACs are all met. One should

not, however, confuse NRC authorization to operate a power plant in accordance with its license with a finding that the licensee is necessarily in compliance with every regulatory requirement of that license. ITAACs relate to those issues significant enough that the staff can not make a finding that the plant was built and will operate in accordance with the COL. If staff determines prior to operations that a licensee will not be in compliance with a regulation or a portion of the license that was not significant enough to be included in an ITAAC, the normal enforcement process still applies. As with any violation, the NRC staff will have to determine if the violation is so significant that an immediately effective order is necessary to protect public health and safety, but the entire spectrum of enforcement actions from civil penalties to notices of violation will be available to the NRC. Members of the public, through the 2.206 process, are also able to recommend that the NRC staff exercise enforcement action related to such non-compliances. Clearly, when a licensee has advance notice that they will be in immediate violation of a requirement if they commence operations, they run the risk of having a violation characterized as willful and subject to escalated enforcement action, absent agreement with the staff on corrective actions and the exercise of enforcement discretion if those corrective actions will not be completed prior to commencement of operations. It is unrealistic to believe that any late emerging issues of COL compliance that have safety significance cannot be addressed through the enforcement process, for if the enforcement process is not capable of addressing such emerging issues we raise a question as to the fundamental soundness of our entire licensing regime.

#### Commissioner Diaz

In my vote on SECY-00-0092, Combined License Review Process, I questioned the advisability of interjecting the subjectivity of "programmatic" ITAAC into the COL process at that time. I also indicated that having the ITAAC include "programmatic" activities was contrary to the understanding of ITAAC to which the Commission agreed in the late 1980's, i.e., that ITAAC would apply only to "hardware." Commission intent in the late 1980's is the subject of differing interpretations, and now, the assertion that programmatic ITAAC are precluded as a matter of law is not easily sustained in light of recent analysis by the Office of the General Counsel.

In SECY-02-0067, the staff recommended that COL applicants contain ITAAC for operational programs required by regulations, for example training (programmatic ITAAC). I believe that requiring ITAAC for "operational programs required by regulations" goes beyond the language and intent of the regulations and the law. I can envision a licensee providing sufficient information regarding a training program, and indeed almost all programs, in the application such that an ITAAC for the program is not necessary. Therefore, I disapprove the staff's recommendation that COL applications must contain ITAAC for operational programs required by regulations.

A key question now is what will be considered sufficient in the application, apart from ITAAC, and what approach will be applied to determining when ITAAC are still required. The staff states that "ITAAC are needed to verify implementation matters that could not be fully resolved prior to issuance of a COL." Insofar as this approach contemplates or permits ITAAC for the verification of all matters of implementation and compliance with regulations, this is an expansion that I believe goes well beyond the content of the rule and the law. ITAAC are not intended to be an inspection check list or a check list of all items in the license, the Atomic Energy Act of 1954, and the Commission's regulations. It is not necessary, in my view, for programs to be implemented before this necessary and sufficient determination can be made, particularly if the applicant demonstrates that it has successfully implemented the programs at NRC-licensed facilities. Although the NRC

inspection process does not replace a particular ITAAC, an ITAAC for a program should not be necessary if the program is fully described in the application, found to be acceptable by the NRC at the COL stage, and implementation is covered by the NRC inspection program or other appropriate mechanisms.

The burden is on the applicant to provide the necessary and sufficient programmatic information for approval of the COL without ITAAC, or the necessary and sufficient ITAAC. In short, there is no substitute for quality, completeness and thoroughness in the application; these characteristics are requisite to the application, not voluntary.

It is in the best interest of all parties that necessary and sufficient programmatic information be provided in the application, minimizing the need for ITAAC and permitting resolution of programmatic issues as part of the COL decision. Thus, the staff should work to bring added predictability to the process by developing the appropriate guidelines, with Commission approval of the final product, that will support the submission of necessary and sufficient information on programs in applications and clarify when programs beyond emergency planning, if any, require or are likely to require ITAAC in the combined license application. The current staff paper provides little but the most general indication of how the staff will determine when ITAAC are necessary, although it provides a long list of programs under consideration. The staff has indicated that it would work with stakeholders to develop COL ITAAC that are as objective as possible. However, this is not the first step (with the exception of emergency planning). First, as it has done in many other areas, the staff should be available to meet with stakeholders as it develops more specific guidance on what information is necessary and sufficient in the application such that an ITAAC for that program would not be necessary.

Moreover, at least for the first few COLs that the Commission receives, the Commission should approve the requirement of any specific programmatic ITAAC. It may be, however, that the decision to require the use of programmatic ITAAC may remain so important or be so particularized that the Commission should continue this involvement in all COL applications as long as needed.

This approach would enhance the early resolution of programmatic issues (I believe in most cases without an ITAAC) and should result in a stable, predictable, and timely process for reviewing these applications with full public participation.

#### Commissioner McGaffigan

In my August 2000 vote on SECY-00-0092, Combined License Review Process, I espoused the position that the words of the statute, specifically, the words “. . . necessary and sufficient to provide adequate assurance . . .” [emphasis added], required that ITAAC must comprehensively cover both hardware and programmatic issues. However, upon further consideration, and in light of the Chairman’s compelling analysis, I now fully agree with the conclusion that there is no legal requirement for programmatic ITAAC except for the explicit statutory requirement regarding emergency planning. Indeed, I am more skeptical than the Chairman about the possibility that programmatic ITAAC directly related to construction may prove necessary in any specific case. In the two examples the Chairman cites, where there might conceivably be a need for post-construction programmatic ITAAC, fire protection and security, there will be ongoing programs to inspect before start-up which can be subjected to our normal oversight process. If the items in

these two areas are truly construction related (e.g., are the right sprinklers where they are supposed to be, are the defensive positions of the armed responders constructed as designed?), then they would lend themselves to a hardware ITAAC. Therefore, I would currently oppose any programmatic ITAAC outside of emergency planning.

We must not lose sight that a key difference between the two-step licensing process of Part 50 and Combined Operating License (COL) process of Part 52 is that the COL holder already has an operating license when it approaches readiness to load fuel, achieve initial criticality, and begin power operations. The Chairman notes the implications of this difference in the third footnote of his vote on SECY-02-0067. Historically, construction permit holders had the burden of proof when it came to demonstrating readiness for an operating license. However, the Chairman points out that for OL holders, "if the staff must exercise its enforcement authority to ensure that various programs are adequate, the burden is on the staff to demonstrate that such action is necessary." I would add that the cost-benefit requirements of the backfit rule (10 CFR 50.109) place a very similar burden of proof on the staff with respect to mandating changes to operating plants. Nonetheless, the NRC has successfully exercised its enforcement authority (e.g., Orders) and also imposed backfits when warranted.

The NRC has extensive inspection programs and significant experience in using them to determine that a reactor can operate with reasonable assurance of adequate protection to public health and safety. Indeed, a significant fraction of the NRC budget is devoted to the inspection, oversight, and regulation of operating reactors, and this includes resident inspectors who live near the sites and whose only job is to assure the day-to-day safe operation of their assigned facility. These processes have worked well historically, work well today, and should work well for COL facilities approaching initial operation without being supplemented by any programmatic ITAAC. Moreover, since the first COLs are expected to be for reactors proposed by current licensees using programs already in place at existing, co-located facilities, the staff will already have inspected all the licensee programs listed on page 13 of Attachment 1 to this SECY.

Should a majority of the Commission allow the staff to propose specific programmatic ITAACs on programs beyond emergency planning, I would recommend that the staff should be required to specify to the Commission which ITAACs they would propose for an existing licensee at an existing site by December 1, 2003. The Commission could then decide whether to support such ITAACs. We must clarify this matter as soon as possible; to do otherwise would fail to fulfill the legislative intent to provide clarity and certainty to the licensing process, so that licensees can make informed decisions about seeking a COL.

#### Commissioner Merrifield

I approve the premise underlying the staff's paper on programmatic ITAAC, which is that neither the Atomic Energy Act nor our regulations preclude, as a matter of law, the inclusion of programmatic ITAAC in Combined Operating Licenses. Even an industry commenter concedes that a permissible reading of the AEA is to permit the inclusion of programmatic ITAAC. Moreover, while this commenter is correct that most programmatic issues can be resolved at the COL stage, it is unclear at this time that all programmatic issues can be fully resolved prior to beginning construction of the facility. Therefore, I am unwilling at this time, to preclude as a matter of law or policy, the staff from considering programmatic ITAAC.

However, my approval is conditioned on a majority of the Commission agreeing that the staff revise the present paper to conclude that ITAAC are only permitted for those programmatic issues that are material to licensing and cannot be resolved until construction of the facility begins. The commenter argues that the legislative history and wording of the statute are most comfortably read to focus ITAAC on issues related to construction of the facility. According to that reading, any ITAAC must be closely linked to construction of the facility. However, even this interpretation, with its focus on construction, does not necessarily preclude programmatic ITAAC because there may be programmatic issues for which resolution depends on construction of the facility. I must admit that I can not identify a specific example of where a programmatic issue will depend on information only available after construction begins. But, more importantly, I cannot definitively rule out all possibility that this could occur. If the latter circumstance arises, there must be a disciplined process to address it and unquestionably the ITAAC program was meant to be that disciplined process. Therefore, programmatic ITAAC should not be precluded altogether. However, they should be limited to matters that are material to licensing and that depend on construction. The staff should fully expect that this is a significant hurdle and meant to address an extremely narrow set of issues.

Two significant policy questions are raised by limiting programmatic ITAAC to matters that are material to licensing and for which resolution depends on construction of the facility. First, does such an interpretation deny the public a meaningful opportunity for a hearing and second, does it reduce the staff's ability to enforce programmatic regulatory requirements or license conditions? The answer to both questions, as discussed in more detail below, is that limiting the scope of ITAAC should enhance the hearing process, and should not interfere with the NRC's enforcement authority.

Ensuring that issues material to licensing that do not depend on construction are finally resolved at the COL stage will afford the public the best opportunity to influence the decision on whether to grant a license, and if granted, conditions of any license and proposed construction plans. In a recent licensing case, Hydro Resources, Inc., intervenors argued that holding piecemeal hearings years apart would prejudice their ability to challenge the license. Their clear preference was to acquire information and have an opportunity to challenge issues earlier in the licensing process. The Commission addressed this concern and agreed with the intervenors that certain financial information was required to be filed prior to licensing, even though operation was years off.<sup>7</sup> As the Commission stated in Hydro, "[a] sensible and efficient process requires us to insist that [certain] ... questions be addressed in connection with the initial application and license." Id. at 240.

To resolve issues early will require the applicant to submit detailed plans for its programs at the COL stage. This is entirely consistent with the AEA and our regulations. At the COL stage, the AEA requires applicants to submit adequate information to permit the Commission to finally determine reasonable assurance for most programmatic issues, without the need for ITAAC. Specifically, Part 52 requires the applicant to submit "all of the information required by 10 C.F.R. 50.33, as that section would apply to applicants for construction permits and operating licenses," (emphasis added), and AEA § 185(b) requires an application to "contain[] sufficient information to support issuance" of the COL and therefore, the reasonable assurance determination. The petitioner seems to understand this burden and has stated in a recent Commission meeting that

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<sup>7</sup> CLI-00-8, 51 NRC 227, 237-240 (2000).

providing such information is in the industry's best interest. The industry wants certainty, and the more issues that are resolved early, the more certainty the applicant will have that issues will not be raised later in the proceeding to delay operation. For a mature industry that has many examples of successful operating programs, requiring the applicant to supply detailed information at the COL stage for those matters that do not depend on construction, is reasonable.

For these reasons, I agree with Commissioner McGaffigan that in the end, ITAAC may not prove necessary. The industry could submit an application that is complete enough to allow all programmatic issues to be fully resolved at the construction stage. However, where the application is not complete, the inspection and enforcement process cannot take the place of an ITAAC. Commissioner McGaffigan asserts that in the two examples that the Chairman suggests, "where there might conceivably be a need for post-construction programmatic ITAAC, fire protection and security, there will be ongoing programs to inspect before start-up which can be subjected to our normal oversight process." I have no doubt that there will be adequate inspection processes. However, I am not as convinced as Commissioner McGaffigan that absolutely all programmatic issues material to licensing can be resolved prior to issuance of a COL.

Limiting programmatic ITAAC to matters that are material to licensing and depend on construction does not limit the NRC's enforcement authority. Section 185(b) states that "[t]he Commission shall identify within the combined license the inspection, 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, the provisions of this Act, and the Commission's rules and regulations." Read literally, that provision could be interpreted to mean that compliance with the acceptance criteria is sufficient to demonstrate compliance with the Act, rules and regulations. Under that interpretation, even if the licensee were out of compliance with a regulatory or licensing requirement not subject of an ITAAC, if the acceptance criteria were met, the NRC would have to authorize operation. This reading would lead the staff to require that any matter material to licensing be captured in an ITAAC, even if it is also the subject of a regulation or a license condition, because only failure to meet the acceptance criteria can be a reason to deny authorization. Under this literal interpretation, limiting programmatic ITAAC to only matters that depend on construction would be problematic for enforcement of all other material licensing requirements. However, the literal reading is inconsistent with our broad enforcement power to further our mission to protect health and safety and it is inconsistent with the purpose of Part 52, which was to offer a fair and efficient process for resolving as many issues as possible at the COL stage. For these reasons, that passage must be put in context.

The Commission has broad enforcement authority to ensure that licensees comply with the AEA, rules and regulations. Our enforcement authority should not be different for COL licensees, prior to authorization, than for any other licensees. Such a literal reading would suggest that the day after authorization of operation, the NRC could take whatever action it deems appropriate, including shutting down the plant, but the day before could not take that action unless it was directed at meeting the acceptance criteria. A better reading of the ITAAC provision is that it is intended to bring certainty to the authorization process by requiring the NRC to identify those licensing issues that remain open after issuance of the COL, that must be addressed prior to authorization and, as such, are the matters that are subject to an opportunity for a hearing. Under this interpretation, the section 185(b) ITAAC provision has everything to do with providing certainty in the licensing and hearing processes and nothing to do with our ability to enforce compliance with already resolved licensing issues.

Finally, the paper lists numerous programs for which staff will consider programmatic ITAAC. Keeping in mind that ITAAC should be considered for those programmatic issues that are material to licensing and depend on construction, it is unclear to me, even as a general matter, why some of these programs should be under consideration. For example, why would approval of the fitness for duty program depend on construction of the facility? The staff should reconsider this list taking into consideration whether program approval must await, rather than could await, construction of the facility. Although there has been much discussion about having only "objective" criteria in ITAAC, the staff has made it clear that this goal may prove illusory for some programmatic issues. Therefore, there must be discipline in the staff's process for requiring programmatic ITAAC, otherwise, I agree with the industry commenters that the process could completely undermine the main purpose of promulgating Part 52.

The staff should interact with our stakeholders to identify those issues that are material to the Commission making a reasonable assurance finding at the COL stage. This will give our stakeholders an indication of the detail that the Commission will require at the COL stage.