

POLICY ISSUE NOTATION VOTE

February 26, 2004

SECY-04-0032

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROGRAMMATIC INFORMATION NEEDED FOR APPROVAL OF A
COMBINED LICENSE WITHOUT INSPECTIONS, TESTS, ANALYSES AND
ACCEPTANCE CRITERIA

PURPOSE:

To request the Commission's approval of the attached staff proposal regarding the level of programmatic information needed for approval of a combined license (COL) without inspections, tests, analyses and acceptance criteria (ITAAC) for any particular program. This paper responds to the Commission's direction provided in a September 11, 2002, staff requirements memorandum (SRM) for SECY-02-0067, "Inspections, Tests, Analyses and Acceptance Criteria for Operational Programs (Programmatic ITAAC)."

BACKGROUND:

In the SRM dated September 11, 2002, the Commission stated that "an ITAAC for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the Nuclear Regulatory Commission (NRC) at the COL stage." The Commission further directed that the staff "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 may not be necessary." The Commission also stated in the SRM that "[t]he staff should interact with stakeholders to identify those issues that are material to the Commission making a reasonable assurance finding at the COL stage."

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DISCUSSION:

In response to the Commission's direction, the staff developed the following proposal. A draft Standard Review Plan (SRP) Section 14.3, Appendix E, "Programmatic ITAAC," would be developed for guidance. As part of this guidance, the staff proposed sorting the 14 programs listed in SECY-02-0067 into five categories:

- Category A: Programmatic ITAAC are required. An example of a program that falls into this category is emergency planning.
- Category B: Programmatic ITAAC are not necessary because hardware-related ITAAC address the results to which the program is directed. Examples of programs that may fall into this category are equipment qualification, quality assurance during the design and construction phases,¹ and containment leak rate testing.
- Category C: ITAAC for a program or elements of a program are not necessary because the program and its implementation can be fully described in the application and evaluated at the COL stage.
- Category D: ITAAC for a program or elements of a program are necessary because the program and its implementation cannot be fully described in the application, that is, the COL applicant cannot provide the necessary and sufficient programmatic information for approval of the COL without ITAAC.
- Category E: ITAAC for a program are not necessary because ITAAC will be dispositioned prior to fuel load and the program is not required to be implemented until after fuel load. Examples of programs that may fall into this category include the inservice inspection and inservice testing programs, and the maintenance rule program.

The staff reviewed the 14 programs listed in SECY-02-0067 and determined that 4 of the 14 programs and a portion of a fifth program (quality assurance) listed in the SECY paper did not need programmatic ITAAC. The staff placed these programs in categories B and E above. Also consistent with the SRM, the staff placed emergency planning in Category A—programmatic ITAAC are required. The remaining programs identified in SECY-02-0067 will fall into either Category C or Category D, depending on what information is necessary to fully describe a program and its implementation in accordance with the SRM.² The information

¹Although SECY-02-0067 discussed the quality assurance program as a single set of activities, this paper divides quality assurance program activities into two phases: quality assurance during the design and construction phases, and quality assurance during the operations phase.

²Depending on the contents of a particular COL application, the programs that may fall into Category C or D include: fire protection, radiation protection, security, fitness for duty, training, quality assurance during the operations phase, access authorization, reportability, and licensed operator training.

necessary to fully describe a program and its implementation is the principal issue needing resolution.

In initially responding to the Commission's direction to interact with stakeholders regarding the development of programmatic ITAAC guidance, the staff discussed the above proposal with the Nuclear Energy Institute (NEI) during a public meeting on May 22, 2003.³ The main topics of discussion at the meeting involved Categories C and D above, and the appropriate interpretation of the Commission's SRM regarding whether a COL application's description of a program and its implementation is sufficient to render ITAAC unnecessary. As a result of this meeting, the staff agreed to explore the practical application of "fully described" by examining a program that falls into Category C or D. Of the programs that fall into these categories, the staff chose the fire protection program because (1) the program is safety significant, (2) the staff had access to publicly available information from design certification reviews and operating plants that could be shared with interested stakeholders, and (3) reviewer resources were available in this area. The staff's detailed proposal regarding the fire protection program example is contained in Attachment 1 to this paper.

The staff continued to interact with stakeholders by issuing a *Federal Register* notice (FRN) on July 24, 2003 (68 FR 43767), soliciting comments on the above proposal, including the fire protection example. The staff also placed the proposal and background information on the NRC's public Web site. In addition, the staff held a facilitated and transcribed public workshop on August 25, 2003, to discuss the proposal. The staff received three comment letters from the nuclear industry in response to the FRN. Attachment 2 contains the staff's response to the major comments received during the August 25, 2003, public workshop and to the three comment letters received in response to the FRN. Attachment 2 also includes a discussion of why the quality assurance program portion of the proposal was further refined.

To fully describe a program and its implementation, the staff started with the assumption that the final safety analysis report (FSAR) information would be the minimum information that an applicant would have to submit, regardless of whether ITAAC are necessary. Therefore, the staff's proposal addresses the specifics of what type of information the staff would expect in an FSAR to fully describe the fire protection program. FSAR-level information alone, however, normally would not fully describe program implementation. The staff notes that under the 10 CFR Part 50 licensing process, the staff would review the FSAR to determine program acceptability and would subsequently inspect program development and implementation. Staff findings on these matters were necessary prerequisites to making the findings under 10 CFR 50.57 for issuance of an operating license under that section.

To fully describe the implementation of the program and to distinguish between Category C and D programs, the staff determined that it needed specific information on how the program will be implemented. Using the fire protection program as an example, the staff identified a set of

³In the May 22, 2003 proposal, the staff listed the quality assurance program as belonging to Category B. Subsequently the staff has determined that the quality assurance program should be discussed in terms of quality assurance during the design and construction phase, and quality assurance during the operations phase, and that these two phases should be treated differently.

procedures directly related to the implementation of the fire protection program. These fire protection implementing procedures are of the type that would normally be inspected by the staff prior to granting of an operating license under 10 CFR Part 50. The procedures do not include all of the procedures that an applicant would have to develop, but, rather, are a subset of the overall procedures needed to operate the plant. This would also be true of implementing procedures for other programs that fall into Category C.

The staff believes that, in addition to the FSAR information, if the type of information provided in these procedures were submitted and found to be acceptable prior to issuance of a COL, the program and its implementation would be fully described, meeting the intent of the Commission's SRM, and an ITAAC for the program would not be necessary. This would place the program in Category C of the staff's proposal. If the type of information provided in the implementing procedures could not be supplied, reviewed, and approved prior to issuance of a COL, then an ITAAC would be necessary, placing such programs in Category D of the staff's proposal. In such a case, the applicant would still have to supply the FSAR-level information and the information would have to be found to be acceptable before the applicant received a COL. Regardless of whether the program is in Category C (satisfactory program description, satisfactory implementing information and no ITAAC) or Category D (satisfactory program description and satisfactory ITAAC), the staff believes the Commission could issue the finding in accordance with 10 CFR 52.97(a) that "there is reasonable assurance that the facility will be constructed and operated in conformity with the license, the provisions of the Atomic Energy Act, and the Commission's regulations."

As discussed in Attachment 2, the main concern of members of the public present at the August 2003 workshop was ensuring meaningful public participation associated with ITAAC. Opportunities for public participation are available during meetings related to preapplication reviews; technical exchanges, environmental reviews, ACRS meetings, and mandatory hearings on COL applications; and if a COL is granted, an opportunity to request a hearing on whether ITAAC have been met. Opportunities exist for members of the public to review documents via the NRC website. This allows for more open public participation consistent with the NRC Strategic Plan.

The nuclear industry's main concern, as stated at the meeting and in letters, is that applicants not be required to provide procedure-level⁴ information or make it available to the NRC to support review of a COL application. NEI also stated that providing such procedure-level information at the time of the COL application would be difficult. The staff originally believed that supplying a core body of procedure-level programmatic information would not be burdensome for plants built at existing sites. The staff believes that supplying such procedure-level information addresses the Commission's direction in the SRM that "[i]n fact, most, if not all, of the operational areas in which the staff has proposed ITAACs are ones that can and

⁴Procedure-level information is that information that is typically contained in implementing procedures for a program. This type of information is normally inspected on-site. Some programs contain FSAR information that discuss program attributes and implementation at a high level, and this information is typically reviewed by headquarters staff. Region-based inspectors typically will then verify that the licensee's detailed procedures implement the program properly.

should be resolved at the time of the issuance of the COL.” In the example in Attachment 1, the staff did not identify all the procedures associated with fire protection, only the procedures that fully describe the program’s implementation. However, at the August 2003 workshop and in its letter, NEI stated that “with the exception of the Fitness for Duty Program, most programs have design dependencies.” In essence, NEI asserts that program implementation depends on the design details of plant structures, systems, and components, and plant personnel’s treatment of these design details. NEI further stated that “these man-machine interface issues are typically addressed at the procedure level, such that procedures for existing units could not be provided to support NRC review of a COL application for a standard plant.” NEI’s contention that a program’s implementing procedures depend on the resolution of man-machine interface issues would suggest that the program warrants ITAAC under the SRM. The staff continues to believe that information beyond that normally contained in the FSAR is needed in order to issue a COL without ITAAC for programs that fall into Category C of the staff proposal, with such information being sufficient for the staff to verify implementation of those programs.

The staff believes that its proposal and the information that is included in the fire protection program example in Attachment 1 address the Commission’s direction. If procedure-level information of the type in Attachment 1 cannot be supplied and found acceptable as part of a COL application then ITAAC for that program are necessary. As stated above, the staff believes the Commission’s reasonable assurance finding in accordance with 10 CFR 52.97(a) is possible regardless of whether an operational program falls into Category C (satisfactory program description, satisfactory implementing information and no ITAAC) or Category D (satisfactory program description and satisfactory ITAAC).

RECOMMENDATIONS:

The staff recommends that the Commission approve the above staff proposal for COL operational programs. Specifically, the staff recommends that the Commission approve the following:

1. That the categorization of the programs into the five different categories identified in this paper is appropriate.
2. That procedure-level information be provided or available to the NRC to support review of a COL application. If such information cannot be provided or made available during the COL application review, ITAAC are necessary for that program.

RESOURCES:

The resources to develop guidance in this area is in the Office of Nuclear Reactor Regulation (NRR) budget as part of the new reactor licensing budget.

COORDINATION:

The Office of the General Counsel has no legal objections to this paper.

/RA/

William D. Travers
Executive Director
for Operations

- Attachments:
1. Details of Staff Proposal To Use Fire Protection as an Example Program To Resolve the Level of Programmatic Information Needed for Approval of a Combined License (COL) Without Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)
 2. Discussion of Staff's Disposition of Comments Received in Response to the Staff's Proposal

COORDINATION:

The Office of the General Counsel has no legal objections to this paper.

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WITS: 20000095

ADAMS Accession No. ML040230079

***See previous concurrence**

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OFC	NRR:DRIP	OGC	NRR:ADIP	NRR:D	DEDR	EDO
NAME	DMatthews*	M Itzkowitz	JCraig	JDyer	SCollins	WTravers
DATE	2/12/04	02/18/04	02/18/04	02/19/04	02/26/04	02/26/04

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**Details of Staff Proposal To Use Fire Protection as an Example Program To
Resolve the Level of Programmatic Information Needed for Approval
of a Combined License Without Inspections, Tests,
Analyses, and Acceptance Criteria**

This attachment provides details of the staff's proposal to use fire protection as an example program of the level of programmatic information needed for approval of a combined license (COL) without inspections, tests, analyses, and acceptance (ITAAC) for a program. In the main body of this paper the staff proposed that the following information should be provided for the fire protection program at the COL stage in order to issue a COL without ITAAC for that program.

In the *Federal Register* notice (FRN) dated July 24, 2003 (68 FR 43767), the staff referenced the guidelines that should be followed for the fire protection program at the COL stage in order to issue a COL without ITAAC for that program. The staff proposed to use the fire protection provisions for the AP600 standard nuclear reactor design and the Callaway Plant as a starting point to develop these guidelines. The staff chose the AP600 because it represents the most current review for a standard design that has been certified in accordance with 10 CFR Part 52. The staff chose the Callaway Plant because it represents a plant that was recently licensed in accordance with 10 CFR Part 50 and its final safety analysis report (FSAR) contains information for the fire protection program that is not contained in the AP600 analogous document (i.e., the AP600 design control document (DCD)). The AP600 DCD does not contain this information because it identifies many fire protection program issues as the responsibility of the COL applicant.

Callaway was also chosen because it represents a standardized nuclear unit power plant system (SNUPPS) design. The Callaway Plant FSAR was submitted to the Nuclear Regulatory Commission (NRC) in support of the application by Union Electric for a Class 103 license to operate a nuclear power facility. The FSAR was originally submitted in two parts; the SNUPPS Standard Plant and the Callaway Site Addendum. Some of the chapters common to both reports are currently being combined into one report, the Callaway - Standard Plant. However, in the fire protection area (Section 9.5.1) a SNUPPS Standard Plant Section and a Callaway Site Addendum still exists. Because of similarities to the 10 CFR Part 52 licensing process, the staff believes that the Callaway Site Addendum is particularly useful for addressing expectations of a COL applicant.

The staff proposed that the following information should be provided for the fire protection program at the COL stage in order to issue a COL without ITAAC for that program:

1. The information in the referenced DCD or the applicable analogous information that addresses the COL action items contained in the DCD. For this example, the staff used the COL action items contained in the AP600 DCD.
2. Fire protection program information at a level of detail similar to that contained in Section 9.5.1 of the SNUPPS system standard plant FSAR (and the applicable appendices) for the Callaway Plant.

3. Fire protection program information at a level of detail similar to that contained in Section 9.5.1 (and the applicable appendices) of the Site Addendum portion of the FSAR for the Callaway Plant.
4. Fire protection program information similar to that contained in the following Callaway Plant fire protection program procedures:
 - APA-ZZ-00700, "Fire Protection Program"
 - APA-ZZ-00701, "Control of Impairments of Fire Protections Systems and Components"
 - APA-ZZ-00703, "Fire Protection Operability Criteria and Surveillance Requirements"
 - APA-ZZ-0741, "Control of Combustible Materials"
 - APA-ZZ-00742, "Control of Ignition Sources"
 - APA-ZZ-00743, "Fire Team Organization and Duties"
 - EDP-ZZ-04044, "Fire Protection Reviews"
5. Fire protection implementing information unique to the fire protection program. Examples include procedures similar to the following Callaway Plant procedures:
 - EIP-ZZ-00226, "Fire Response Procedure for the Callaway Plant"
 - FPP-ZZ-0XXXX, "Series of Procedures, Pre-Fire Strategy Procedures"
 - FPP-ZZ-00009, "Fire Protection Training Program"
 - HTP-ZZ-05006, "Fire Involving Radioactive Material or Entry into the RCA"
 - SDP-KC-00002, "Fire Door Position Verification"
 - MSM-ZZ-FG002, "Fire Damper Inspection and Drop Test"
 - QSP-ZZ-65045, "Fire Barrier Penetration Seal Visual Inspection"
6. In addition, the staff proposed that the COL applicant have a license condition similar to Callaway License Condition 2.C(5)(d) for the fire protection program:

The licensee may make changes to the approved fire protection program without prior approval of the Commission only if those changes would not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire.

Each of these 6 items is discussed in more detail below.

AP600 COL Action Items

COL applicants and licensees who reference the certified AP600 standard design will satisfy the requirements and commitments in the DCD, which is the controlling document used in the certification of the AP600 design. Certain items are identified in the AP600 DCD as "Combined License Information Items," and in NUREG-1512, "Final Safety Evaluation Report Related to the Certification of the AP600 Standard Design" (September 1998), as "COL Action Items." These COL action items relate to programs, procedures, and issues that are outside of the scope of the certified design review. These COL action items do not establish requirements; rather, they identify an acceptable set of information for inclusion in a plant-specific DCD. An applicant for a COL should address each of these items in its application. An applicant may

deviate from or omit these items, provided that the deviation or omission is identified and justified in the plant-specific DCD.

For the AP600, Westinghouse included a summary of COL action items in DCD Table 1.8-2, and provided an explanation of the items in the applicable sections of the DCD. Throughout NUREG-1512, the staff identified a number of COL action items that resulted from its review. Each COL action item was assigned a unique identifying number. The number identifies the section in NUREG-1512 where the item is described. For example, COL Action Item 5.3.2-1 is discussed in Section 5.3.2 of NUREG-1512. The COL action items identified in NUREG-1512 are cross-referenced against those identified by Westinghouse in DCD Table 1.8-2 in the following table.

FSER Item	DCD Table 1.8-2	DCD Section	Description
9.5.1-1(a)	9.5-1	9.5.1.8	The COL applicant will establish a fire protection program at the facility for the protection of structures, systems, and components important to safety, and the procedures, equipment and personnel needed to implement the program.
9.5.1-1(b)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The implementation of the fire protection program prior to receiving fuel onsite for fuel storage areas, and for the entire unit prior to reactor startup is the responsibility of the COL applicant.
9.5.1-1(c)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The establishment of administrative controls to maintain the performance of the fire protection systems and personnel is the responsibility of the COL applicant.
9.5.1-1(d)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The establishment of a site fire brigade trained and equipped for fire fighting to ensure adequate manual fire fighting capability for all plant areas containing structures, systems, or components important to safety is the responsibility of the COL applicant.
9.5.1-1(e)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The establishment of a quality assurance program to ensure that the guidelines for the design, procurement, installation and testing, and the administrative controls for fire protection systems are satisfied is the responsibility of the COL applicant.
9.5.1-1(f)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	Inspection and maintenance of fire doors, access to keys for the fire brigade and the marking of exit routes is the responsibility of the COL applicant.

FSER Item	DCD Table 1.8-2	DCD Section	Description
9.5.1-1(g)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The collection and sampling of water drainage from areas that may contain radioactivity is the responsibility of the COL applicant.
9.5.1-1(h)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The control of the use of compressed gases inside structures is the responsibility of the COL applicant.
9.5.1-1(i)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	Portable radio communication for use by the plant fire brigade is the responsibility of the COL applicant.
9.5.1-1(j)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	Fire protection inside containment during refueling and maintenance is the responsibility of the COL applicant.
9.5.1-1(k)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The control of combustible materials in the remote shutdown workstation is the responsibility of the COL applicant.
9.5.1-1(l)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	Fire protection for cooling towers is the responsibility of the COL applicant.
9.5.1-1(m)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The proper storage of welding gas cylinders is the responsibility of the COL applicant.
9.5.1-1(n)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The proper storage of ion exchange resins is the responsibility of the COL applicant.
9.5.1-1(o)	9.5-1	9.5.1.8, Tbl. 9.5.1-1	The proper storage of hazardous chemicals is the responsibility of the COL applicant.
9.5.1-2	9.5-2	9.5.1.8	The revision of the fire hazard analysis to reflect the actual plant configuration is the responsibility of the COL applicant.
9.5.1-3	9.5-4	9.5.1.8	The COL applicant is responsible for ensuring that any deviations from the applicable National Fire Protection Association (NFPA) codes and standards in addition to those specified in the standard safety analysis report (SSAR) are incorporated in to the final safety analysis report with appropriate technical justification.

The staff will review the COL information against the requirements that are applicable and in effect at the time of the COL application. It should be noted that, as with the design certification reviews, any changes to the applicable regulations made from the time of the COL application to COL issuance (if the Commission deems issuing a COL appropriate) would have to be

reflected in the application and the staff's review, as set forth in the statements of consideration for those changes.

If a COL application were received today, the staff would review the information in accordance with the requirements contained in 10 CFR 50.48, "Fire Protection," and GDC 3, "Fire Protection," of Appendix A to 10 CFR Part 50. Conformance with the Standard Review Plan (SRP) is addressed in 10 CFR 50.34(h), which specifies that applications include an evaluation of the facility against the SRP. The fire protection guidance for nuclear power plants specified in the SRP is provided in Branch Technical Position (BTP) Chemical and Mechanical Engineering Branch (CMEB) 9.5-1, "Guidelines for Fire Protection for Nuclear Power Plants," Revision 2, July 1981. In addition to the guidance specified in the BTP, the staff has specified that advanced light-water reactors should provide an enhanced level of fire protection to ensure that safe shutdown can be achieved, assuming all equipment in any one fire area is rendered inoperative as a result of fire damage and that reentry into the fire area by plant personnel for repairs or operator interactions is not possible. The staff's technical positions relating to an enhanced level of fire protection for advanced light-water reactors are contained in the following documents:

- SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements," January 12, 1990, and the associated SRM dated June 26, 1990,
- SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor Designs," April 12, 1993, and the associated SRM dated July 21, 1993, and
- Section 9.3 of NUREG-1242, "NRC Review of Electric Power Research Institute's Advanced Light Water Reactor Utility Requirements Document," August 1992.

In addition, applicable NFPA codes, standards, and recommended practices will be used to aid the staff's review. The staff also believes that Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants," April 2001, will provide useful guidance for its review of a COL application.

With the exception of Regulatory Guide (RG) 1.189, which was published after the AP600 final safety evaluation report (FSER) was issued, the AP600 was reviewed against the requirements and guidance identified in the previous paragraph. The AP600 fire protection program can be found in Section 9.5.1 of the AP600 DCD and the staff's safety evaluation can be found in NUREG-1512, Section 9.5.1.

In order to facilitate public comments on this proposal during the Summer of 2003, the staff placed the proposal as well as background documentation on the NRC's public Web site. The web address for this information is the following:

<http://www.nrc.gov/reactors/new-licensing/col-supporting-documentation.html>.

To place this portion of the staff's proposal in context, the staff placed the following information on the Web:

- AP600 DCD, Section 9.5.1
- NUREG 1512, Section 9.5.1
- Regulatory Guide 1.189

SNUPPS Standard Plant FSAR for the Callaway Plant

The Standard Plant FSAR for the Callaway Plant provides information analogous to the AP600 DCD. The staff believes that Callaway's Standard Plant FSAR information can place in context the information that is contained in the Site Addendum portion of the Callaway FSAR. Therefore, the staff provided the following information on the NRC's public Web site to place this portion of the staff's proposal in context:

- Callaway FSAR Standard Plant Section 9.5.1, "Fire Protection System"
- Callaway FSAR Standard Plant Appendix 9.5A, "Design Comparison to Regulatory Positions of Regulatory Guide 1.120, Revision 1, Dated November 1977, Titled - Fire Protection Guidelines for Nuclear Power Plants"
- Callaway FSAR Standard Plant Appendix 9.5B, "Fire Hazards Analysis"

Site Addendum Portion of the FSAR for the Callaway Plant

The staff believes that the Site Addendum portion of the FSAR for the Callaway Plant provides useful guidance for a COL application. For example, Site Addendum Sections 9.5.1.5, "Personnel Qualification and Training," 9.5.1.8, "Callaway Plant Fire Brigade," 9.5.1.9, "Fire Fighting Procedures," and 9.5.1.12, "Administrative Controls," provide examples of the level of detail that the staff would expect in a COL application for these areas. Therefore, the staff provided the following information on the NRC's public Web site to place this portion of the staff's proposal in context:

- Callaway FSAR Site Addendum Section 9.5-1, "Fire Protection System"
- Callaway FSAR Site Addendum Appendix 9.5A, "Fire Protection Evaluation"
- Callaway FSAR Site Addendum Appendix 9.5B, "Fire Hazards Analysis for Site Facilities Outside the Standard Power Block"
- Callaway FSAR Site Addendum Appendix 9.5E, "Fire Protection Evaluation"

Fire Protection Program and Implementing Procedures

The NRC staff proposes that in addition to the information provided above, the type of information provided in procedures directly related to the implementation of the fire protection program should be supplied at the time of the COL application so that the NRC can make a decision before the COL is granted regarding the need for ITAAC for the fire protection program. Callaway's procedure APA-ZZ-00700, "Fire Protection Program" contains an Appendix 2 which lists the following as fire protection program documents:

- FSAR, Standard Plant, Sections 9.5.1, 9.5.2, and 9.5.3, and Appendices 9.5A through E
- FSAR Site Addendum, Sections 9.5.1, and 9.5.2, and Appendices 9.5A through E

- The fire protection program as described in the Safety Evaluation Report (SER) through Supplement 4
- APA-ZZ-00701, "Control of Impairments of Fire Protections Systems and Components"
- APA-ZZ-00703, "Fire Protection Operability Criteria and Surveillance Requirements"
- APA-ZZ-0741, "Control of Combustible Materials"
- APA-ZZ-00742, "Control of Ignition Sources"
- APA-ZZ-00743, "Fire Team Organization and Duties"
- EDP-ZZ-04044, "Fire Protection Reviews"

The staff believes that information similar to that contained in the procedures that are referenced in Appendix 2 to APA-ZZ-0700 and APA-ZZ-0700 itself should be furnished for staff review at the time of the COL application. Therefore, the staff provided the Callaway fire protection implementing procedures listed above on the NRC's public Web site to place this portion of the staff's proposal in context.

Fire Protection Procedures Unique to the Fire Protection Program

In addition to the procedures listed above that are an integral part of Callaway's fire protection program, there are other procedures that are unique to Callaway's fire protection program that describe the program's implementation. Procedures that are referenced by the fire protection program procedures include the following:

- EIP-ZZ-00226, "Fire Response Procedure for the Callaway Plant"
- FPP-ZZ-0XXXX, "Series of Procedures, Pre-Fire Strategy Procedures"
- FPP-ZZ-00009, "Fire Protection Training Program"
- HTP-ZZ-05006, "Fire Involving Radioactive Material or Entry into the RCA"
- SDP-KC-00002, "Fire Door Position Verification"
- MSM-ZZ-FG002, "Fire Damper Inspection and Drop Test"
- QSP-ZZ-65045, "Fire Barrier Penetration Seal Visual Inspection"

The staff proposes that the type of information provided in these "secondary" procedures should be furnished for review at the time of the COL application so that the NRC can make a decision before the COL is granted regarding the need for ITAAC for the fire protection program. A more detailed review of the fire protection procedures for an applicant may identify additional procedures that should be provided at the time of a COL application.

COL License Condition

Generic Letter (GL) 86-10, "Implementation of Fire Protection Requirements," and GL 88-12, "Removal of Fire Protection Requirements from Technical Specifications," discuss the regulatory treatment of the fire protection program. GL 86-10 requested that licensees incorporate the NRC-approved Fire Protection Program in their FSARs. GL 86-10 encouraged licensees, upon completion of this program, to apply for an amendment to their operating licenses (1) to replace current license conditions regarding fire protection with a new standard condition and (2) to remove unnecessary fire protection Technical Specifications (TS). GL 88-12 provided additional information in this area based on experience with implementation of GL 86-10 for new operating licenses.

GL 86-10 proposed the following standard fire protection license condition:

(Name of Licensee) shall implement and maintain in effect all provisions of the approved fire protection program as described in the Final Safety Analysis Report for the facility (or as described in submittals dated _____) and as approved in the SER dated _____(and Supplements dated _____) subject to the following provision:

The licensee may make changes to the approved fire protection program without prior approval of the Commission only if those changes would not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire.

The applicable License Condition for Callaway is contained in License Conditions 2.C(5)(c) and 2.C(5)(d). License Condition 2.C(5)(d) for Callaway states the following:

The licensee may make changes to the approved fire protection program without prior approval of the Commission only if those changes would not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire.

SECY-00-0092, "Combined License Review Process," dated April 20, 2000, contains a proposed generic COL. The Commission approved the form and content of this generic COL in an SRM dated September 5, 2000. However, the proposed generic COL did not contain a fire protection program license condition similar to that contained in Callaway's license or discussed in Generic Letter 86-10. The staff believes that a COL should have a license condition for the fire protection program.

**Discussion of Staff's Disposition of Comments Received in
Response to the Staff's Proposal**

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I. Background

As stated in the main body of this document, the staff held a facilitated and transcribed public workshop on August 25, 2003, and issued a *Federal Register* notice (FRN) on July 24, 2003 (68 FR 43767), soliciting comments on its proposal on programmatic inspections, tests, analyses, and acceptance criteria (ITAAC). The staff received three comment letters from industry in response to the FRN. This attachment provides a discussion of the main points made at the August 25, 2003, workshop and also addresses the key issues identified in the three letters from industry.

The August 25, 2003, corrected transcripts, the August 25, 2003, meeting summary and the industry's three comment letters are available in the Agencywide Documents Access and Management Systems (ADAMS) in the Nuclear Regulatory Commission (NRC) Public Document Room located at One White Flint North, 11555 Rockville Pike, Public File Area O1F21, Rockville, Maryland. The information is also available electronically from the Publicly Available Records (PARS) component of ADAMS. The ADAMS accession numbers for the documents are as follows:

- August 25, 2003, meeting summary - ADAMS Accession No. ML032530004
- August 25, 2003, corrected transcripts - ADAMS Accession No. ML032530003
- September 15, 2003, letter from Ron Simard, Nuclear Energy Institute - ADAMS Accession No. ML032690843
- September 15, 2003, letter from George A. Zinke, Entergy Nuclear Inc. - ADAMS Accession No. ML032661176
- September 15, 2003, letter from L. B. Long, Southern Nuclear Operating Company - ADAMS Accession No. ML032661172

ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). For more information, contact the NRC Public Document Room (PDR) reference staff at 1-800-397-4209 or 202-634-3273 or by e-mail to pdr@nrc.gov.

II. August 25, 2003, Workshop Comments

Several key issues were discussed during the workshop on August 25, 2003. The workshop was in the form of a roundtable discussion facilitated by Chip Cameron of the NRC's Office of the General Counsel. Although the focus of the meeting was on the roundtable discussion, there were opportunities for members of the audience to offer comments and ask questions. The members of the roundtable are listed below.

<u>Name</u>	<u>Organization</u>	<u>Name</u>	<u>Organization</u>
James Lyons	NRC, Program Director - New, Research and Test Reactors (RNRP)	David Ritter	Public Citizen's Critical Mass Energy and Environmental Program
Jerry Wilson	NRC, RNRP	Paul Gunter	Nuclear Information and Resource Service
Joe Sebrosky	NRC, RNRP	Eddie Grant	Exelon

<u>Name</u>	<u>Organization</u>	<u>Name</u>	<u>Organization</u>
Russ Bell	Nuclear Energy Institute (NEI)	Al Passwater	Polestar
Ben George	Southern Nuclear	Ron Simard	NEI

The roundtable discussion addressed issues from individuals representing the citizens groups and those from industry.

II.a Citizens Group Comments

A key issue for both of the representatives of citizens groups was a concern for the quality of public participation during the Part 52 process. Another concern of one of the citizens groups was the change process associated with ITAAC.

II.a.1 Quality of Public Participation

Both citizens group representatives stated that they were interested in meaningful opportunities for the public to participate in the 10 CFR Part 52 licensing process. The staff noted that the ITAAC are determined in the proceeding on the application for a combined license (COL), which is a mandatory hearing with an associated opportunity for public participation. The staff also noted that this mandatory hearing would be completed before construction of the reactor could begin. The staff stated that after this mandatory hearing, if the COL is granted, the reactor can be constructed and the NRC can verify if the ITAAC have been successfully completed. The staff also stated that after construction is complete or nearly complete, there is an opportunity for a hearing in accordance with 10 CFR 52.103, and the staff discussed the importance of ITAAC in the process. The staff noted that a request for a hearing in accordance with § 52.103 is limited to whether the acceptance criteria contained in the ITAAC have been met.

The industry representatives noted that absent ITAAC, interested parties or people have other opportunities to express their concerns. One of these opportunities that was noted was that the public could use the 10 CFR 2.206 petition process to raise concerns. A response from a citizens group representative was that public participation is “considerably degraded” under 10 CFR 2.206.

Supplemental Staff Response

The concern regarding public participation during the 10 CFR Part 52 licensing process is consistent with the concerns that were raised during the rulemaking for Part 52. SECY-02-0067, “Inspections, Tests, Analyses, and Acceptance Criteria for Operational Programs (Programmatic ITAAC),” dated April 15, 2002, noted that the 1989 statements of consideration for the final rule stated that “[t]he deepest differences among the commenters concern the consequences of standardization and other devices for early resolution of licensing issues for the licensing process. . . . Many of the commenters attribute to the Commission an intent to do away with public participation in the licensing process.”

As noted in SECY-02-0067, the Commission's response, as documented in the statements of consideration for the 1989 rule, was the following:

The Commission has given more consideration to this issue than to any other procedural question raised by the proposed rule. As a result, the proposed rule's provisions on hearings just before operation have been revised in the final rule However, the final rule still provides for an opportunity for a hearing on limited issues before operation under a combined license. But the mere fact of this opportunity does not mean that the rule is hiding the old two-step process under a different name. By far the greater part of the issues which in the past have been considered in operating license hearings would, under the new rule, be considered at the combined license stage or in a certification proceeding, including the bulk of emergency planning issues. Similarly, the mere fact that any hearing prior to operation would be limited does not mean that the Commission is attempting to remove the public from the licensing process. 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 design certification, early site permit, and combined license parts of the process.

The staff believes that the proposal contained in the main body of this document is consistent with the intent of 10 CFR Part 52 and the Commission's staff requirements memorandum (SRM) dated September 11, 2002. By reviewing and inspecting implementing procedures for certain programs before the issuance of the combined license, the staff is moving these issues up front in the licensing process. Because such information would be reviewed prior to a decision on whether to grant a COL, it could be the subject of the mandatory hearing on the COL application. The staff believes that by reviewing and inspecting such procedures before making a determination on whether to grant a COL, the staff would not need ITAAC to verify implementation of the fire protection operational program.

Industry expressed a concern that if the procedures were developed and approved in the COL proceeding, they would become part of the "licensing basis" and expand the information that is contained in the final safety analysis report (FSAR). The staff mentioned during the meeting that Part 52 does have a provision that allows the application to include information that is not otherwise included in the FSAR. The staff also discussed the idea of reviewing the procedures on site and making the results of the inspections publicly available in an inspection report. Similar processes have been used during design certification reviews. That is, the staff inspected information that was used to support an application without having the actual information on the docket. However, the results of such inspections were placed on the docket either in the safety evaluation report or an inspection report.

A citizens group representative stated that by not having the procedures on the docket and publicly available, they would not have the chance to review them and determine if they had any issues associated with them. The staff responded by stating that for operating reactors today most operating procedures are not available publicly. However, the results of staff inspections of the operating procedures are made publicly available through inspection reports.

The staff intends to explore the issue of the status of the operating procedures further if the Commission approves the position outlined in the main body of this document. The staff will

discuss with stakeholders whether or not the procedures need to be submitted with the application to obviate the need for ITAAC or if it is sufficient to have the procedures available for inspection during the staff's review of the COL application.

II.a.2 Change Process Associated with ITAAC

A member of a public citizens group questioned how ITAAC could be changed after they had been agreed to by the staff. The person wanted to know how malleable ITAAC were and if public participation was possible if the ITAAC were changed after a COL was issued.

The staff responded during the meeting that once ITAAC are approved and incorporated into a COL, they are not intended to be easily changed. The staff stated that for a COL applicant or licensee there were several possibilities and the public participation afforded depended on where in the process the ITAAC change was made.

Supplemental Staff Response

The NRC has issued a brochure, NUREG/BR-0298, "Nuclear Power Plant Licensing Process," which discusses the 10 CFR Part 52 licensing process and opportunities for public involvement.

ITAAC Developed During 10 CFR Part 52 Standard Design Certifications

If a public interest group chooses, it may become involved in the development of ITAAC. This can be done either during the public meetings held with the staff and the applicant during the staff's review of the application, which includes the development of the safety evaluation report for the design, or during the administrative review of the design certification application. The public meetings that are held between the staff and the applicant are conducted in accordance with the Commission's policy statement on "Enhancing Public Participation in NRC Meetings," dated May 28, 2002 (67 FR 36920). This policy statement allows for members of the public, including public interest groups, if they so choose, to obtain factual information about the design, and also allows for the public to communicate with the staff after the business portion of the meeting, but before the meeting is adjourned. The administrative review is performed after the staff has made a determination on the acceptability of the design and is done as part of the process to codify the design as a rule. For example, Appendix A of 10 CFR Part 52 is the design certification rule for the U.S. Advanced Boiling Water Reactor.

The administrative review of a design certification application is governed by 10 CFR 52.51. Section 52.51 was affected by the Commission's recent amendment to its Rules of Practice in 10 CFR Part 2 to make the NRC's hearing process more effective and efficient. The final rule was effective February 13, 2004, and is discussed in a FRN dated January 14, 2004 (69 FR 2182). The new section 52.51 states in part that "the notice of proposed rulemaking in the FRN must provide an opportunity for the submission of comments on the proposed design certification rule."

Changes to ITAAC Contained in a Certified Design

A COL applicant may choose to reference a certified design in its application. If it chooses such an approach, any ITAAC that were developed, reviewed, approved and codified during the

design certification process would not normally be reconsidered. However, there is a change process for ITAAC that fall into this category.

The certified designs are codified in regulations and are contained in appendices to 10 CFR Part 52 as discussed above. 10 CFR Part 52, Appendix A, Section VIII, "Processes for Changes and Departures," discusses the change process associated with Tier 1 information. Tier 1 information includes the ITAAC for the design. The changes that are possible are generic changes to Tier 1 information and plant-specific exemptions from Tier 1 information, as well as plant specific orders changing such information. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1). The new section that is effective February 13, 2004, states:

[T]he Commission may not modify, change, rescind, or impose new requirements on the certification, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that a modification is necessary to either bring the certification or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate public health and safety or the common defense and security. The rulemaking procedures must provide for notice and opportunity for public comment.

Therefore the public has the opportunity to comment during the rulemaking process.

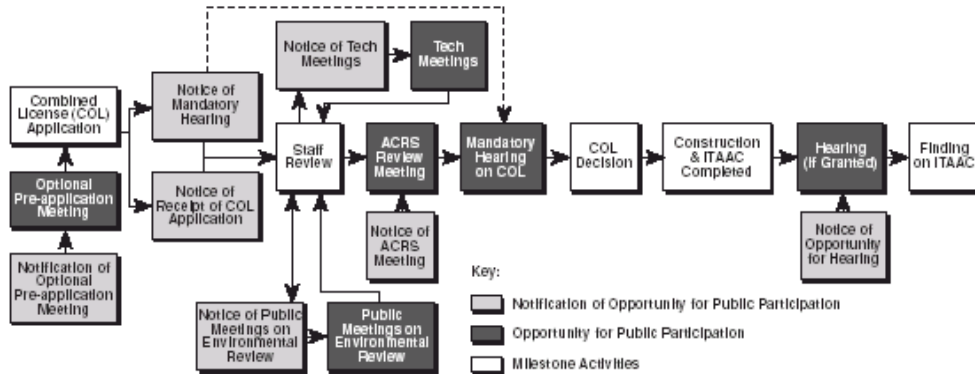
The Commission may also issue a plant-specific order for a certified design in accordance with 10 CFR 52.63(a)(3). There would be an opportunity to request a hearing in connection with any such plant-specific order, just as there is for any enforcement proceeding.

Section VIII.A.4 of the certified design rules discusses changes through exemptions that are made to the ITAAC that are part of the certified design. An applicant or licensee who references a certified design may seek an exemption from one or more elements of the design certification. Such exemptions may be sought before or after a COL is issued. The change process for exemptions is governed by 10 CFR 52.63(b)(1) and 10 CFR 52.97(b). These sections state that the granting of an exemption must be subject to litigation in the same manner as other issues in the operating license or COL hearing.

ITAAC Submitted as Part of a COL application

Figure 4 of NUREG/BR-0298 provides a diagram of public involvement during the review of a combined license and is included below for reference. Any ITAAC that are submitted as part of a COL application, such as those related to emergency planning, would be subject to the mandatory hearing on the COL application in accordance with 10 CFR 52.85. During this process, interested members could seek to intervene in the proceeding and challenge the wording of ITAAC or the lack of ITAAC for those issues that are reviewed during that proceeding. The amount of material that is subject to the hearing depends on what issues have previously been decided and afforded finality. For example, if a COL application references a certified design, ITAAC associated with that design would not normally be the subject of the COL hearing unless an exemption is requested as discussed above.

Figure 4 - Opportunities for Public Involvement During the Review of Combined Licenses



Regardless of whether a COL references a certified design, the issue of ITAAC associated with operational programs is subject to litigation in accordance with 10 CFR 52.85. This is because operational programs are reviewed at the COL stage. If an interested party believes that ITAAC are needed for a particular operational program and none are provided in the COL application, the chance to raise the issue in a hearing by the interested party is afforded by the Notice of Hearing on the COL application. Once this hearing on the COL is completed, the finding on the ITAAC is made and it is the intent of the 10 CFR Part 52 process that the ITAAC remain unchanged except in limited circumstances.

II.b Industry Comments

During the August 25, 2003, workshop Nuclear Energy Institute (NEI) and industry officials raised several issues, most of which were reiterated in the response letters to the FRN. There were areas of agreement that were identified during the workshop that were not included in the response letters. The areas of agreement are discussed below. The major disagreements with the staff's proposal that NEI and industry discussed during the August 25, 2003, workshop were also captured in the written responses to the FRN. Therefore, the areas of disagreement are discussed in Section III of this attachment.

II.b.1 Categorization of the Programs

NEI did not object to a portion of the proposal contained in the main body of this document. Namely, during the August 25, 2003, workshop NEI did not object to Category A, Category B, Category C, or Category E for the programs. During the August 25, 2003, workshop NEI noted the following about these categories:

- NEI recognized that emergency planning will most likely require ITAAC in accordance with the Commission's direction in the staff requirements memorandum (SRM). The staff's proposal placed emergency planning in Category A - that is, programmatic ITAAC are required. Although NEI did not think that it was a good idea to have emergency planning ITAAC, NEI conceded that emergency planning ITAAC would likely need to be developed.
- NEI also indicated that there was no disagreement with Category B of the staff's proposal, namely that programmatic ITAAC are not necessary for certain programs because hardware-related ITAAC address the results to which the program is directed.
- Regarding Category C programs, NEI stated that it believed this category was consistent with the Commission's direction in the SRM that programmatic ITAAC are not necessary because the program and its implementation can be fully described in the application and found to be acceptable at the COL stage.
- NEI also indicated that it agreed that ITAAC are not necessary for Category E programs because ITAAC will be dispositioned prior to fuel load and such a program is not required to be implemented until after fuel load. NEI did question why this category was not more broadly applied to other programs (see Section III.d of this attachment for more discussion of this issue).

II.b.2 Some Programmatic Information To be Supplied at the COL Stage

There was general agreement on some of the information that should be supplied at the COL stage for the fire protection program. Specifically, there was general agreement with the staff's proposal that the following information should be provided for the fire protection program at the COL stage in order to issue a COL without ITAAC for that program:

1. The information in the referenced designed control document (DCD) or the applicable analogous information that addresses the COL action items contained in the DCD.
2. Fire protection program information at a level of detail similar to that contained in Section 9.5.1 of the SNUPPS Standard Plant FSAR (and the applicable appendices) for the Callaway Plant.
3. Fire protection program information at a level of detail similar to that contained in Section 9.5.1 (and the applicable appendices) of the Site Addendum portion of the FSAR for the Callaway Plant.

NEI's handouts at the meeting, which are also attached to its comment letter, provided FSAR Section 9.5.1, "Fire Protection System," for a combined license application for the first AP-1000

plant or "AP-1000-1." As described during the meeting, NEI's response appears to be consistent with this portion of the staff's proposal. In response to a question from the staff at the August 25, 2003, workshop, an industry panelist who developed the AP-1000-1 FSAR Section 9.5.1 stated that it is roughly equivalent to the level of information that is in the current Callaway FSAR. The example also specifically addresses the AP600 COL action items contained in the design control document. The staff has not reviewed the AP-1000-1 COL FSAR proposed by NEI in detail, but at a high level the staff noted in the meeting that the FSAR appears to be consistent with this portion of the staff's proposal. The staff noted that there were areas such as for administrative controls where the Callaway FSAR had more detail than NEI's proposal. However, the staff believes that, given time, it could come to agreement with NEI on the level of FSAR information needed to address the first three issues identified in the staff's proposal regarding the level of information expected to be supplied in the COL application.

II.b.3 Fire Protection License Condition

The staff proposed that the COL applicant have a license condition similar to Callaway License Condition 2.C(5)(d) for the fire protection program:

The licensee may make changes to the approved fire protection program without prior approval of the Commission only if those changes would not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire.

SECY-00-0092, "Combined License Review Process," dated April 20, 2000, contains a proposed generic COL. The Commission approved the form and content of this generic COL in an SRM dated September 5, 2000. However, the proposed generic COL did not contain a fire protection program license condition similar to that contained in Callaway's license or discussed in GL 86-10, "Implementation of Fire Protection Requirements." The staff's proposal in Attachment 1 of this paper contains a COL license condition for the fire protection program. The industry did not object to this portion of the staff's proposal during the workshop or in its written comments. The staff believes after discussions with interested stakeholders on other COL issues that the generic combined license contained in SECY-00-0092 may need to be revised. The staff will collect these issues, revise the generic combined license, and inform the Commission in a separate paper.

III. Written Comments

All three industry commenters agreed that the principal issue is what information is necessary to fully describe a program and its implementation. Other issues that the industry raised in the meeting and in their letters include:

- use of training program as an example
- litigation risk associated with the post-construction hearing
- the justification for the staff not proposing ITAAC for the inservice inspection and inservice testing program should be more broadly applied

III.a Concerns Related to the Definition of "Fully Described"

NEI stated in its letter that "two key questions need to be addressed to determine the nature of operational information that must be provided in [a] COL application or otherwise available for NRC review":

1. What will provide reasonable assurance that operational programs, such as fire protection, will meet NRC requirements and provide adequate protection of public health and safety.
2. What type and level of information on program implementation is needed to support NRC reasonable assurance finding(s) at the COL stage.

The issue involves the interpretation of the term "fully described" in the following sentence contained in the Commission's SRM dated September 11, 2002:

Although the NRC inspection process does not replace a particular ITAAC, an ITAAC for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the NRC at the COL stage.

NEI's and industry's comments relate to Category C and D programs that are identified in the staff's proposal contained in the main body of this paper. The staff listed eight programs that could fall into either category based on whether the program and its implementation can be "fully described" in the application. The staff's proposal includes guidelines for the fire protection program for the level of programmatic information that would be needed in order to issue a COL without ITAAC for that program. The staff's proposal used Callaway as an example and included fire protection implementing procedures unique to the fire protection program.

The industry objects to the fire protection program example and the fire protection procedures that the staff references in the proposal. Specifically, the industry does not believe it is necessary to provide information similar to the seven Callaway procedures (which along with the Callaway FSAR material constitute the fire protection program documents for Callaway) at the time of a COL application. Nor does the industry believe that it is necessary to provide fire protection implementing procedures unique to the fire protection program at the time of the COL application (the staff's proposal references seven Callaway procedures as examples).

In written as well as oral comments made during the August 25, 2003, workshop, industry representatives stated that they do not believe the Commission intended by its September 11, 2002, SRM that, for the NRC to grant a COL without ITAAC on programs, a COL applicant should provide more operational program information than that which is "necessary and sufficient" for the NRC staff to make its reasonable assurance finding(s) on the acceptability of the programs. NEI states in its letter that it "disagree[s] strongly" with the staff's

conclusion that it is necessary that some procedure-level information be provided or available to the NRC to support review of a COL application. NEI also stated the following in its letter:

It is not necessary to provide procedure-level information to support the findings required for COL, nor is it practical for COL applicants to develop such information prior to COL issuance.

In addition, Southern Company stated in its letter that program descriptions similar to those contained in current final safety analysis reports will be sufficient to support reasonable assurance findings by the NRC staff.

Difficulty in Supplying Procedures at the COL Stage

In addition to objecting to providing the procedure-level information at the time of a COL application, NEI also stated that providing such procedure-level information at the time of the COL application would be difficult. During the workshop, the staff explained its position that procedure-level information on operational programs could be provided at the COL stage based on the belief that new units would be proposed for locations next to operating plants. Therefore, the staff believed that COL applicants could have available and could provide program procedures based on the nearby plant. NEI stated during the meeting, and reiterated in its written response, that with the exception of the fitness-for-duty program, most programs have design dependencies. NEI stated that these man-machine interface issues are typically addressed at the procedure level, such that procedures for nearby plant units could not be provided to support NRC review of the COL application for a future plant. In essence, NEI asserts that program implementation depends on the design details of plant structures, systems, and components, and plant personnel's treatment of these design details.

In addition, during the August 25, 2003, meeting, NEI indicated that COL applicants will not have plant staff in place to write the procedures for some programs, such as fire protection, until after the COL is issued. NEI also stated that procedure development is an iterative process that parallels plant construction, with newly hired plant staff, some of whom will write the procedures, on which others will be trained and drilled, revealing problems with the procedures. NEI argues that the procedures will be repeatedly revised during program implementation.

Staff Response

The staff believes that the key issues are:

- What information is necessary to fully describe a program and its implementation in the staff's definition of a Category C program such that an ITAAC is not necessary?
- Is procedure-level information for a program necessary at the COL stage in order to issue a COL without ITAAC for verification of that program?

The issue is not what information is necessary to provide a reasonable assurance finding with respect to program adequacy at the COL stage. Rather, the issue is what additional information is needed, if any, to issue a COL without ITAAC to verify the adequacy of implementation of an operational program. The staff is in general agreement with NEI about

the type of information that would need to be provided to meet NRC requirements for programs with ITAAC (i.e., the information described in Section II.b.2 above). The staff believes that additional information beyond what would normally be provided in an FSAR is needed in order to meet the direction in the Commission's SRM to fully describe the program and its implementation and to issue a COL without ITAAC for such a program. Under the Part 50 licensing process, the staff would review the FSAR to determine program acceptability and would subsequently inspect program development and implementation. Staff findings on these matters were necessary prerequisites to making the findings under 10 CFR 50.57 for issuance of an operating license under 10 CFR 50.57.

The staff believes that to issue a COL **without ITAAC** for verification of adequate implementation of an operational program, a review of the type of information provided in the implementing procedures for that program is necessary. Part of the set of fire protection procedures are those similar to that contained in the following Callaway Plant fire protection program procedures:

- APA-ZZ-00700, "Fire Protection Program"
- APA-ZZ-00701, "Control of Impairments of Fire Protections Systems and Components"
- APA-ZZ-00703, "Fire Protection Operability Criteria and Surveillance Requirements"
- APA-ZZ-0741, "Control of Combustible Materials"
- APA-ZZ-00742, "Control of Ignition Sources"
- APA-ZZ-00743, "Fire Team Organization and Duties"
- EDP-ZZ-04044, "Fire Protection Reviews"

The basis for the staff asking for the information that is provided in these procedures is contained in APA-ZZ-00700. Appendix 2 to this procedure lists Callaway FSAR information and the above procedures as "fire protection program documents."

In addition to this information, the staff would expect to review other fire protection implementing information unique to the fire protection program. Examples include information similar to the information found in the following Callaway Plant procedures:

- EIP-ZZ-00226, "Fire Response Procedure for the Callaway Plant"
- FPP-ZZ-0XXXX, "Series of Procedures, Pre-Fire Strategy Procedures"
- FPP-ZZ-00009, "Fire Protection Training Program"
- HTP-ZZ-05006, "Fire Involving Radioactive Material or Entry into the RCA"
- SDP-KC-00002, "Fire Door Position Verification"
- MSM-ZZ-FG002, "Fire Damper Inspection and Drop Test"
- QSP-ZZ-65045, "Fire Barrier Penetration Seal Visual Inspection"

In order to perform a review of an application and consider issuing a COL without ITAAC for verification of adequate implementation of an operational program, a description of how the program will be implemented, similar to the information found in the above procedures should be available. If the information cannot be made available because of resource and design-related issues during the review of the COL application, then providing ITAAC for that program would be acceptable. Consistent with the staff's proposal, this would place such programs in Category D - ITAAC for a program or elements of the program are necessary because the program and its implementation cannot be fully described in the application.

Need for Implementing Procedures

NEI's letter notes the following regarding implementing procedures:

Fire Protection Program procedures must be developed and made available for review when it is time for the NRC staff to inspect Fire Protection Program implementation prior to operation. As indicated by Fire Protection Inspection Procedure 64704, NRC review of detailed procedures is important to enable the staff to understand how program requirements are being met and to verify the adequacy of implementation. However, these implementation details are not necessary prior to COL issuance to support licensing reviews based on the standard review plan (SRP) and the associated reasonable assurance findings on program acceptability

The staff agrees with some of NEI's statements and disagrees with others. Inspection Manual Chapter (IMC) 2513, "Light Water Reactor Inspection Program - Preoperational Testing and Operational Preparedness Phase," dictated the timing of various inspections, including those related to fire protection, during the operating license review under 10 CFR Part 50. (IMC-2513 is no longer an actively maintained IMC; however, the staff believes the information that it contains is useful.) IMC-2513 indicates that the fire protection program inspection (IP 64704) is part of the minimum inspection program on which the staff would base its decision on the applicant's readiness for operating license issuance. IP 64704 objectives are to (1) evaluate the overall adequacy and implementation of the licensee's approved fire protection program, (2) review the procedural incorporation and implementation of any changes permitted or required by the NRC in the fire protection program, and (3) determine the adequacy of the licensee's system for conducting programmatic changes necessitated by quality assurance audit results, generic deficiencies, or events. The inspection verifies that the licensee has developed technically adequate procedures to implement the entire fire protection program. In addition, it evaluates the implementation of the procedures, verifies the proper installation of fire protection systems, evaluates the readiness of licensee's personnel to prevent and fight fires, and evaluates the effectiveness of licensee controls.

The staff agrees with NEI that NRC review of detailed procedures is important to enable the staff to understand how program requirements are being met and to verify the adequacy of implementation. The procedures do not include all of the procedures that an applicant would have to develop, but, rather, are a subset of the overall procedures needed to operate the plant. This would also be true of implementing procedures for other programs that fall into Category C.

The staff understands that the implementing procedure review done in accordance with IP 64704 is needed in order to issue a COL without ITAAC for the fire protection program. If the fire protection procedures or similar information are not available during review of a COL application, then a reasonable assurance finding with respect to program adequacy at the COL stage is still possible based on the information normally contained in an FSAR; however, the staff believes that such a COL would need to include ITAAC to verify the development and implementation of the fire protection procedures.

III.b Use of Training Program as an Example

NEI's letter also provides an example related to the training program required by 10 CFR 50.120. NEI referenced words in an ongoing Part 52 rulemaking (see 68 FR 40025) that would clarify what information must be provided to support the issuing of the COL. In the proposed rule, the Commission proposed to revise the language in § 52.78 to clarify its requirements and to redesignate it as § 52.209. The proposed rule provides that the application must "describe" the training program required by § 50.120 in the application, and proposes a separate requirement for the combined license holder to establish and implement a training program. NEI states that it agrees with the distinction identified in the Part 52 proposed rule between "describing" programs in the COL application and "establishing and implementing" them prior to operation.

The staff disagrees with NEI. A fundamental assumption for the proposed rule was that ITAAC for training would be a condition of a COL. The staff does not intend to treat the training program any differently than the fire protection program. That is, if the training program procedures are not available during the review of the COL application, then a reasonable assurance finding at the COL stage is still possible based on the information discussed in the supplementary information of the proposed rule. However, the staff believes that such a COL would have ITAAC to verify the implementation of the training program. The staff notes that the proposed rule could be revised to require that the training program be implemented before a decision is made on a COL application, and no ITAAC would then be needed in accordance with the September 11, 2002, SRM.

III.c Litigation Risk Associated With the Post-Construction Hearing

The NRC staff asked if the industry's opposition to ITAAC on operational programs was motivated primarily by the desire to reduce litigation risk associated with the post-construction hearing. In its letter NEI stated the following to address the staff's question:

The scope of the post-construction hearing corresponds to the scope of ITAAC, and so, as a general matter, the risk of litigation increases as the scope of ITAAC increases. This increase would be non-linear to the extent that additional ITAAC do not contain objective acceptance criteria. The industry fully accepts the litigation risk associated with the required scope of ITAAC; prospective applicants will weigh this risk and many other factors in making their business decision on a new nuclear plant project. We oppose ITAAC that are neither required nor necessary because such ITAAC add undue regulatory burden in the form of increased litigation risk in the post-construction hearing. As discussed above, ITAAC on programs are not required to support reasonable assurance findings at COL or to assure adequate protection of public health and safety prior to operation.

The staff believes that any issue relating to the adequacy of ITAAC for operational programs would properly be litigated only in the mandatory hearing on the COL application. If the mandatory hearing results in the issuance of a COL, the adequacy of the ITAAC in the COL, including those for operational programs, cannot subsequently be litigated in a hearing held pursuant to 10 CFR 52.103. Rather, in accordance with 10 CFR 52.103(f), a member of the

public who wishes to challenge the adequacy of ITAAC after a COL has been issued may file a petition pursuant to 10 CFR 2.206 requesting enforcement action with respect to the ITAAC. The industry may find acceptable the litigation risk associated with the mandatory hearing on whether the COL should be issued because this may occur at a stage before substantial resources have been dedicated to constructing a plant.

III.d Treatment of the Inservice Inspection and Inservice Testing Program

NEI commented during the workshop and in its letter about the staff's proposed Category E - an ITAAC for a program is not necessary because ITAAC will be dispositioned prior to fuel load and the program is not required to be implemented until after fuel load. The staff's proposal placed the maintenance rule and the inservice inspection and inservice test program in this category. NEI asked why, if the staff can make its reasonable assurance findings without ITAAC or procedure-level information on these programs, does the staff believe that ITAAC are needed on other programs?

The staff answered during the workshop that ITAAC are the sole basis for the decision that is made by the Commission on whether or not to authorize operation. Matters like the maintenance rule that take place after fuel load will be controlled by license conditions just like other operational issues that are performed after fuel loading like low-power testing. The staff also mentioned that when category E was developed, it considered how such programs would be handled under the 10 CFR Part 50 licensing process, which still can be used. Requirements such as the maintenance rule were promulgated after the last operating licenses were issued. The staff stated during the workshop that it envisioned license conditions associated with the implementation of these programs.

Staff Supplemental Response

The staff believes that under the 10 CFR Part 50 licensing process, the inservice inspection and inservice testing program and the maintenance rule would not be implemented until after issuance of an operating license and initial fuel load. Therefore, the adequacy of the implementation of these programs would not be ripe for a challenge in a hearing on an operating license application. For the same reason, implementation of these same programs prior to authorization to load fuel in accordance with 10 CFR Part 52 would also not be ripe for challenge. (It should be noted that the adequacy of the program description will be reviewed during the review of the application, which could result in license conditions governing implementation, all of which might be litigated at the mandatory COL hearing.) Therefore, the staff believes that by placing these programs in Category E, it is being consistent with how they would be treated under a Part 50 licensing process. The staff further believes that the rest of its categorization of programs is consistent with this philosophy.

IV. Changes to the Staff's Proposal Subsequent to the August 25, 2003, Workshop

Subsequent to the August 25, 2003, workshop, the staff determined that the term "quality assurance program" was too broad of a term. Consistent with the staff's original proposal, the staff determined that the quality assurance program description should be discussed in two phases. The two phases are: quality assurance during the design and construction phases and quality assurance during the operations phase. These two categories follow the guidance

contained in Sections 17.1 and 17.2 of NUREG-0800, "Standard Review Plan Review of Safety Analysis Reports for Nuclear Power Plants LWR Edition," respectively.

For quality assurance during the design and construction phases, the staff believes that programmatic ITAAC are not necessary because hardware-related ITAAC address the results to which the program is directed. Therefore, this program is proposed to be placed in Category B of the staff's proposal. Because there are no such hardware-related ITAAC for quality assurance during the operations phase the staff proposes that this program be placed in either Category C or D based on the availability of quality assurance operations phase program information prior to issuance of a COL

V. Conclusions

The staff has reviewed the comments that it received during the workshop and in the written responses to the FRN and has not made any changes to its proposal based on these responses. With the exception of clarifying the treatment of the quality assurance program, the staff did not change its proposal. The staff believes it needs Commission guidance on whether the staff's approach to this matter fulfills the intent of the Commission's SRM dated September 11, 2002. The staff believes that information beyond that normally contained in an FSAR is needed in order to issue a COL without ITAAC for programs that fall into Category C of its proposal, with such information being sufficient to verify implementation of those programs.