

POLICY ISSUE NOTATION VOTE

October 28, 2005

SECY-05-0197

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: REVIEW OF OPERATIONAL PROGRAMS IN A COMBINED LICENSE
APPLICATION AND GENERIC EMERGENCY PLANNING INSPECTIONS,
TESTS, ANALYSES, AND ACCEPTANCE CRITERIA

PURPOSE:

To describe the staff's plan for reviewing operational programs in a combined license (COL) application and to obtain Commission approval to:

1. Include license conditions for operational programs in a COL.
2. Identify the list of operational programs required to be included in a COL application through current efforts to update the Nuclear Regulatory Commission (NRC) standard review plan.
3. Allow the use of proposed generic emergency planning/emergency preparedness (EP) inspections, tests, analyses, and acceptance criteria (ITAAC) as a model for inclusion in COL applications.

SUMMARY:

The staff has concluded that all operational programs discussed in this paper can be fully described in a COL application. The COL application would not call for ITAAC for an operational program if the program and its implementation, with the exception of EP, are fully

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described in a COL application. The staff is proposing that each COL contain license conditions associated with the timing of implementation for these programs. The staff is also providing the Commission with the results of its work with external stakeholders on generic EP ITAAC.

BACKGROUND:

In a September 11, 2002, staff requirements memorandum (SRM) for SECY-02-0067, "Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Operational Programs (Programmatic ITAAC)," the Commission provided direction to the staff that a COL applicant is not necessarily required to have ITAAC for an operational program with the exception of EP. In this SRM, the Commission stated the following:

[A]n 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. The burden is on the applicant to provide the necessary and sufficient programmatic information for approval of the COL without ITAAC.

The Commission defined "fully described" in a May 14, 2004, SRM for SECY-04-0032, "Programmatic Information Needed for Approval of a Combined License Application Without Inspections, Tests, Analyses, and Acceptance Criteria."

In this context, "fully described" should be understood to mean that the program is clearly and sufficiently described in terms of the scope and level of detail to allow a reasonable assurance finding of acceptability. Required programs should always be described at a functional level and at an increased level of detail where implementation choices could materially and negatively affect the program effectiveness and acceptability.

In SRM-SECY-04-0032, the Commission directed the staff as follows:

The staff should complete its work on the information necessary for the COL application for each of the programs for which the staff had previously assumed ITAACs would be required (fire protection, training, quality assurance during operation, fitness for duty, access authorization, radiation protection, physical security, licensed operator, and reportability programs). . .and present its results to the Commission.

In response to the direction provided in SRM-SECY-04-0032, the staff held seven public meetings with the Nuclear Energy Institute (NEI) COL task force to discuss the COL application information needed to review the operational programs identified in NEI's letter of May 14, 2001 (ML011370644). These public meetings were held in conjunction with public meetings discussing NRC comments on NEI 04-01, Revision D, "Draft Industry Guideline for Combined

License Applicants Under 10 CFR Part 52,” dated December 21, 2004 (ML050110295). The staff also held additional public meetings with NEI to discuss updates to NUREG-0800, “Standard Review Plan [SRP] of Safety Analysis Reports for Nuclear Power Plants,” related to certain operational programs (quality assurance and radiation protection). These public meetings are related because the NEI COL task force plans to include guidance related to operational programs in NEI 04-01.

In preparation for the public meetings discussing operational programs, the staff evaluated whether each program and its implementation could be fully described in a COL application, consistent with the direction provided by the Commission. In response to a request from the staff, NEI provided its proposal to address SRM-SECY-04-0032 in its letter to the NRC dated August 31, 2005 (ML052510037). This paper presents the results of the staff’s work and its interactions with external stakeholders and provides recommendations to the Commission.

DISCUSSION:

The staff has concluded that a COL applicant can fully describe all the operational programs and their implementation, with the exception of EP, listed in NEI’s letter dated August 31, 2005. Therefore, if these programs and their implementation are fully described, they will not require ITAAC. These include the operational programs identified in the May 14, 2004, SRM, with one exception. After discussions with the NEI COL task force, the staff concluded that reportability is not an actual program but rather a collection of requirements that are either part of the quality assurance program or not reviewed in a COL application.

A COL applicant may, at its option, choose to submit a complete program description for any particular program, but omit implementation information and instead include ITAAC. The staff also notes that unique circumstances involving a particular application may raise an implementation issue on an operational program that is best resolved by an ITAAC. The staff expects such circumstances to be rare.

COL Application Information Required to Review Operational Programs

Title 10 of the *Code of Federal Regulations* (10 CFR), Section 52.79, “Contents of applications; technical information,” requires that a COL application contain a final safety analysis report (FSAR). Specifically, 52.79(b) states, in part:

The application must contain the technically relevant information required of applicants for an operating license by 10 CFR 50.34. The final safety analysis report and other required information may incorporate by reference the final safety analysis report for a certified standard design.

The technical information requirements of 10 CFR 50.34 include the submission of information on operational programs. Therefore, the COL applicant is required to provide an FSAR discussion for operational programs in a COL application. The staff is proposing to clarify

operational program information requirements for COL applications in the proposed rulemaking to 10 CFR Part 52, which will soon be provided to the Commission for consideration.

Implementation of Operational Programs

In the public meetings on operational program reviews, the staff and the NEI COL task force discussed the implementation of each program listed in NEI's letter of May 14, 2001. The staff identified an issue from these meetings related to implementation of operational program commitments. A substantial portion of operational program development activities will occur after the issuance of a COL. The NRC intends to inspect each operational program to verify that the key elements of each program on which the staff relied to make a reasonable assurance finding have been or will be incorporated into the program. NEI's letter of August 31, 2005, proposes license conditions associated with implementation of operational programs.

The implementation strategy currently in the regulations reflects licensing in accordance with 10 CFR Part 50, where an operating license is issued after construction is completed. Under a Part 52 COL, a reasonable assurance finding on all operational programs required by regulation must be made before the license is issued and the plant is constructed. Most operational programs need to be implemented at or before fuel load.

In accordance with Commission direction, implementation milestones for operational programs that do not have ITAAC should be fully described or referenced in the FSAR. The staff believes the description should include one or more implementation milestones depending on whether the program will be implemented all at once or on a phased basis. As an example, portions of the radiation protection, fire protection, and security programs are implemented before fuel is brought on site while the inservice testing program is required to be implemented when the plant is placed in commercial service. The staff would review and approve the proposed implementation milestones for each operational program in the course of reviewing the COL application and will make a reasonable assurance finding on each program and its proposed implementation, including the adequacy of the implementation milestones. These findings will be documented in the staff's safety evaluation report (SER).

License Conditions for Implementing Operational Programs

The regulations do not specify implementation requirements for a majority of operational programs listed in Attachment 1 of this paper. The staff recognizes that few, if any, of these programs will need to be implemented when the COL is issued. There is a potential issue concerning the implementation of operational programs for which no implementation requirements are specified in the regulations. Under the Part 50 licensing regime, this subset of programs would be required to be fully implemented when the operating license was issued. Therefore, one would expect that these programs would be implemented upon COL issuance under Part 52. To address this issue, the staff has proposed a set of license conditions that will link program implementation, which is fully described in the FSAR, to the license. The license conditions described below will also provide certainty for the NRC as to when the operational

programs are scheduled to be implemented, as well as for the licensee as to when NRC inspectors would plan to inspect these programs.

NEI's August 31, 2005, letter states:

We agree that for programs required by regulation, the FSAR should describe the programs and their implementation. Also, we agree that a license condition would be imposed concerning program implementation.

NEI has proposed license conditions related to the fire protection and security programs in its letter dated August 31, 2005. With regard to fire protection, NEI has proposed to modify the license condition provided in NRC Generic Letter (GL) 86-10, "Implementation of Fire Protection Requirements," with two separate license conditions, one each for implementing and changing the fire protection program. The staff proposes to retain the generic language in GL 86-10, which is found in the licenses of all operating reactors, for a COL. The license condition included in GL 86-10 is as follows:

(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.

Regarding security, NEI has proposed a license condition requiring the licensee to implement and maintain in effect the approved physical security, guard training and qualifications, and safeguards contingency plan. The staff proposes to retain the security license condition based on the generic COL provided in SECY-00-0092, "Combined License Review Process."

The licensee shall fully implement and maintain in effect all provisions of the physical security plan, security personnel training and qualification plan, and safeguards contingency plan, and all amendments made pursuant to the authority of 10 CFR 50.90, 50.54(p), 52.97[, and Section VIII of Appendix ___ to Part 52] when nuclear fuel is first received onsite, and continuing until all nuclear fuel is permanently removed from the site.

License conditions similar to those proposed by NEI could address the remaining operational programs listed in Attachment 1 that do not have implementation requirements in the regulations. The staff, however, recommends a different approach and is proposing the following license condition:

The licensee shall implement the programs or portions of programs identified in Table__ on or before the associated milestones in Table__.

The table referenced in this license condition will be included in the license. It will specify each operational program that does not have implementation requirements in the regulations at the time the COL is issued and its associated implementation milestones. The number of implementation milestones would depend on whether the program was implemented on a phased basis or all at once. For example, the staff expects that the radiation protection program will have 4 implementation milestones (sources on site, fuel on site, fuel load, and first shipment of waste) whereas the motor-operated valve (MOV) program will be fully implemented at a specific milestone before plant startup. The portion of the program implemented at a particular milestone would be described in the implementation section of the FSAR.

NRC intends to inspect operational programs and their implementation as they are developed and put into place. These inspections would verify that the program being implemented is consistent with the FSAR. In addition, these inspections would verify that any changes made to the programs as described have not adversely impacted the bases for the Commission's findings of reasonable assurance. Any adverse impacts discovered during inspection will be subject to enforcement action.

NEI proposed in its August 31, 2005, letter that COL applicants include a table in the FSAR listing each operational program and the section in the FSAR where its implementation is fully described. NEI also proposed that within 12 months after issuance of the COL, the licensee make available a schedule to support inspection of its operational programs and provide periodic updates of the schedule until fuel load.

The staff agrees with NEI's proposal for a license condition requiring the licensee to provide operational program implementation schedules to facilitate NRC inspection. The staff agrees that the licensee should provide an implementation schedule semiannually starting 1 year after the issuance of a COL. However, recognizing that maintaining NRC inspection schedules will be critical to ensuring that the Commission has timely information on operational readiness, the staff proposes that within 12 months of fuel load, the licensee submit an updated program implementation schedule monthly until the last operational program listed in the FSAR table has been fully implemented or the plant has been placed into commercial service, whichever comes first. The staff proposes this reporting license condition be written as follows:

Within 12 months after COL issuance, the licensee shall submit to the NRC an implementation schedule for the operational programs listed in FSAR Table [13.X]. The schedule shall be updated every 6 months until 12 months before scheduled fuel load, and monthly thereafter until either the last program in FSAR Table [13.x] has been fully implemented or the plant has been placed into commercial service, whichever comes first.

The timing and closure of operational program inspections will be discussed in a future paper concerning construction inspection program policy issues.

Scope of Operational Programs Reviewed in a COL Application

During the public meetings on operational programs, the staff and NEI discussed what programs, beyond the 14 listed in the NEI letter of May 14, 2001, were required by regulation, and would be reviewed in a COL application. NEI provided the following expanded list of programs in Attachment 2 of its letter dated August 31, 2005:

Containment Leakage Rate Testing	Emergency Preparedness
Fire Protection	Maintenance Rule
Operator Training	Operator Requalification
Plant Staff Training	Physical Security
Access Authorization	Vehicle Control
Radiation Protection	Fitness-for-Duty
Process and Effluent Monitoring and Sampling	Reactor Vessel Material Surveillance
Preservice Inspection	Quality Assurance - Operations
Preservice Testing	Inservice Inspection
Equipment Qualification	Inservice Testing
Weapons Training and Weapons Qualification and Requalification	

This expanded list of operational programs constitutes the programs that NEI is proposing to list in the FSAR that would be subject to the reporting license condition. Table 1 of Attachment 1 to this paper reconciles the two lists of operational programs provided by NEI letters dated May 14, 2001, and August 31, 2005. Table 1 also shows that certain operational programs, such as the security program, contain one or more separate operational programs. The staff reviewed the list of operational programs included in the August 31, 2005, letter, and concludes that these programs are required by regulation. The staff will review these programs in a COL application and make a reasonable assurance finding on each of the operational programs.

The staff believes that NEI's operational program list is not complete. All operational programs included in the above list are required by regulation, reviewed in a COL application, and inspected to verify program implementation as described in the FSAR. Using these criteria for operational programs, the staff concludes that the MOV program required by 10 CFR 50.55a(b)(3)(ii) is an operational program that should be added to the list. The NRC staff plans to review the MOV program information in a COL application and inspect the MOV

program before plant startup when sufficient program documentation is available to conduct this inspection. The staff also concludes that the safeguards contingency plan operational program required by 10 CFR 50.34(d) should be included in the expanded list of operational programs. This program is similar to the weapons training and qualification and requalification program in that it is part of the physical security program. These two programs are listed in Table 2 of Attachment 1 to this paper.

A COL applicant may choose to use an operational program to satisfy a regulation although the program is not explicitly required by regulation. In this case, the COL applicant should add this operational program to the list of programs in the FSAR. This addition would only be applicable to the individual COL applicant and not to all future COL applicants.

Standard Review Plan (SRP) Guidance for Operational Programs

Guidance to review all operational programs in a COL application is or will be included in the SRP. The tables in Attachment 1 of this paper identify SRP sections where applicable review guidance for each operational program will be located. The staff anticipates that the guidance contained in the update to NUREG-0800 will address the Commission's direction in SRM-SECY-04-0032. Specific schedule information regarding updating the SRP will be provided in response to SRM-M050406 dated May 10, 2005.

Several SRP sections are currently being revised, in part, to provide updated review guidance in preparation for the review of COL applications. The staff proposes to use the SRP update effort as a mechanism to identify any additional operational programs that meet the criteria for inclusion in a COL application. This approach would facilitate timely staff review and stakeholder feedback if any additional operational programs meet the criteria. An updated list of programs will be included in updated staff application guidance. The staff is proposing to seek stakeholder feedback on the scope of operational programs in a COL application in the statement of considerations to the proposed rule change to 10 CFR Part 52.

Generic Emergency Planning ITAAC

After the issuance of SRM-SECY-02-0067, the staff worked with NEI and the Department of Homeland Security/Federal Emergency Management Agency (DHS/FEMA) to develop generic EP ITAAC. The staff and NEI held a number of public meetings to discuss the issues related to generic EP ITAAC. As stated in an NRC letter dated June 15, 2005 (ML051390065), EP ITAAC present a first-of-a-kind example of programmatic ITAAC under 10 CFR Part 52, and reflect the collective efforts of the NRC and FEMA staff, industry and other stakeholder input, and incorporation of various lessons learned from previous design certification reviews. They are generic in nature, and would be tailored by each COL applicant to its specific reactor design and EP program requirements. NEI has incorporated the generic EP ITAAC into NEI 04-01. The EP ITAAC are included in Attachment 2 of this paper.

While the generic EP ITAAC included in Attachment 2 of this paper reflects what the staff believes to be a reasonable basis for the development of the minimum EP ITAAC in a COL application, the acceptability of proposed plant-specific EP ITAAC will be reviewed on a case-by-case basis.

COMMITMENTS:

There are no additional commitments in this paper.

RECOMMENDATIONS:

That the Commission:

1. *Approve* inclusion of license conditions for operational programs in a COL. Specifically:
 - a. License conditions for implementation of the fire protection and security operational programs.
 - b. A license condition applying to the remaining operational programs listed in Attachment 1 of this paper that do not have implementation requirements. These programs or portions of programs and associated implementation milestones would be listed in the license.
 - c. A license condition that specifies that the licensee shall make available to the NRC staff a schedule 12 months after issuance of a COL that supports planning for and conduct of NRC inspections of operational programs listed in the operational program FSAR table. The schedule shall be updated every 6 months until 12 months before scheduled fuel load, and every month thereafter until either the operational programs listed in the FSAR table have been fully implemented or the plant has been placed in commercial service, whichever comes first.
2. *Approve* further additions to the operational programs listed in this paper, as supplemented by the MOV testing and safeguards contingency plan operational programs, if any additional programs required by regulation are identified through the SRP update process.
3. *Allow* the use of the generic EP ITAAC included in Attachment 2 to this paper as the minimum set of ITAAC for EP included in a COL application.

RESOURCES:

The resources to complete the recommendations in this paper are contained in the Office of Nuclear Reactor Regulation (NRR) and the Office of Nuclear Security and Incident Response (NSIR) budgets as part of the new reactor licensing budget. The resources in NRR and NSIR are less than 0.1 FTE in FY 06 and FY 07.

COORDINATION:

The office of the General Counsel has no legal objection to this paper.

/RA/

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- Attachments:
1. Operational Programs
Reviewed in a Combined
License Application
 2. Generic EP ITAAC Table

COORDINATION:

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