

December 17, 2004

ORGANIZATION: Nuclear Energy Institute (NEI)

SUBJECT: SUMMARY OF NOVEMBER 9, 2004, MEETING WITH NEI TO DISCUSS EMERGENCY PLANNING (EP) INSPECTIONS, TESTS, ANALYSES, AND ACCEPTANCE CRITERIA (EP ITAAC) AND DISCUSSION OF COMBINED LICENSE (COL) APPLICATION ISSUES

On November 9, 2004, a public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) and NEI at NRC Headquarters in Rockville, MD. Staff from the Department of Homeland Security/Federal Emergency Management Agency (DHS/FEMA) also participated in the meeting. The purpose of this meeting was to discuss EP ITAAC and issues associated with a combined license (COL) application. A list of meeting attendees and the meeting agenda are included as Attachment 1.

NRC and NEI handouts were provided during the meeting. The handouts can be accessed through the Agencywide Documents Access and Management System (ADAMS) under Accession No. ML043240352 (Attachments 2 through 8). This system provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the handouts located in ADAMS, contact the NRC Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdrc@nrc.gov](mailto:pdrc@nrc.gov).

#### EP ITAAC Portion of the Meeting

The EP ITAAC portion of the meeting was a follow-up to NEI's letter dated September 15, 2004, (ADAMS Accession No. ML043230044), and a telephone conversation on November 2, 2004, between the NRC staff and NEI. The September 15, 2004, letter proposed various NEI revisions to the EP ITAAC based on discussions in previous meetings. During the November 2, 2004, telephone conversation the NRC staff discussed with NEI a revised EP ITAAC Table 13.3-1 (ADAMS Accession No. ML043200752), which reflected NEI's letter and the NRC staff's position on the proposed EP ITAAC.

During the meeting, the NRC staff and NEI agreed that the EP ITAAC reflected in Planning Standards 1.0 through 7.0 of Table 13.3-1 were acceptable. Therefore, the meeting was focused on resolution of outstanding issues associated with EP ITAAC in Planning Standards 8.0 and 9.0. During the meeting, NEI provided some minor editorial changes to Table 13.3-1.

The discussion of items 8.1.1 and 8.1.3, addressed the definition of onsite and offsite exercises, including when identified exercise deficiencies need to be corrected. An onsite deficiency, according to 8.1.1, would have to be corrected prior to fuel load. An offsite deficiency, according to 8.1.3, would be corrected prior to the reactor exceeding 5 percent of rated power. An ITAAC is based on events occurring prior to fuel load. Some aspects of EP, however, are based on events occurring prior to exceeding 5 percent of rated power. NEI pointed out that offsite deficiencies generally involve issues that are outside of the licensee's control. NEI also stated that the 120-day clock, for FEMA to verify corrections to deficiencies, might put a strain

on a new licensee. FEMA staff stated that current practices usually result in verifying deficiency corrections within the 120-day period.

The NRC staff quoted the regulation related to the issuance of a license, found in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.47(d), which states that a license authorizing fuel loading and/or low power testing and training may be issued after the NRC finds that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

The NRC staff suggested that if item 8.1.3 was not acceptable to the Commission, then a license condition could be written into a COL, which would state that the offsite deficiencies would be resolved prior to exceeding 5 percent of rated power. NEI questioned the NRC staff on the definition of a deficiency and a weakness, as they related to Item 8.1.1. The NRC staff stated that NRC Inspection Manual Chapter 0612, "Power Reactor Inspection Reports," provides a definition for these two terms.

For item 9.1, the NRC staff informed NEI that a licensee may need to submit an exemption request to the regulation (i.e., Appendix E to 10 CFR Part 50, Section V), to allow them to submit the procedures 180 days prior to fuel load, since the regulation states that the procedures are to be submitted 180 days prior to having "nuclear material" onsite. Both sides agreed that in the long term, the regulation needs to be changed. NEI questioned whether the letter that is submitted with the detailed implementing procedures could be used to verify that the ITAAC had been met. The NRC staff said it could be.

For item 8.1, the NRC staff commented that, in the column titled "Inspections, Tests, Analyses," the term "exercise" is not consistent with the term "test," used in the other items. It was agreed that the word "test" would appear in parenthesis after the words, "A full-participation exercise..." At the conclusion of the meeting, the NRC staff, FEMA, and industry had generally agreed on a final version of generic EP ITAAC, in support of COL applications and reviews.

Proposed Approach for Response to SRM-SECY-04-0032

The NRC staff presented a status of their approach to address SRM-SECY-04-0032, "Programmatic Information Needed for Approval of a Combined License Without Inspections, Tests, Analyses, and Acceptance Criteria." The staff noted that the following operational programs were listed in SECY-02-0067, "Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Operational Programs (Programmatic ITAAC)."

Emergency Planning	Physical Security
Quality Assurance	Fire Protection
Radiation Protection	Access Authorization
Fitness for Duty	Training
Licensed Operator	Reportability
Containment Leak Rate Testing	Maintenance Rule
Inservice Inspection and Inservice Testing	Equipment Qualification

The staff also noted that emergency planning would have ITAAC. In discussing ITAAC for the remaining operational programs listed above, staff requirements memorandum (SRM)-SECY-02-0067 stated the following:

Although the NRC inspection process does not replace a particular ITAAC, an ITAAC should not be necessary if the program and its implementation are **fully described** in its application [*emphasis added*].

Additional clarification of the phrase “fully described” was provided in SRM-SECY-04-032:

... “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.

The staff stated that they plan to respond to SRM-SECY-04-0032 prior to December 31, 2005. The approach that has been proposed to address the SRM involves evaluating the information required by 10 CFR 52.79(b) to be submitted in the COL application (i.e., the final safety analysis report [FSAR]) plus any additional information necessary to fully describe the operational program, which would include a discussion of the program implementation. The staff would document their evaluation in the final safety evaluation report. For programs that were not implemented prior to the issuance of the COL, a condition would be placed in the license.

The staff noted that the Commission did not eliminate the possible utilization of ITAAC for operational programs. In fact, SRM-SECY-02-0067 states that the staff should inform the Commission if it plans to require any specific programmatic ITAAC for at least the first few COL applications. The staff stated that their proposed approach does not assume that all operational programs will have ITAAC. In addition, the staff stated that a COL applicant may propose ITAAC for selected operational programs for consideration by the staff.

NEI stated that they wanted to discuss which specific programs were part of this approach. One specific example cited by NEI was reportability, which NEI representatives did not believe was within the scope of this operational program discussion. The staff stated that reportability was one of the programs listed in SECY-02-0067. In addition, SRM-SECY-04-032 specified that the staff identify the information necessary in a COL application for nine specific operational programs (fire protection, training, quality assurance during operation, fitness for duty, access authorization, radiation protection, physical security, licensed operator, and reportability) and present those results to the Commission. The staff stated that they will likely perform this for all the operational programs listed in SECY-02-0067 with the exception of emergency planning. The staff and NEI both agreed to participate in public meetings starting early next year to discuss the information needed for specific operational programs beyond what will be included in the FSAR to support NRC staff review of that program.

#### Discussion of NEI's COL Application Guidance Document (NEI 04-01)

NEI presented the status of NEI 04-01. NEI stated that they plan to issue the draft COL application guide in December 2004 and would like the NRC staff to formally comment on the document. NEI stated that they are seeking endorsement of Revision 1 of the document by the end of 2005. NEI stated that this schedule supports the schedule of future COL applicants.

NEI provided a draft table of contents of the COL application guidance document which is included in Attachment 7 of this meeting summary. NEI stated that the guidance document is approximately 200 pages in length and contains two lengthy appendices. NEI stated that where they did not feel there was "controversy," specific guidance was included in the document. NEI did note that the status of the 10 CFR Part 52 rulemaking is complicating the development of the COL application guide.

The document includes chapter by chapter guidance for the FSAR, as well as COL action items (identified in the referenced design certification and early site permit [ESP] if applicable) as well as interface requirements. The document also identifies key references such as the NRC standard review plan (SRP), regulatory guides (RG), and unresolved safety issues/generic safety issues. Special topics that are discussed include the design reliability assurance program, ITAAC, plant-specific design ITAAC, and plant-specific technical specifications.

NEI also provided a revised figure outlining their proposed components of a COL application which is included as Attachment 6. The NRC staff previously reviewed this figure and provided comments in a public meeting dated January 29, 2004. NEI stated in this meeting that some of the comments have been incorporated into the figure but did not disposition each comment previously provided by the staff.

NEI stated that it was important to separate the design control document for a certified design from the site specific information contained in a COL application because there is a separate change process for each. The NRC staff stated that Section IV of each design certification rule in 10 CFR Part 52 contains requirements on incorporating certified design information into a COL application and those requirements should be the starting point for COL application guidance. NEI stated that they would provide an example of information that was already approved in a design certification and an early site permit versus information that is part of the COL application.

With regard to site specific ITAAC, NEI stated that they do not regard this as being different as compared with ITAAC included in a design certification rule. The ITAAC would focus on key aspects of the design feature. NEI stated that applicants would only provide site-specific design ITAAC for significant interface requirements (see Attachment 7, Slide 8). The NRC staff objected to this statement, stating that ITAAC was not part of the basis for interface requirements and that they would expect ITAAC on site specific features such as the cooling tower and service water system.

NEI further commented on several specific topics as discussed below:

Reliability Assurance Program: NEI noted that this was new to design certification and that a draft SRP existed and it is assumed that it will be available. NEI also noted that the operational reliability assurance program was a combination of existing programs.

Quality Assurance (QA): NEI noted that the regulatory guides were outdated and the associated SRP section had been removed from use. While an example exists for an operating QA program, there is no example of a construction QA program. NEI requested that the staff update the guidance in this area. They also stated that they regard this issue as a high priority.

Technical Specifications (TS): With regard to making major changes to the generic TS from the certified design, NEI would like the staff to comment on their proposal to submit one exemption request covering changes in the TS that are not bracketed. In addition, NEI would like to know if this exemption request should be included with the COL application or after discussions with the NRC. NEI also stated that the applicants would identify TS that they regard as generic.

NEI noted that information for certain portions of the plant specific TS may not be available when the COL application is submitted to the NRC. In addition, certain TS supporting documents, such as the offsite dose calculation manual, will not be available at the time of the COL application. NEI would like the NRC comment on whether these issues would need to be resolved before the COL is issued or would conditions on the license be appropriate to address certain issues in this area.

Chapter 19 (Severe Accidents) and the Probabilistic Risk Assessment (PRA): NEI stated that they are considering streamlining Chapter 19 such that it will not include everything that was included in the design control document (DCD) of the certified design. NEI noted that they are proposing that the DCD be referenced in the safety analysis report and not an integral part of the report. The NRC staff noted that Chapter 19 of each DCD is different and stated that further discussions in this area would be necessary.

NEI also noted that the COL action items in design certifications (such as the AP1000) discuss as-built information. The NRC stated that there was no correlation between the COL action items and the proposed rule changes to 10 CFR Part 52.

NEI stated that they envision PRA as a separate document from the safety analysis report that would be retained from the design certification as opposed to be resubmitted. The NRC staff stated that, in light of the recent notice of proposed rulemaking for 10 CFR Part 52, that additional discussions on this issue were necessary.

Human Factors Engineering: NEI briefly noted issues in this area for future discussion including which ITAAC should be completed for the COL application and the time table at which human factors engineering issues should be resolved (prior to COL, at COL and after COL). NEI stated that they believe the following issues can be resolved after the COL is issued: 1) human system interface design, 2) human factors validation and verification, and 3) design implementation.

NRC COL Review Guidance: NEI requested that the staff provide them with a status of the SRP update. Their belief is that a COL review standard would be helpful as it was in the review of ESPs. NEI stated that if they had a choice, they would ask the NRC to develop a COL review standard before completing the SRP update, but not at the expense of the review of NEI 04-01. NEI further stated that a COL review standard would be a complement to the application guidance and committed to look at what they can do to provide a bridge to a NRC COL review standard. The NRC stated that it had limited resources available but would like to discuss the issue further and identify specific areas where the NRC could possibly provide review guidance.

#### Concluding Remarks

NEI concluded the meeting by stating that their first priority was to complete the COL application guidance document and submit it to the NRC sometime in December 2004. In addition, they requested discussions with the NRC on operational programs, Chapter 19/PRA, criteria for site specific design ITAAC, a COL review standard, and plant-specific TS. The NRC stated that meetings on operational programs could take place sometime in January 2005. NEI proposed that the inservice testing and inservice inspection operational programs be the subject of those meetings.

*/RA/*

Steven Bloom, Project Manager  
New Reactors Section  
New, Research and Test Reactors Program  
Division of Regulatory Improvement Programs  
Office of Nuclear Reactor Regulation

Project No. 689

Attachments: 1. List of attendees and agenda

cc w/ atts: See next page

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Steven Bloom, Project Manager  
New Reactors Section  
New, Research and Test Reactors Program  
Division of Regulatory Improvement Programs  
Office of Nuclear Reactor Regulation

Project No. 689

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cc w/ atts: See next page

ADAMS ACCESSION NUMBER:ML043240352

\* see previous concurrence

OFFICE	PM:RNRP	PM:RNRP*	NSIR/DPR/EPD*	SC:RNRP*
NAME	SBloom	JColaccino	DBarss	LDudes
DATE	12/16/04	11/29/04	12/3/04	12/15/04

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RNRP R/F  
SBloom  
JColaccino  
LDudes

E-Mail

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JDyer (RidsNrrOd)  
RBorchardt  
BSheron (RidsNrrAdpt)  
FEltawila  
NRR/ADPT Secretary [RidsNrrAdpt]  
RNRP Group  
DMatthews  
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MStutzke  
DRoberts  
STingen  
Psekerak

DJohnson  
CSchulten  
RMclntyre  
TFoley  
DThatcher  
SAlexander  
TMensah (NRR Communication Coord)  
ACRS (RidsAcrcsMailCenter)  
OPA  
MEI-Zeftway  
MAAshley  
JBlake  
RGardner  
CPaulk  
LCampbell  
Mltzkowitz, OGC  
RWeisman, OGC  
GMizuno, OGC  
TKenyon  
NIqbal  
PQualls  
DBarss  
BMusico  
DNelson, OE

External e-mail

bhupinder.singh@hq.doe.gov  
tom.miller@hq.doe.gov  
Vanessa.Quinn@dhs.gov  
Kenneth.Wierman@dhs.gov  
James.Purvis@dhs.gov

**EP ITAAC and Issues Associated With a Combined License (COL) Application**

**NEI Meeting**

**November 9, 2004**

**Attendance List**

**NRC**

Laura Dudes           NRR/DRIP/RNRP  
Joe Colaccino        NRR/DRIP/RNRP  
Steven Bloom        NRR/DRIP/RNRP  
Jerry Wilson         NRR/DRIP/RNRP  
Dariusz Szwarc      NRR/DRIP/RNRP

**NEI**

Adrian Heymer  
Russell Bell  
Cedric Jobe  
Bob Fuld

Dan Barss

NSIR/DPR/EPD

**Other Interested Attendees**

Bruce Musico  
Mary Ann Ashley  
Bob Weisman  
Marty Stutzke  
Darrell Roberts  
Steve Tingen  
Naeem Iqbal  
Patrick Sekerak  
Don Johnson  
David Terao  
Thomas Kenyon  
Carl Schulten

NSIR/DPR/EPD  
NRR/DIPM/IIPB  
OGC  
NRR/DSSA/SPSB  
NSIR/DPR/EPD-A  
NRR/DIPM/IPSB  
NRR/DSSA/SPLB  
NRR/DE/EMEB  
NSIR  
NRR/DE/EMEB  
NRR/DRIP/RLEB  
NRR/DIPM/IROB

Al Passwater        Polestar  
J. G. Cesare        Enercon Services  
J. Alan Beard       GE Nuclear  
Eddie Grant         Exelon  
Michael Bourgeois   Entergy  
Steve Routh         Bechtel  
Michael Soslard     AECL  
Jim Chapman         Scientech  
Steve Frantz         Morgan Lewis  
Shinichi Hayatune   Energy USA  
Hiroyki Yoshida     Toshiba  
Sandra Sloan         Areva  
Carl Berger          Energetics  
Yuichi Hayashi      AP1000 Project  
                          Westinghouse (Kansai)  
Don Hutchings       Westinghouse  
Jim Winters          Westinghouse  
Geroge Zinke         Entergy  
Joe Hegner           Dominion  
Charles Brinkman    Westinghouse  
Larry Dibal          Black & Veatch  
John Costello        Dominion  
Ben George           Southern Nuclear

**DHS/FEMA**

Kenneth Weirman  
James Purvis

## Agenda

November 9, 2004, Meeting with Nuclear Energy Institute (NEI)  
Regarding Emergency Planning, Inspections, Tests, Analyses,  
and Acceptance Criteria (EP ITAAC), and Issues Associated  
with a Combined License (COL) Application

<u>Time</u>	<u>Subject</u>	<u>Presenter</u>
1:00 pm	Introductions and opening remarks	NRC/NEI
1:05 pm	Emergency Preparedness Inspection, Test, Analysis, and Acceptance Criteria (ITAAC)	NRC
2:00 pm	Discussion of Staff Requirements Memorandum to SECY 04-0032 - Programmatic Information Needed for Approval of A Combined License Without ITAAC	NRC
2:15 pm	Overview of Plans and Scope of NEI 04-01, Guidelines for Combined License (COL) Applications	NEI
2:30 pm	Break	
2:45 pm	Discussion of Specific COL Application Issues	NEI
	<ul style="list-style-type: none"><li>• COL Application Contents, Including Final Safety Evaluation Report (FSAR)</li><li>• Scope and Level of Detail of Plant-Specific Design Description and ITAAC</li><li>• Operational Reliability Assurance Program and COL Design Reliability Assurance Program</li><li>• FSAR Chapter 19 (Severe Accidents) and the Probabilistic Risk Assessment</li><li>• FSAR Chapter 18 (Human Factors Engineering)</li><li>• COL Application Treatment of Operational Programs</li><li>• Development of Plant-Specific Technical Specifications</li><li>• NRC Staff Review Guidance for COL Application</li></ul>	
4:45 pm	Public comment	
5:00 pm	Adjourn	

Combination List:

cc: Mr. Charles Brinkman  
Westinghouse Electric Co.  
Washington Operations  
12300 Twinbrook Pkwy., Suite 330  
Rockville, MD 20852

Mr. David Lochbaum, Nuclear Safety Engineer  
Union of Concerned Scientists  
1707 H Street, NW, Suite 600  
Washington, DC 20006-3919

Mr. Paul Gunter  
Nuclear Information & Resource Service  
1424 16<sup>th</sup> Street, NW, Suite 404  
Washington, DC 20036

Mr. James Riccio  
Greenpeace  
702 H Street, NW, Suite 300  
Washington, DC 20001

Mr. Adrian Heymer  
Nuclear Energy Institute  
Suite 400  
1776 I Street, NW  
Washington, DC 20006-3708

Mr. George Alan Zinke  
Project Manager  
Nuclear Business Development  
Entergy Nuclear  
M-ECH-683  
1340 Echelon Parkway  
Jackson, MS 39213

Mr. Thomas P. Miller  
U.S. Department of Energy  
NE-20, Rm. A286  
Headquarters-Germantown  
19901 Germantown Road  
Germantown, MD 20874-1290

Ms. Marilyn Kray  
Vice President, Special Projects  
Exelon Generation  
200 Exelon Way, KSA3-E  
Kennett Square, PA 19348

Mr. Laurence Parme  
Manager, GT-MHR Safety &  
Licensing  
General Atomics Company  
P.O. Box 85608  
San Diego, CA 92186-5608

Mr. Joseph D. Hegner  
Lead Engineer - Licensing  
Dominion Generation  
Early Site Permitting Project  
5000 Dominion Boulevard  
Glen Allen, VA 23060

Mr. Edward L. Quinn  
MDM Services Corporations  
Utility Operations Division  
28202 Cabot Road, Suite 205  
Laguna Nigual, CA 92677

Ms. Lynn Connor  
Doc-Search Associates  
2211 sw 1<sup>ST</sup> Ave - #1502  
Portland, OR 97201

Mr. Paul Leventhal  
Nuclear Control Institute  
1000 Connecticut Avenue, NW  
Suite 410  
Washington, DC 20036

Ms. Patricia Campbell  
Winston & Strawn  
1400 L St., NW  
Washington, DC 20005

Mr. W. Edward Cummins  
AP600 and AP1000 Projects  
Westinghouse Electric Company  
P.O. Box 355  
Pittsburgh, PA 15230-0355

Dr. Robert E. Gamble  
Engineering Manager, ESBWR  
GE Nuclear Energy  
175 Curtner Avenue, MC 365  
San Jose, CA 95125

December 21, 2004

Dr. Jack W. Roe  
Vice President  
Advanced Technologies & Laboratories  
International, Inc.  
20010 Century Boulevard, Suite 500  
Germantown, MD 20874

Mr. Stephen P. Frantz  
Morgan, Lewis, & Bockius, LLP  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004

Mr. Gary Wright, Manager  
Office of Nuclear Facility Safety  
Illinois Department of Nuclear Safety  
1035 Outer Park Drive  
Springfield, IL 62704

Mr. Brendan Hoffman  
Research Associate on Nuclear Energy  
Public Citizens Critical Mass Energy  
and Environmental Program  
215 Pennsylvania Avenue, SE  
Washington, DC 20003

Mr. Tom Clements  
6703 Gude Avenue  
Takoma Park, MD 20912

Mr. Lionel Batty  
Nuclear Business Team  
Graftech  
12300 Snow Road  
Parma, Ohio 44130

Mr. Ian M. Grant  
Canadian Nuclear Safety Commission  
280 Slater Street, Station B  
P.O. Box 1046  
Ottawa, Ontario  
K1P 5S9

Mr. Edward F. Sproat, III  
Vice President - Int'l Projects  
Exelon Generation  
200 Exelon Way  
Kennett Square, PA 19348

Mr. Vince Langman  
Licensing Manager  
AECL Technologies Inc.  
481 North Frederick Avenue  
Suite 405  
Gaithersburg, MD 20877

Dr. Regis A. Matzie  
Senior Vice President and  
Chief Technology Officer  
Westinghouse Electric Company  
2000 Day Hill Road  
Windsor, CT 06095-0500

Mr. Ed Wallace, General Manager  
Projects  
PBMR Pty LTD  
PO Box 9396  
Centurion 0046  
Republic of South Africa

Mr. Dobie McArthur  
Director, Washington Operations  
General Atomics  
1899 Pennsylvania Avenue, NW  
Suite 300  
Washington, DC 20006

Mr. Russell Bell  
Nuclear Energy Institute  
Suite 400  
1776 I Street, NW  
Washington, DC 20006-3708

Vanessa E. Quinn, Chief  
Radiological Emergency Preparedness  
Section  
Nuclear & Chemical Hazards Branch  
Federal Emergency Management  
Agency/DHS  
500 C Street, SW  
Washington, D.C. 20472

Mr. Ron Simard  
6170 Masters Club Drive  
Suwanee, GA 30024

E-Mail:  
jim.mallay@framatome-anp.com