July 14, 2008

MEMORANDUM TO: John A. Nakoski, Chief
Quality Assurance and Vendor Branch 2
Division of Construction Inspection and Operational Programs
Office of New Reactors

FROM: Aida Rivera-Varona, Operations Engineer ***/RA/***
Quality and Vendor Branch 2
Division of Construction Inspection and Operational Programs
Office of New Reactors

SUBJECT: SUMMARY OF THE JULY 1, 2008, MEETING TO DISCUSS THE REVIEW OF THE NUCLEAR ENERGY INSTITUTE TECHNICAL REPORT 06-14A, "QUALITY ASSURANCE PROGRAM DESCRIPTION"

On July 1, 2008, a Category 2 public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) and representatives of Nuclear Energy Institute (NEI) at the NRC headquarters offices in Rockville, Maryland. A list of meeting attendees is included in Enclosure 1.

By letter dated April 25, 2007, the NRC staff issued a Safety Evaluation Report (SER) for NEI 06-14, "Quality Assurance Program Description." As requested by the SER, NEI incorporated the SER into the document and reissued it as NEI 06-14A on July 23, 2007. NEI 06-14A provides a generic template for use by early site permit (ESP) and combined license (COL) applicants to implement applicable requirements related to the Quality Assurance Program (QAP). Since last year, the industry had begun using the document as part of the COL applications and since then, industry members, NEI personnel, and the NRC staff have identified a number of changes that needed to be made to the document.

On May 7, 2008, NEI submitted NEI 06-14A, Revision 5, for NRC review. The purpose of the meeting was to discuss the portions of NEI 06-14A that the NRC staff identified as possible areas of improvement based on the staff's review of COL applications that had used NEI 06-14A.

First, the staff discussed the organizational structure described in Part II, Section 1, "Organization," of NEI 06-14A. The lack of an adequate organizational structure description is an issue that the staff has identified among all COL quality assurance program descriptions (QAPDs) submitted at this time. The staff requested that NEI 06-14A be modified to provide additional guidance on the level of detail required to meet the regulatory requirements and staff expectations. The staff explained that users of NEI 06-14A have not provided an adequate description of the responsibilities and quality relationships during construction phase and operation phase, nor a description of the process for transferring responsibilities from construction and operations. This has resulted in additional requests for information (RAI) to COL applicants. In addition, the staff requested that NEI 06-14A provide additional guidance to ensure that functional responsibilities, levels of authority and interfaces for all positions responsible for the establishment of the quality assurance program be fully described.

With respect to commercial grade calibration services, Part II, Section 7.2, "NQA-1-1994 Commitment," of NEI 06-14A describes an NRC-approved exception to NQA-1-1994,

Supplement 7S-1, for commercial-grade calibration services from a calibration laboratory. The staff mentioned that NEI 06-14A needs to revise the relationship of the accrediting bodies and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). The staff will provide its proposed wording as part of RAIs on Revision 5 of NEI 06-14A.

In addition, the staff discussed the additional calibration laboratories (ACLASS Accreditation Services (ACLASS), the Laboratory Accreditation Bureau (L-A-B), and the International Accreditation Service (IAS)) that have become a U.S. based signatory to the ILAC MRA and have been recently approved by the staff. The staff mentioned that based on the staff's understanding of the commercial calibration laboratory accreditation process, and ACLASS, L-A-B, and IAS current status as U.S.-based signatories to the ILAC MRA, the staff considers the accreditation programs of ACLASS, L-A-B, and IAS to be another acceptable alternative to the methods used to qualify commercial-grade calibration service suppliers.

Related to commercial grade dedication programs, the staff discussed the usability of NRC Regulatory Information Summary (RIS) 2002-22, "Use Of EPRI/NEI Joint Task Force Report, 'Guideline On Licensing Digital Upgrades: EPRI TR-102348, Revision 1, NEI 01-01: A Revision of EPRI TR-102348 to Reflect Changes to the 10 CFR 50.59 Rule," in support of dedication programs. Attachment 1 of RIS 2002-22 provides the NRC staff's safety evaluation of the EPRI/NEI joint task force report. The staff noted that the NRC safety evaluation specifically states that the regulatory framework for the evaluation consisted of (1) the requirements outlined in SRP Chapter 7 for the licensing process for digital I&C components in nuclear power plants and (2) the requirements for implementing digital replacements under the 10 CFR 50.59 rule. The staff mentioned that neither SRP Chapter 7 nor 10 CFR 50.59 provides guidance on commercial grade dedication activities.

The staff asked for clarification on the use of RIS 2002-22 to support commercial grade dedication programs. NEI noted that this referred to additional documents that could be use to supplement commercial grade dedication programs and that it was never the intent to use the 50.59 rule for commercial grade dedication programs. NEI added that this guidance was provided by the staff as an example at a past meeting to supplement guidance for commercial grade dedication, but at this time the industry would remove the reference. The staff mentioned this reference might not be the appropriate example and provided reference to the Electric Power Research Institute (EPRI) topical report TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," dated October 1996 as approved by the Safety Evaluation by the Office of Nuclear Reactor Regulation, "EPRI Topical Report TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," dated July 17, 1997, as better examples to support dedication activities.

As another topic, the staff mentioned that additional brackets are needed to account for differences in the scope of QAPDs to allow the user to determine the specific information applicable for the type of application. Based on the review of current COL applications, the staff has found that some COL applicants are leaving requirements in the QAPDs that are not applicable based on the scope of the QAPD.

As a request from NEI, the staff also discussed the following topics:

- Counterfeit and Fraudulent Parts: It was noted that the staff and the industry are working to address this issue. Both, the staff and the industry, agree to continue to work together in this area.

- Foreign and U.S. Requirements: The staff mentioned that at this time, the Multinational Design Evaluation Program (MDEP) is working to compare the different codes and standards used in each country and analyze their differences.

- Suppliers and NQA-1 1994: The staff mentioned that some questions had been received regarding the use of NQA-1-1994 instead of Appendix B. The staff mentioned that the industry needs to continue to issue purchase orders to vendors referencing the requirements of Appendix B to 10 CFR Part 50. The staff emphasized that the use of NQA-1-1994 is an acceptable means of meeting the requirements of Appendix B to 10 CFR Part 50; however, it is not an equivalent or replacement to the requirements themselves.

- NEI Technical Report 08-02, "Problem Identification and Resolution for New Power Plants During Construction." On June 5, 2008, NEI submitted NEI 08-02 for staff review. NEI developed this document as an industry guideline to promote consistent, effective implementation of the construction phase PI&R. The NRC Construction Inspection Program (CIP) will inspect licensee programs for identifying and correcting problems and will base its CIP assessment process, in part, on satisfactory performance in this area. The staff is currently reviewing the document and will provide comments at a future meeting.

In summary, the staff stated that the meeting had been very helpful for purposes of understanding general issues that the staff has identified during the review of QAPDs in COL applications. NEI agreed with the comments and was planning to make certain revisions to the document in response to RAIs that the staff will issue on each of the areas discussed during the meeting.

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Enclosure: As stated

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2. Meeting Summary: ML081930273

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Attendance List

Name	Organization
Juan Peralta	NRC/NRO
Aida Rivera-Varona	NRC/NRO
Richard McIntyre	NRC/NRO
Kerri Kavanagh	NRC/NRO
Kenneth Heck	NRC/NRO
Andrea Keim	NRC/NRO
Jonathan Ortega-Luciano	NRC/NRO
Samantha Crane	NRC/NRO
Donna Sinks	NRC/NRO
Sabrina Cleavenger	NRC/NRO
Milton Concepcion	NRC/NRO
Jose G. Jimenez	NRC/NRO
Jim Fisicaro	NEI
Jim Cassidy	Duke Energy
Sherry Grier	Duke Energy
Marion Smith	STP
David Robillard	PSEG Power, LLC
Rick Weis	Florida Power and Light
John Giddens	Southern Nuclear
John Traynor	Unistar Nuclear
Steve Meyer	Ameren
H.A. (Ted) Manning	Worley Parsons
Raj Jolly	Bechtel
Ron Carver	Luminant
Terry Dunn	ASME/NQA-1
George Zinke	Entergy
Charles D. Tyler	SCE&G
Kerry Rhoads	Dominion
Nancy Chapman	Bechtel
Dean Raleigh	Advantage Scientech

ENCLOSURE 1