

November 3, 2015

Mr. Marc Nichol  
Senior Project Manager,  
Quality Issues and Licensing Action  
Nuclear Energy Institute  
1201 F Street NW, Suite 1100  
Washington, DC 20004

SUBJECT: SUMMARY OF THE OCTOBER 16, 2015, PUBLIC MEETING WITH NUCLEAR ENERGY INSTITUTE TO DISCUSS THE DISCUSS NEI 14-09, "GUIDELINES FOR IMPLEMENTATION OF 10 CFR PART 21 REPORTING OF DEFECTS AND NONCOMPLIANCE."

On October 16, 2015, a Category 3 public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) and Nuclear Energy Institute (NEI). The NRC staff had previously issued a public meeting notice dated September 28, 2015, as documented in the Agencywide Documents Access and Management System (ADAMS) under accession number ML15268A455. The meeting notice includes the meeting agenda.

The NRC staff conducted this meeting to discuss the results of the initial review of NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance." The meeting discussion focused on a list of topics where NRC staff and NEI were not aligned so NEI can prepare for a Public Meeting scheduled for November 5, 2015 to present proposals to address NRC's concerns. Enclosure 1 provides a list of attendees. The meeting handout used during the discussion is located in ADAMS under accession number ML15287A350 and is provided as Enclosure 2.

The NRC staff presented different perspectives for consideration on NEI 14-09 and some suggestions to be added to NEI 14-09. The NRC staff noted that the guidance was geared toward a reactor licensee perspective with minimal guidance provided to vendors or third party dedication entities and the guidance did not address the purchaser taking 10 CFR Part 21 responsibility when dealing with overseas suppliers. Also, the NRC staff noted a lack of clarity between the discovery and evaluation phases, and the link between 10 CFR Part 21 and corrective action program.

The NRC staff suggested to include a discussion on entities that provide safety-related software with the message that software can affect safety-related items. The NRC staff informed NEI about certain areas where the vendors would benefit from licensee's knowledge of the significance of 10 CFR Part 21 and the benefits of maintaining open dialog between licensee and vendor on a potential Part 21 evaluation.

NEI agreed to present a proposal to address NRC's concerns and to revise the NEI 14-09 guidance to reach consensus between NRC staff and NEI.

In the discussion related to Fuel Cycle Facilities, the NRC staff agree to create guidance for implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance; and incorporate industry comments. The NRC staff is planning to endorse NEI 14-09 and incorporate the materials and fuel cycle guidance in a regulatory guide.

Please direct any inquiries to Aixa Belen at 301-415-6263 or via e-mail [aixa.belen@nrc.gov](mailto:aixa.belen@nrc.gov); or Paul Prescott at 301-415-3026 or via e-mail at [paul.prescott@nrc.gov](mailto:paul.prescott@nrc.gov).

Sincerely,

**/RA Thomas Kendzia acting for/**  
Kerri Kavanagh, Chief  
Quality Assurance and Vendor Inspection Branch  
Division of Construction Inspection  
and Operations Programs  
Office of New Reactors

Enclosures:  
List of Attendees

cc w/encls:  
See next page

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Please direct any inquiries to Aixa Belen at 301-415-6263 or via e-mail [aixa.belen@nrc.gov](mailto:aixa.belen@nrc.gov); or Paul Prescott at 301-415-3026 or via e-mail at [paul.prescott@nrc.gov](mailto:paul.prescott@nrc.gov).

Sincerely,

**/RA Thomas Kendzia acting for/**  
**Kerri Kavanagh, Chief**  
 Quality Assurance and Vendor Inspection Branch  
 Division of Construction Inspection  
 and Operations Programs  
 Office of New Reactors

Enclosures:  
 List of Attendees

cc w/encls:  
 See next page

DISTRIBUTION:

**ADAMS Accession No.:ML15306A450**                      **\*via e-mail**                      **NRC-001**

<b>OFFICE</b>	NRO/DCIP/MVIB	NRO/DCIP/QVIB	NRO/DCIP/QVIB
<b>NAME</b>	ABelen	PPrescott	KKavanagh
<b>DATE</b>	11/03/2015	11/03/2015	11/03/2015

**OFFICIAL RECORD COPY**

List of Attendees

Meeting with Nuclear Energy Institute (NEI) to discuss the results of the initial review of NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," on October 16, 2015.

<b><u>NAME</u></b>	<b><u>AGENCY/AFFILIATION</u></b>
Janet Schlueter	NEI
Marc Nichol	NEI
Steve Schilthelm	BWXT
Jim Gresham	Westinghouse
Robert Theuret	Westinghouse
Doug Weaver	Westinghouse
Tom Loomis	Exelon
Frederick Willis	Southern Nuclear
Mike Dunkelberger	MPR Associates
Jay Gardiner*	Curtiss-Wright
Paul Garcia*	AREVA
Marc H. Tannenbaum*	EPRI
Frederick Puleo*	South Texas Project Electrical Generating Station
William A. Horin*	Winston and Strawn LLP
Rob Burg*	Engineering Planning and Management
Justin Wearne*	PSEG
Mari Jaworsky*	Duke Energy
Leslie J. Collins*	Westinghouse
Carlo L. Sisco*	Winston and Strawn LLP
Marvin Lewis*	Public
Aixa Belen	Nuclear Regulatory Commission
Paul Prescott	Nuclear Regulatory Commission
Kerri Kavanagh	Nuclear Regulatory Commission
Aaron Armstrong*	Nuclear Regulatory Commission
Jermaine Heath	Nuclear Regulatory Commission
Soly Soto	Nuclear Regulatory Commission
Solomon Sahle	Nuclear Regulatory Commission
Patrick Castleman	Nuclear Regulatory Commission
Kimyata Morgan Butler	Nuclear Regulatory Commission

\* People participating on the phone

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