

March 28, 2017

MEMORANDUM TO: David Curtis, Acting Chief
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Office of New Reactors

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SUBJECT: SUMMARY OF THE FEBRUARY 16, 2017, PUBLIC MEETING TO
DISCUSS MODERNIZATION PLAN NO. 3 – COMMERCIAL-GRADE
DEDICATION OF DIGITAL EQUIPMENT

On February 16, 2017, the U.S. Nuclear Regulatory Commission (NRC) staff held a Category 2 public meeting with representatives from Nuclear Energy Institute (NEI) to continue discussions on improved guidance for commercial grade dedication (CGD) of digital equipment. The meeting included clarification of the industry's proposed use of standards and third party certification as part of the CGD process, a presentation of the CGD process, and a detailed discussion of the staff's initial considerations for the industry's research activity. All meeting materials including the summary and transcript are available in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession No. ML17045A184.

Enclosures:

1. Meeting Summary
2. Participant List

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SUBJECT: SUMMARY OF THE FEBRUARY 16, 2017, PUBLIC MEETING TO DISCUSS
 MODERNIZATION PLAN NO. 3 – COMMERCIAL-GRADE DEDICATION OF DIGITAL
 EQUIPMENT DATED MARCH 28, 2017

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ADAMS ACCESSION No.: ML17045A416 (Meeting summary), ML17045A184 (package),
 ML17045A582 (Staff Slides), ML17044A027 (NEI document discussed), ML17045A351 (Meeting Transcript)
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Meeting to Discuss Modernization Plan No. 3 – Commercial Grade Dedication of Digital Equipment

Meeting Summary

On February 16, 2017, U.S. Nuclear Regulatory Commission (NRC) staff met with representatives from the Nuclear Energy Institute (NEI). The purpose of the meeting was to continue discussions on the development of improved guidance for commercial grade dedication (CGD) of digital equipment. Information related to the meeting, including the meeting materials, attendees list, and transcript, may be found in the Agencywide Documents Access and Management System (ADAMS) package Accession No. ML17045A184.

After a review of the agenda and introductory remarks, the meeting focused on the following topics:

- CGD Process
- Clarification of the industry’s proposed use of third party certification based on International Electrotechnical Commission (IEC) 61508¹ for acceptance of digital instrumentation and control (I&C) equipment as part of the commercial dedication process as documented in its submittal dated February 1, 2017 (ADAMS Accession No. ML17044A027)
- NRC staff’s initial considerations for industry’s proposed research activity conducted by the Electric Power Research Institute (EPRI) (ADAMS Accession No. ML16312A079)
- Referenced documents in EPRI NP-5652, Revision 1: “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications”²

The NRC staff presented the CGD process under 10 CFR Part 21,³ and discussed the differences between “qualification” and “dedication” in reference to industry’s proposal to use third party certifiers for the use of digital equipment. The staff noted that the qualification process may be part of the dedication process and that the dedication of equipment provides reasonable assurance that the equipment will perform its intended safety function in accordance with Appendix B to 10 CFR Part 50.⁴ With respect to the industry’s proposal to use third party certifiers, the staff noted that the qualification process may be more applicable in achieving the industry’s objective. The NEI representatives confirmed that the focus of third party certification is to address the unique critical characteristic, dependability, in EPRI TR-106439, “Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications”. The EPRI research proposal and objectives are to establish the efficacy of the third party certification process (i.e., do products with third party certification indicate reliable operation in the field).

¹ IEC-61508, “Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems.”

² EPRI 3002002982, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety Related Applications, Revision 1 to EPRI NP-5652 and TR-102260.” Staff presentation slide number 14, references EPRI NP-5652, Revision 1.

³ 10 CFR Part 21, “Reporting of Defects and Noncompliance.”

⁴ 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.”

The NRC staff continued its presentation with the expectations for a dedicating entity; i.e., the organization that performs the dedication process, and the entity's responsibilities in maintaining records, and evaluating and reporting changes as necessary. The NRC staff further noted that it did not expect the International Electrotechnical Commission (IEC), whose standard IEC-61508 is referenced in the industry's proposal, to assume the dedicating entity's responsibilities defined in 10 CFR Part 21.

The NRC staff discussed a relevant review wherein the NRC staff concluded that an NEI technical report⁵ provides an acceptable approach for licensees and suppliers to use laboratory accreditation by Accreditation Bodies in lieu of performing commercial-grade surveys for procurement of calibration and testing services. The NRC staff noted that applying a process similar to that found in the NEI 14-05, Revision 1, could be a viable option should NEI and other industry representatives form a group to perform periodic oversight of the third party certification process, and the NRC technical staff finds IEC 61508 acceptable. NEI clarified it is not requesting staff review and endorsement of IEC 61508. The research seeks review and endorsement of the outcome of the safety integrity level (SIL) certification. The NRC staff will evaluate the need to review IEC 61508 based on the outcome of NEI's technical evaluation of the process.

The NEI representatives noted that its proposal for third party certification does not include any changes to the current processes, and that the third party certification process is not a dedication process. It was also noted that IEC 61508 is not a third party dedication process. The NEI representatives discussed leveraging the advantages of the goals of the third party certification process and how these goals may be applied to digital equipment.

The EPRI representative presented its projection that the research will be completed in the first quarter of 2018, and that the staff's considerations identified during the November 3, 2016, meeting⁶ will help inform the research. The EPRI representative noted that the NRC's Office of Regulatory Research (RES) has a current Memorandum of Understanding (MOU) with EPRI and that monthly calls are conducted to discuss aspects of the research and the schedule. Based on a question by the NRC staff, the NEI representatives clarified that the SIL certification process is a qualification process that may ultimately benefit utilities by ensuring equipment dependability.

The NRC staff re-stated (as clarified in the NEI material for this meeting, ADAMS Accession No.: ML17044A027) that should SIL-3 certification prove suitable to demonstrate the dependability characteristics cited by manufacturers, this does not address all other characteristics or dictate that the equipment meets requirements or is suitable for the application. NEI stated that this will allow the NRC to focus the regulatory process on the application of equipment to nuclear plants (which it is uniquely qualified to do) while leveraging a global best practice and ultimately result in more dependable and safer systems. A licensee reinforced that the vulnerabilities lie largely in the application, not the basic critical characteristics – which resulted in concurrence in the room.

⁵ NEI 14-05, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services."

⁶ The November 3, 2016, public meeting information is found in ADAMS Accession No. ML16132A380.

During the November 3, 2016, public meeting, the NRC staff identified several considerations for NEI and EPRI in the development of its research plan. The set questions⁷ identified by the staff were reviewed and initial clarifications were provided as follows:

- What entity will submit a request to the NRC for conducting an evaluation on the adequacy of the proposed third-party certification process and IEC 61508?
Initial clarification from NEI: The results from the EPRI research will inform the response. NEI is not requesting staff review and endorsement of IEC 61508, rather the research seeks review and endorsement of the outcome of the SIL certification. The staff will evaluate the need to review IEC 61508 based on the outcome of NEI's technical evaluation of the process.
- What entity will conduct an evaluation of the IEC's third-party audit certification process?
Initial clarification from NEI: NEI plans to leverage the methods in NEI 14-05, Revision 1.
- What entity will provide membership access to the third-party certification audit records?
Initial clarification from NRC: NEI 14-05, Revision 1, describes auditable controls over the process. This question (and the next) request information on who will confirm that the SIL is still the same or has changed – across all third party certification bodies.
- What entity will provide membership access to the results of evaluations conducted by the third-party organizations?
Initial clarification from NRC: See question above.
- What entity will maintain ongoing oversight of the third-party certification process?
Initial clarification from NEI: The Nuclear Procurement Issues Committee (NUPIC) or another entity identified by the EPRI research.
- What entity will ensure Part 21 responsibilities for evaluating and reporting are satisfied?
Initial clarification from NEI: No differences in the practices conducted today (i.e., the licensee or other dedicating entity with a 10 CFR Part 50, Appendix B, quality assurance program is responsible).

The NRC staff noted that the February 22, 2017, public meeting on the Integrated Action Plan (IAP) will seek feedback since the most recent draft of the IAP. In addition, the version expected to be published in April 2017, may be different from version discussed at the public meeting.

The NRC staff presented the final topic on the references found in Section 14.1 of EPRI 3002002982.⁸ Specifically, four (4) of the six (6) documents listed in the references have not been evaluated by the NRC. The NEI representatives noted that these four (4) documents will not be submitted for NRC staff evaluation and endorsement; rather, the EPRI research will inform the path forward for leveraging third party certification for digital equipment. The NEI representatives further clarified that they know of no other activities that will seek NRC review or endorsement of these documents.

⁷ The first and last questions identified in the November 3, 2016, public meeting summary are combined in the first bullet of this list.

⁸ EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety Related Applications, Revision 1 to EPRI NP-5652 and TR-102260." Staff presentation slide number 14, references EPRI NP-5652, Revision 1.

The NRC staff questioned how it can be determined how useful this will be to the overall process: Will we invest more time now than can be saved later? How much time is NRC or industry spending on this now? Can we convince ourselves that this will produce better results? NEI reinforced the strong belief that this can be better, is not a relaxation of standards but rather a suggestion that the application of a global best practice, with orders of magnitude more operating experience, is better than what can be done in isolation.

The NRC staff provided the status of draft regulatory guide (DG)-1292⁹ as going through internal review and concurrence, and awaits a date to brief the Advisory Committee on Reactor Safeguards. This new guide, once issued, is expected to be regulatory guide (RG) 1.164.

The NEI representatives clarified that the scope of the EPRI research is only applicable within the actions of MP No. 3, and that the MOU between the NRC/RES and EPRI seeks to ensure that the NRC remains aware of the progress and results of the EPRI research. The NRC will also be able to provide technical comments on the research through the MOU.

Upon conclusion of the business portion meeting, a member of the public provided a comment on whether the testing is catching the right errors and counterfeit items. In response to the comment, the NRC staff noted that these concerns are also shared by the NRC staff.

The NRC staff identified one follow-up action item discussed during the meeting: the NRC staff will discuss internally the need to evaluate the IEC 61508 standard and related standards with the potential to work into the MP No. 3 schedule.

The NEI representatives stated that the current process described in EPRI TR-106439 for accepting digital I&C equipment for use in a safety system is not standards based, but rather reaching a reasonable level of assurance of quality by making a judgment based on a combination of the product development process and its documentation and operating history. Allowing third party certification into the process adds rigor to the acceptance process.

Prior to closing the meeting, the NRC staff confirmed that the meeting transcript, along with a summary of the meeting, will be available on the NRC Public Meeting Notice website for this February 16, 2017, public meeting, under the "Related Documents" section of the notice.

Project No. 689

⁹ Draft Regulatory Guide (DG)-1292, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants."

**Meeting to Discuss Modernization Plan No. 3 –
Commercial-Grade Dedication of Digital Equipment
February 16, 2017**

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