UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 2, 2019

MEMORANDUM TO: Dennis C. Morey, Chief
Licensing Processes Branch
Division of Licensing Projects
Office of Nuclear Reactor Regulation

FROM: Joseph A. Golla, Project Manager ***/RA/***
Licensing Processes Branch
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SUBJECT: SUMMARY OF PUBLIC MEETING ON NOVEMBER 15, 2018, WITH THE NUCLEAR ENERGY INSTITUTE REGARDING AN INSPECTION WORKSHOP RELATED TO DIGITAL INSTRUMENTATION AND CONTROLS MODIFICATIONS

On November 15, 2018, the U.S. Nuclear Regulatory Commission (NRC) staff held a workshop with the Nuclear Energy Institute (NEI) and other stakeholders on digital instrumentation and controls (DI&C) inspections. The purpose of the workshop was to provide clarity on the types of licensing audits and post-license amendment inspections performed under the Alternate Review Process introduced in digital I&C Interim Staff Guidance (ISG)-06, "Licensing Process," Revision 2 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18269A259). A transcript of the workshop can be found at ADAMS Accession No. ML19085A447. This workshop also continues discussions between the NRC staff and NEI and other stakeholders during a June 13-14, 2018 tabletop exercise. Transcripts of the tabletop exercise can be found in ADAMS at Accession Nos. ML19085A483 and ML19085A484.

Staff from the NRC Office of Nuclear Reactor Regulation, Division of Engineering, Division of Inspection and Regional Support, and Division of Operating Reactor Licensing; Office of New Reactors, Division of Component Integrity; and Region II, Division of Reactor Safety, participated in the workshop.

Industry representatives from the NEI, Duke Energy, Excel Services, Entergy, Exelon, MPR Associates, NextEra Energy, Southern Nuclear, GE-Hitachi, and Rolls Royce also participated in the workshop.

The staff made a presentation (ADAMS Accession No. ML18319A015) that described the draft ISG-06, Revision 2, which defines the licensing process used to support license amendment request (LAR) reviews associated with safety-related DI&C equipment modifications in operating plants and in new plants once they become operational. Revision 2 introduces the Alternate Review Process which allows for an earlier issuance of a license amendment. This process provides the flexibility for a licensee to submit an LAR before factory acceptance testing (FAT) or before the detailed hardware and software design is complete. However, it is expected that some detailed hardware and software information needed to reach a safety determination will be developed before the LAR is submitted.

An LAR based on the Alternate Review Process should provide the design information needed to demonstrate regulatory compliance, and should describe the licensee's vendor oversight plan (VOP). The LAR should also include appropriate commitments to implement remaining development phases by the licensee's quality assurance (QA) program, after the license amendment is issued. The staff may translate some of the regulatory-significant commitments into license conditions, as part of the approval.

The staff clarified that topical report reviews were not within the scope of ISG-06, Revision 2, but the guidance of the ISG could be used to perform these reviews.

The staff made a presentation on the general roles and responsibilities of the various NRC staff regarding DI&C modifications (ADAMS Accession No. ML18319A015). This included the typical responsibilities of the DI&C technical reviewers, the staff in the Division of Inspection and Regional Support, the vendor inspectors, and the regional inspectors. The following DI&C inspection procedures were identified as those providing protocol and requirements for performing these activities: Inspection Procedure 35710, "Quality Assurance Inspection of Software Used in Nuclear Applications," Inspection Procedure 65001.22, "Inspection of Digital Instrumentation and Control (DI&C) System/Software Design Acceptance Criteria (DAC) – Related to ITAAC," and Inspection Procedure 52003, "Digital Instrumentation and Control Modification Inspection." The staff noted that it will be considering whether any of these inspection procedures will be revised, or if a new Alternate Review Process-specific procedure will be developed, in consideration of the existing procedures.

Industry asked the staff to clarify the role of vendor inspections. The staff explained that vendor inspectors look at how the licensee has engaged the vendor in the identification of issues of concern. In parallel, the vendor inspectors would look at how the vendor is implementing purchase order requirements provided by the licensee to fulfill a purchase order.

The staff made a presentation on the types of audit and inspection activities that may be performed (ADAMS Accession No. ML18319A017). The licensing audit activities may include: review of non-docketed material, licensee vendor oversight, and configuration management. The inspection activities may include: verification of licensee vendor oversight activities (per the VOP), verification of how the licensee and the vendor are performing those activities, and verification of site installation and testing.

NEI made a presentation describing industry's perspective on NRC inspection activities performed in relation to a modification performed under the Alternate Review Process (ADAMS Accession No. ML18302A036). NEI described the licensee activities related to vendor oversight, and described industry efforts that resulted in a standardized design process adopted by all US nuclear plant operators. The following industry guidance documents were identified as those providing protocol and requirements for performing these activities: IP-ENG-001: Standard Design Process, NISP-EN-04: Standard Digital Engineering Process, EPRI 3002011816: Digital Engineering Guide. NEI explained that this new standardized design process would provide the adequate level of vendor oversight which is typically performed by the NRC staff during the Tier 1, 2 and 3 licensing review process.

NEI explained that vendor oversight is more process driven and does not include all the technical document reviews. The technical review is a separate activity performed by the licensee as part of the engineering change, and covers the design acceptance of output documents. NEI stated that it will consider how to include the technical aspects into the VOP. NEI proposed that a new NRC inspection paradigm should focus on the review of the licensee's

vendor oversight documentation. NEI stated that NRC inspections should first focus on the licensee's vendor oversight reports documenting vendor audits/inspections of the detailed design, implementation, and test processes; and only if the NRC identifies gaps in the vendor oversight process, would it be appropriate for the NRC to augment licensee inspections at the vendor's site. NEI stated that the licensee has the option to invite NRC staff strictly as an observer of the licensee's oversight activities, but that this would not be an NRC inspection of the licensee's oversight activities.

The staff disagreed and explained that the NRC's inspection paradigm has always had an element of document review and an element of direct observation. The staff explained that an inspection of the licensee's vendor oversight would also include a direct observation of some of those oversight and vendor activities.

NEI expressed that their concern is that the staff would perform a vendor inspection each time a modification was performed. So if multiple utilities performed the same modification using the same vendor, the staff would perform the same inspection at the vendor's facility each time. The staff stated that, in such cases, it would not expect to be repeating inspections of the same modification, oversight, and vendor processes.

NEI asked for clarification of section C.2.1 of the ISG, Details of License Amendment Request Content, where the VOP is discussed. In particular, NEI asked the staff to clarify what the phrase "the Vendor Oversight Plan, when executed, can also be used to ensure the vendor uses, as a reference, the 2015 version of NQA-1, Part II, Subpart 2.7" meant. The staff explained that the intent was for the vendor to consider the 2015 version of NQA-1, but it was not meant as a requirement that the vendor should replace their current QA program with the 2015 version of NQA-1. The staff worked with industry representatives to modify the phrase and improve clarity. The modified sentence reads as follows:

> The Vendor Oversight Plan, when executed, can also be used to ensure that the vendor uses an adequate software QA program; for example, the NRC-endorsed 2015 version of the American Society of Mechanical Engineers Nuclear Quality Assurance (NQA)-1, Part II, "Quality Assurance Requirements for Nuclear Facility Applications," Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications."

Both the staff and industry representatives agreed that the modified verbiage was acceptable. The draft ISG-06, Rev. 2 was revised to incorporate it.

Industry provided the staff with a VOP summary example (ADAMS Accession No. ML18317A202), which would be provided in an LAR using the Alternate Review Process. The staff noted that the VOP summary example is very high level and does not include a list of oversight activities to be performed. The VOP summary lists topical areas to be covered by the oversight activities but does not identify the activities such as audits, code reviews, or document reviews that would be performed to verify that vendor performance is acceptable. As mentioned earlier, NEI stated that it will consider how to include the technical aspects of the design change into the VOP.

The staff noted that the VOP references Section D.4, *Digital Instrumentation and Control System Development Processes*, of ISG-06, Rev. 2. Section D.4, which applies to the Alternate Review Process, provides the guidance for software development plans, but not the guidance for evaluating the implementation of the plans, which is found in Section D.9, *Other Review*

Guidance for Tier 1, 2, and 3 Reviews, of ISG-06, Rev. 2. NEI responded that in an actual VOP tied to a real application, the VOP would reference specific LAR sections that describe the guidance for implementation of a plan, and not ISG-06.

The staff stated that it can provide some input to the VOP summary example. A call or meeting may be scheduled in 2019 to go over this material.

As discussed above, NEI presented the staff with an example of a VOP summary which would be provided in an LAR using the Alternate Review Process under ISG-06 Rev. 2. Under the Alternate Review Process the staff would primarily review development plans as part of its licensing review. Activities related to design implementation and outputs will not be part of the licensing review, but would still be overseen by licensees using their VOP after NRC license approval. The licensee's oversight of vendor activities would be subject to NRC inspection. At the meeting, the staff noted that the VOP summary example is very high level and does not include a list of oversight activities to be performed. The VOP summary lists topical areas to be covered by the oversight activities but does not identify the activities that would be performed by the licensee to verify that vendor performance is acceptable. The staff discussed the guidance in BTP 7-14 as the type of information that the staff has traditionally used in license reviews and audits of vendor design implementation and design outputs under the traditional licensing review process (e.g., ISG-06 Rev 1).

During the workshop NEI requested that staff provide a description of the acceptance criteria that could be used to support industry's development of a VOP. The staff noted that it can provide a description of the acceptance criteria for design implementation and design outputs found in BTP 7-14 sections B.3.2 and B.3.3. In an e-mail to NEI dated February 11, 2019, the staff transmitted an attached document containing excerpts from BTP 7-14 which have traditionally been the key areas of design implementation and outputs that staff has focused on during license reviews and audits under the traditional licensing review process (e.g., ISG-06 Rev 1.) This document may be viewed by the public at ADAMS Accession No. ML19087A230.

The staff stated to NEI that the document should not be construed as formal NRC guidance for the development of licensee's VOPs, and should not be considered alone to define the potential scope of future NRC inspections of the licensee's oversight of vendor activities for designs approved under the Alternate Review Process.

No comments or questions were received at the meeting from members of the public.

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301-415-1002
Enclosure:
Attendees List

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ADAMS Accession Nos.:
ML19087A256 -Package
ML19086A059 -Meeting Summary
ML18312A333 -Meeting Notice)
ML19085A447 -Workshop Transcript)
ML19085A483 -Tabletop Transcript Day 1)
ML19085A484 -Tabletop Transcript Day 2)
ML18319A015 -Staff Presentation)
ML18319A017 -Staff Presentation)
ML18302A036 -NEI Presentation)
ML18317A202 -VOP Summary Example)
ML19087A230 -Implementation and Design Output Criterion)

NRC-001

OFFICE	**NRR/DLP/PLPB/PM**	**NRR/DLP/PLPB/BC**	**NRR/DLP/PLPB/PM**
NAME	JGolla	DMorey	JGolla
DATE	4/1/2019	4/1/2019	4/2/2019

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NRC Public Meeting Attendance

November 15, 2018

Frank Novak	GEH
Mark Burzynski	Rolls-Royce
David Herrell	MPR Associates
Neil Archambo	Duke Energy
Steve Dragovich	Exelon
Steve Vaughn	NEI
Ray Herb	SNC
Warren Odess-Gillett	NEI
John Schrage	Entergy
Pareez Golub	Excel Services
Samir Darbali	NRC
Rich Stattel	NRC
Mike Waters	NRC
Deanna Zhang	NRC
Calvin Cheung	NRC
Eric Benner	NRC
Theo Fanelli	NRC
Greg Galletti	NRC
Doug Bollock	NRC
Joe Golla	NRC
Wesley Frewin*	NextEra Energy
Jana Bergman*	Scientec

*participated via telephone

Enclosure