



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

April 25, 2022

MEMORANDUM TO: Jeanne A. Johnston, Chief
Long Term Operations and
Modernization Branch
Division of Engineering and External Hazards
Office of Nuclear Reactor Regulation

FROM: Bhagwat Jain */RA/*
Plant Licensing Branch IV
Division Operating Reactor Licensing
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SUBJECT: MEETING SUMMARY OF MARCH 23, 2022, DIGITAL
INSTRUMENTATION AND CONTROLS PUBLIC WORKSHOP TO
SHARE NRC AND INDUSTRY PERSPECTIVES ON LICENSING
AND INSPECTION LESSONS LEARNED AND HUMAN FACTOR
ENGINEERING REVIEWS

On March 23, 2022, the U.S. Nuclear Regulatory Commission (NRC) staff held a virtual digital instrumentation and control (DI&C) public workshop with various industry stakeholders. The purpose of the workshop was to share insights and discuss the licensing and inspection lessons learned from recent DI&C modernization projects, and human factor engineering (HFE) reviews. The NRC staff, Nuclear Energy Institute (NEI), Idaho National Laboratory (INL), Entergy Operations, Inc. (Entergy), NextEra Energy, and Constellation Energy Generation, LLC made formal presentations at the workshop. Over 100 stakeholders attended the workshop and the participants engaged in robust discussions on matters presented by the NRC and stakeholders. The meeting notice and agenda, dated March 3, 2022, are available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML22080A153.

NRC staff from the Office of Nuclear Reactor Regulation's Division of Engineering and External Hazards and Division of Reactor Oversight; Office of Nuclear Security and Incidence Response; and Region IV presented topics related to the licensing and inspection of DI&C upgrades and HFE reviews. The workshop began with the staff's discussion of DI&C licensing, inspection and HFE reviews lessons learned. The staff's presentation was followed by NEI and INL presentations on alternate approach to HFE reviews. For the remainder of the workshop, representatives from Entergy, NextEra Energy, and Constellation Energy Generation, discussed their observations and experiences with the licensing and inspections lessons learned and HFE reviews.

The following material was presented on licensing and inspections lessons learned and HFE reviews during the workshop:

- “Staff’s Lessons Learned Presentation March 23, 2022 Digital I& C Workshop” (includes NRC Slides on Licensing and Inspection Lessons learned and HFE Reviews) (ADAMS Package Accession No. ML22077A409)
- NEI and INL Presentation, March 23, 2022, “NRC Digital I&C Workshop” (ADAMS Accession No. ML22080A021)
- Entergy Presentation, “WF3 [Waterford Steam Electric Station, Unit 3 or Waterford 3] Core Protection Calculator Project”. (ADAMS Accession No. ML22076A194)
- NextEra Energy Presentation (ADAMS Accession No. ML22076A195)
- Constellation Energy Generation Presentation, “Limerick Generating Station Digital Modernization Project Lessons Learned and Challenges, NRC Digital I&C Workshop” (ADAMS Accession No. ML22076A196)

A summary of the workshop is provided in the following. A written detailed transcript of the workshop is publicly available in ADAMS Accession No. ML22089A010.

(A) Staff Licensing Lessons Learned

The NRC staff presented its licensing lessons learned from the recently approved license amendment request (LAR) for DI&C upgrade of the Waterford 3 core protection calculator project and observations from pre-application activities for the planned LARs for Turkey Point and Limerick DI&C modernization projects. The staff discussed the intent of the alternate review process (ARP) in DI&C Interim Staff Guidance (ISG)-06, deviations from the ARP, overlap of licensing review and system development schedules in ARP and tiered review processes, effect of multiple supplemental information on licensing review and audit schedules, vendor oversight plan (VOP) audits and vendor inspection, integrated reviews performed by various technical discipline, and outlined a licensing path to success, both for the licensee and the staff.

Highlights of the NRC staff’s lessons learned from the licensing reviews and pre-application interactions with the licensees for Turkey Point and Limerick DI&C modernization projects are provided below.

- The Tier 1 licensing review schedule overlaps with the system design implementation and testing lifecycle phases, whereas the ARP licensing review schedule is compressed to overlap with the system design and early implementation.
- The VOP audit is a significant part of the licensing process for the NRC staff to verify how the licensee is implementing the VOP and to determine if there is reasonable assurance that the licensee will implement the VOP after the license amendment has been issued.
- Multiple supplemental information submitted by the licensee extend the licensing review schedule and compresses the VOP audits and vendor inspections.
- It may be beneficial for a licensee and the NRC staff if the full VOP is submitted in the LAR instead of a summary, provided that the full VOP is not a lengthy document.

- A VOP audit should take place after the vendor audit or if a vendor inspection does take place during licensing, then after the vendor inspection.
- NRC staff's LAR review of a DI&C modification encompasses various technical review disciplines. The staff from I&C branch and other technical branches (e.g., Nuclear System Performance, Human Factor Engineering, Cybersecurity) is involved in performing the integrated licensing review and inspections of a DI&C modernization project.
- For a successful implementation of a DI&C modernization project, the industry, in order to get the digital modifications license approved and installed in time, must provide all the necessary and complete information that will enable the NRC staff to make a safety determination on the adequacy of the digital modification within the licensee's required time.
- The NRC staff and licensees must be flexible in adapting to the licensing process deviations and be accountable for those changes.
- The NRC staff and the licensee should plan for productive communications during pre-application and licensing review meetings, maintain openness on the scope of the modifications and the ARP deviations, and have realistic expectations of what the licensing review process is going to look like if the application doesn't meet the guidance in the DI&C ISG-06.
- The NRC staff and the licensee should continue to leverage lessons learned and the use of innovative licensing review tools like open items list process and virtual audits.

(B) Staff Inspection Lessons Learned

Quality Assurance and Vendor Inspections

The NRC staff conducted audit and inspections of Westinghouse for the Waterford 3 Core Protection Calculator System (CPCS) Upgrade Project that included development activities, requirements phase, factory acceptance test (FAT) phase, Procedure 43002, "Routine Inspections of Nuclear Vendors," and Procedure 35710, "Quality Assurance Inspection of Software Used in Nuclear Applications."

The highlights of NRC staff's lessons learned from these audits and inspections are provided below.

- Use of the ARP or traditional Tier 1 approach will inform when/what vendor inspections are conducted based on the design maturity
- The following Digital I&C system development activities may not follow traditional waterfall lifecycle phases.
 - Design changes may occur following completion of design and implementation phases that will require regression analysis

- Results of FAT and site acceptance testing (SAT) may trigger additional design changes
- Completion of vendor verification and validation (V&V) and VOP activities may occur later in lifecycle phases
- Scheduling of vendor inspections should account for the dynamic aspects of the DI&C system development
- Required frequency of vendor inspections depend on the complexity of the digital I&C system under development.
- Close coordination is required to support both vendor inspection and licensee's VOP activities simultaneously.
- Communications between the NRC, licensee, and vendor is very critical for adequate scheduling and resource allocation for the inspection activities.

Regional Inspections

The NRC Region IV staff completed Waterford 3 inspections for the FAT and SAT. The highlights of inspections lessons learned is provided below.

- Inspection Procedure (IP) 52003, "Digital Instrumentation and Control Modification Inspection (ADAMS Accession No. ML21113A169) was not issued until July 1, 2021, and the LAR was not approved until after the FAT inspection, which presented challenges for the licensee and inspection team.
- Regional inspection scheduling should account for the FAT and SAT testing activities and not the issuance of the test report to call the FAT and SAT inspection complete. For installation, the team considers return to service as complete.
- Communications between the NRC staff (regional, licensing, and cyber security), vendor and the licensee are critical due to the dynamic aspects of the digital I&C system development.
- During the FAT, both the vendor and regional inspections teams are expected to be onsite for major milestones which introduces overlapping priorities and requires significant coordination from the licensee.
- Inspection resource estimates should be realistic for FAT, SAT, and installation activities.
- Execution of the VOP is the responsibility of the licensee. This includes performance of oversight activities on the design artifacts and development activities for the requirements, design, implementation, integration, and FAT phases of the system development lifecycle in accordance with the VOP.
- Lessons learned during the FAT, SAT, and installation phase should be used in real-time inspection planning and scoping.

(C) Staff's Response to Comments on DI&C Modification Inspection Procedure 52003

The NRC staff also discussed responses to 15 NEI comments on Inspection Procedure (IP) 52003, provided in a letter dated August 13, 2021. NEI noted that two comments regarding verification of secure development and operational environment (SDOE) assessment, and the verification of power quality measurements were most important. The staff noted that it would consider NEI comments in a future inspection procedure update after exercising it for Turkey Point and Limerick. In response to NEI's general observation regarding lack of VOP guidance, the staff noted that it is considering developing VOP guidance after the implementation of the ARP for first few ARP LARs (i.e., after Turkey Point and Limerick), in a separate document along with incorporation of other potential lessons learned from the use of ISG-06. The VOP guidance will not be included in the IP 52003.

(D) Human Factor Engineering ReviewsNRC Staff Presentation

The NRC staff discussed its expectations of the HFE information in the LAR including the information that should be available to the staff to make safety findings and issue the licensing decision. The staff also discussed its LAR review guidance, safety review process, and schedule challenges for HFE validation of DI&C modernization projects. The staff offered multi-stage validation (MSV) and alternative test beds as potential alternative solutions. There was a robust discussion on several aspects of the staff's HFE presentation. The discussion centered around the industry seeking clarification on the LAR contents and on details and schedule of V&V testing of various HFE elements.

The highlights of the HFE review challenges and NRC staff's proposed solutions discussed in the workshop are provided below.

LAR review challenges

- At the time ISG-06 was developed, HFE review was not envisioned within the scope of ISG-06. Recent modifications are more significant than initially considered.
- Licensee's proposed schedules of V&V activity for HFE tends to occur outside of the time when the NRC staff will be conducting the license amendment review. For example, integrated system validation (ISV) test results may not be available to NRC staff to make its safety finding and before issuing a licensing decision by the licensee's requested time of LAR approval.
- Modification of simulators while still maintaining its other functions (e.g., operator licensing training and other activities) has posed a challenge to some licensees.

NRC Staff's proposed solution

- Consider use of an MSV process and perform validation activities throughout the design and development stages.

- Provide early-stage MSV testing results and ISV implementation plans to provide a basis for safety determination and a reasonable assurance that the eventual ISV testing will be successful. However, MSV does not eliminate the need for ISV testing.
- Consider alternative test beds (e.g., glass-topped simulators) to full-scope simulators to allow testing without modifying the plant simulator.
- Use an MSV test program and spread-out validation activities throughout the course of the design work into separate discrete steps.
- Provide a timeline that clearly demonstrates what information will be available at what points throughout the NRC review period to allow the staff to plan a timely audit of HFE activities.

(E) NEI Alternate Approach to HFE Validation

NEI presented an alternate approach to HFE evaluation and validation. The alternate approach was presented to the NRC staff for the first time and involves an HFE program plan that is based on INL research in conjunction with a license condition to perform the ISV. The NEI approach is different from the staff's proposed MSV approach for HFE evaluation because NEI approach commits to a license condition to perform ISV testing. NEI requested feedback and a follow-up discussion with the staff on the alternate approach and if there are regulatory barriers to implement it. Staff noted that it would require more detailed information on the proposed license condition to fully understand the alternate approach and provide any meaningful feedback to the industry.

(F) Industry Licensing and Inspection Lessons Learned

Entergy

A representative of Entergy presented its licensing lessons learned from the recently approved LAR for DI&C upgrade for the Waterford 3 core protection calculator project, that involved the replacement of an outdated digital computer system with the Westinghouse Common Q system, and the inspection lessons learned from FAT and SAT. Highlights of key lessons learned are provided below.

- Vendor Oversight Plan (VOP) – Define early on the contents of VOP and the level of details in VOP summary that is docketed. This can minimize revisions to VOP and VOP summary.
- Regional Inspector – Engage with regional inspectors early in the process. Efficiencies and consistency can be gained by involving regional inspectors earlier in different audits, inspections, and pre-submittal meetings, so they're aware of what's been discussed, and even some of the technical details of the affected system, and then transition to FAT and SAT.
- Communication Plans - The 'Open Item List' process and Certrec – The electronic reading room system is very effective and an efficient means to communicate and navigate through documents and manage the additional information NRC staff requires for its safety reviews.

- Managing Interactions – Managing concurrent oversight, inspection, and audits during licensing and testing by various organizations (NRC’s Quality Assurance and Vendor Inspection Branch, Regional Inspection Branch, the equipment vendor, and the licensee) can be challenging and overwhelming.

There was a follow-up discussion on challenges to plan the information that a licensee needs to provide on the docket in the development life cycle. The NRC staff clarified that for the ARP, the information that is needed and should be provided as part of the initial LAR for a safety evaluation is included in Enclosure B of DI&C ISG-06.

NextEra Energy

A representative from NextEra Energy presented its lessons learned from pre-application activities for a planned LAR for Turkey Point. The licensee plans for a safety-related digital upgrade of reactor protection, system engineering, safety features, actuation systems, and nuclear instrumentation system replacement. Highlights of key observations and comments and lessons learned are provided below.

- Pre-submittal meetings are very beneficial and should be scheduled close together to have continuity of the NRC staff from one pre-submittal meeting to the next.
- The ARP is very difficult to follow, and the challenge is to distinguish between criteria and approaches for ARP and the tiered process.
- HFE is out of DI&C ISG-06 scope and no clear direction for HFE evaluation is provided by the NRC staff.

The NRC staff noted that the tiered process is oriented towards a product-based evaluation. Whereas the ARP is more based on a process-based evaluation. The staff’s safety conclusions are the same for both the processes, but the bases of safety conclusion are different.

Constellation Energy Generation, LLC

A representative from Constellation Energy Generation, LLC presented its lessons learned from pre-application activities for a planned LAR for Limerick modernization project to digitize reactor protection system, nuclear steam supply shut off system, and emergency core cooling system. Highlights of key observations and comments and lessons learned are provided below.

- The MSV introduces regulatory uncertainty. Since ISV must be completed before the implementation, it puts a timing constraint on both the licensee and the NRC.
- A list of documents that must be included in complex digital modifications, such as the Limerick project, is not available.
- Pre-submittal meetings are beneficial, but it is difficult to get NRC staff’s feedback whether a topic has been covered in sufficient depth to take it off the to do list.
- The NRC post-meeting summaries are at a high level to determine whether the licensee fully addressed NRC questions, comments, and concerns.

- NRC staff's early comments on pre-submittal meeting presentation material is very beneficial.
- Restructure the pre-submittal meetings to encompass the project scope in order to be more efficient to ensure that specific topics are addressed to NRC staff's satisfaction to reduce potential requests for additional information (RAIs).

In response to Constellation Energy Generation's observations and suggestions, the NRC staff noted that the process for pre-application meetings is resource limited to spend more time and effort on pre-application activities, including preparing detailed meeting summaries and reviewing draft version of a LAR. The staff is limited by the processes and resources to provide formal feedback on pre-decisional matters. The staff noted that it will continue to find ways to make the pre-application process more efficient and effective.

After the workshop, an industry stakeholder provided a written comment to the NRC staff (ADAMS Accession No. ML22083A174) on his understanding of the role of RAIs in the ARP such that the ARP does not allow for RAIs. The staff clarified, that based on the review of the docketed information for the licensing action, the NRC staff request RAIs when necessary to make a safety determination regardless of if the licensee is using the ARP or a traditional licensing process.

Next Steps

There were no specific follow-up actions.

There was a strong consensus for NRC to have a follow-up meeting next year on digital licensing and other topics of interest to both NRC and industry.

The NRC staff did not make any regulatory decisions or commitments at the meeting. No members of the public identified themselves on the teleconference.

Please direct any inquiries to 301-415-0603 or by e-mail to Bhagwat.Jain@nrc.gov.

Enclosure:
List of Attendees

LIST OF ATTENDEES

MARCH 23, 2022, DIGITAL INSTRUMENTATION AND CONTROLS PUBLIC WORKSHOP

TO SHARE NRC AND INDUSTRY PERSPECTIVES ON

LICENSING AND INSPECTION LESSONS LEARNED

AND HUMAN FACTOR ENGINEERING REVIEWS

Microsoft Teams Meeting

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Bhagwat Jain	U.S. Nuclear Regulatory Commission (NRC)
Khoi Nguyen	NRC
Hang Vu	NRC
Lauren Nist	NRC
Jeanne Johnston	NRC
Tony Nakanishi	NRC
Kim Lawson-Jenkins	NRC
David Rahn	NRC
Sergiu Basturescu	NRC
Rossnyev Alvarado	NRC
Justin Vazquez	NRC
Charles Peabody	NRC
Brian Green	NRC
Paul Rebstock	NRC
Steven Alferink	NRC
Ming Li	NRC
Christopher Cook	NRC
Kerri Kavanagh	NRC
Jesse Seymour	NRC
Dinesh Taneja	NRC
David Desaulniers	NRC
Richard Stattel	NRC
Samir Darbali	NRC
Gregg Galletti	NRC
Eric Lee	NRC
Ronaldo Jenkins	NRC
Joseph Ashcraft	NRC
Shakur Walker	NRC
Jack Zhao	NRC
Shiattin Makor	NRC
Michael Marshall	NRC
Stacey Rosenberg	NRC
Calvin Cheung	NRC
Jorge Cintron-Riveria	NRC
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John Connelly	Constellation
Kenneth Cutler	Constellation
Mark Dirado	Constellation
Francis Mascitelli	Constellation
David Molteni	Constellation
Mark Samselski	Constellation
Gerald Segner	Constellation
Jana Berman	Curtiss-Wright
Robert Chenkovich	Dominion Energy
Fernando Ferrante	Electric Power Research Institute (EPRI)
John Weglian	EPRI
Jacob Champagne	Entergy Operation, Inc. (Entergy)
Greg Norris	Entergy
Georgia Dikeakos	Framatome
Tom Geary	Framatome
Brian Haynes	Framatome
Ron Jarrett	Framatome
Brian Mamahon	Framatome
Jacek Nowakowski	Framatome
Phillip Opsal	Framatome
Ted Quinn	Framatome
Francis Novak	GE PowerPortfolio
Ronald Boring	Idaho National Laboratory (INL)
Bao Han	INL
Joe Jeffrey	INL
Vince Gilbert	Model Performance
Anson Tran	MPR
Danny Duong	MPR
Paul Heaney	MPR
David Herrell	MPR
Warren Bush	NextEra Energy, Inc.
Wesley Ferwin	NextEra Energy, Inc.
Alan Campbell	Nuclear Energy Institute
Mike Wiwel	PSEG Nuclear
Pareez Golub	Sargent & Lundy
David Hooten	Sargent & Lundy
Raymond Herb	Southern Company
Mark Burzynski	Sunport
William Walsh	U.S. Department of Energy
Warren Odess-Gillett	Westinghouse Electric Company LLC (Westinghouse)
Marcus Adside	Unknown
Neil Archambo	Unknown
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Sophie Gutner	Unknown
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Marry Miller	Unknown
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Craig Primer	Unknown
Andy Nack	Unknown
Steven Pope	Unknown
James Watkins	Unknown
James Watkins	Unknown

¹Unknown' organization indicates that the participant's affiliation was not provided by the issuance of this meetingsummary.

SUBJECT: MEETING SUMMARY OF MARCH 23, 2022, DIGITAL INSTRUMENTATION AND CONTROLS PUBLIC WORKSHOP TO SHARE NRC AND INDUSTRY PERSPECTIVES ON LICENSING AND INSPECTION LESSONS LEARNED AND HUMAN FACTOR ENGINEERING REVIEWS DATED APRIL 25, 2022

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***by email**

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