POLICY ISSUE
(Information)

October 9, 2018 SECY-18-0100

FOR: The Commissioners

FROM: Margaret M. Doane
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SUBJECT: ANNUAL UPDATE REGARDING THE INTEGRATED STRATEGY TO MODERNIZE THE NUCLEAR REGULATORY COMMISSION'S DIGITAL INSTRUMENTATION AND CONTROL REGULATORY INFRASTRUCTURE

PURPOSE:

This paper provides the annual status update of ongoing work and planned future activities to improve the U.S. Nuclear Regulatory Commission's (NRC's) digital instrumentation and control (I&C) regulatory infrastructure. This paper does not address any new commitments.

SUMMARY:

The staff continues to make progress in implementing the Commission-approved digital I&C integration action plan (IAP). Over the last year the staff has engaged with the industry in many public meetings to discuss recent accomplishments and the challenges and priorities that may be unique to specific digital I&C stakeholders. The staff also sought feedback on its plan to re-baseline the IAP to reflect updated accomplishments and challenges. Consequently, the staff and industry have aligned on the priorities for near- and long-term improvements to the NRC's regulatory structure.

The staff improved the clarity of the 10 CFR 50.59 process that licensees use to make digital modifications without prior NRC approval. The staff has received feedback that industry is implementing modifications using this guidance. The staff also made progress in resolving many common cause failure regulatory questions.

The staff continues to make progress in streamlining the licensing review process for major digital upgrades as is evidenced by recent staff revision of interim staff guidance. This proposed revision would reduce the scope of licensee document submittals and would provide an alternative for earlier approval. The staff engaged industry on plans to develop industry guidance for the implementation of commercially available digital devices.

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The staff is re-baselining the IAP in the next planned update in November 2018 to continue making tactical improvements to the regulatory infrastructure, and to perform a broad evaluation of strategic improvements to the regulatory infrastructure.

As these modernization activities are ongoing, the staff continues to approve digital I&C licensing action requests while maintaining adequate protection of the health and safety of the public. In addition, the staff is focusing on high-priority activities with the greatest near-term tactical impact. The longer term strategy is to evaluate and strategically implement broader improvements to the NRC's digital I&C regulatory infrastructure.

BACKGROUND:

The Commission directed the staff to develop an integrated strategy to modernize the NRC's digital I&C regulatory infrastructure in Staff Requirements Memorandum (SRM) SECY-15-0106, dated February 25, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16056A614), "Proposed Rule: Incorporation by Reference of Institute of Electrical and Electronics Engineers [(IEEE)] Standard (Std) 603-2009, 'IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations' (RIN 3150-AI98)" (ADAMS Accession No. ML113190983). Further, the Commission directed the staff to engage in public workshops and meetings with relevant standards setting committees, digital I&C vendors, licensees, and any other external stakeholders to reach a common understanding of the digital I&C regulatory challenges and priorities and to create an action plan to address them. The Commission also directed the staff to present any policy issues that are ripe for Commission consideration along with the plan.

The staff, in coordination with stakeholders, identified key topics to modernize the NRC's digital I&C regulatory infrastructure including protection against common cause failure (CCF), digital I&C upgrades and replacements under Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.59, "Changes, tests, and experiments," acceptance of commercial grade digital equipment for safety-related applications, and licensing process improvements. The staff's modernization of the NRC's digital I&C regulatory infrastructure focuses on operating reactors, new and advanced reactors, and digital I&C vendors. The highest industry priorities have been primarily focused on regulatory improvements associated with obsolescence issues and plant reliability improvements for the operating reactor fleet.

The staff developed an IAP. The IAP includes Modernization Plans (MPs) that address key topics mentioned above and that contain specific activities with defined outcomes and timelines. The specific MPs are: (1) Protection Against Common Cause Failure; (2) Considering Digital I&C in Accordance with 10 CFR 50.59; (3) Acceptance of Digital Equipment; and (4) Assessment for Modernization of the I&C Regulatory Infrastructure. The staff submitted the IAP to the Commission for approval in May 2016.[1]

The Commission approved the staff's planned approach in October 2016[2] and requested annual updates regarding the status of ongoing work and planned future activities for MPs 1 through 4 of the IAP. The staff has continued to update the plan to reflect current strategy and activities in

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[1] SECY-16-0070, "Integrated Strategy to Modernize the Nuclear Regulatory Commission's Digital Instrumentation and Control Regulatory Infrastructure," dated May 31, 2016 (ADAMS Accession No. ML16126A137).

[2] SRM-SECY-16-0070, "Staff Requirements – SECY-16-0070 – Integrated Strategy to Modernize the Nuclear Regulatory Commission's Digital Instrumentation and Control Regulatory Infrastructure," dated October 25, 2016 (ADAMS Accession No. ML16299A157).

modernizing the regulatory infrastructure. With input from stakeholders, Revision 1 to the IAP[3] was issued in March 2017 and Revision 2 to the IAP[4] was issued in January 2018. Revision 3 to the IAP is in development with a scheduled issue date of November 2018. The staff held a public meeting in July 2018[5] to discuss potential changes to the IAP.

Enclosure 1 to this paper provides the status for MPs 1 through 4. Enclosure 2 to this paper provides a list of specific interactions with stakeholders to maintain a common understanding of the digital I&C regulatory challenges and priorities.

DISCUSSION:

In implementing the IAP, the staff made significant progress this past year in addressing near-term regulatory challenges and providing confidence to digital I&C stakeholders, while also approving new digital designs for use by the operating and new and advanced reactor fleet. The staff also continues to consider the longer-term strategies such as but not limited to establishment of durable guidance, to include a more risk-informed and performance-based regulatory infrastructure.

I. Stakeholder Engagement

In implementing the IAP and associated MPs, the staff engages with external stakeholders via public meetings to ensure common understanding and priority of regulatory challenges in adopting digital I&C, and identify and incorporate stakeholders' views in developing solutions. These engagements are with licensees and applicants, members of relevant standards setting committees, digital I&C vendors, and other external stakeholders, and are listed in Enclosure 2. Additionally, the staff meets with Nuclear Energy Institute (NEI)-led industry digital I&C working groups to discuss specific digital I&C topics. These engagements have significantly contributed to the accomplishments described in Section II below.

Implementing the IAP revealed that different communities of external digital I&C stakeholders (operating reactors, new reactors, advanced reactors, and digital I&C vendors) have many common interests in digital I&C implementation, but also have unique priorities regarding modernization of the regulatory infrastructure in terms of scoping, timing, and overall benefit. In defining the future activities to pursue as part of the broader modernization approach, the staff is considering both the principles set by the Commission in SRM-SECY-15-106 and the unique needs for each of these communities. Specifically, operating reactor licensees continue to: (a) address obsolescence issues, (b) make modifications to improve plant reliability, and (c) evaluate strategic upgrades to reactor protection systems and engineered safety features actuation systems within the framework of their existing licensing basis. This licensing basis is typically founded upon current general design criteria (GDCs) and the standards in IEEE Std 279 or IEEE Std 603-1991. New and advanced reactor stakeholders are developing digital platforms for highly integrated I&C systems and architectures for new and advanced reactor designs. These future reactor designs may benefit from a licensing framework different than the GDCs and IEEE standards incorporated in current regulations. Digital I&C vendors, noting that nuclear digital I&C is a global enterprise, may first develop equipment against the International

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[3] Integrated Action Plan to Modernize Digital Instrumentation and Controls Regulatory Infrastructure, Revision 1, dated March 31, 2017 (ADAMS Accession No. ML17102B307).

[4] Integrated Action Plan to Modernize Digital Instrumentation and Controls Regulatory Infrastructure, Revision 2, dated January 31, 2018 (ADAMS Accession No. ML18016B023).

[5] July 25, 2018 Public Meeting on Digital Instrumentation and Control Integrated Action Plan, Revision 3 Status and Broader Modernization Plan 4B Activities (ADAMS Package Accession No. ML18204A313).

Electrotechnical Commission (IEC) standards for digital I&C, rather than to U.S. IEEE standards referenced in our regulations or endorsed in regulatory guides (RGs) (e.g., IEEE Std 279 and IEEE Std 603 in 10 CFR 50.55a). While past vendors have successfully demonstrated that IEC based systems can satisfy relevant IEEE standards, the vendors have challenged the value of this demonstration for NRC approval of their systems for use in the U.S.

At the July 2018 public stakeholder meeting on Revision 3 to the IAP, the staff discussed recent accomplishments and the current understanding of the challenges and priorities that may be unique to specific digital I&C stakeholders. The staff also sought feedback on its plan to re-baseline the IAP to reflect these updated accomplishments and challenges. The general feedback received was that stakeholders favor the staff looking more broadly at a strategic modernization of the digital I&C regulatory infrastructure, as long as the staff continues to make progress on the near-term, high-priority tactical activities. From this meeting and subsequent input provided by stakeholders, the staff and industry have aligned on the priorities for near-term and long-term improvements to the regulatory infrastructure. The staff will continue to engage with industry to understand their challenges, priorities, and potential solutions as the IAP is being updated and implemented.

II. Accomplishments

The staff improved the clarity of the 10 CFR 50.59 process that licensees use to make digital modifications without prior NRC approval. On May 31, 2018, the staff issued Regulatory Information Summary (RIS) 2002-22, Supplement 1[6], "Clarification on Endorsement of Nuclear Energy Institute Guidance in Designing Digital Upgrades in Instrumentation and Control Systems," for preparing and documenting "qualitative assessments" that can be used to evaluate the likelihood of failure of a proposed digital modification, including the likelihood of failure due to a CCF. Licensees can use these qualitative assessments to support a conclusion that a proposed digital I&C modification has a sufficiently low[7] likelihood of failure when addressing the criteria in 10 CFR 50.59. Also, this supplement clarified guidance for determining under 10 CFR 50.59 whether a change requires a license amendment. The staff has received feedback from external stakeholders that industry is now implementing modifications using this guidance. NEI is conducting industry workshops on using RIS 2002-22, Supplement 1. The staff has observed these workshops to gain additional insights to incorporate into its own separate training for inspectors, scheduled to begin in late 2018. To ensure that all interested stakeholders (e.g., non-NEI members) have the opportunity to engage the NRC on the implementation of RIS 2002-22, Supplement 1, the staff will also hold a public meeting to discuss and incorporate the lessons-learned from the NRC inspector training and NEI workshops.

The staff and industry continue to address the need for broader guidance for 10 CFR 50.59 screening and evaluations of digital I&C upgrades in order to reduce licensing uncertainty and clarify the regulatory process. In April 2016, and as supplemented in July 2018[8], NEI prepared advance drafts of NEI 96-07, Appendix D , "Supplemental Guidance for Application of 10 CFR

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[6] RIS 2002-22, Supplement 1, "Use of EPRI [Electric Power Research Institute]/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,'" dated May 31, 2018 (ADAMS Accession No. ML18143B633).

[7] "Sufficiently low" means much lower than the likelihood of failures that are considered in the updated final safety analysis report (UFSAR) (e.g., single failures) and comparable to other CCFs that are not considered in the UFSAR (e.g., design flaws, maintenance errors, calibration errors).

[8] Draft NEI 96-07, Appendix D, "Guidelines for 10 CFR 50.59 Evaluations," Appendix D, "Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications", dated July 17, 2018 (ADAMS Accession No. ML18199A647)

50.59 to Digital Modifications," which contained screening and evaluation guidance on the specific licensing criteria in 10 CFR 50.59 for all types of digital upgrades. The staff held public meetings with NEI to discuss staff comments on the drafts and suggested specific edits to the proposed appendix. Based on these ongoing engagements, NEI plans to revise and submit the final version of NEI 96-07, Appendix D, for NRC endorsement by December 2018.

The staff also made progress in resolving many CCF regulatory questions. In addition to the RIS 2002-22, Supplement 1, discussed above, the staff completed an assessment of CCF licensing challenges and provided SECY-18-0090[9], "Plan for Addressing Potential Common Cause Failure in Digital Instrumentation and Controls," in September 2018. The plan discusses consistent application of the NRC's position on defense against CCF in current and future digital I&C system designs, and, intent to update and clarify licensing guidance. Specifically, the staff will update branch technical position (BTP) 7-19[10], "Guidance for Evaluation of Diversity and Defense-in-Depth in Digital Computer-Based Instrumentation and Control Systems," as discussed in SECY-18-0090.

The staff continues to make progress in streamlining the licensing review process for major digital upgrades. For example, the staff revised Interim Staff Guidance (ISG) DI&C-ISG-06[11], "Licensing Process," which defines the licensing process used to support the review of license amendment requests associated with safety-related digital I&C equipment modifications in operating plants and in new plants once they become operational. The proposed revision reduces the scope of licensee document submittals and provides an alternative for earlier approval, which, unlike the current process, would precede factory acceptance testing, for digital designs that are based on approved topical reports. With this revised guidance, the staff has continued to encourage early pre-application interactions for licensees planning major digital upgrades. The staff issued the draft DI&C-ISG-06 for comment in August 2018 and expects to complete the final version by December 2018.

Lastly, the staff engaged NEI on their plans to develop industry guidance for the implementation of commercially available digital devices, with appropriate evaluation by licensees, applicants, and suppliers while ensuring compliance with regulations and policy. Specifically, the staff plans to evaluate the use of Safety Integrity Level certification per IEC 61508, "Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems," data to supplement commercial grade dedication of digital equipment per 10 CFR 50 Part 21, "Reporting of Defects and Noncompliance." This certification process is currently being independently evaluated by EPRI to support the NRC staff and industry needs for this effort.

As these modernization activities are ongoing, the staff continues to approve digital I&C licensing action requests for all communities, in an efficient and effective manner. Recent licensing action successes include reviews of generic topical reports from the Lockheed Martin Nuclear Protection and Control, and NuScale Highly Integrated Protection System platforms; license amendment requests for Vogtle Electric Generating Plant, Units 3 and 4, and Hope Creek Generating Station, Unit 1 power range neutron monitoring systems; and the design certification applications for the Advanced Power Reactor 1400 and the NuScale Power, LLC (NuScale) small modular reactor. Of specific note, the staff successfully evaluated the highly

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[9] SECY-18-0090, "Plan for Addressing Potential Common Cause Failure in Digital Instrumentation and Controls," dated September 12, 2018 (ADAMS Package Accession No. ML18179A066).
[10] BTP 7-19, "Guidance for Evaluation of Diversity and Defense-In-Depth in Digital Computer-Based Instrumentation and Control Systems," Revision 7, dated August 2016 (ADAMS Accession No. ML16019A344).
[11] Digital I&C ISG-06, "Licensing Process," dated July 31, 2018 (ADAMS Accession No. ML18123A118).

integrated I&C systems for the NuScale small modular reactor, using the approach of the NuScale design-specific review standard (DSRS) Chapter 7 that is based on adherence to the fundamental safety principles and risk importance/safety significance focus. This was the first time the applicant and the staff used the DSRS Chapter 7 guidance to prepare and evaluate a highly integrated I&C design. Use of this approach resulted in the completion of the safety evaluation report in an efficient and effective safety-focused manner.

III. Future Vision of the Digital I&C IAP

The staff is re-baselining the IAP in the next planned update. The integrated strategy has been updated to reflect a two-fold approach: (1) continue to implement specific MPs for making tactical improvements to the regulatory infrastructure, primarily to address near-term digital upgrade challenges identified by the operating reactor fleet; and (2) perform a broad evaluation of strategic improvements to the regulatory infrastructure, including supporting research, to address stakeholder challenges and improve the effectiveness of NRC licensing and oversight. Protection against CCF, digital I&C upgrades and replacements under 10 CFR 50.59, acceptance of commercial grade digital equipment for safety-related applications, and licensing process improvements will continue to be high-priority activities with the greatest near-term tactical impact. The draft plan has been updated to reflect completion of the RIS supplement and review of CCF policy issues. A new modernization plan activity for improving guidance in BTP 7-19 for addressing diversity and defense-in-depth against CCF has been added, consistent with SECY-18-0090.

The longer-term strategy is to evaluate and strategically implement broader improvements to the NRC's digital I&C regulatory infrastructure. To accomplish this goal, the staff is re-baselining the framework of the longer-term activities (MP 4B) in the IAP, which will include plans to complete a strategic assessment and implement supporting research. The goal is to identify impactful improvement activities consistent with the Commission direction in SRM-15-0106, while considering the challenges and potential impediments that may be unique to specific digital I&C stakeholder communities. The revised plan lists potential improvement activities that will be assessed, and are categorized based on the type of regulatory improvement and benefit in addressing Commission direction. These areas include: (1) identification and implementation of significant structural changes to the regulations or major RGs to reduce complexity, and focus on the fundamental safety principles that are appropriate for all designs; (2) improvement to NRC review efficiency and enhancement of existing guidance to be more performance-based, and risk-informed; and (3) development of guidance to provide enhanced predictability of reviews and ensure that no unnecessary impediment exist in the review of digital technologies.

As part of the broader modernization effort, the staff intends to specifically evaluate a risk-informed regulatory framework based on higher level design principles with a goal to substantively improve the effectiveness of new reactor and vendor approvals, and provide long-term strategic benefits for operating reactors. The staff will examine high-level, performance-based I&C safety design principles as an alternative to the current regulatory framework associated with IEEE Std 279 and IEEE Std 603-1991, with a goal to address challenges for international vendors. In this regard, the staff is considering the use of well-tested, alternative digital I&C standards (e.g., IEC standards). Additionally, the staff has continued to engage the consensus standard development organizations on updates to IEEE Std 603 and IEEE Std 7-4.3.2, "IEEE Standard Criteria for Programmable Digital Devices in Safety Systems of Nuclear Power Generating Stations," to address regulatory issues previously identified in the staff's past rulemaking proposal in SECY-15-106. Lastly, the staff

has initiated important digital I&C research in the areas of risk-informing approaches to the regulatory infrastructure, identification and resolution of CCF issues, and identification and resolution of issues arising from the use of emergent digital technologies.

In 2018, an independent NRC Transformation Team was formed to identify potential transformational changes to NRC's regulatory framework, culture and infrastructure to further enhance our effectiveness, efficiency and agility. In SECY-18-0060[12], "Achieving Modern Risk-Informed Regulation," the Transformation Team recommended, in part, that the Commission direct the staff to develop a new regulation to define high-level performance-based I&C safety design principles and associated regulatory guidance that documents the acceptable standards that may be used to meet these principles. The recommendation for digital I&C in SECY-18-0060 is currently before the Commission for consideration. The strategic assessment will incorporate this recommendation, and the IAP may be further updated to integrate Commission direction on this matter, as warranted.

Policy Issues for Commission Consideration

In the last annual SECY paper update, a preliminary evaluation performed by the staff determined that there was one potential policy issue regarding CCF that warrants Commission consideration. After a more thorough evaluation, the staff concluded that there are no policy issues in this area at this time. Specifically, the staff concluded that the Commission's direction in SRM-SECY-93-087, which addresses CCF in digital I&C systems, provides adequate flexibility for regulatory modernization activities that support near-term digital I&C implementation. As discussed in Section II above and in SECY-18-0090, the staff will update and clarify licensing guidance to ensure consistent application of the NRC's position on defense against CCF in current and future digital I&C system designs. Updated licensing guidance will support the near-term licensing needs identified by stakeholders. The staff will also evaluate how to address CCF in broader regulatory infrastructure activities described in Section III above.

CONCLUSION:

Implementation of the IAP is improving the regulatory infrastructure, removing unnecessary impediments, and reducing regulatory uncertainty. The staff is also routinely communicating with external stakeholders to ensure NRC requirements and guidance maintain safety and do not pose an unnecessary impediment to advancement in nuclear applications of digital technology. Consistent with Commission direction, future staff updates on the status of the IAP will continue to be provided to the Commission annually.

RESOURCES:

No additional resources beyond those currently identified in the IAP are anticipated. The staff continues to assess the resources associated with these activities as part of the normal budget development process.

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[12] SECY-18-0060, "Achieving Modern Risk-Informed Regulation," dated May 23, 2018 (ADAMS Package Accession No. ML18110A186).

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections.

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Enclosures:
1. Updates to the Digital I&C Integrated Action Plan
2. Overview of Staff Engagement with External Stakeholders

SUBJECT: UPDATE REGARDING THE INTEGRATED STRATEGY TO MODERNIZE THE NUCLEAR REGULATORY COMMISSION'S DIGITAL INSTRUMENTATION AND CONTROL REGULATORY INFRASTRUCTURE DATED

SRM-S16-0070-1

ADAMS Package No.: ML18275A327
ADAMS Accession No.: ML18255A351
ADAMS Enclosure 1 No.: ML18275A344
ADAMS Enclosure 2 No.: ML18275a333 ***via e-mail**

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