

Digital Instrumentation and Controls Licensing and Inspection Workshop (Morning Session)

February 10, 2021

Workshop Goals

- Provide an update on Digital I&C licensing and inspection activities
- Share lessons learned and insights from the use of ISG-06, Alternate Review Process
- Clarify the scope of licensing and inspection activities associated with the Alternate Review Process
- Request feedback from industry on lessons learned

Workshop Agenda (AM)

- Introduction and Workshop Goals
- Digital Modifications Under 10 CFR 50.59
- Licensing Activities
- Overview of Digital I&C Modernization: External

Workshop Agenda (PM)

- ISG-06 Alternate Review Process Reflection: NRC
- ISG-06 Alternate Review Process Reflection: Industry
- Open Discussion and Next Steps
- Public Comments

DIGITAL MODIFICATIONS UNDER 10 CFR 50.59

Tools to Support Digital Upgrades

- RIS 2002-22, Supplement 1, “Clarification on Endorsement of Nuclear Energy Institute Guidance in Designing Digital Upgrades in Instrumentation and Control Systems”
- NEI 96-07, Appendix D, “Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications”
- RG 1.187, Revision 2, “Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments”
- Regional Inspector Training
- Proposed Digital OpE Smart Sample for Inspectors

RIS 2002-22, Supplement 1

- RIS 2002-22 Supplement 1, ‘Clarification on Endorsement of Nuclear Energy Institute Guidance in Designing Digital Upgrades in Instrumentation and Control Systems,’ was issued in May 2018
 - Clarifies guidance for preparing and documenting “Qualitative Assessments”
 - Not for replacement of:
 - Reactor Protection System (wholesale)
 - Engineered Safety Features Actuation System (wholesale)
 - Modification/Replacement of the Internal Logic Portions of These Systems
 - NEI Industry Workshops conducted in 2nd half of 2018
 - NRC inspector training conducted in December 2018 and June 2019
 - Public Meeting held in February 2019
 - Industry feedback that the RIS guidance was useful for conducting digital mods

NEI 96-07, Appendix D

- NEI 96-07, Appendix D, ‘Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications,’ was issued in May 2020 and endorsed by RG 1.187 in June 2020
 - “Appendix D does not alter and, unless explicitly noted, should not be interpreted differently than the guidance contained in NEI 96-07, Rev. 1. Rather, Appendix D provides focused guidance for the application of 10 CFR 50.59 to activities involving digital modifications.” (Section 1.2)
 - Appendix D provides the first screening guidance for digital modifications (NEI 01-01 did not have screening guidance).
 - Human Factors Engineering (HFE) Evaluation guidance
 - NEI industry training in progress. First training was conducted January 20-22, 2021

NEI 96-07, Appendix D Endorsement

- From April 2016 through 2017, the NRC staff and industry participated in monthly public meetings to resolve NRC comments on draft NEI 96-07, Appendix D
- In December 2017, NEI and the NRC staff mutually agreed to place the review of NEI 96-07, Appendix D on hold to dedicate resources to the issuance of RIS 2002-22, Supplement 1
- RIS 2002-22 Supplement 1 was issued on 05/31/18
- July – November 2018, resolve comments on Appendix D and issue draft RG 1.187 Revision 2 in May 2019
 - Draft RG 1.187 had one exception and several clarifications. The exception involved how to evaluate 10 CFR 50.59 Criterion VI (Create the possibility for a malfunction of an SSC with a different result)
- From July 2019 – May 2020 work on revising Appendix D so that exception could be removed from draft RG 1.187

RG 1.187, Revision 2

- The NRC staff evaluated NEI 96-07, Appendix D, as applied to digital modifications only.
- The NRC staff endorsed NEI 96-07, Appendix D, Revision 1, as a means for complying with the requirements of 10 CFR 50.59 when conducting digital I&C modifications, subject to four clarifications in the RG:
 - Relationship to NEI 01-01
 - Changes from NEI 96-07, Revision 1
 - Human-System Interface
 - Use of Acceptance Criteria as Evaluation Results
 - Sufficiently Low Likelihood of Software Common Cause Failure
 - Appendix D, Section 4.3.6, Step 6: Basic Assumptions and Acceptance Criteria

Digital I&C Modification Inspection Training

- Regional Inspector Training was conducted in December 2020 on NEI 96-07, Appendix D; RG 1.187; and a refresher on RIS 2002-22, Supplement 1
- Most digital modifications are inspected through IP 71111.18, “Plant Modifications,” or 71111.17T, “Evaluation of Changes, Tests and Experiments”
- For digital modifications that involved a license amendment, IP 52003, “Digital Instrumentation and Control Modification Inspection,” (IMC 2515 Appendix C) is the correct IP
 - Undergoing a revision
 - May bring more inspection resources (Vendor Inspection Branch)
 - Not a ROP Baseline IP
- New IMC 0355, “Changes, Tests, and Experiments” was issued on January 29, 2021
 - One paragraph on digital I&C mods that point inspectors to NEI 96-07, Appendix D, RG 1.187, and RIS 2002-22, Supplement 1 for digital I&C mods under 50.59 guidance

Inspection- Smart Sample Development

- With digital I&C modifications becoming more prevalent NRC inspectors were looking for tools that could help them when inspecting new digital systems
- Staff determined the most efficient course of action would be to develop a digital I&C OpE Smart Sample
 - Useful tool providing additional technical guidance for inspectors while inspecting digital I&C systems
 - Can be used by inspectors under current ROP baseline inspections
- Working Group formed to develop the smart sample including regional inspectors and technical staff from NRC HQ

OPEN DISCUSSION

DIGITAL I&C LICENSING

ISG-06 Purpose and Scope

- Defines the licensing process used to support the review of licensee amendment requests (LARs) associated with safety-related DI&C equipment modifications in operating plants and in new plants once they become operational.
- Provides guidance for activities performed before LAR submittal and during LAR review. The NRC staff uses the process described in the ISG to evaluate compliance with NRC regulations.
- ISG-06 is used in conjunction with SRP Chapter 7.

ISG-06, Revision 1

Revision 1 introduced the concepts of “Tiers” and “Phases”:

- Tiers – a general guide for defining the scope or complexity of a review:
 - Tier 1 – references a previously approved topical report (TR)
 - Tier 2 – references a previously approved TR with deviations
 - Tier 3 – does not reference a previously approved topical report
- Phases – a general guide for defining the NRC staff activities to be performed during the review.
 - Phase 0 – Pre-Application Meetings with the NRC Staff
 - Phase 1 – Initial Application (LAR)
 - Phase 2 – Continued Review and Audit (Supplemental Information)
 - Phase 3 – Implementation and Inspection

ISG-06, Revision 1 Lessons Learned

- ISG-06, Rev. 1 has been used to review the Diablo Canyon Plant Protection System DI&C LAR (ADAMS Accession No. ML16139A008), the Hope Creek Power Range Neutron Monitoring System LAR (ADAMS Accession No. ML17216A022), and DI&C topical report reviews.
- Based on these reviews, the staff identified several improvements that could be made to ISG-06, Rev. 1.
- Industry expressed concerns that:
 - Significant resources are required for procuring, developing, and testing a full digital I&C design before the license amendment is issued.
 - Several review criteria topical areas were repetitive.
- In 2017, staff formed a working group under the DI&C Integrated Action Plan to revise ISG-06 based on lessons learned and industry feedback.

ISG-06, Revision 2

- The NRC working group met regularly with industry between 2017 and 2018 to develop the ISG revision.
- The Tier 1, 2 and 3 Review Process was streamlined and eliminated the system planning evaluation criteria.
- The Alternate Review Process (ARP) was introduced.
- Revision 2 focused on the information needed to make the required regulatory findings, instead of the submittal of specific documents.
- A tabletop exercise and an inspection workshop were held to discuss the LAR contents to be developed under the ARP (see next slides).
- ISG-06, Rev. 2 issued on December 2018 in time to support upcoming LARs.

Alternate Review Process Tabletop Exercise

- Held on June 13-14, 2018 (ADAMS Accession Nos. ML19085A483 and ML19085A484).
- Staff and industry went over how specific LAR sections would be developed based on the draft ISG-06, Rev. 2 ARP guidance:
 - New System Architecture
 - System Development Process
 - Pre-application Coordination meetings
 - Resolution of Topical Report Plant-Specific Action Items
 - Human Factors Engineering
 - Secure Development and Operational Environment
 - Recommended Inspection Items
 - Licensee Commitments
 - Vendor Oversight Plan (VOP) Summary
- Improvements were made to the ISG draft based on the tabletop discussions.

Alternate Review Process Inspection Workshop

- Held on November 15, 2018 (ADAMS Accession No. ML19086A059).
- The purpose was to provide clarity on the types of licensing audits and post-license amendment inspections expected to be performed under the ARP.
- Discussed the vendor oversight process and VOP Summary example.
- Discussed the scope of VOP and vendor inspections under the ARP.
- Staff provided a description of the acceptance criteria for design implementation and design outputs in Branch Technical Position (BTP) 7-14 sections B.3.2 and B.3.3 (ADAMS Accession No. ML19087A230).
- Improvements were made to the ISG draft based on the workshop discussions.

Current DI&C Licensing Activities

- Waterford 3
 - Core Protection Calculator System
 - LAR submitted on July 2020
 - Approval requested by August 2021
- Turkey Point Units 3 & 4
 - Reactor Protection System, Engineered Safety Feature Actuation System, Nuclear Instrumentation System
 - Pre-submittal meetings on December 2020 and January 2021
 - LAR submittal expected in May/June 2021
- Limerick
 - Reactor Protection System, Nuclear Steam Supply Shutoff System, Emergency Core Cooling System
 - Pre-submittal meeting on June 2020
 - LAR submittal expected in September 2022

NRC Resource Planning for Major Digital Modernization Projects

- NRC recommends Letter of Intent 6-12 months prior to LAR submittal.
- Reach out through your NRC licensing Project Manager if you intend to submit a Digital I&C amendment in 2021 or 2022.
- Early pre-submittal meetings encouraged to better understand the scope and complexity of planned submittal.

Licensing Infrastructure Development

Completion of BTP 7-19 Revision 8

- “Guidance for Evaluation of Defense in Depth and Diversity to Address Common-Cause Failure Due to Latent Design Defects in Digital Safety Systems,” (ML20339A647) Issued January 26, 2021.
- Addresses the issue of CCF in digital I&C systems with consideration of system safety significance. This allows more flexibility in potential design and analytical solutions to address CCF.
- Restructured to improve organization of information and readability.
- Refinements within BTP 7-19, Revision 8
 - “Alternative Methods”
 - Qualitative Assessment (based upon RIS 2002-22 Supplement 1)
 - Clarified guidance on Spurious Operation
 - “Justification for Not Correcting Specific Vulnerabilities”

NEI 20-07

- Draft NEI 20-07 proposes an alternative method (i.e. software assurance case) to address software common cause failure (SWCCF) in high safety-significant safety-related (HSSSR) systems and components
- NEI 20-07 is proposed to work within the framework set forth in BTP 7-19, Revision 8
 - Note: BTP 7-19 is cited as part of staff guidance for the regulatory evaluation under ISG-06, Revision 2
- Staff is currently engaging NEI in pre-submittal interactions to assess the feasibility and potential applicability of the proposed approach.
- First public meeting held on January 12, 2021 (ML21025A392)

Planned Updates to Regulatory Guides

- The staff are striving to improve the clarity and cohesiveness of the I&C regulatory infrastructure
 - Including more recent and relevant code and consensus standards; and,
 - Allowing a more effective navigation and use of the available guidance
- Plans to update the following RGs:
 - RG 1.153 to endorse IEEE 603-2018 which includes a new clause addressing CCF that creates a potential to degrade or defeat the safety system function
 - RG 1.152 to endorse IEEE 7.4-3-2-2016 that includes new guidance for secure development and operational environment (SDOE), Independence (e.g. data communications), hazard identification and software tools
 - RG 1.168 to assess graded-approach alternatives for the specified software integrity level guidance and assess the feasibility of consolidating software criteria in RGs 1.168 through 1.173

OPEN DISCUSSION

Acronyms

ADAMS – Agencywide Documents Access and Management System

ARP – Alternate Review Process

ASME – American Society of Mechanical Engineers

BTP – Branch Technical Position

CCF – common cause failure

D3 – Defense-in-Depth and Diversity

DI&C – Digital Instrumentation and Controls

DRA – Division of Risk Assessment

FAT – Factory Acceptance Test

FMEA – Failure Modes and Effects Analysis

GDC – General Design Criteria

HW – Hardware

HFE – Human Factors Engineering

Acronyms

- HSSSR – high safety-significant safety-related
- IEEE – Institute of Electrical and Electronics Engineers
- I&C – Instrumentation and Controls
- IP – Inspection Procedure
- IRT – Integrated Review Team
- ISG – Interim Staff Guidance
- LAR – License Amendment Request
- MP – Modernization Plan
- NEI – Nuclear Energy Institute
- NQA – Nuclear Quality Assurance
- NRC – Nuclear Regulatory Commission
- OpE – operational experience
- QA – Quality Assurance

Acronyms

- RAI – Requests for Additional Information
- RIS – Regulatory Issue Summary
- RG – Regulatory Guide
- SAT – Site Acceptance Test
- SDOE – Secure Development and Operational Environment
- SPM – Software Program Manual
- SW – Software
- SWCCF – software common cause failure
- TR – Topical Report
- TS – Technical Specifications
- VOP – Vendor Oversight Plan
- V&V – Verification and Validation