



Integrated Action Plan to Modernize Digital Instrumentation and Controls Regulatory Infrastructure

Contents

Concurrence	3
Summary.....	4
1.0 Introduction	5
2.0 Background	6
3.0 Updating Processes for this Integrated Action Plan.....	8
4.0 Detailed Modernization Plans	8
MP #1. Protection Against Common Cause Failure	11
Introduction	11
Background.....	11
Objectives	12
Actions	12
Status.....	13
Potential Regulatory Challenges and Policy Issues	13
Interactions with other Action Plan Items.....	13
MP #2. Considering Digital Instrumental & Control in Accordance with 10 CFR 50.59.....	14
Introduction	14
Background.....	14
Objectives	15
Actions	15
Status.....	16
Potential Regulatory Challenges and Policy Issues	16
Interactions with Other Action Plan Items	16
MP #3. Commercial Grade Dedication of Digital Equipment.....	17
Introduction	17
Background.....	17
Objectives	18
Actions	18
Status.....	19
Potential Regulatory Challenges and Policy Issues	19
Interactions with other Action Plan Items.....	19
MP #4. Assessment for Modernization of the Instrument & Control Regulatory Infrastructure	20

Introduction	20
Background.....	20
Objectives	20
Actions	22
Status.....	22
Potential Regulatory Challenges and Policy Issues	22
Interactions with other Action Plan Items.....	22
Appendix A	23

**Integrated Action Plan to Modernize
Digital Instrumentation and Controls
Regulatory Infrastructure**

Concurrence

ADAMS ACCESSION No: ML16097A182:

*concurrence via e-mail

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Integrated Action Plan to Modernize Digital Instrumentation and Controls Regulatory Infrastructure

Summary

This is an integrated action plan (IAP) that responds to Staff Requirements Memorandum (SRM) to SECY-15-0106¹, "Proposed Rule: Incorporation by Reference of Institute of Electrical and Electronics Engineers Standard 603-2009, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations," which directs the staff to develop an integrated strategy to modernize the U.S. Nuclear Regulatory Commission's (NRC's) digital instrumentation and control (I&C) regulatory infrastructure. Consistent with Commission direction, this plan describes a strategy that engages external stakeholders to reach a common understanding of digital I&C regulatory challenges, priorities, and potential solutions to address them. The plan considers the broad context of digital I&C regulatory challenges and includes related activities being pursued by the staff. The plan was developed with NRC staff and external stakeholder input. In resolving the regulatory challenges, the plan provides for frequent public and stakeholder interactions. A senior management steering committee (SC) will oversee the resolution of digital I&C regulatory challenges identified within the plan. As the IAP is implemented and the modernization plans are accomplished, the staff will submit any recommended changes to NRC policies to the Commission.

As analog I&C becomes obsolete, operating nuclear facilities are considering replacing these analog I&C safety systems with digital technology. New reactors incorporate digital safety systems into their designs. Digital I&C technology has advantages, including automated monitoring and alerts for standby safety functions, and predictive algorithms to maintain critical safety systems. Digital I&C systems also present potential vulnerabilities that need to be assessed, including failures due to increased complexity of digital systems and the introduction of coding errors, common cause failure (CCF)² modes, and limited operating history of digital systems in nuclear safety related applications. The NRC and industry stakeholders have identified the need to modernize the regulatory infrastructure to efficiently address risks associated with the introduction of digital technology for nuclear safety applications.

The staff, in coordination with stakeholders, identified three key topics that would have the greatest impact, in the near-term, in addressing regulatory challenges and improving timeliness, efficiency, and effectiveness. The staff will prioritize and implement the complete set of regulatory activities, including building upon those in the first three key topics, needed to provide near-term regulatory clarity and support industry confidence to perform digital I&C upgrades.

The longer-term goal is to evaluate and implement the follow-on steps for continued improvement of the NRC's digital I&C regulatory infrastructure. The infrastructure improvements will result in a state in which the nuclear power industry can obtain regulatory approval to use digital technology that provides for adequate safety and security through processes that are efficient, minimize uncertainty, and can be consistently applied across different technologies. The staff will review and modify the current regulatory structure to be more performance-based and flexible by using new methods in the most effective way and

¹ Agencywide Documents Access and Management System (ADAMS) Accession No. ML16056A614.

² CCF: Potential vulnerabilities due to common errors in redundant digital I&C divisions.

updating the regulatory and guidance structure to acknowledge changes in the technology, the way it is developed, and how it is used. The staff will evaluate the results of implementation of the near-term activities and, with continued stakeholder interaction, will develop a performance-based, technology-neutral regulatory infrastructure that will anticipate the evolution and future development of digital I&C technology as it is applied to nuclear technologies.

For the longer-term items, the staff will identify actions needed to implement a simpler, streamlined and agile I&C regulatory infrastructure that will effectively address larger scale digital I&C upgrades. This effort will also improve the clarity of the priorities and sequencing of further improvements with consideration of the objectives of transparency, regulatory stability and predictability, effective consideration of the cumulative effects of regulation, and efficient and effective use of limited NRC resources.

The staff has taken immediate action to develop a strategy to modernize the NRC's regulatory infrastructure. This strategy will also serve as a learning platform, to identify needs for future improvements in NRC's regulatory and guidance framework and acknowledge ongoing changes in the technology. Staff will engage the public and relevant stakeholders in the improvement of license reviews and other regulatory processes to develop a performance based, technology-neutral regulatory infrastructure.

The details of this plan describe an integrated strategy with near-term and long-term goals to modernize the regulatory infrastructure. Proposed changes include updating the regulatory requirements, policies, and guidance for digital I&C consistent with the Commission-directed attributes in SRM-SECY-15-0106 as listed below:

1. The plan should include the establishment of a senior management SC to oversee resolution of digital I&C regulatory challenges.
2. Any new or revised requirements addressed in the action plan should be performance-based rather than prescriptive.
3. Digital I&C safety requirements should be technology neutral, however, guidance should be tailored if necessary. The same requirements should apply to operating and new reactors.
4. Guidance should focus on acceptable approaches to complying with requirements and may include specific technology focused provisions. If only one approach is acceptable to the staff to ensure safety based on current understanding, and this approach is appropriately technology-neutral and performance-based, then it should be included in a requirement rather than in guidance.
5. NRC requirements and guidance should not pose an unnecessary impediment to advancement in nuclear applications of digital technology.

This IAP is a living document. It will be updated based on progress made on related activities and modified, if necessary, based on Commission direction and new information.

1.0 Introduction

This document describes the staff's integrated action plan for modernizing the I&C regulatory infrastructure in response to SRM-SECY-15-0106. This integrated action plan will ensure safety and security while improving the predictability and consistency of the agency's regulatory process for licensing and oversight of digital I&C systems. This plan builds upon ongoing regulatory activities, stakeholder feedback concerning the previous draft versions of the action

plan, and specific Commission direction in SRM-SECY-15-0106 to modernize the digital I&C regulatory infrastructure.

2.0 Background

In operating nuclear facilities, I&C equipment obsolescence is becoming significantly burdensome to licensees, and if not resolved, has the potential to impact the safety and security of operations. The implementation of digital technology in safety and security systems can be useful for resolving obsolescence issues, reducing uncertainties in the maintenance of plant safety, reducing opportunities for human error, reducing maintenance costs, and potentially improving safety. New nuclear facility designs being submitted for NRC licensing review incorporate modern, highly-integrated I&C design approaches. Such approaches and technology promise benefits to nuclear facility safety, security, and operation, including increased reliability and diagnostics and improved human-machine interfaces. Many industry stakeholders (i.e., licensees, applicants, and vendors) desire to take advantage of these potential safety and reliability benefits.

The NRC maintains a robust regulatory program for ensuring the safety and security of nuclear facilities protected and operated with analog and digital I&C systems.³ Using its current regulatory infrastructure, the staff continues to review and approve license amendments for specific digital I&C systems, and evaluate new reactor applications that fully incorporate highly integrated digital technologies. To prepare for the review of applications for small modular reactor (SMR) design certifications and combined licenses, the staff has developed a design-specific review standard (DSRS). The DSRS reflects a number of important lessons the staff learned while using the Standard Review Plan (SRP) NUREG-0800 to review new large light water reactor designs. One of the lessons learned incorporated into this guidance emphasizes fundamental I&C design principles such as independence, redundancy, repeatability, predictability, and diversity and defense-in-depth, as derived through design and analysis, such as hazard analysis, to prevent loss or impairment of a safety function. This guidance addresses significant aspects of the I&C design in a unified manner.

The NRC provides oversight on the construction, implementation, use, and maintenance of digital I&C technologies, and maintains an operational experience evaluation program to uncover any systemic issues with digital I&C systems. The staff updates its infrastructure (e.g., Regulatory Guides (RGs) and SRPs) to address new types of digital technologies and emergent regulatory issues in specific areas. The staff will continue to perform routine updates of RGs under normal processes, and perform various research activities to support emergent and long-term regulatory activities. This includes participation in consensus standards development activities (e.g., IEEE; International Society of Automation; American Nuclear Society; American National Standards Institute). The NRC is currently working to update RG 1.180, "Guidelines for Evaluating Electromagnetic and Radiofrequency Interference in Safety-Related Instrumentation and Control Systems," to endorse revised and new industry consensus standards addressing electromagnetic and radiofrequency interference qualification processes. The staff also conducts research to support development of the technical bases for future regulatory infrastructure improvements and emergent licensing challenges. For example, the NRC is currently performing key research activities in the area of digital system hazard analysis to be used in developing future regulatory guidance for evaluating digital safety systems. Such

³ This program was significantly improved in 2007 - 2011 when staff working groups, industry, and other stakeholders developed interim staff guidance to address digital I&C regulatory challenges at that time.

continued update and maintenance of the I&C regulatory infrastructure has helped the continued safe operation of reactors and materials facilities.

Some industry stakeholders have expressed concern that the current digital I&C licensing and oversight process for power and non-power reactors is cumbersome and inefficient, and/or unpredictable. Some have stated they are hesitant to pursue the deployment of digital I&C through license amendments, new applications, or changes under the Title 10 of the *Code of Federal Regulations* (10 CFR) 50.59 process, unless regulatory efficiency and predictability can be improved. As a result, the staff interacted with industry to discuss its concerns regarding these regulatory challenges. In response to these interactions, the staff developed an action plan to define specific regulatory challenges to be addressed and propose paths for resolving them. In January 2016, the NRC released its working version of this draft action plan (ADAMS Accession No. ML16014A085) to solicit feedback from stakeholders. The draft action plan described the staff's interpretation of several challenges to be addressed in response to stakeholder comments regarding their licensing and oversight experience in implementing digital I&C. The draft action plan also considered staff experience in evaluating digital safety system designs submitted as part of license applications or amendments, while implementing the interim staff guidance developed as a result of the 2007-2011 digital I&C project. The draft action plan identified key regulatory challenges and opportunities for improvement, including potential enhancements to policies, rules, guidance, practices, and processes in licensing and oversight.

On February 25, 2016, the Commission issued SRM-SECY-15-0106, which disapproved the staff's recommendation to publish for comment in the Federal Register a proposed rule which would incorporate by reference into 10 CFR 50.55a the IEEE Standard (Std.) 603-2009, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." This proposed rule had included, along with the incorporation by reference of IEEE Std. 603-2009, additional conditions for addressing digital hazards analysis, independence, and digital communications. In the SRM, the Commission directed the staff to develop an integrated strategy, with proposed implementation milestones, to modernize the NRC's digital I&C regulatory infrastructure. In developing an integrated action plan, the Commission directed the staff to consider the broader context of digital I&C regulatory challenges and include all related activities being pursued by the staff including incorporation by reference of IEEE Std. 603-2009, updates to the policy on CCF in SRM-SECY-93-087, and development of guidance for 10 CFR 50.59 evaluations of digital I&C upgrades.

The Commission also directed the staff to engage in public workshops and meetings with the relevant IEEE standards setting committee, licensees, vendors, and other external stakeholders to reach a common understanding of the digital I&C regulatory challenges, priorities, and potential solutions to address them. The Commission also directed the development of the plan to be guided by the following principles:

- The staff's plan should include the establishment of a senior management SC to oversee resolution of digital I&C regulatory challenges.
- Any new or revised requirements addressed in the action plan should be performance-based rather than prescriptive.
- Digital I&C safety requirements should be technology neutral, however, guidance should be tailored if necessary. In addition, the same requirements should apply to operating and new reactors.

- Guidance should focus on acceptable approaches to complying with requirements and may include specific technology-focused provisions. If only one approach is acceptable to the staff to ensure safety based on current understanding, and this approach is appropriately technology neutral and performance-based, then it should be included in a requirement rather than in guidance.
- NRC requirements and guidance should not pose an unnecessary impediment to advancement in nuclear applications of digital technology.

3.0 Updating Processes for this Integrated Action Plan

The digital I&C SC was established to provide senior management oversight of the formulation of the strategy and execution of this action plan to modernize the digital I&C regulatory infrastructure. The SC is comprised of Division Directors with management responsibility for I&C technology in the Office of Nuclear Reactor Regulation (Chairperson), Office of New Reactors, and the Office of Nuclear Regulatory Research, and supplemented as needed with members from the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of Nuclear Security and Incident Response (NSIR). The SC ensures appropriate management focus on the resolution of regulatory issues and enhancement initiatives.

The SC will periodically assess the status and effectiveness of this integrated action plan consistent with the Commission direction in SRM-SECY-15-0106, and evaluate the progress of meeting the overall objectives of the modernization of the NRC's I&C regulatory infrastructure. The SC will be supported by managers and staff in the offices with expertise and shared responsibility in the field of digital I&C. This IAP will be implemented and updated by the respective NRC line organizations under the supervision of the SC. Ownership of each modernization plan will be assigned to appropriate NRC office leads. This integrated action plan will be updated semi-annually to indicate progress made within each activity, so that the document can also be used as a reporting/briefing tool. Changes to the modernization plans that are identified during these periodic reviews shall be agreed upon by the SC.

4.0 Detailed Modernization Plans

The following four Modernization Plans (MPs) will be used to resolve regulatory challenges, provide confidence to licensees, and modernize the I&C regulatory infrastructure. Detailed plans have been developed for each activity. These activities are inter-related and the NRC working groups will ensure integration and coordination on common issues.

1. **Protection Against Common Cause Failures.** This activity addresses the staff evaluation of the NRC's existing positions on defense against CCF. CCF can compromise the independence of redundant divisions of digital I&C systems or result in failures within divisions. The NRC's current position on CCF is guided by SRM-SECY-93-087 and SRP-BTP-7-19. The NRC's current position does not include specific criteria to eliminate the potential of software CCF from consideration in a defense-in-depth and diversity analysis. The objective of assessing the NRC position on potential CCF is to ensure safety and security while enhancing efficiency, clarity, and confidence in determining the potential for CCF in the analysis of digital I&C systems. This effort will examine the technical basis to evaluate a graded approach based on safety significance, including consideration of the likelihood of CCF and a risk-informed, consequence based regulatory structure. This will include examination of

state-of-the-art analysis in other digital I&C applications, such as other industries and from other countries.

2. **Considering Digital Instrument & Control in accordance with 10 CFR 50.59.** This activity addresses the need for clarity of mutual industry and staff understanding that NRC guidance is being properly translated into industry actions for performing 10 CFR 50.59 evaluations of digital I&C plant modifications. Under existing guidance for the 10 CFR 50.59 screening and evaluation of digital I&C systems, several licensees have improperly performed 10 CFR 50.59 analyses for modifications of I&C systems using digital technologies. Industry stakeholders have stated they are hesitant to pursue the deployment of digital I&C upgrades through changes under the 10 CFR 50.59 process because of regulatory uncertainty. The objective of this effort is to ensure there is adequate guidance with sufficient clarity for staff and stakeholder understanding of 10 CFR 50.59 evaluations of digital I&C upgrades.
3. **Commercial Grade Dedication of Digital Equipment.** This activity will support improved guidance for commercial grade dedication (CGD) of digital equipment. Many digital I&C and other digital equipment that is readily available in the marketplace was not designed specifically for use in nuclear facilities and has not been designed, developed, and fabricated in accordance with NRC quality assurance criteria (as defined in Appendix B to 10 CFR Part 50). This plan provides activities intended to evaluate the suitability of additional guidance and industry standards and determine if the NRC will evaluate whether it should endorse standards for the purpose of defining critical characteristics of commercial grade items (CGI) and the mechanism by which they are verified. The staff is currently updating guidance for reviewing CGD, including specific reference to digital equipment. The staff will engage with stakeholders to better understand current challenges, potential benefits, and evaluate recommended solutions concerning CGD.
4. **Modernization of the Instrument & Control Regulatory Infrastructure.** The objective of this effort is to perform a comprehensive modernization assessment to identify further improvements to the regulatory infrastructure (regulations and guidance) and develop plans for accomplishing such improvements. The staff will assess progress on the first three MPs in the action plan and the list of topics provided in Appendix A of this plan to determine the appropriate sequencing of activities based on meeting the following key objectives:
 - A. Prioritize and implement the complete set of regulatory activities, including building upon those in the first three MPs, needed to provide near-term regulatory clarity and support industry confidence to perform digital I&C upgrades. These activities will include but may not be limited to: a) implementing an updated CCF position into technical guidance for use both in concert with endorsed 10 CFR 50.59 change authority guidance and additional licensing guidance improvements, b) improving licensing guidance including evaluating lessons learned from review of license applications, including factory acceptance testing and scope of supporting application material, c) developing inspection guidance for digital I&C upgrades performed under 10 CFR 50.59 and license application approvals.

The staff has initially identified these additional topic areas as being necessary to meet objective 4A and will seek stakeholder feedback in identifying the complete list

of activities from its review of all activities listed in Appendix A. The staff will develop detailed schedules for additional, high-priority near-term topics during the comprehensive modernization assessment.

The staff will implement revised guidance to improve the efficiency of the license application review process. Also the staff will work with industry stakeholders to identify efficiency metrics for new application reviews.

- B. Identify actions needed to implement a simpler, streamlined, and agile I&C regulatory infrastructure that will ensure safety and security while effectively addressing larger scale digital I&C upgrades to operating reactors and the I&C designs for new and advanced reactors. The outcome will also improve clarity regarding the interrelationships between the regulatory issues, the priorities and sequencing of further improvements, and the supporting research that is needed to accomplish such improvements to meet both objectives.

Completion of the modernization efforts will ensure safety and security and result in greater regulatory efficiency, predictability, and agility in addressing long-term digital I&C applications by the nuclear industry. Both the near-term and long-term goals of the IAP involves the development of technical bases to support resolution of identified technical issues. The development of the technical basis to support the comprehensive modernization activities in MP #4B will likely require relatively greater research activities.

MP #1. Protection Against Common Cause Failure

Introduction

This modernization plan describes the activities and schedule for addressing methods for evaluating the potential for CCF, which could lead to safety-significant failures. CCF can compromise the independence across redundant divisions, across echelons of defense, across monitors, and monitored elements, etc. As part of modernizing the NRC's digital I&C regulatory infrastructure, the staff will evaluate the necessity and sufficiency of NRC's existing positions on defense against CCF and on methods and criteria to assess the adequacy of defense-in-depth and diversity measures.

Background

The NRC set its position on CCF in SRM-SECY-93-087 item II.Q. The SRM provides specific acceptance criteria for the evaluation of CCF, which the staff implemented in SRP-BTP-7-19. Item II.Q of the SRM includes the following position, "The applicant shall assess the defense-in-depth and diversity of the proposed instrumentation and control system to demonstrate that vulnerabilities to common mode failures have adequately been addressed." An intention behind the defense-in-depth and diversity philosophy is to protect against residual unknowns (beyond design basis) such as engineering deficiencies. However, SRM-SECY-93-087 does not include specific criteria to eliminate the potential of software CCF from consideration in a defense-in-depth and diversity analysis. SRP-BTP 7-19 includes two criteria to eliminate the consideration of software CCF, based on demonstration of internal diversity or assurance that the systems are sufficiently simple that all possible software failure paths have been tested and eliminated. The staff's position was last provided to the Commission in SECY-09-0061, "Status of the Nuclear Regulatory Commission Staff Efforts to Improve the Predictability and Effectiveness of Digital Instrumentation and Control Reviews" (ADAMS Accession No. ML090790409).

Representatives of the nuclear industry (industry) find the current digital I&C licensing and oversight process for power and non-power reactors cumbersome, inefficient, and/or unpredictable. In particular, they have suggested the current guidance to perform I&C modification has insufficient details regarding: a) how to address the potential for CCF (e.g., potential plant vulnerabilities from having identical redundant digital I&C divisions, or mistakes made or errors introduced by processes for implementing configuration changes); b) how to acceptably analyze the potential for CCF for its safety impact; and c) how this analysis may be acceptably used in licensing activities. Further, licensees have stated that the current regulatory treatment and acceptance criteria dealing with the potential for CCF in the analysis of digital I&C systems has been problematic. Specifically, they have stated that the proper application of the screening criteria for "simple systems" in SRP-BTP 7-19 regarding 100% testability, and the lack of a graded approach based on safety significance place a high burden for demonstrating that adequate digital I&C system development processes have been employed - especially for systems containing localized embedded digital I&C components. Therefore, the resolution of CCF concerns is the lead technical issue and a critical enabler for addressing other issues related to digital I&C. Industry stakeholders are looking for clearer NRC staff guidance on methods for analysis of the potential for CCF of digital I&C systems. In addition, industry is seeking a more risk-informed, consequence-based regulatory infrastructure that removes uncertainty, ambiguity, and overlap in requirements and enables technical consistency.

In April 2016, industry submitted its comments to the draft digital I&C integrated action plan which included recommendations to resolve CCF concerns. Industry agrees with the staff that review of the CCF concerns is a high-priority regulatory issue. In its recommendations, industry proposed use of and greater reliance upon development practices and deterministic defensive measures within digital I&C systems to minimize the impact of potential CCF. Specifically, they suggested the staff credit development practices and deterministic defensive measures within digital I&C systems that play a part in assuring that CCF will be unlikely. Also, industry recommended the use of other previous analyses to demonstrate that CCF is bounded. The staff will consider the recommendations proposed by industry as part of the broader effort to develop a technical basis evaluating the current NRC position and evaluation of the alternatives available to resolve CCF concerns.

Objectives

The objective of this effort is to provide clarity and confidence to licensees in determining the potential for CCF in the analysis of digital I&C systems. This clarification should serve to improve the ability of licensees to evaluate a proposed design of or modification to digital safety systems (including their components) through an NRC license amendment application (10 CFR 50.90) or change under 10 CFR 50.59. To achieve this objective, the staff will evaluate the current NRC position on CCF, including clarification of the scope of systems addressed under the position and how the position might appropriately incorporate a graded approach. The examination of a graded approach will be based on safety significance, including consideration of the likelihood of CCF and a risk-informed, consequence based regulatory structure. This will include examination of state-of-the-art analysis in other digital I&C applications, such as other industries, and countries. This technical basis will support staff recommendation to the Commission. In addition, the staff will engage industry through workshops and public meetings to discuss its findings and refine the plan accordingly.

Actions

Activity	Schedule
1. Complete evaluation of existing position and regulations related to CCF.	March 30, 2016 (c)
2. Engage industry and public stakeholders in workshops and targeted meetings to gather insights on key technical and policy issues.	March 21, 2016 (c) June 7, 2016 September 2016
3. Prepare a technical basis document to summarize the evaluation of the NRC position and regulations.	October 2016
4. Obtain external technical experts review of technical basis.	December 2016
5. Complete comment resolution of technical basis.	February 2017
6. Work with industry to conduct a demonstration of proposed CCF modification to CCF regulatory position prior to developing implementation guidance.	April 2017
7. Presentation to the Advisory Committee on Reactor Safeguards.	June 2017
8. SECY paper to the Commission identifying proposed action to modify or affirm existing position.	July 2017

Activity	Schedule
9. Implement resolution identified in SECY paper.	TBD

This schedule includes making the technical basis document available for a public comment period of 30 days, in addition to the engagement with the public during the development of the technical basis. The comment period will start after the technical basis document is complete. The staff considers this necessary since the technical basis will be used to support proposed modification to the current NRC position. In addition, the staff will request review of its technical basis by a diverse set of technical experts. This review will be performed in parallel with the public comment period. In the same manner, this review period will start after the technical basis document is complete.

Status

(As of May 1, 2016)

A public meeting is scheduled for June 7, 2016.

The working group is currently preparing the technical basis paper that will summarize the staff's evaluation of the current NRC position.

Potential Regulatory Challenges and Policy Issues

Any change or affirmation of the current CCF position is a potential policy issue that would be coordinated with the Commission. The staff will also consult with the Commission if any additional potential policy issues relevant to CCF are identified when implementing this activity.

Potential actions for addressing CCF issues will have to be informed by consideration of backfitting, regulatory analysis, and cumulative effects of regulation.

Staff actions will be impacted if industry does not participate in the demonstration activities.

Interactions with other Action Plan Items

CCF of digital I&C systems is an important aspect supporting the working group responsible for improving licensee guidance for incorporating digital I&C using the 10 CFR 50.59 process (MP #2).

Implementation of the resolution of CCF as identified in the SECY paper will be addressed as in objective (A) of MP #4.

MP #2. Considering Digital Instrumental & Control in Accordance with 10 CFR 50.59

Introduction

This action plan describes the activities and schedule for improving guidance for incorporating digital I&C using the 10 CFR 50.59 process. These activities will address the need for clarity of mutual industry and NRC staff understanding that NRC guidance is being properly translated into industry actions for performing 10 CFR 50.59 evaluations of digital I&C plant modifications. This action plan applies to operating reactors, new reactors, non-power production, and utilization facilities (e.g., research and test reactors and medical isotope processing facilities).

NRC intends to evaluate guidance for the licensing criteria in 10 CFR 50.59 within the scope and schedule of this review. MP #1 describes the plan for evaluating and updating the NRC position on CCF, which may lead to future updated guidance on accepted technical methodologies applicable to 10 CFR 50.59 evaluations. MP# 4 describes the plan for evaluating additional regulatory infrastructure activities such as technical guidance development, integrating progress that is made on this activity and CCF (MP #1).

Background

Inadequate guidance for the 10 CFR 50.59 screening and evaluation of digital I&C systems has contributed to several licensees having improperly performed 10 CFR 50.59 analyses for modifications of I&C systems using digital technologies. The current guidance addresses both 10 CFR 50.59 licensing positions and technical methodologies, which has resulted in ambiguity on key evaluation issues such as CCF in digital modifications. The staff held several public meetings with industry representatives on this subject, and indicated where the industry guidance should be improved. Industry representatives stated that they are hesitant to pursue the deployment of digital I&C upgrades through changes under the 10 CFR 50.59 process because of regulatory uncertainty and a lack of clarity in the regulatory process.

RG 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," provides the staff's endorsement of industry guidance for evaluating the impact on plant safety analyses for plant modifications performed under 10 CFR 50.59. The objectives of 10 CFR 50.59 are to ensure that licensees: (1) evaluate proposed changes to their facilities for their effects on the licensing basis of the plant, as described in their updated final safety analysis report, and (2) obtain prior NRC approval for changes that meet specified criteria as having a potential impact upon the plant license basis. RG 1.187 endorsed Revision 1 of NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluation," dated November 2000, which provides methods that are acceptable to the NRC staff for complying with the provision of 10 CFR 50.59.

Regulatory Issue Summary (RIS) 2002-22, "Use of EPRI/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,'" provides the NRC staff's endorsement for the use of NEI 01-01⁴. However, experience with implementing digital I&C

⁴ ADAMS Accession No. ML020860169

upgrades under 10 CFR 50.59 at nuclear facilities has revealed several shortfalls in the screening of modifications, addressing the appropriate design criteria, and evaluating the impact of proposed digital I&C on established licensing basis. A key issue identified as a result of recent oversight experience has been licensee assessment of potential CCF and any potential new malfunctions, with respect to addressing the specific criteria in 10 CFR 50.59(c)(2).

In a November 2013 letter to the Nuclear Energy Institute (NEI) (ADAMS Accession No. ML13298A787), the staff summarized its concerns regarding licensee implementation of the current guidance in NEI 01-01. In response, NEI formed a working group to update its guidance for implementing digital I&C modifications under 10 CFR 50.59. The NEI working group found that additional guidance was needed to support certain aspects of evaluating the impact of such modifications on plant safety.

In April 2016, NEI provided draft Appendix D to NEI 96-07 for digital modifications. NEI requested NRC endorsement of the appendix through a new regulatory guide, separate of RG 1.187. NEI has stated that draft Appendix D is only focused on evaluating the specific licensing criteria in 10 CFR 50.59 for digital I&C, and not the supporting technical methodologies for addressing CCF and failure likelihoods. NRC endorsed technical methods and associated regulatory positions are addressed in other existing regulatory documents. NEI is therefore not providing or referencing any technical methodologies in Appendix D. NEI recognizes that the NRC position on CCF will be updated separately as part of MP #1.

Objectives

The objective is to ensure there is adequate guidance for 10 CFR 50.59 evaluations of digital I&C upgrades. The NRC is evaluating draft Appendix D to NEI 96-07 for possible endorsement in NRC regulatory guidance to supersede its endorsement of NEI 01-01.

Actions

Activity	<u>Schedule</u>
1. Receive NEI guidance document, Appendix D 96-07, Guidelines for 10 CFR 50.59 Evaluations.	April 4, 2016 (c)
2. Conduct public meeting: NEI presented the guidance in Appendix D and engaged with NRC staff discussion.	April 28, 2016 (c)
3. Complete review of Appendix D and provides comments to NEI.	June 2016
4. Conduct public meeting: NEI feedback on staff review and comments.	June 2016
5. Receive revised Appendix D from NEI.	3 rd /4 th Qtr Calendar Year (CY) 2016
6. Complete review of revised Appendix D.	4 th Qtr CY 2016
7. Coordinate with industry to conduct table top exercise using the revised appendix D to verify the new guidance is clear and consistent.	4 th Qtr CY 2016
8. Decide on appropriateness of issuing interim endorsement letter, and issues letter, if appropriate.	4 th Qtr CY 2016
9. Begin update of regulatory guidance.	4 th Qtr CY 2016

Status

(As of May 1, 2016)

Ongoing staff review of NEI's submission of draft version of Appendix D to NEI 96-07.

Potential Regulatory Challenges and Policy Issues

The staff will consult with the Commission if any potential policy issues are identified in implementing this activity.

Potential actions for modifying the current 10 CFR 50.59 change control process will have to be informed by consideration of backfitting, regulatory analysis, and cumulative effects of regulation.

Staff actions will be impacted if industry does not participate in tabletop exercise.

Interactions with Other Action Plan Items

On-going coordination with the CCF working group is necessary to ensure alignment with NRC regulatory guidance and NRC policy for addressing CCF (MP #1).

Implementation of the revised guidance will be addressed as part of the MP #4, including methods of NRC endorsement of the NEI guidance, developing appropriate inspection guidance, consideration of changes to policies and regulations, and consideration of streamlined licensing processes for certain digital I&C upgrades that may not be implemented under 10 CFR 50.59.

MP #3. Commercial Grade Dedication of Digital Equipment

Introduction

The staff is currently updating generic agency guidance in support of CGD processes, including specific reference to digital equipment. Staff has also identified activities to: a) engage with stakeholders; b) further evaluate domestic and international standards; and, c) continue to improve NRC regulatory infrastructure and guidance for CGD of digital equipment. The staff will engage with stakeholders to better understand current challenges and evaluate recommended solutions. In addition to the guidance, challenges include third party dedication and whether to allow for certification of third party dedicators. Although existing guidance documents provide insights in this area, some have not been fully evaluated by the staff. Once the staff has reviewed this guidance the agency will be able to identify how to best improve the regulatory infrastructure.

Background

Many I&C and other digital equipment readily available in the marketplace were not designed specifically for use in nuclear facilities and have not been subject to NRC quality assurance criteria (as defined in Appendix B to 10 CFR Part 50). In order for this equipment to be used in safety-related and important-to-safety digital equipment (those whose adverse performance could challenge the assumptions in safety analyses), they must undergo CGD under 10 CFR Part 21. For the purposes of this discussion, we will refer to this equipment as CGI.

In order for CGI to be properly dedicated, critical characteristics (important design, material, performance, and dependability characteristics) must be defined and verified for the CGI to provide reasonable assurance that the equipment will perform its intended safety function. The verification step is critical and must be performed by a dedicating entity (equipment manufacturer, NRC licensee, or an independent third-party dedicator). Increasing the number of digital CGIs in the marketplace which have been dedicated could help to streamline the procurement process and reduce the licensing burden for nuclear facilities.

Industry guidance has been developed to clarify what steps are needed when evaluating and accepting CGI as dedicated equipment. Work is underway, through the development of Draft Regulatory Guide (DG)-1292 "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants", to improve NRC guidance in support of CGD processes and reference some of these standards. Specifically, Revision 1 of Electric Power Research Institute (EPRI) NP-5652 and TR-102260, "Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," Section 14.1 on digital equipment and computer programs integral to plant safety systems include references to two technical reports which have been reviewed and endorsed by the NRC:

- EPRI TR-106439 "Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications"; and,
- EPRI TR-107330 "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants"

This plan provides activities intended to evaluate the suitability of additional guidance and standards and determine if the NRC should endorse them for the purpose of defining critical characteristics of CGI and the mechanism by which they are verified.

Digital equipment is sometimes embedded within other components used in nuclear facilities. As noted, this equipment is not specifically designed for nuclear applications. However, there may be advantages to using this commercial-grade digital equipment, such as the large amount of operating experience generated from use in non-nuclear applications.

In addition to dedicated digital devices and I&C components, establishing improved guidelines for CGD will also be applicable to embedded digital devices (EDDs). As equipment is replaced within licensee facilities, new safety-related components may contain EDDs. The staff recently issued RIS 2016-05, "Embedded Digital Devices in Safety-Related Systems," to alert industry for the need to control implementation of these devices. Certain forms of CCF and other new vulnerabilities can result from the introduction of EDDs.

Industry has stated that NRC licensing burden and licensee regulatory risk could be reduced by entrusting certification of commercially available digital hardware and software to independent third parties with demonstrated expertise and experience. This independent, third-party "certification" has been effective in some other industries. These certifications, including certification to International Electrotechnical Commission 61508, "Functional Safety", are used to demonstrate a high quality development process was used to develop digital hardware and software equipment. The use of this process, either alone or in conjunction with the CGD process, could reduce the scope of digital systems reviews that the staff needs to complete. The staff will need to evaluate this concept and any policy implications that it may have.

Objectives

The goal of this activity is to identify needed improvements to the regulatory infrastructure. The objective of any regulatory improvements is to ensure that the implementation of digital devices (including EDDs) is being appropriately evaluated by licensees, applicants, and suppliers; and in compliance with regulations and policy.

Actions

Activity	Schedule
1. Public Meeting to discuss resolution of RIS 2016-05 public comments.	April 06, 2016 (c)
2. Issue RIS 2016-05.	April 29, 2016 (c)
3. Obtain public comments on DG-1292.	July 2016
4. Stakeholder interaction to discuss proposed use of standards and third party process "certifiers".	3 rd /4 th Qtr CY 2016
5. Assess results of stakeholder information gathering and examine potential approaches for reviewing and endorsing additional EPRI guidance related to CGD.	1 st Qtr CY 2017
6. Issue RG-xxxx "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants".	March 2017
7. Investigative and research activities to evaluate third-party process "certification" for digital equipment.	CY 2017
8. Complete analysis and develop recommendations regarding third-party process "certification" working with stakeholders.	CY 2018

Status

(As of May 1, 2016)

Draft RG-1292 is being reviewed in preparation for issuance for public comment period.

Potential Regulatory Challenges and Policy Issues

There is potential for change in scope due to resolution of CCF (MP #1) and through review and consideration of stakeholder proposals for alternative approaches for addressing this issue.

Staff evaluation may identify potential policy issues arising from analysis and recommendations related to third-party process “certification.” The staff will consult with the Commission if any potential policy issues are identified in implementing this activity.

Potential actions for addressing commercial grade dedication issues will have to be informed by consideration of backfitting, regulatory analysis, and cumulative effects of regulation.

Interactions with other Action Plan Items

This activity will take into account the results from activities relating to CCF (MP #1) and 10 CFR 50.59 (MP #2). To provide the broadest possible agency alignment, this plan will also be coordinated with staff supporting fuel-cycle facilities (NMSS), identification of critical digital assets (NSIR), vendor inspections, and identification of counterfeit or fraudulent parts.

This activity will also be coordinated within the context of the assessment activities as part of MP #4 to modernize the regulatory infrastructure.

MP #4. Assessment for Modernization of the Instrument & Control Regulatory Infrastructure

Introduction

While activities in MP #1-3 above are considered by staff and industry to be important in the near-term, MP #4 focuses on: identifying and implementing the complete set of activities needed to provide near-term regulatory clarity and support industry confidence to perform digital I&C upgrades; and, identifying additional efficiencies and improvements to effectiveness to modernize the regulatory infrastructure in support of the long-term goal. This activity entails a broad look at the current I&C regulatory infrastructure (regulations and guidance), experiences from past licensing, inspection, and operating experience, and stakeholder suggestions and priorities. This activity and the continuing work on the previous three activities will be executed in a coordinated and integrated manner.

Background

MPs #1-3 of this plan identify specific activities in which significant work will be accomplished in 2016 and 2017. The staff has identified other issues and areas for potential improvement to the regulatory infrastructure, many which may be dependent on outcome of MPs #1-3. Some potential improvement items are broad-scoped in nature and others are focused on more specific regulatory challenges. Therefore, it is prudent to begin work on these activities in 2017 after progress is made on MPs #1-3.

A list of modernization topics is provided in Appendix A. This list is based on stakeholder feedback and experience from staff across multiple NRC Offices. The staff's broad assessment will include evaluation of the list as part of the scope of the action plan. The staff will explore new high-level performance-based requirements or expectations, simplified regulatory infrastructure that allows for future designs and technologies, and the concept of other innovative processes such as third-party assessment or certification.

Objectives

The objective of this effort is to perform a comprehensive modernization assessment to identify further improvements to the regulatory infrastructure and develop plans for accomplishing such improvements. The staff recognizes that some additional modernization topics will be longer term in nature, while others can also support more near-term digital I&C plans by industry. The staff will update and consider the list of topics in Appendix A to determine the appropriate sequence of activities. There are two key objectives with the assessment:

(A) Near-Term. Prioritize and implement the complete set of regulatory activities, including building upon those in the first three MPs, needed to provide near-term regulatory clarity and support industry confidence to perform digital I&C upgrades. These activities will include but may not be limited to: a) implementing an updated CCF position into technical guidance for use both in concert with endorsed 50.59 change authority guidance and additional licensing guidance improvements, b) licensing guidance including evaluating lessons learned from review of license applications, including factory acceptance testing and scope of supporting application material, c) developing inspection guidance for digital I&C upgrades performed under 10 CFR 50.59 and license approvals.

The staff has initially identified these additional topic areas as being necessary to meet objective A and will seek stakeholder feedback in identifying the complete list of activities from its review of all activities listed in Appendix A. The staff will develop detailed schedules for additional, high-priority near-term topics during the comprehensive modernization assessment.

Completion of these regulatory activities should result in common understanding with stakeholders that there is appropriate regulatory clarity and predictability, and industry confidence in performing new digital I&C upgrades under 10 CFR 50.59 change authority and licensing requests. To support digital upgrades under 10 CFR 50.59, the staff will coordinate with the industry to perform table top exercises with the staff on proposed upgrades to verify the new guidance is clear and consistent, and results in predictable conclusions. The staff will work with industry to conduct a demonstration of the proposed modification to CCF regulatory position prior to developing implementation guidance. Once insights are gained from the demonstration of the proposed CCF changes, the staff will implement revised guidance to improve the efficiency of the license application review process and will work with stakeholders to identify efficiency metrics for application reviews.

(B) Long-term. Broadly evaluate the current overall I&C regulatory infrastructure and consider other important areas beyond those identified in the near-term activities, such as past review experiences, ongoing licensing review and research efforts, lessons learned from operating experience, insights from other safety-critical industries, and international perspectives to identify and prioritize the improvements to modernize the regulatory infrastructure over the longer term in light of evolving approaches to I&C. Success within this objective will be reflected by a simpler, streamlined, and agile I&C regulatory infrastructure that will effectively address large scale digital I&C facility upgrades and I&C designs for new and advanced reactors, as well as medical radioisotope production and irradiation facilities. In developing these longer-term improvement approaches, the staff's efforts will be coordinated with the industry and other stakeholders, including utilities, vendors, manufacturers, standards development organizations, and members of the public that are expected to have a role in achieving the intended success of this modernization effort. The staff will use the principles and attributes directed by the Commission and will consider those identified by the industry as success measures. The principles and attributes include (but are not limited to): safe, secure, performance-based, technology-neutral, efficient, effective, consistent, predictable, durable, simple, unambiguous, timely, scalable, and agile. The outcome will also improve the clarity on the interrelationships between the regulatory issues, the priorities and sequencing of further improvements, and the supporting research that is needed to accomplish such improvements to meet both objectives. The staff will conduct research activities as part of the development of technical bases for these activities as needed to support long-term modernization efforts. Completion of these modernization efforts will result in greater regulatory efficiency and agility in addressing long-term digital I&C applications by the nuclear industry.

Actions

Develop and evaluate options and sequence of activities for improving the I&C regulatory infrastructure, in concert with activities performed in MPs #1 -3. The following activities will be performed.

Activity	Schedule
1. Update candidate list of modernization topics in Appendix A and begin assessment.	January 2017
2. Identify, prioritize, and begin evaluation and implementation of additional regulatory improvements needed beyond those needed in MPs #1-3 to meet Objective 4A (i.e., near-term objectives).	March 2017
3. Conduct a series of public stakeholder meetings (e.g., public workshops) for additional feedback.	January - April 2017
4. Coordinate with stakeholders to identify potential regulatory gaps and potential options for improving the regulatory infrastructure for Objective 4B.	May 2017
5. Develop additional detailed modernization plans for implementing near-term and longer-term improvements to the regulatory infrastructure.	TBD

Status

A working group will be established in late 2016 and the modernization assessment will begin in January 2017.

Potential Regulatory Challenges and Policy Issues

The staff will consult with the Commission if any potential policy issues are identified in implementing the modernization assessment in this activity.

Resource requirements will be periodically assessed and those actions that provide the most significant improvements will be addressed using the current Planning Budgeting and Performance Management process.

The broad scope of the assessment and its resultant approaches may require additional resources to achieve the goal of modernizing the I&C regulatory infrastructure. In addition, modernization will have to be informed by consideration of backfitting, regulatory analysis, and cumulative effects of regulation.

A key regulatory challenge is understanding the relationships and key dependencies between current efforts to update the regulatory infrastructure (MPs #1-3) and the various items for potential improvement.

Staff actions will be impacted if industry does not participate in a CCF demonstration or 10 CFR 50.59 tabletop exercise.

Interactions with other Action Plan Items

The progress and results of MPs #1-3 will be integrated in this plan.

Appendix A

Additional Regulatory Infrastructure Modernization Topics (May 2016)

The following are additional topics for future modernization efforts in 2017, after work has progressed on MPs #1-3 of the action plan.

(i) Improved Licensing Review Guidance for Digital I&C Systems

Industry stakeholders believe that the level of technical detail submitted in license applications, license amendments, and licensing topical reports, as well as the timing and sequence of the technical information expected to be submitted for NRC evaluation during the review cycle should be reassessed and improved. Key issues that will be considered in future modernization activities for licensing review guidance include (but are not limited to) the concept of evaluating and approving new digital I&C prior to the factory acceptance test, and the timing and sequence of providing supporting documentation during the licensing review period. The NRC will also consider developing guidance on voluntary, applicant-proposed cybersecurity evaluations in design reviews.

(ii) Improvement in Regulatory Consistency from Licensing to Inspection

Industry stakeholders believe that upfront agreement and communication on generic digital I&C technical matters between licensing staff and the regional office inspection staff is required to increase predictability. Key issues that will be considered in future modernization activities may include improved mechanisms for sharing information and feedback from licensing to inspection activities, and inspection experience back to future licensing activities.

(iii) Incorporation by Reference (IBR) of IEEE Standard 603-2018 into 10 CFR 50.55(a).

In SECY-15-0106, the staff proposed to the Commission to incorporate by reference IEEE Std. 603-2009 with certain licensing and technical conditions into 10 CFR 50.55a. The Commission did not approve publishing the proposed rule. Key issues that will be considered in future modernization activities will include NRC participation in the consensus standard development process for IEEE Std. 603 and potential incorporation of a subsequent IEEE Std. 603 standard into regulation.

(iv) Approval of Endorsement of IEEE Standard 7-4.3.2 into a Regulatory Guide

In SECY-15-0106, the NRC staff proposed to the Commission to IBR IEEE Std. 603-2009 with certain conditions into 10 CFR 50.55a. Although not approved by the Commission, some of the proposed, digital-specific conditions in SECY-15-0106 are more closely aligned with the scope and purpose of IEEE Std. 7-4.3.2. Key activities to be considered in future modernization efforts may include; engaging the consensus standard development organization to evaluate technical guidance in IEEE Std. 7-4.3.2; NRC participation in the consensus standard development process for IEEE Std. 7-4.3.2, and potential approval or endorsement of the standard in a RG.

(v) EDDs

NRC issued RIS 2016-05 to heighten awareness of current regulatory requirements and technical positions for EDDs. The staff intends to further assess the introduction of EDDs into nuclear facility equipment used by licensees and applicants for systems considered important to safety. Key issues that will be considered in future modernization activities may include evaluation of the degree to which licensees are installing EDDs in their facilities and additional regulatory issues related to MPs #1-3.

(vi) Holistic Review of the Regulatory Infrastructure

A holistic regulatory view and approach could be developed that is guided by required fundamental safety principles that would be performance-based, technology neutral, and risk-informed. It would include evaluation of international practices (e.g., standards, guidance, safety cases), evaluation of critical digital I&C application approaches in other non-nuclear industries, applicability of a design specific review standard-like approach (e.g., such as proposed for SMRs), advanced reactors activities, and methods of performing hazard analysis.

(vii) Improved Guidance for Evaluation of Highly-Integrated Digital Technologies

Proposed new reactor I&C designs with advanced and highly integrated digital technologies are more challenging for staff to evaluate under current review standards. In general, the current assessment approach does not credit the safety benefits offered by new design approaches and technology, nor does it adequately identify methods to apply for evaluating whether the hazards have been minimized. Key issues that will be considered in future modernization activities will be to improve regulatory guidance for licensees that may addresses topics such as effective hazards analysis and fundamental safety design principals of independence, defense-in-depth, redundancy, and deterministic performance.

(viii) Consistency and Integration of Multiple Regulatory Guidance Documents

Industry stakeholders believe that a full assessment of the SRP content and organization related to digital I&C, and the multiple associated digital I&C-related regulatory guidance documents needs to be performed because the current approach is overly complex and difficult for industry to navigate. Key issues that will be considered in future modernization activities for regulatory guidance include possible methods for consolidating and organizing new and operating reactor RGs, Branch Technical Positions, interim staff guidance, and standard review plans.

(ix) Improved Guidance for Evaluation of Proposed Alternatives to Regulatory Guides and Standards

NRC staff may benefit from improved guidance to address evaluation of licensee-submitted proposed alternatives to the criteria in regulatory guidance and endorsed codes and standards, applicable to the licensing of digital I&C systems and components. Key issues that will be considered in this modernization activity include identifying gaps in current guidance that create a consistency challenge for technical reviewers of proposed alternative solutions.

(x) Improved Process for Digital I&C Topical Report Evaluations

The expenditure of NRC staff resources for the review of digital I&C platform topical reports has not gained the efficiencies in performing licensing evaluations as was originally envisioned. A process is needed to effectively and efficiently address updates to topical reports. Industry wishes the NRC to recognize that a vendor can use a screening and evaluation procedure to document the assessment to changes in a platform to maintain its original topical report qualification. Key issues that may be considered in this modernization activity include engaging vendor and licensee stakeholders to identify topical report challenges and establish a process for maintaining topics for frequent reference in future license applications.