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NUCLEAR REGULATORY COMMISSION
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NRC REGULATORY ISSUE SUMMARY 2013-####
EMBEDDED DIGITAL DEVICES IN SAFETY-RELATED SYSTEMS,
SYSTEMS IMPORTANT TO SAFETY, AND ITEMS RELIED ON FOR
SAFETY¹

ADDRESSEES

All holders of, and applicants for, a power reactor operating license or construction permit under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," including those that have permanently ceased operations and have spent fuel in storage in the spent fuel pool.

All holders of, and applicants for, a power reactor combined license, standard design approval, or manufacturing license, and all applicants for a standard design certification, under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

All holders of, or applicants for, licenses for fuel cycle facilities engaged in conversion and deconversion,² as well as enrichment, fuel fabrication, and mixed-oxide fuel fabrication.

All holders of, or applicants for, certificates of compliance for fuel cycle facilities engaged in gaseous diffusion enrichment.

All holders of, and applicants for, an operating license for nonpower reactors under 10 CFR Part 50, except those that have permanently ceased operations and have returned all of their fuel to the U.S. Department of Energy.

¹ "Safety-related systems, systems important to safety, and items relied on for safety" will be referred to as "safety systems" in the rest of this document.

² Conversion and deconversion facilities are licensed under 10 CFR Part 40, "Domestic Licensing of Source Material." New 10 CFR Part 40 conversion and deconversion facilities, consistent with the Commission's October 7, 2007 staff requirements memorandum (SRM) to SECY-07-0146 (ADAMS Accession No. ML072830536), must develop an integrated safety analysis (ISA is used as the common acronym) and the associated digital requirements for safety systems in compliance with 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material."

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to clarify the NRC's technical position on existing regulatory requirements for the quality and reliability of basic components with embedded digital devices. This RIS reminds addressees of the need to identify, review, document, and control embedded digital devices in safety systems, in order to comply with 10 CFR 50.55a(h), "Protection and Safety Systems;" Appendix A, "General Design Criteria for Nuclear Power Plants;" and Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." Identification, review, documentation, and control of embedded digital devices in basic components are necessary to demonstrate the quality and reliability of safety systems. This demonstration should address material control, development processes, and equipment qualification. Addressees should be aware that similar to other types of digital systems in nuclear facilities, there could be a potential plant vulnerability that may result from common-cause failures (CCFs) of non-diverse embedded digital devices in safety system execute features (e.g., motor control centers, actuated equipment).

For purposes of this RIS, an embedded digital device is a digital component consisting of one or more digital electronic parts that use software, software-developed firmware, or software-developed logic that is integrated into equipment to implement one or more system requirements.

This RIS also would apply to the embedded digital devices in safety systems for fuel cycle facilities, in order to comply with the following:

- 10 CFR Part 40, "Domestic Licensing of Source Materials," section 40.31, "Application for Specific Licenses," paragraph (j)(2)(ii) and 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," for conversion and deconversion² facilities.
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," paragraphs 70.61, "Performance Requirements," through 70.65, "Additional Content of Applications," for enrichment, fuel fabrication, and mixed-oxide fuel fabrication facilities.
- 10 CFR 76.87, "Technical Safety Requirements," and 10 CFR 76.89, "Criticality Accident Requirements," for gaseous diffusion fuel cycle facilities.

The NRC's intent in issuing this RIS is to heighten awareness that embedded digital devices may exist in procured safety systems without the devices having been explicitly identified in the procurement documentation. Undetected software-related errors in embedded digital devices may have safety consequences. Therefore, addresses should implement early efforts to identify these devices.

The regulations that apply to the use of embedded digital devices found in this and other sections of this RIS are repeated below in a bullet list format for convenience and easy reference under the heading "Summary of Applicable Regulations." The guidance for the acceptance criteria that the applicable regulations have been met concerning the use of embedded digital devices are listed together for convenience and easy reference below under the heading "Summary of Applicable Staff Guidance."

This RIS requires no action or written response on the part of an addressee.

BACKGROUND INFORMATION

Nuclear power plants, non-power reactors, and fuel cycle facilities have increased the use and reliance upon digital technology in plant systems and components (e.g., instrumentation and controls (I&C), electrical systems, and fluid systems). It is important to ensure that the digital technology introduced in nuclear plant systems and components is identified, reviewed, and controlled by the licensees and applicants. These plant systems and components may be safety-related and include plant systems and components such as emergency diesel generators, pumps, valve actuators, motor control centers, breakers, priority logic modules, and uninterruptible power sources.

NRC Information Notice (IN) 1994-020, "Common-Cause Failures Due to Inadequate Design Control and Dedication," describes a CCF incident of an emergency diesel generator load sequencer at Beaver Valley Power Station, Unit 2, following the replacement of electromechanical timer/relays with microprocessor-based timer/relays. This incident occurred before additional guidance (e.g., EPRI TR-106439 and NEI 01-01) was developed to ensure that adequate equipment qualification or commercial-grade item dedication is performed on a digital component replacing an analog component before the replacement component is put into service. Even so, the incident illustrates that a digital microprocessor-based replacement can produce a new susceptibility to a CCF. In this case, the commercial-grade item dedication that was performed for this component did not adequately represent the inservice environment to demonstrate the replacement component's compatibility.

The NRC issued IN 2007-015, "Effects of Ethernet-Based Non-Safety Related Controls on the Safe and Continued Operation of Nuclear Power Stations," to alert licensees about the effects of potential interactions and unanticipated failures of Ethernet-connected nonsafety equipment on the safety and performance capability of nuclear power plants. On August 19, 2006, Browns Ferry Nuclear Plant, Unit 3, operators initiated a manual reactor shutdown following the loss of both reactor recirculation pumps. The root cause investigation determined that the recirculation pump variable frequency drive controllers malfunctioned because of excessive traffic on the plant integrated computer system network. The excessive traffic was likely caused by a faulty programmable logic controller (PLC) in the condensate demineralizer controller on the same network. The failure mode of excessive data rates, which could exceed the capacity of a communications link or the ability of nodes to handle excessive traffic, has also been recently identified by the staff in DI&C-ISG-04, "Task Working Group #4: Highly-Integrated Control Rooms-Communications Issues (HICRc), Interim Staff Guidance [ISG]." This was not a failure mode of concern for the technology used when the plant was started up in 1977, but should have been considered when the PLC and the plant Integrated Computer System were added as upgrades since initial operation of the plant. While PLCs are not considered embedded digital devices, this event illustrates that vendors, licensees, and applicants must understand the operation and failure modes of digital systems (including embedded digital devices) and the effects of these failure modes on plant operations and safety.

Safety-related systems and components that include embedded digital devices must satisfy regulatory requirements, including quality and reliability, commensurate with the safety significance of the systems and components. The digital issues addressed in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (SRP) Chapter 7 for nuclear power plants, NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors", Chapter 7,

and DI&C-ISG-7³, “Task Working Group #7: Digital Instrumentation and Control [DI&C] Systems in Safety Applications at Fuel Cycle Facilities, Interim Staff Guidance,” for fuel cycle facilities, are applicable to embedded digital devices in safety-systems and components. These issues⁴ include potential CCF, sensitivity to electromagnetic interference (EMI) and radio-frequency interference (RFI), and the potential to contribute EMI or RFI to safety systems. The electromagnetic compatibility (EMC) qualification of the original equipment may not be sufficient to allow direct replacement with new equipment that contains an embedded digital device unless each embedded digital device has been identified, reviewed, and tested and the new equipment has been tested for compatibility with the inservice environment.

The 10 CFR 50.59, “Changes, Tests, and Experiments,” rule contains requirements for the process by which licensees may make changes to their facilities and procedures as described in their updated final safety analysis reports without prior NRC approval. Similarly, 10 CFR 70.72, “Facility Changes and Change Process,”⁵ or 10 CFR 76.68, “Plant Changes,” contains requirements for the process by which fuel cycle facility licensees or certificate holders may make changes to their facilities and their safety program documents without prior NRC approval. Safety program documents are required within 10 CFR 70.62, “Safety Program and Integrated Safety Analysis,”⁵ and 10 CFR 76.87, “Technical Safety Requirements.” For nuclear power plants, non-power reactors, and fuel cycle facilities, licensees shall maintain records of changes to the facility. These records must include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require a license amendment. The records of changes to the facility should show that any potential safety issue from the use of embedded digital devices has been adequately addressed.

SUMMARY OF ISSUE

The key issue is that the increased use of embedded digital devices in safety equipment may increase a facility’s vulnerability to a CCF, challenge equipment EMC, or degrade equipment reliability. Potential safety issues from using embedded digital devices should be adequately addressed. Existing regulatory requirements (e.g., 10 CFR Part 50; Appendix A to 10 CFR Part 50, General Design Criterion 1; Appendix B to 10 CFR Part 50; 10 CFR 70.62(d); 10 CFR 76.93)^{6,7} address quality assurance requirements for systems that perform safety functions, and the increased presence of embedded digital devices in commercial-grade components creates a need for heightened awareness and attention by vendors, licensees, and applicants. This heightened awareness is important for new nuclear power plants, nonpower reactors, and fuel cycle facilities as well as modernization at existing facilities, because safety systems in these facilities may include commercial equipment with embedded digital devices (e.g., initial

³ Although DI&C-ISG-07 applies to 10 CFR Part 70 fuel cycle facilities, it also can be used as guidance for 10 CFR Part 40 facilities for DI&C issues.

⁴ The issue of potential counterfeit electronic parts is not discussed in this RIS, because it is a concern beyond just embedded digital devices in safety systems and is being addressed elsewhere.

⁵ Applies to new conversion and deconversion facilities according to the Commission SRM to SECY-07-0146.

⁶ For fuel cycle facilities, the quality assurance requirements vary by facility. For example, Appendix B to 10 CFR Part 50 is applicable to mixed-oxide fuel fabrication facilities. Other facilities use different requirements. For example, 10 CFR 70.62 (d) or 10 CFR 70.64(a)(1) are used for conversion² and deconversion² facilities, fuel fabrication, and enrichment facilities, and 10 CFR 76.93 is used for gaseous diffusion enrichment facilities.

⁷ For non-power reactors, Title 10, Section 50.34(a)(7), of the Code of Federal Regulations requires each non-power reactor applicant for a construction permit to build a production or utilization facility to include, in its preliminary safety analysis report, a description of the quality assurance program to be applied to the design and construction of the structures, systems, and components of the facility. Furthermore, 10 CFR 50.34(b)(6)(ii) requires that each applicant for a license to operate a facility include, in the final safety analysis report, a description of the managerial and administrative controls to be used to ensure safe operation.

installation or upgraded components). This key issue is further summarized in the following three categories:

(1) The Need to Ensure Adequate Quality and Reliability of Embedded Digital Devices that Exist in Actuation Equipment

(List of associated regulations: 10 CFR Part 21; 10 CFR Part 50, Appendix B for nuclear power plants and mixed-oxide fuel fabrication facilities; 10 CFR 70.62 (d) or 10 CFR 70.64(a)(1) for conversion and deconversion² facilities, fuel fabrication, and enrichment facilities; 10 CFR 76.93 for gaseous diffusion enrichment facilities; 10 CFR 50.34(a)(7); and 10 CFR 50.55a(h).)

- Regulations and review guidance established in SRP Chapter 7 for nuclear power plants, NUREG-1537 for non-power reactors, and NUREG-1520, NUREG-1718, and DI&C-ISG-07 for fuel cycle facilities focus on the safety-related system control and protection logic. Digital technology is being introduced into actuation and actuated equipment, such as motor controllers, sequencers, pumps, valve actuators, breakers, uninterruptable power supplies, emergency diesel generator controls, etc.
- In many instances, equipment consisting of commercial-grade products with older non-digital technology is being replaced with commercial grade products containing embedded digital devices that include software, software-developed firmware, or software-developed logic that may not have been developed in accordance with guidance and acceptable industry standards such as those identified in Branch Technical Position (BTP) 7-14 and BTP 7-19 in NUREG-0800 or Institute of Electrical and Electronics Engineers (IEEE) Standard (Std.) 603.

(2) The Need to Address Potential Plant Vulnerabilities to CCFs

(List of associated regulations: 10 CFR 40.31(j)(2)(ii) and 10 CFR Part 70, Subpart H, for conversion and deconversion² facilities; 10 CFR Part 70, paragraphs 70.61 through 70.65, for enrichment, fuel fabrication, and mixed-oxide fuel fabrication facilities; 10 CFR 76.87 and 10 CFR 76.89 for gaseous diffusion fuel cycle facilities; 10 CFR Part 50, Appendix A, specifically General Design Criterion 22; and 10 CFR 50.55a(h).)

- Applicable regulations, guidance, and industry standards (e.g., BTP 7-19, IEEE Std. 603, etc.) are relied on to assure the safety system sense and command features provide the logic signals to the safety system execute features. It may be possible that the intended safety protection could be defeated by an undetected error in the software or software-developed logic in embedded digital devices within these redundant safety system execute features that could prevent one or more trains of redundant equipment from accomplishing their intended safety function.
- The guidance in BTP 7-19 is helpful when considering potential CCFs of embedded digital devices located in equipment performing safety system execute features.
- Consideration of CCF applies to important to safety equipment to the extent that a CCF could create a condition that is beyond the design basis of safety-related equipment (i.e., when it is not bounded by the plant design-basis accident analysis and a plant vulnerability results with respect to a radiological release).

(3) The Need to Ensure Sufficient Procurement Planning and Material Control To Identify, Review, Test, and Control Embedded Digital Devices

(List of associated regulations: 10 CFR 40.31(j)(2)(ii) and 10 CFR Part 70, Subpart H, for conversion and deconversion² facilities; 10 CFR Part 70, paragraphs 70.61 through 10 CFR 70.65, for enrichment, fuel fabrication, and mixed-oxide fuel fabrication facilities; 10 CFR 76.87 and 10 CFR 76.89 for gaseous diffusion fuel cycle facilities; 10 CFR Part 50, Appendix B; and 10 CFR Part 21.)

- Vendors of commercial products that contain embedded digital devices should document the devices sufficiently to alert licensees to the presence of the embedded digital devices.
- Licensees should include, as part of their specification for vendors supplying commercial products, requirements to identify the use of embedded digital devices and to sufficiently document the quality of the embedded digital devices to support a commercial-grade item dedication per guidance in Regulatory Guide (RG) 1.152, Revision 3, July 2011, which currently endorses IEEE Std. 7-4.3.2-2003 with limitations.
- In the early stages of their design efforts, vendors, licensees, and applicants should fully understand the challenges that embedded digital devices may pose. Procurement activities, including the commercial-grade item dedication processes, should be sufficient to ensure adequate quality and to prevent the introduction of components that could degrade system reliability.

SUMMARY OF APPLICABLE REGULATIONS

- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- 10 CFR Part 40, "Domestic Licensing of Source Material," Section 40.31, "Application for Specific Licenses," paragraph (j)(2)(ii)
- 10 CFR 50.34(a)(7), "Contents of Applications; Technical Information," Quality Assurance Program
- 10 CFR 50.34(b)(6)(ii), "Managerial and Administrative Controls to be Used to Assure Safe Operation"
- 10 CFR 50.55a(h), "Protection and Safety Systems"
- 10 CFR 50.59, "Changes, Tests, and Experiments"
- 10 CFR Part 50 Appendix A, "General Design Criteria for Nuclear Power Plants," including General Design Criteria 1, "Quality Standards and Records," and General Design Criteria 22, "Protection System Independence"
- 10 CFR Part 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"

- 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants”
- 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” paragraphs 70.61, “Performance Requirements,” through 70.65, “Additional Content of Applications,” for enrichment, fuel fabrication, and mixed-oxide fuel fabrication facilities
- 10 CFR 70.62, “Safety Program and Integrated Safety Analysis,” including Section 70.62(d)
- 10 CFR 70.64, “Requirements for new facilities or new processes at existing facilities,” including Section 70.64(a)(1)
- 10 CFR 70.72, “Facility Changes and Change Process”
- 10 CFR 76.68, “Plant Changes”
- 10 CFR 76.87, “Technical Safety Requirements”
- 10 CFR 76.89, “Criticality Accident Requirements,” for gaseous diffusion fuel cycle facilities.
- 10 CFR 76.93, “Quality Assurance,” used for gaseous diffusion enrichment facilities

SUMMARY OF APPLICABLE STAFF GUIDANCE

- Staff Requirements Memorandum SECY 93-087 II.Q, “Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs” April 2, 1993 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML003708056).
- Staff Requirements Memorandum SECY 07-0146, “Regulatory Options for Licensing New Uranium Conversion and Depleted Uranium Deconversion Facilities,” October 10, 2007 (ADAMS Accession No. ML072830536).
- Regulatory Guide (RG) 1.152, “Criteria for Use of Computers in Safety Systems of Nuclear Power Plants,” Revision 3, July 2011 (ADAMS Accession No. ML102870022).
- RG 1.180, “Guideline for Evaluating EMI/RFI in Safety-Related I&C Systems,” Revision 1, October 2003 (ADAMS Accession No. ML032740277).
- RG 2.5, “Quality Assurance Program Requirements for Research and Test Reactors,” Revision 1, June 2010 (ADAMS Accession No. ML093520099).
- DI&C-ISG-04, “Task Working Group #4: Highly-Integrated Control Rooms-Communications Issues (HICRc), Interim Staff Guidance,” Revision 1, March 6, 2009 (ADAMS Accession No. ML083310185).
- DI&C-ISG-07, “Task Working Group #7: Digital Instrumentation and Control Systems in Safety Applications at Fuel Cycle Facilities, Revision 1,” December 1, 2010 (ADAMS Accession No. ML101900316).

- NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (SRP), Branch Technical Position (BTP) 7-19, “Guidance for Evaluation of Diversity and Defense-in-Depth in Digital Computer-Based Instrumentation and Control Systems,” Revision 6, July 2012 (ADAMS Accession No. ML110550791).
- NUREG-1520, Revision 1, “Standard Review Plan for the Review of a Licensee Application for a Fuel Cycle Facility,” May 2010 (ADAMS Accession No. ML101390110).
- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors; Format and Content,” February 1996, (ADAMS Accession No. ML042430055).
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors; Standard Review Plan and Acceptance Criteria,” February 1996, (ADAMS Accession No. ML042430048).
- NUREG-1718, “Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility,” August 2000 (ADAMS Accession Nos. ML003741461 and ML003741581).
- NRC Safety Evaluation Report, “Review of EPRI Topical Report TR-106439—Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications (TAC NO. M94127),” July 17, 1997 (ADAMS Accession No. ML092190664).
- NRC Regulatory Issue Summary 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,” November 25, 2002 (ADAMS Accession No. ML023160044).

RELATED INDUSTRY GUIDANCE

- Electric Power Research Institute (EPRI) TR-106439, “Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications,” October 1996 (ADAMS Accession No. ML103360462).
- Nuclear Energy Institute (NEI) 01-01 / EPRI TR-102348, Revision 1, “Guideline on Licensing Digital Upgrades,” March 2002 (ADAMS Accession No. ML020860169).

OTHER RELATED GENERIC COMMUNICATIONS

NRC Information Notice 1994-020, “Common-Cause Failures Due to Inadequate Design Control and Dedication,” March 17, 1994 (ADAMS Accession No. ML031060589).

NRC Information Notice 2007-015, “Effects of Ethernet-based, Non-Safety Related Controls on the Safe and Continued Operation of Nuclear Power Stations,” April 17, 2007 (ADAMS Accession No. ML071010303).

NRC Information Notice 2010-010, “Implementation of a Digital Control System under 10 CFR 50.59,” May 28, 2010 (ADAMS Accession No. ML100080281).

BACKFITTING AND ISSUE FINALITY

This RIS clarifies the NRC's technical position on existing regulatory requirements related to embedded digital devices and heightens awareness that these devices may exist in safety systems. The staff position in the RIS does not represent a new or changed position with respect to the need for applicants and licensees to identify, review, document, and control embedded digital devices in safety systems, in order to comply with 10 CFR 50.55a(h), "Protection and Safety Systems;" Appendix A, "General Design Criteria for Nuclear Power Plants;" and Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and other NRC regulations and guidance as identified above under "Summary of Applicable Regulations," and "Summary of Applicable Staff Guidance." Therefore, this RIS does not represent backfitting as defined in 10 CFR 50.109(a)(1), 10 CFR 70.76, 10 CFR 76.76, or is otherwise inconsistent with any issue finality provision in 10 CFR Part 52. Therefore, the NRC did not prepare a backfit analysis for this RIS or further address the issue finality criteria in Part 52.

FEDERAL REGISTER NOTIFICATION

[Discussion to be provided in final RIS.]

CONGRESSIONAL REVIEW ACT

[Discussion to be provided in final RIS.]

PAPERWORK REDUCTION ACT STATEMENT

This RIS contains and references information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collection requirements were approved by the Office of Management and Budget, approval numbers 3150-0035, 3150-0020, 3150-0011, 3150-0151, and 3150-0009.

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The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

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