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July 19, 2013

Ms. Cindy K. Bladey
Chief, Rules, Announcements, and Directives Branch (RADB)
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments on Draft Regulatory Issue Summary (RIS) 2013–XX, "Embedded Digital Devices in Safety-Related Systems, Systems Important to Safety, and Items Relied on For Safety" (Docket ID NRC-2013-098)

Project Number: 689

Dear Ms. Bladey:

The NRC, through the Federal Register Notice (78FR29392) and Docket ID: NRC-2013-098, issued for public comment the Draft Regulatory Issue Summary (RIS) 2013–XX, "Embedded Digital Devices in Safety-Related Systems, Systems Important to Safety, and Items Relied on For Safety." The Nuclear Energy Institute (NEI)[1] offers the attached table of comments and the following comments for NRC consideration.

As currently written, the RIS has the potential to significantly complicate the application of digital technology and could have far reaching equipment reliability and cost implications.

When issuing a RIS, the NRC typically summarizes and clarifies existing requirements and guidance; however, in this RIS the content effectively redefines digital technology and establishes new requirements and criteria that do not currently exist. It represents a new or changed position with respect to systems important to safety and items relied on for safety. A clearer distinction should be made in the RIS between treatment of safety-related embedded devices and non-safety-related devices.

[1] The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

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The fuel cycle facilities licensed pursuant to Parts 40, 70 or 76 are not all subject to the same quality assurance (QA) requirements. Thus, the RIS should be modified to explicitly state that for the fuel facilities NOT subject to Appendix B this RIS does not represent new NRC expectations or requirements for QA and commercial grade dedication (CGD) programs at their facilities. As written, it could be inferred otherwise by licensees, stakeholders, inspectors and NRC staff.

To better match the scope of regulatory applicability, the RIS should be divided into sections so that the licensees can see the summary of their relevant regulations.

If you have any questions or require additional information, please contact me at 202-739-8086, gac@nei.org.

Sincerely,

Gordon A. Clefton

Attachment

Comments on Draft Regulatory Issue Summary 2013-xx,
"Embedded Digital Devices in Safety-Related Systems, Systems Important to Safety, and Items Relied on For Safety"

Section	Comment	Proposed Resolution
General	This RIS effectively redefines digital technology and establishes new requirements and criteria that do not currently exist.	The RIS should only summarize and clarify existing requirements and guidance.
General	This RIS represents a new or changed position with respect to systems important to safety and items relied on for safety.	The RIS should provide a clearer distinction between treatment of safety-related embedded devices and non-safety-related devices. A definition of 'important to safety' should be referenced (from a current source acceptable to the NRC and Industry).
General	This RIS contains a strong emphasis on concerns about Common Cause Failure (CCF); however, no practical guidance is given regarding how to address the concern. The reference to Branch Technical Position (BTP) 7-19 is not applicable to the entire scope contained in the RIS.	The RIS should provide more practical guidance to address concerns related to CCF or point to available guidance.
General	The RIS contains no acknowledgement that embedded digital devices are, more often than not, relatively simplistic in their functionality compared to larger digital control/protection systems where Software Common Cause Failure (SWCCF) concerns have traditionally been focused.	The RIS should acknowledge that certain types of embedded digital devices are very simplistic by nature and that this simplicity should be a factor in evaluating susceptibility to common cause failure.

Section	Comment	Proposed Resolution
General	The fuel cycle facilities licensed pursuant to Parts 40, 70, or 76 are not all subject to the same Quality Assurance (QA) requirements. Specifically, fuel cycle facilities licensed relatively recently committed to Part 50, Appendix B during the licensing process; others that have been in operation for decades did not. Those fuel cycle facilities not subject to Appendix B are implementing a graded QA program (as allowed by NRC requirements) and may or may not have a Commercial Grade Dedication (CGD) program in place since many parts are purchased "off the shelf."	The RIS should be modified to explicitly state that, for the fuel cycle facilities NOT subject to Appendix B, this RIS does not represent new NRC expectations or requirements for QA and CGD programs at their fuel cycle facilities.
General	This RIS seems to make QA mandatory in all cases, with no exception. This approach ignores the fact that a large number of fuel cycle facilities safety systems are designed to fail safe and not fail in such a manner as to pose a safety issue.	The RIS should allow licensees to take a risk-informed, graded approach to QA, consistent with Part 70.
General	Industry references are available that address embedded digital devices. International Electrotechnical Commission (IEC) Standard 62671 is dedicated specifically to treatment of embedded digital devices in commercially available equipment. Section 8.5 deals with some practical measures to address concerns related to common cause failure.	The RIS could use the pertinent information of IEC Standard 62671 as a reference in providing practical guidance on CCF.

Section	Comment	Proposed Resolution
General	An accepted definition of "digital" is drawn from IEEE-100 and IEEE 7-4.3.2-2003 which state: "A functional programmable unit that consists of one or more associated processing units and peripheral equipment, that is controlled by internally stored programs, and that can perform substantial computation, including numerous arithmetic or logic operations, without human intervention". The RIS contradicts this definition with the following verbiage: "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". Effectively the NRC is attempting to bring a range of devices that do not meet the IEEE definitions under the digital umbrella, e.g. Application Specific Integrated Circuits (ASICs), Field Programmable Gate Arrays (FPGAs), and Complex Programmable Logic Devices (CPLDs). These devices do not have microprocessors nor do they execute software. From a licensee perspective, these are basic components that are not computerized so forcing the application of the ISGs and BTPs is inappropriate.	The RIS should use the industry accepted definition of 'digital' and ensure that basic components that are not computerized are not included in the scope.

Section	Comment	Proposed Resolution
General	There is no official definition of a 'digital' component. Classifying basic components as "digital" would likely force licensees to classify basic components as Critical Digital Assets (CDAs), placing them under the scope of the Cyber Security Rule (10CFR73.54). Thus, a significant number of additional basic components would be added that would dilute the individual management without any gain in plant safety.	The RIS should ensure that 'digital' definitions do not cause basic components to be classified as CDAs.
Intent	The RIS states that it "requires no action or written response on the part of an addressee"; however, if interpreted broadly, NRC is changing its expectations of several fuel cycle facilities with regard to QA and CGD programs.	The RIS should be modified to use separate sections that summarize the regulations applicable to groups of licensees.
Intent	Some expectations of licensees provided in the RIS are not within the licensee's control, e.g., procured items or systems where the vendor designed and installed an embedded digital device without the knowledge of the end user.	The RIS should address such instances with respect to the NRC's expectations of licensees.
Intent	Most fuel cycle facilities are not subject to Part 50 Appendix B QA requirements; therefore, they would not apply the full breadth of QA requirements alluded to in the RIS. Most fuel cycle facilities not subject to Appendix B do not apply CGD to Items Relied On For Safety (IROFS), in whole or in part. Note: The issue of CGD at fuel cycle facilities is also relevant to the ongoing NRC-industry discussion on the Draft Regulatory Basis for Part 21 that would potentially impose CGD on all fuel cycle facilities in the absence of a safety issue or problem statement.	The RIS should recognize that fuel cycle facilities have a graded QA program with a different scope as allowed by 10CFR70.

Section	Comment	Proposed Resolution
Footnotes	The terms, safety systems, IROFS, and basic components are used interchangeably throughout the RIS without regard to how these terms are uniquely used in Part 70 which is causing unnecessary confusion within the industry.	The RIS should recognize that definitions are unique to specific types of licensees and apply them accordingly in the RIS.
Summary of Issue	It is misleading to state that existing requirements for management measures (10CFR70.62(d) and 70.64(1)(1)) for new processes at existing fuel cycle facilities currently require QA procurement of the embedded digital device to support CGD since this is not representative of the NRC-approved licensed programs in operation today.	The RIS should recognize the NRC approved licensed programs in operation today.
Summary of Issue	This RIS indicates vendors supplying commercial products should document the quality of embedded digital devices to support commercial grade dedication per Regulatory Guide (RG) 1.152 which currently endorses IEEE 7-4.3.2, "IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations". RG 1.152, in Section B "Discussion," specifically states that IEEE 7-4.3.2 does not provide adequate guidance relative to dedication of commercial grade digital equipment, and instead endorses EPRI TR-106439, "Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications" for this topic.	The RIS should be revised to be consistent with NRC endorsements in current Regulatory Guides.