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NRC REGULATORY ISSUE SUMMARY 2017-XX
UPDATE TO THE STAFF ENDORSEMENT ON THE 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"
(REPORT PREVIOUSLY ENDORSED WITHIN RIS 2002-22)

ADDRESSEES

All holders and applicants for power reactor operating licenses or construction permits under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel, and 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."

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing a clarification to the staff's endorsement of the Electric Power Research Institute (EPRI)/Nuclear Energy Institute (NEI) Joint Task Force report entitled, "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," (hereinafter referred to as "NEI 01-01.") In RIS 2002-22 (ADAMS Accession Number ML023160044), the staff previously endorsed the use of the NEI 01-01 document as guidance in designing and implementing digital upgrades to instrumentation and control systems a) to ensure that digital upgrade regulatory and technical issues are adequately addressed, b) to provide criteria for performing the 10 CFR 50.59 evaluation and, if necessary, c) to identify when licensees need to submit a License Amendment Request under 10 CFR 50.90.

Specifically, within this RIS, the staff clarifies the applicability of its endorsement for proposed system and component upgrades to systems that initiate and complete design basis preventative or mitigative safety functions credited in the plant safety analyses, versus proposed

system and component upgrades to systems that support the successful operation of those systems or perform non-safety related functions. This RIS also provides clarification of the staff's endorsement of NEI 01-01 regarding the use of criteria stated within NEI 01-01 to address the performance of plant safety evaluations as outlined in 10 CFR Part 50.59, "Changes, tests, and experiments." Specifically, the staff clarifies its endorsement of the NEI 01-01 guidance for performing adequate qualitative [Based on your framework document, you are also requiring deterministic assessments, not just qualitative assessment. I agree with this.] assessments of proposed digital I&C changes within the scope of the endorsement. The documentation of appropriately prepared qualitative assessments is considered an acceptable means for supporting the development of adequate responses to safety evaluation criteria required to be addressed under 10 CFR Part 50.59(c)(2)(i) through (viii). The attachment to this RIS and its enclosures document the staff's clarified basis for continuing its endorsement of NEI 01-01.

Where potential conflicts may exist between the contents of this RIS and that of RIS 2002-22 regarding acceptable guidance for performing 10 CFR 50.59 evaluations, the provisions within this RIS shall supersede those provided within RIS 2002-22.

It is intended that this RIS provide clarity of the staff's endorsement of NEI 01-01 for use in future digital I&C changes to licensed nuclear power plants. No backfitting is intended or approved in connection with the issuance of this RIS.

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

BACKGROUND INFORMATION

By letter dated March 15, 2002, NEI submitted EPRI TR-102348, Revision 1 (NEI 01-01) for staff review. This report replaced the original version of EPRI TR-102348, dated December 1993, which the NRC endorsed in Generic Letter (GL) 95-02, "Use of NUMARC/EPRI Report TR-102348, 'Guideline on Licensing Digital Upgrades,' in Determining the Acceptability of Performing Analog-to-Digital Replacements Under 10 CFR 50.59," dated April 26, 1995. In 2002, the staff issued Regulatory Issue Summary (RIS) 2002-22 to notify addressees that the NRC had reviewed NEI 01-01: "A Revision of EPRI TR-102348 To Reflect Changes to the 10 CFR 50.59 Rule," and was endorsing the report for use as guidance in designing and implementing digital upgrades to nuclear power plant instrumentation and control systems.

Following the staff's 2002 endorsement of NEI 01-01, holders of construction permits, standard design certifications, and operating licenses have been using this guidance, as endorsed, in support of the performance of digital I&C-related design modifications, in conjunction with Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," dated November 2000, which endorsed NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations," Revision 1, dated November 2000.

Subsequent to the issuance of the staff's 2002 endorsement of NEI 01-01, NRC inspections of plant digital I&C modifications performed under 10 CFR 50.59 have revealed that some licensees have encountered difficulties in addressing the guidance and acceptance criteria within other applicable technical guidance documents while conforming to the endorsed guidance within NEI 01-01 and subsequently performing effective safety evaluations as required by 10 CFR 50.59, as amended. NRC staff inspections of design modifications performed by some licensees have also revealed weaknesses in the adequacy of documentation specifying the technical basis regarding licensee conclusions that the safety evaluation criteria within 10 CFR 50.59 are being met in the proposed modernization project, and that no prior NRC staff review (via evaluation of a license amendment request) is required.

For example, licensees encounter difficulty addressing the staff review acceptance criteria regarding the adequacy of diversity and defense-in-depth (D3) analyses to address the potential for common cause failure, as outlined within NUREG-0800 Standard Review Plan Chapter 7, Branch Technical Position BTP 7-19, "Guidance for Evaluation of Diversity and Defense-in-Depth in Digital Computer-Based Instrumentation and Control Systems," Revisions 6 and 7) when they attempt to apply them for use in lower safety-significant I&C systems under the 10 CFR 50.59 design change evaluation process, and subsequently provide an effective response to 10 CFR 50.59(c)(2) safety evaluation criteria (i) through (viii). As another example, staff inspectors have identified cases where licensee documentation supporting the technical basis for conclusions reached in 10 CFR 50.59 evaluations is unclear as to which applicable industry codes and standards were followed, and which specific aspects of those standards provides the basis for concluding the 10 CFR 50.59 safety evaluation criteria are satisfied.

Section 5.2 of NEI 01-01 provides guidance regarding the need for D3 analyses to be completed for key reactor protection and engineered safeguards features systems. Based on regulatory experience with the use of NEI 01-01, the staff has identified that the applicability of this guidance to certain portions of plant systems needs to be clarified. (The staff notes that guidance for assessing the diversity and defense-in-depth of digital I&C systems was originally developed for use by NRC staff in their review of high safety-significant I&C systems such as reactor protection systems and engineered safeguards systems in conjunction with its evaluation of license applications and amendments, rather than for use in performing design changes for less safety significant systems under 10 CFR 50.59.)

In an effort to remedy the difficulties described above, the staff, NEI, and industry representatives have been meeting to discuss these issues and are working to develop revised guidance for incorporating digital I&C systems under the 10 CFR 50.59 process, and new guidance for addressing the potential for digital system related common cause failures. This effort is part of a broader effort to modernize the current regulatory infrastructure to efficiently address risks associated with the introduction of digital technology for nuclear power plant applications that have potential impact on plant safety. The staff's plan for accomplishing this regulatory modernization, is outlined in the NRC "Integrated Action Plan to Modernize Digital Instrumentation and Controls Regulatory Infrastructure" (ADAMS Accession Number ML17XXXXXXX), including the planned schedule for completion of key infrastructure

improvements. As part of this plan, however, the staff and stakeholders have identified an immediate need for clarification of the staff's guidance for performing adequate safety evaluations of proposed digital I&C modernization projects being implemented under the 10 CFR 50.59 design change process.

In this RIS, the staff is clarifying the applicability its previous endorsement of NEI 01-01 to RPS and ESF initiation, ~~and~~ completion and manual control functions [Several Ch. 15 events credit manual operator actions.], versus its applicability to safety support systems and non-safety systems. The staff is also clarifying its position with regard to acceptable methods for applying the guidance in NEI 01-01 to digital I&C modifications performed under the 10 CFR 50.59 process, in conjunction with the use of the staff's other technical guidance documents. The staff's previous endorsement is also being augmented to provide the staff's position on acceptable methods for developing and documenting qualitative assessments of the proposed digital I&C design change to serve as a technical basis for responding to the eight safety criteria that must be evaluated within 10 CFR 50.59(c)(2)(i) through (viii).

ISSUE SUMMARY

The revision of 10 CFR 50.59 effective on March 13, 2001, used evaluation criteria that are difficult to apply to software-based I&C systems. Therefore, the EPRI/NEI Joint Task Force included relevant supplemental guidance in developing NEI 01-01, and provided supplemental guidance on the use of NEI 96-07 for evaluating the safety of proposed digital upgrades to I&C systems.

In its 2001-2002 review of NEI 01-01, the staff concluded that the document provides suitable guidance both for designing a digital I&C replacement and for determining whether it can be implemented under 10 CFR 50.59 without prior staff approval. Nevertheless, the staff's evaluation of the report attached to RIS 2001-22 provided statements that qualify the NRC staff's endorsement, and provided staff positions on several aspects of the design and licensing processes. In particular, the staff noted that when using the submittal as guidance for the analysis of digital modifications of some safety-significant systems such as the reactor protection system and engineered safety features actuation systems, "it is likely these digital modifications will require staff review (i.e., via a license amendment under 10 CFR 50.90) when the 10 CFR 50.59 criteria are applied and evaluated."

It is the intent of this RIS to provide further clarification of the staff's endorsement stated in RIS 2002-22 with regard to the endorsed scope of its applicability, and the methods licensees can use to document its assessments of the design features and capabilities of proposed digital I&C changes to licensed facilities, to facilitate the development of adequate responses to the 10 CFR 50.59 criteria that must be evaluated for any facility changes proposed to be conducted under 10 CFR 50.59. For example, the staff's guidance for performing adequate qualitative assessments in Enclosure 2 of this RIS is not intended for use in making proposed changes to logic systems forming a part of reactor protection systems and engineered safety feature

systems initiation, completion and manual control [Again credited manual actions are as safety significant as the ESFAS, sometimes more so.] systems, for which a license amendment request is needed. In addition, this RIS provides clarification of the endorsement in other areas where recent inspections have revealed inconsistencies in licensee adoption of guidance within NEI 01-01.

Changes proposed under 10 CFR 50.59

NEI 01-01 contains several references to key sections within NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations," Revision 1 (November 2000), an industry guidance document that is endorsed within Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments." When followed properly while implementing a proposed facility design change, NEI 96-07 provides for the use of qualitative assessments and qualitative engineering judgment and/or industry precedent when addressing whether the frequency of ~~accidents~~ malfunctions occurring would be more than minimally increased, or whether a possibility for a malfunction of a system or component important to safety has been introduced that could alter the conclusions of the safety analysis. Guidance within NEI 96-07 states that normally, the determination of ~~an accident~~ a malfunction [Question 2 is about malfunctions, not accidents] frequency increase is based upon a qualitative assessment using engineering evaluations consistent with the UFSAR analysis assumptions. However, a plant-specific accident frequency calculation or PRA may be used as one of the tools for evaluating the effects of a proposed activity in a quantitative sense. Also, "reasonable engineering practices, engineering judgment and PRA techniques, as appropriate," should be used in determining whether the frequency of occurrence of ~~an accident~~a malfunction would more than minimally increase as a result of implementing a proposed activity. The effect of a proposed activity on the frequency of ~~an accident~~a malfunction must be "discernable and attributable" to the proposed activity in order to exceed the "more than minimal increase" standard. This concept was endorsed in RG 1.187, along with the endorsement of the balance of the NEI 96-07, Revision 1 document.

NEI 01-01 provides a failure analysis-based and D3 analysis-based approach to manage risk that encompasses digital-specific issues and other possible failure causes, addressing both according to their potential effects at the system level. This RIS clarifies the staff's previous endorsement regarding the need for performance of D3 evaluations of potential digital I&C upgrades to RPS and ESF systems to confirm adequate diversity exists, in accordance with regulatory requirements and NEI 96-07 guidance, as well as the performance of defense-in-depth (D2) assessments of safety support systems and non-safety systems [You are introducing a completely new concept here that is not supported by your framework document. As I have commented many times, there are two parts to a D3 analysis (1) an assessment of CCF vulnerability (we call this a CCF susceptibility analysis) and (2) an assessment of the plant's ability to cope with a CCF, when a CCF is credible (we call this a CCF malfunction results analysis). Both of these analyses are needed even for control systems and support systems.

This is consistent with your framework document]. The clarified endorsement in this RIS identifies important design attributes and quality measures [I just want to point out that here you distinguish design attributes from quality measures. This distinction should be made everywhere, because qualitative measures alone are not sufficient to reach a conclusion that a CCF is not credible or to reach a conclusion that the likelihood of CCF is significantly less than a single failure.] that, if applied appropriately, could be considered as adequate to demonstrate a sufficient reduction in uncertainty when performing qualitative assessments of likelihood of occurrence of a potential CCF for such lower-safety significant digital I&C proposed upgrades. Whereas the guidance in NEI 01-01 provides a "road map" to relevant standards and other sources of detailed guidance, the clarified endorsement of NEI 01-01 within this RIS identifies how the potential effectiveness of the design features and quality measures that are applied to the proposed design using such standards and guidance should be described and evaluated within licensee documentation supporting any conclusions that a reduction in uncertainty could be credited.

NRC inspections of plant modifications recently implemented or proposed have uncovered inconsistencies and weaknesses in the documentation of digital upgrade technical and safety evaluations performed by licensees. These specific evaluations have not included adequate documentation of the licensee's technical basis as to why it may be concluded that a particular plant design, once implemented, will not result in more than a minimal increase in the frequency of occurrence of an accident (10 CFR 50.59(c)(2)(i)) [This RIS should make it clear that unless there is an I&C malfunction there can be no accident caused by an I&C system. Therefore, for I&C systems it is sufficient to refer to Question 2 when answering Question 1.], or more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety (10 CFR 50.59(c)(2)(ii)) [This RIS should make it clear that unless a CCF is as likely as a single failure, the contribution of a CCF to malfunction frequency is negligible. Therefore, to answer this question licensees must assess the likelihood of single failures, not CCFs.]. A similar weakness was found in the manner in which licensees document the technical basis as to why a particular proposed modification will not create a possibility for an accident of a different type (10 CFR 50.59(c)(2)(v)), and why the proposed modification will not create a possibility for a malfunction of an SSC important to safety with a different result (10 CFR 50.59(c)(2)(vi)) [This RIS should make it clear that for Questions 5 and 6 a bounded plant-level end-result is not a different type of accident and not a malfunction with a different result. The distinction in 'bounded' criteria (i.e., analysis methods and acceptance criteria) must be explained for CCFs that are within the design basis and CCFs that are beyond design basis.] .

To remedy this, the staff has included within Enclosure 2 of this clarified endorsement of NEI 01-01, its position on the minimum content, rationale, and evaluation factors that must be addressed and evaluated within licensee-developed qualitative assessments that serve as input to developing responses to the 10 CFR 50.59 safety evaluation criteria. Specifically, the guidance within Enclosure 2 describes the staff expectations for such qualitative assessments to document an adequate technical basis for conclusions that are made regarding the relative likelihood of failure of the proposed digital I&C modification, based on evidence demonstrating

how adequate design measures, quality processes, layers of defense, and operating experience were considered to contribute to such likelihood of failure.

Clarification of staff endorsement of NEI 01-01 to address 12 concerns regarding the interpretation of specific provisions within NEI 01-01

On November 5, 2013, the NRC issued a letter (ADAMS Accession No. ML13298A787) to NEI summarizing 11 NRC staff concerns regarding inconsistent interpretation of provisions within the guidance of NEI 01-01. On October 9, 2014, the NRC issued a meeting summary (ADAMS Accession No. ML14255A059) that identified a 12th concern. Within this RIS, the staff considers the concerns regarding adequate means for addressing the evaluation criteria in 10 CFR 50.59 to be resolved for safety support systems and non-safety systems. The remaining concerns that are not addressed here, will be addressed as part of the staff's evaluations for possible endorsement of Appendix D to NEI 96-07 addressing 10 CFR 50.59 processes, and new NEI guidance NEI 16-16, now being developed to address common cause failure of digital systems, as described within the NRC Digital I&C Integrated Action Plan, as summarized in SECY 17-XXXX. (ADAMS Accession Number ML17XXXXXXXX.)