

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR REACTOR REGULATION  
OFFICE OF NEW REACTORS  
WASHINGTON, D.C. 20555-0001

July 2017

**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 **BY 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, licensing, and implementing digital upgrades and replacements in a consistent and comprehensive manner. This included providing guidance for the following activities:

- a. Carry out the design and implementation process for digital replacements in a manner that ensures regulatory requirements and good engineering practices are followed.
- b. Perform evaluations to comply with the requirements in 10 CFR 50.59.
- c. Prepare a license amendment request (LAR) when the 10 CFR 50.59 evaluation indicates that prior NRC review is required before implementing plant changes.
- d. Comply with other regulatory requirements pertaining to digital replacements in nuclear

~~power plants to instrumentation and control systems a) to ensure that digital upgrade regulatory and technical issues are adequately addressed, b) to provide criteria enabling the appropriate performance of 10 CFR 50.59 screenings and evaluations and, if necessary, c) to identify when licensees need to submit a License Amendment Request under 10 CFR 50.90 for plant upgrades using digital technology.~~

Specifically, within this RIS, the staff clarifies the applicability of its endorsement of NEI 01-01 for proposed system and component upgrades to protection systems, and to systems that support the successful operation of those systems or perform non-safety related functions. This

**Commented [vxf1]:** Consider adding some detail about how this RIS is to be used in conjunction with the original RIS, and what, if any content is superseded.

DRAFT

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 10 CFR Part 50.59 rule, "Changes, tests, and experiments." Specifically, the staff clarifies its endorsement of the NEI 01-01 guidance for crediting deterministic and qualitative criteria for performing and documenting adequate qualitative assessments of proposed digital I&C changes within the scope of the endorsement. The documentation of ~~appropriately prepared adequately performed~~ qualitative assessments is considered an acceptable means for supporting the development of ~~adequate~~ responses to criteria required to be addressed under 10 CFR Part 50.59(c)(2)(i) through (viii). The attachment (Attachment 1) to this RIS provides clarification as to the staff's basis for continuing its endorsement of NEI 01-01, provided that the licensee documents qualitative assessments ~~are documented~~ in accordance with the guidance contained in Attachment 1. therein.

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 implementing digital I&C changes to licensed nuclear power plants that are initiated after its issuance. 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. ~~NEI 01-01 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 50.59 Evaluations as required by 10 CFR 50.59(c)(2), as amended. NRC staff inspections of design modifications performed by some licensees have also revealed weaknesses in the adequacy of documentation specifying of the technical basis regarding licensee conclusions that the evaluation criteria within 10 CFR 50.59(c)(2) are being met in the proposed modernization project, and that no prior NRC staff review (such as by via staff 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 and diversity (D3) analyses to address the potential for common cause failure, as outlined in versions of 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," issued after NEI 01-01 was issued Revision 7) when they attempt to apply staff review acceptance criteria them for use in lower safety-significant I&C systems/components under the 10 CFR 50.59 design change evaluation process, and subsequently provide an effective response to 10 CFR 50.59(c)(2) 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 Evaluation criteria are satisfied.

**Commented [vxf2]:** This could be subject to interpretation. Please consider clarifying or removing.

**Commented [vxf3]:** This could imply that digital upgrades to systems always "screen in". Please clarify.

Section 5.2 of NEI 01-01 provides guidance regarding the need for D3 analyses to be completed for key reactor protection trip and engineered safety features actuation systems. Specifically, Section 5.2.1 states that a formal defense-in-depth and diversity analysis per BTP 7-19 is expected "only for substantial digital replacements of RTS and ESFAS..." ... This scope is consistent with the scope of systems addressed in BTP 7-19 when NEI 01-01 was issued Based on regulatory experience with the use of NEI 01-01, the staff has identified that the applicability of this guidance to of the scope of plant systems needs to be clarified. , since later versions of BTP 7-19 expanded the scope of applicability. (The staff notes that guidance for assessing the diversity and defense-in-depth and diversity of digital I&C systems/components was originally developed for use by NRC staff in their review of high safety-significant I&C systems/components such as reactor trip 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 related design modifications 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 ML17102B307XXXXXXXX), 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 10 CFR 50.59 Evaluations associated with proposed digital I&C modernization projects being implemented licensees are implementing under the design change process.

In this RIS, the staff is clarifying the applicability of the previous endorsement of NEI 01-01 to reactor protection functions, and its applicability to manual control functions, and 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 clarified 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 criteria that must be addressed within 10 CFR 50.59(c)(2)(i) through (viii) in order to make a change to the facility without first obtaining a license amendment under 10 CFR 50.90.

## SUMMARY OF ISSUE

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 whether a proposed change to the design of the plant as described in the UFSAR using digital I&C technology has an impact on the plant licensing basis, and requires prior review by the NRC staff.

In its 2001 to 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 licensed and implemented under 10 CFR 50.59 without prior staff approval. Nevertheless, the staff's evaluation of the report attached to RIS 2002-22 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 (NEI 01-01) as guidance for the analysis of digital modifications of some safety-significant systems such as the reactor trip 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(c)(2) criteria are applied and assessed/evaluated."

**Commented [vxf4]:** There does not appear to be any areas of this RIS or attachment that discuss manual control functions. Suggest defining how, or if, manual controls are to be credited in the qualitative assessment process.

**Commented [vxf5]:** There are some industry members who interpret that the previous guidance (RIS 2002-22) did not apply to non-safety systems. Please clarify or remove this statement.

**Commented [vxf6]:** If the RIS is clarifying an endorsement or position contained in other NRC technical guidance documents, please be specific and identify those areas within the RIS.

**Commented [vxf7]:** Industry and NRC staff should discuss further what is an "acceptable method", and level of evidence required for modifications that "screen out".

It is the intent of this RIS to provide further clarification of the staff's endorsement stated in RIS 2002-22 with regard to a) the endorsed scope of its applicability; b) considerations for documentation of conclusions regarding whether a digital I&C modification can be appropriately implemented within the 10 CFR 50.59 process; and c) clarifications to the staff's technical evaluation attached to RIS 2002-22 pertaining to documentation of qualitative assessments and other statements made.

**Commented [vxf8]:** Refer to previous comment on clarifying the scope of the new RIS used in conjunction with the existing RIS

**Commented [vxf9]:** Please be specific with respect to what "technical evaluation" is being referred to here.

### Scope of Applicability of Qualitative Assessment Guidance

In Section 2.2 of the staff's evaluation of NEI 01-01 (Attachment 1 of RIS 2002-22) the staff noted that the guidance of NEI 01-01 "is intended to apply to both small and large-scale digital replacements, from the simple replacement of an individual analog meter with a microprocessor-based instrument up to the complete change out of a reactor protection system with a new, integrated digital system or replacements of mechanical or electrical equipment if the new equipment uses digital technology." In Section 3.1 of the staff's evaluation of NEI-01-01, the staff acknowledges that with regard to the replacement of complex systems, "particularly the reactor protection system (RPS) and engineered safety features actuation systems (ESFASs), there is no consensus method for determining the likelihood of software malfunctions, and system-level failure modes may exist that can have consequences different from those previously analyzed in the UFSAR. Hence, the staff believes that when using the submittal as guidance for the analysis of digital modifications of some safety-significant systems such as the RPS and ESFASs, it is likely these digital modifications will require prior staff review when 10 CFR 50.59 criteria are applied."

**Commented [vxf10]:** Please clarify whether the Attachment to the RIS is considered by the NRC staff to be bases, or guidance.

In this RIS, the staff is clarifying that it is the staff's expectation that the analysis and documentation of possible digital technology-related failures, including possible CCFs, within proposed modifications to the safety logic portions of all reactor trip system (RTS)-RPS and engineered safety features initiation systems (e.g., ESFAS and other ESF actuation logic systems) should implement the analysis process outlined in NUREG 0800, 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," and NUREG-6303, "Method for Performing Diversity and Defense-in-Depth Analyses of Reactor Protection Systems." Documentation of the results of the BTP 7-19/NUREG-6303 analyses should be part of the documentation needed to support a decision as to whether prior staff review is required before the proposed modification can be implemented. However, when evaluating whether proposed digital technology changes to the non-logic portions of RPS and ESF actuation systems, and other proposed safety support systems, auxiliary systems, and non-safety systems, the guidance for adequately documenting qualitative assessments as described in the attachment to this RIS (Attachment 1) should be followed.

**Commented [vxf11]:** Staff comments on NEI 01-01 Appendix D have requested CCF be changed to SCCF (Software Common Cause Failure). Suggest further discussion on going forward use of "CCF" versus "SCCF", and correcting all instances in this document

**Commented [vxf12]:** This RIS is requiring (staff expectation) that BTP 7-19 is to be followed by licensees. The use of BTP 7-19 can be problematic for licensees performing 50.59 Evaluations. Also, BTP 7-19 refers to codes and standards that are not part of many plant licensing bases. Please consider removing or clarifying this statement. As an example, previous NRC precedent (Shearon Harris Inspection Report, dated 8-12-2013) stated in part that..."the criteria in the BTP was intended to provide guidance to NRC staff.....and not as criteria to implement digital modifications.."

**Commented [vxf13]:** Please remove this requirement, or clarify the basis and necessity to perform the a D3 in accordance with NUREG 6303 in order to support the 50.59 evaluation to conclude that NRC review is required.

**Commented [vxf14]:** NEI and NRC staff have discussed this during recent public meetings. Perhaps some examples of what "non-logic" is referring to would be helpful to end users.

### Digital I&C 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 assessing/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 likelihood/frequency of 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 a malfunction frequency increase is based normally 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 likelihood/frequency of occurrence of a malfunction would more than minimally increase as a result of implementing a proposed activity. The effect of a proposed activity on the likelihood/frequency of 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 a 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 evaluation as to whether there is any reduction in the defense-in-depth or independence either directly described or implied within the plant licensing basis, due to any changes in safety support systems, auxiliary systems, and non-safety systems. The clarified endorsement in this RIS identifies the need for documenting key design attributes and quality management measures that, when 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 (i.e., non-RTSPS and non-ESF initiation system) 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 management measures that are applied to the proposed design using such standards and guidance should be described and assessed/evaluated within licensee documentation supporting any conclusions that a reduction in uncertainty could be credited.

The NRC staff expectation regarding the documentation of qualitative assessments is to be able to describe the licensee's basis (rationale) for concluding that a particular plant design, once implemented, will not result in:

**Commented [vxf15]:** When considering information in NEI 96-07, use of PRA is generally limited to Evaluation Question 1 - accident frequency, not to malfunction likelihood (Evaluation Question 2).

**Commented [vxf16]:** Considering the comment above, should this be "accident" versus "malfunction"?

**Commented [vxf17]:** To be consistent with NEI 96-07, consider maintaining the terms "accident frequency" and "malfunction likelihood". There appears to be mixing of these terms in this RIS.

**Commented [vxf18]:** This is a complex sentence that should be revised for clarity

**Commented [vxf19]:** See previous comment on this term.

- more than a minimal increase in the frequency of occurrence of an accident (10 CFR 50.59(c)(2)(i)), and
- 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)).

Unless there is an I&C malfunction of the digital system/component, there can be no postulated operational occurrences or accidents that are caused by the digital system/component, an I&C system. Therefore, when responding to the criterion in 10 CFR 50.59(c)(2)(i), it is considered acceptable to base the response on the response to the criterion in 10 CFR 50.59(c)(2)(ii). Also, unless a CCF is as likely to occur as a single failure (which should already be addressed in the design), the additional contribution of a new potential CCF to malfunction likelihood/frequency should be shown to be negligible, and licensees and design certification holders should be able to demonstrate a basis for concluding there is no more than a minimal increase in the likelihood of occurrence of a malfunction.

Similarly, the NRC staff expectation regarding the documentation of qualitative assessments is to be able to describe the licensee's basis (i.e., rationale) for concluding that a particular proposed modification will not:

- create a possibility for an accident of a different type (10 CFR 50.59(c)(2)(v)), and
- create a possibility for a malfunction of an SSC important to safety with a different result (10 CFR 50.59(c)(2)(vi)).

A bounded plant-level end result is not considered a different type of accident or a malfunction with a different result. When considering and addressing/evaluating the impact of potential new CCFs that are of sufficient frequency that need to be accounted for within the plant design basis, design basis analysis methods and acceptance criteria should be used. When evaluating the impact of potential new CCFs that are of negligible frequency, existing design basis analysis methods and acceptance criteria may be used, as well as beyond design basis analysis methods (best estimate) and acceptance criteria may be used in evaluating whether the plant level effect is bounded.

To assist licensees in preparing acceptable qualitative assessments supporting the rationale for responding to the 10 CFR 50.59(c)(2) criteria needed to conclude whether or not prior staff evaluation is required to implement the proposed digital modification, the staff has clarified within Attachment 1 of this RIS, the staff's position on the minimum content, rationale, and evaluation factors that should be addressed and assessed/evaluated within licensee-developed qualitative assessments that serve as input to developing responses to the 10 CFR 50.59 evaluation criteria. Specifically, the clarified guidance within Attachment 1 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 an evaluation of relevant operating experience were considered to contribute to such likelihood of failure.

For example, the clarified guidance in Attachment 1 identifies the need to provide adequate documentation in the modification package, which should be (that is then-referenced in the

**Commented [vxf20]:** Requiring the impact to be "negligible" fails to consider the case in which the additional contribution of a new potential CCF to malfunction likelihood could be "discernable," but still NOT more than minimal (as allowed by NEI 96-07, Section 4.3.2). Please consider the need to add "discernable, but NOT more than minimal criterion" (See Appendix D, Section 4.3.1 and 4.3.2).

**Commented [vxf21]:** If the activity increases accident frequency, malfunction likelihood, creates an accident of a different type, or a malfunction with a different result, a LAR is required. There is not further evaluation needed. It is acceptable to have a new malfunction - just not a new malfunction result. NEI and staff need to further discuss and align on the treatment of "beyond design basis" in the context of 50.59.

qualitative assessment,) as to what specific design standards were followed in the development of the proposed digital &C modification. This is to ensure that well-defined processes (as applicable, based on the safety significance of the equipment) for project management, software design, development, implementation, verification, validation, software safety analysis, change control, and configuration control were employed and are being credited in supporting the portion of the technical basis of the qualitative assessment demonstrating a high quality development process was used. These design standards need not be the specific standards endorsed in USNRC regulatory guides; however, an evaluation should be documented as to why the particular portions of the design standards are considered to be adequate for the particular application, commensurate with the level of safety significance of the proposed modification, or its consequences of failure results.

**Commented [vxf22]:** The term "project management" may have different meanings to different engineers/utilities. Please clarify what is the context of "project management" as used here.

**Commented [vxf23]:** NEI and NRC staff should discuss the expectation of the level of documentation required to "reconcile" codes and standards. A formal line by line reconciliation may not be appropriate for many SSC upgrades. "Best Practice" may be an adequate justification.

#### Clarification of Other Statements in Attachment 1 of RIS 2002-22

Section 3.2.2 of the staff's evaluation of NEI 01-01 (Attachment 1 of RIS 2002-22) the staff noted that "for some relatively simple digital equipment, engineering evaluations may show that the risk of failure due to software is not significant and need not be ~~considered~~ ~~evaluated~~ further, even in applications of high safety significance." At the time this statement was made, it was intended to refer to the sections within the staff guidance currently known as BTP 7-19, pertaining to the evaluation of simple digital equipment, such as embedded digital devices that may be found in actuating equipment. The NRC guidance at the time described simple as "the component function can be completely demonstrated by test." Subsequent revisions to BTP 7-19 (e.g., in, Section 1.9 of the current version) incorporated a more specific states that one design attribute that is sufficient to eliminate consideration of software-based or software logic-based CCF: "Testability – A system is sufficiently simple such that every possible combination of inputs and every possible sequence of device states are tested and all outputs are verified for every case (100% tested)." Recently, a RIS 2016-05, "Embedded Digital Devices in Safety-Related Systems" was made available that addresses the use of such simple digital devices. RIS 2016-05 states that the guidance in BTP 7-19 is helpful when considering postulated CCFs in systems with components containing EDDs in equipment performing safety-related system execute features. In this RIS, the staff clarifies that an adequately documented qualitative assessment, as described in Attachment 1 to this RIS, documenting the technical and qualitative basis (rationale) for concluding that simple digital systems and devices have been adequately tested is acceptable. This qualitative rationale may credit test results for all reasonably testable combinations of input states along with a documented technical justification that any states not practical to test are not expected to ever occur for the particular application.

Section 3.2.2 of the staff's evaluation of NEI 01-01 (Attachment 1 of RIS 2002-22) also states that the 10 CFR 50.59 rule does not require licensees to document the screening if there is no change to the facility or procedures described in the UFSAR. It also states that "Appendix B of the submittal, "Outline for Documenting 10 CFR 50.59 Screens and Evaluations," provides an outline that licensees may use to document their screenings. The staff has reviewed Appendix B

**Commented [vxf24]:** Editorial comment on nested quotations

and concludes that it provides useful guidance for licensees and recommends its use.” This RIS clarifies the statement regarding Appendix B of NEI 01-01. Specifically, the guidance in Appendix B should address the clarifications within this RIS regarding the appropriate documentation of qualitative assessments used for screening and evaluations, as described in Attachment 1 to this RIS.

**Commented [vxf25]:** This would be a useful area to discuss during a “tabletop” meeting, to align on expectations for using both Appendix B of NEI 01-01, and the new RIS Qualitative Assessment Guidance.

Section 3.2.3 of the staff’s evaluation of NEI 01-01 (Attachment 1 of RIS 2002-22) states:

The staff’s position regarding documentation of 10 CFR 50.59 evaluations is accurately reflected in the second paragraph in Appendix A to the submittal, which states: “The 10 CFR 50.59 questions should be answered in sufficient detail, either by reference to a source document or by direct statements, that an independent third party can verify the judgements.” The staff has reviewed Appendix A, “Supplemental Questions for Addressing 10 CFR 50.59 Evaluation Criteria,” and Appendix B, “Outline for Documenting 10 CFR 50.59 Screens and Evaluations,” and, based on the foregoing, concludes that the guidance therein is acceptable for licensees to use in performing and documenting their 10 CFR 50.59 evaluations.

This RIS clarifies the statement regarding Appendix A and Appendix B of NEI 01-01. Specifically, the documentation aspects described in the NEI 01-01 guidance in Appendix A and Appendix B should address the clarifications within this RIS regarding the appropriate documentation of qualitative assessments used for screening and evaluations, as described in Attachment 1 to this RIS.

**Commented [vxf26]:** Same comment as previous one regarding use of NEI 01-01 Appendices in conjunction with the new RIS.

#### **Resolution of Staff Concerns Regarding Licensee Interpretations of NEI 01-01 Criteria**

On November 5, 2013, the NRC issued a letter (ADAMS Accession No. ML13298A787) to NEI summarizing ~~eleven~~4 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 ~~twelfth~~12th concern.

**Commented [vxf27]:** Consider noting all 12 concerns and identifying which are addressed by this RIS, and which are not.

This section will contain the resolution of the 5 pertinent actionable staff concerns out of the 12 original concerns.

Within this RIS, the staff considers the concerns regarding adequate means for addressing the ~~evaluation~~ criteria in 10 CFR 50.59(c)(2) to be resolved for safety support systems, auxiliary 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 ML17XXXXXXX.)

## **BACKFITTING AND ISSUE FINALITY**

This RIS clarifies the NRC's technical position on existing regulatory requirements related to performing digital I&C modifications under the 10 CFR 50.59 process. The NRC staff position in the RIS does not represent a new or changed position with respect to the need for applicants and licensees to perform adequate 10 CFR 50.59 evaluations, or to comply with 10 CFR 50.55a(h), "Protection and Safety Systems;" 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants;" 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants;" and other NRC regulations and guidance. Therefore, this RIS does not represent backfitting, as defined in 10 CFR 10.109(a)(1), or 10 CFR 70.76, nor is it 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**

The NRC published a notice of opportunity for public comment on this RIS in the *Federal Register* (XX FR XXXXXX) on May XX, 2017. The Commission received comments from XXXXXXXXXXXX. The staff's resolution of those comments is publicly available under ADAMS Accession No. ML17XXXXXXXXX. The NRC published a notice of opportunity for public comment on the draft revised RIS in the *Federal Register* (XX FR XXXXXX) on May XX, 2017. The Commission received XX sets of comments as identified in the NRC staff's resolution of these comments in a publicly available document under ADAMS Accession No. ML17XXXXXXXXX. This RIS reflects the NRC staff's consideration of these comments.

## **CONGRESSIONAL REVIEW ACT**

The NRC has determined that this RIS is not a rule as designated by the Congressional Review Act (5 U.S.C. §§ 801-808) and, therefore, is not subject to the Act.

## **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 (OMB), approval numbers 3150-0035, 3150-0020, 3150-0011, 3150-0151, and 3150-0009.

## **Public Protection Notification**

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.

CONTACT

Please direct any questions about this matter to the technical contacts listed below or to the appropriate regional office.

Louise Lund, Director  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

John Lubinski, Director  
Division of Engineering  
Office of Nuclear Reactor Regulation

Robert Caldwell, Deputy Director  
Division of Engineering Infrastructure and  
Advanced Reactors  
Office of New Reactors

Brian Thomas, Director  
Division of Engineering  
Office of Nuclear Regulatory Research

Technical Contacts:

DRAFT

