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

November 25, 2002

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"

ADDRESSEES

All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to notify addressees that the NRC has reviewed 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," and is endorsing the report for use as guidance in designing and implementing digital upgrades to instrumentation and control systems. The attached safety evaluation documents the staff's basis for endorsing the report. 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 replaces 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.

Since the issuance of GL 95-02, several changes in the regulatory environment have affected the licensing of analog-to-digital and digital-to-digital replacements:

- The NRC expanded its regulatory review guidance in Revision 4 of Chapter 7 of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" (SRP), dated June 1997, to cover digital systems.

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- On October 4, 1999, the NRC published a final rule amending 10 CFR 50.59, "Changes, Tests, and Experiments," to redefine the criteria for whether NRC review (i.e., a license amendment) is required before implementing certain plant changes. (The amended 10 CFR 50.59 became effective on March 13, 2001, 90 days after the issuance of applicable regulatory guidance.)

- On December 13, 2000, the NRC announced the availability of 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.

Recognizing the impact of these changes, EPRI, with support from NEI, convened a task force to update the original guidance contained in TR-102348-1993. The purpose of the revision is to assist licensees in designing and implementing digital replacements in a consistent manner.

ISSUE SUMMARY

The revision of 10 CFR 50.59 effective on March 13, 2001, uses evaluation criteria that are difficult to apply to software-based I&C systems. The EPRI/NEI Joint Task Force therefore included relevant supplemental guidance in the report. The EPRI/NEI Joint Task Force report serves as a road map through existing regulatory requirements for the design and implementation of digital upgrades to I&C systems. The report also provides supplemental guidance on the use of NEI 96-07 for digital upgrades to I&C systems.

The NRC staff has reviewed this report and has concluded that it provides suitable guidance both for designing a digital replacement and for determining whether it can be implemented under 10 CFR 50.59 without prior staff approval. The staff's evaluation of the report is attached to this RIS. Note that statements in the evaluation qualify the NRC staff's endorsement of the report and provide staff positions on several aspects of the design and licensing processes. In particular, the staff believes 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 when 10 CFR 50.59 criteria are applied.

The staff's evaluation of the EPRI/NEI Joint Task Force report is based on staff guidance provided in U.S. NRC Standard Review Plan, NUREG-0800, Chapter 7, "Instrumentation and Controls," Revision 4, June 1997, and on experience gained from the three digital systems (platforms) that the NRC has reviewed and generically qualified for use in safety applications in nuclear power plants. The staff has determined that its acceptance of the EPRI/NEI report does not involve any new staff position or interpretation.

BACKFIT DISCUSSION

This RIS requires no action or written response. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment was not published in the *Federal Register* because this RIS is informational.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not request any information collection.

If you have any questions about this matter, please contact the person listed below.

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Attachments:
1. Safety Evaluation
2. List of Recently Issued NRC Regulatory Issue Summaries

REVIEW AND EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION OF THE EPRI/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"

1.0 INTRODUCTION

By letter dated March 15, 2002, the Nuclear Energy Institute (NEI) submitted a 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," for review by the Nuclear Regulatory Commission (NRC). This report replaces the original version of TR-102348, dated December 1993, which the NRC endorsed as stated in Generic Letter 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.

Since GL 95-02 was issued, several changes in the regulatory environment have affected the licensing of analog-to-digital and digital-to-digital replacements. Recognizing the impact of these changes, the Electric Power Research Institute (EPRI), with support from NEI, convened a task force to update the original guidance in TR-102348-1993 to reflect the following changes in the regulatory environment:

- The NRC expanded its regulatory review guidance in Revision 4 of Chapter 7 of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" (SRP), dated June 1997, to cover digital systems.

- On October 4, 1999, the NRC published a final rule amending 10 CFR 50.59, "Changes, Tests, and Experiments," to redefine the criteria for whether NRC review (i.e., a license amendment) is required before implementing certain plant changes. (The amended 10 CFR 50.59 became effective on March 13, 2001, 90 days after the issuance of applicable regulatory guidance.)

- On December 13, 2000, the NRC announced the availability of 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.

The stated reason for revising the guidance is to assist licensees in designing and implementing digital replacements in a consistent and comprehensive manner. This includes providing guidance for the following activities:

- Carry out the design and implementation process for digital replacements in a manner that ensures regulatory requirements and good engineering practices are followed.

- Perform evaluations to comply with the requirements in 10 CFR 50.59.

- Prepare a license amendment request (LAR) when the 10 CFR 50.59 evaluation indicates that prior NRC review is required before implementing plant changes.

- Comply with other regulatory requirements pertaining to digital replacements in nuclear power plants.

By letter dated July 24, 2001, the submitters provided a draft of the proposed revision. The staff studied the draft version and provided questions and comments. These questions and comments were discussed at length in a public meeting at NRC headquarters in Rockville, Maryland, on October 11, 2001, in an effort to reach consensus on important issues. The submittal reflects the discussion at that meeting.

2.0 BACKGROUND

2.1 Regulatory Framework

The regulatory framework for this evaluation consists of (1) the requirements outlined in SRP Chapter 7 for the licensing process for digital I&C components in nuclear power plants and (2) the requirements for implementing digital replacements under the 10 CFR 50.59 rule.

Because the guidance in the submittal touches on all aspects of the digital replacement process, the regulatory framework for the evaluation of the changes to TR-102348-1993 encompasses the entire licensing process as it applies to digital I&C components in nuclear power plants. This framework consists of the technical requirements of 10 CFR Part 50, especially 10 CFR Part 50, Appendix A, “General Design Crieteria for Nuclear Power Plants,” and 10 CFR 50.55a(h), “Protection and safety systems.” The staff uses the regulatory guides and the endorsed industry codes and standards as the basis for evaluating conformance to the NRC's regulations. SRP Table 7-1, "Acceptance Criteria and Guidelines for Instrumentation and Control Systems Important to Safety," lists the acceptance criteria and guidelines applicable to I&C systems that are important to safety. The submittal does not propose alternative or less conservative guidance for meeting the existing regulatory requirements for digital replacements.

The 10 CFR 50.59 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 (UFSARs) without prior NRC approval. The NRC revised the rule, effective in 2001, to redefine the criteria for whether prior NRC review is required before implementing such changes. The objectives of 10 CFR 50.59 are to ensure that licensees (1) evaluate the effects of certain proposed changes to their facilities, as described in the UFSAR, and (2) obtain prior NRC approval for changes that are found under the specified criteria to potentially impact the basis for issuing the operating license.

2.2 Submitters' Rationale for Revising EPRI TR-102348-1993

The intent of TR-102348-1993 was (and the intent of the revision is) to help licensees design and implement digital replacements, perform 10 CFR 50.59 evaluations, and develop information to support LARs. The submittal supplements NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," by proposing ways to address and resolve digital-specific issues in the design and evaluation process. The proposed risk management approach is based on failure analysis and addresses digital-specific issues and other possible failure causes, according to their potential effects at the system level. The submittal also clarifies the treatment of potential software-related common-cause failures and the use of defense-in-depth and diversity evaluations to confirm that adequate backups exist where needed.

Since EPRI issued TR-102348-1993, the NRC has revised 10 CFR 50.59. In addition, other changes in the regulatory environment have affected the licensing of digital replacements. The revisions to TR-102348-1993 were based on the following principles:

- The existing licensing process, including 10 CFR 50.59, applies to digital replacements. TR-102348-1993 has been updated to reflect the revised 10 CFR 50.59 rule and the industry guidance for implementing this rule (i.e., NEI 96-07, Revision 1, which was endorsed by RG 1.187).

- The issues associated with digital replacements should be addressed in the context of their potential impact on the system being modified, reflecting the state of the system after the proposed replacement is integrated with and installed in the plant. This approach focuses attention on the system functions that are important to the safe and reliable operation of the plant and on how these functions can be affected by potential failures of the digital equipment. A failure analysis with an appropriate level of detail is needed to properly assess the potential for and impact of failures.

- The submittal is intended to provide a road map to relevant industry standards, guidelines, reports, regulatory requirements, and other documents that can be used to address digital replacement issues.

The guidance in the submittal is intended to apply to 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. It also applies to digital-to-digital replacements.

3.0 EVALUATION

In its review of the submittal, the staff has applied the above regulatory framework to ensure that the guidance offered therein (1) conforms to the requirements of 10 CFR Part 50 and currently endorsed guidance for implementing digital replacements that is not different from or less conservative than the guidance of the existing licensing framework, and (2) conforms to the requirements of 10 CFR 50.59 and the guidance in RG 1.187.

3.1 The Submittal as Guidance for Designing Digital I&C Replacements

The staff has reviewed the submittal with regard to the present requirements for implementing digital replacements of I&C systems that are important to safety in nuclear power plants, and, as set forth below, finds that its guidance is consistent with the existing NRC-endorsed guidance for digital I&C in safety systems in nuclear power plants.

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.

Because there is currently no acceptable way to quantitatively establish the reliability of digital systems, the submittal gives considerable attention to the qualitative assessment of the dependability of and risk associated with I&C systems. The guidance in the submittal identifies qualitative approaches within existing endorsed guidance with regard to software issues, including software-related common-cause failure issues, without proposing alternatives to the existing guidance. Therefore, the guidance in the submittal does not propose to alter, or offer less conservative guidance for, the existing licensing process for LARs to implement digital replacements.

Although the staff has endorsed many of the documents cited in the submittal as acceptable guidance for meeting the applicable regulatory requirements, it is noted that many other cited documents have not been reviewed or endorsed. Licensees may use unendorsed guidance with caution, but it is each licensee’s responsibility to demonstrate that the resulting designs meet regulatory requirements.

The staff has reviewed the submittal and finds that the guidance it provides is in conformance with the requirements of 10 CFR Part 50, including Appendix A and 10 CFR 50.55a(h). The submittal cites the regulatory guides and endorsed industry codes and standards that are referenced in Chapter 7 of the SRP. The staff uses these guidelines for evaluating conformance to the NRC's regulations. On this basis, the staff concludes that licensees can use the submittal as guidance for designing digital replacements in I&C systems that are important to safety in nuclear power plants.

3.2 The Submittal as Guidance for Licensing Digital I&C Replacements

After determining that a proposed change is safe and effective, licensees decide how to implement the change. The 10 CFR 50.59 process is one means for the licensee to implement such a change without prior NRC approval, if the replacement does not involve a change to the technical specifications (TSs) or is not controlled by some other regulatory requirement.

3.2.1 Guidance on More Specific Regulations and Changes to the Technical Specifications

The submittal refers licensees to the guidance in NEI 96-07, Revision 1, which the staff endorsed in RG 1.187, for guidance on the issue of whether a more specific regulation applies to a given change. On this basis, the staff concludes that this guidance is acceptable.

The guidance in the submittal regarding a licensee's review of changes to the TSs is unchanged from that in TR-102348-1993, which the staff endorsed in GL 95-02. On this basis, the staff concludes that this guidance is acceptable.

3.2.2 10 CFR 50.59 Screening of Digital I&C Replacements

The first step in 10 CFR 50.59 screening is to determine whether the change affects a design function described in the UFSAR. If not, a licensee may implement the change without conducting a 10 CFR 50.59 evaluation (i.e., the change "screens out"). By contrast, if the change does affect a design function described in the UFSAR (i.e., the change "screens in"), the licensee must evaluate the change pursuant to 10 CFR 50.59(c)(2).

The screening guidance for digital I&C components and systems in the submittal supplements the screening guidance in NEI 96-07, Revision 1. This supplemental guidance is offered because the new 10 CFR 50.59 rule uses criteria that can be difficult to apply to software-based systems for which there is minimal precedent. For example, there is no consensus method for determining the likelihood of a malfunction of software-based systems. The staff finds that the examples in the submittal offer useful guidance for the screening process, but the licensee must not substitute those examples for adequate engineering analysis applicable to the specific proposed change. Rather, each licensee must conduct its own 10 CFR 50.59 screening evaluation specific to the plant under consideration, and the design must conform to the applicable regulatory framework.

Section 4.3.2 of the submittal states that consensus methods have been developed for evaluating the dependability of digital equipment, including the potential for common-cause failure attributable to software. In Section 5.1.3, the submittal further states: "However, there are no established consensus methods for accurately quantifying reliability of software. Consequently, software failure analysis typically involves making qualitative judgements regarding the dependability of the system." Thus the statement in Section 4.3.2 should not be taken to imply that consensus methods have been developed to *quantify* the reliability or dependability of digital equipment. It is the staff's position that there are no established consensus methods for accurately *quantifying* the reliability and dependability of digital equipment.

The screening guidance and examples in the submittal rely heavily on a correct assessment of dependability. As used in the submittal, dependability is a broad concept that incorporates various characteristics of digital equipment, including reliability, safety, availability, and maintainability. The assessment and documentation of the dependability of a proposed digital replacement are part of the design process. Two key elements of the engineering assessments are (1) evaluating the dependability of the digital equipment and its associated software and (2) analyzing potential failures.

Software failure analysis typically involves making qualitative judgements of the dependability of the system or using conservative bounding levels for failure probability, as appropriate. Section 4.3.2 of the submittal points out that with respect to screening digital replacements, one important question is whether the software has adverse effects on a design function described in the UFSAR. An adverse effect may be the potential marginal increase in likelihood of failure as a result of introducing the software. For redundant safety systems, this marginal increase in likelihood creates a similar marginal increase in the likelihood of a common failure in redundant

channels. The submittal states: "On this basis, most digital upgrades to redundant safety systems should be conservatively treated as 'adverse' and screened in for further evaluation under the 10 CFR 50.59 process." This statement reflects the staff's position that most digital replacements to redundant safety systems should be conservatively treated as adverse and screened in for further evaluation. However, 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 evaluated further, even in applications of high safety significance.

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. However, 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 and concludes that it provides useful guidance for licensees and recommends its use.

On the basis of its review of the submittal, the staff concludes that the submittal guidance provides a reasonable method for determining if a digital replacement results in a change to the facility or procedures described in the UFSAR that would be governed by 10 CFR 50.59 and, therefore, is acceptable.

3.2.3 10 CFR 50.59 Evaluation of Digital I&C Replacements

If the screening process shows that a proposed change would affect a design function described in the UFSAR, the licensee is required to conduct a 10 CFR 50.59 evaluation to determine whether the design requires a TS change or satisfies the criteria defined in 10 CFR 50.59(c)(2). Section 4.3 of NEI 96-07, Revision 1, lists the eight 10 CFR 50.59 evaluation criteria and provides guidance on each. If the evaluation shows that the proposed change meets one of the criteria, the licensee must submit the proposed design change in a LAR.

In Section 4.4, "10 CFR 50.59 Evaluation," the submittal again lists the eight 10 CFR 50.59 evaluation criteria and provides additional guidance with regard to digital replacements. This section of the submittal received considerable attention at the public meeting in October 2001, and the submitters made several additions to Section 4.4 to reflect the consensus of the participants at the meeting. Appendices A and B have also been added since the October 2001 meeting. The staff reviewed the guidance in the submittal against the requirements of 10 CFR 50.59(c)(2) and the guidance in NEI 96-07, Revision 1.

Licensees are required under 10 CFR 50.59 to maintain records that "include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license amendment." Because such judgments may be difficult to duplicate and understand at a later time, it is the staff's position that the basis for the engineering judgment and logic used in the determination should be documented to the extent practicable. This type of documentation is of particular importance in areas where no established consensus methods are available, such as software reliability, dependability of digital systems, and the use of commercial-grade hardware and software that lacks full documentation of the design process.

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.

The guidance in the submittal has two main parts, including (1) guidance through the existing regulatory requirements and NRC-endorsed guidance documents for designing digital replacements and (2) guidance through the process for licensing the replacement, including the 10 CFR 50.59 evaluation. In Figure 3-1, "The Digital Upgrade Process," the submittal gives an overview of the full digital replacement process and shows how the parts work together to achieve an acceptable result. Figure 3-1 also indicates the sections of the submittal in which the licensee should look for guidance on each activity. Figure 3-1 contains many blocks, but only the block in the lower right corner (i.e., "Licensing Process and 10 CFR 50.59") lists the activities that relate to the 10 CFR 50.59 evaluation process. However, the 10 CFR 50.59 evaluation process depends upon the documentation records of the design process and the engineering judgments in many of the other blocks in Figure 3-1. Without the documentation, there may exist no basis for the evaluations called for in the 10 CFR 50.59 evaluation process. Therefore, it is important that judgments on dependability, the likelihood of failures, and the significance of identified potential failures be documented in the failure analysis documentation.

On the basis of the foregoing review, the staff concludes that the submittal is acceptable with regard to the 10 CFR 50.59 evaluation requirements.

3.2.4 Human Factors

The staff has reviewed the submittal and finds that it satisfactorily incorporates the staff's previous comments and the input from the October 2001 meeting and that it adequately addresses human-factors-related concerns for digital replacements and, therefore, is acceptable.

The staff observes that NUREG-0700 (Reference 9 in the submittal) should be cited as Revision 2, May 2002, and NUREG-0711 (Reference 10 in the submittal) should be cited as Revision 1, May 2002. These are the current versions of these documents.

3.2.5 Defense-in-Depth and Diversity

The definition of common-cause failures remains unchanged from the original version of TR-102348. Section 2, "Definitions and Terminology," states: "Common-cause failures in redundant systems compromise safety if the failures are concurrent failures, that is, failures that occur over a time interval during which it is not plausible that the failures would be corrected."

The issue of defense-in-depth and diversity has evolved considerably since TR-102348-1993 was endorsed by GL 95-02. The staff has reviewed the submittal and finds that its guidance with regard to defense-in-depth and diversity refers to the appropriate current regulatory requirements and guidance and, therefore, is acceptable.

3.2.6 Security Considerations

In response to the staff's request at the October 2001 meeting, the submitters added Section 5.3.4.5, "Security Considerations." This section directs licensees to sections in the SRP and endorsed industry standards that address regulatory requirements and guidance for security issues. The staff has reviewed Section 5.3.4.5 and concludes that it cites the appropriate regulatory requirements and NRC-endorsed guidance and, therefore, is acceptable.

4.0 CONCLUSION

On the basis of its review (described above), the staff finds that the design guidance in the submittal is in accordance with the requirements of 10 CFR Part 50, including Appendix A and 10 CFR 50.55a(h). The staff also finds that the guidance conforms to the criteria for determining whether a digital replacement can be implemented under the 10 CFR 50.59 rule without prior staff approval. Consequently, the staff concludes that licensees can use the submittal as guidance both for designing a digital replacement and for determining whether the replacement can be accomplished under the 10 CFR 50.59 rule without prior staff approval. However, 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.