U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE 1.187, Revision 3

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GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59, "CHANGES, TESTS, AND EXPERIMENTS"

A. INTRODUCTION

Purpose

This regulatory guide (RG) provides licensees with a method that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for use in complying with the NRC's regulations on the process by which licensees, under certain conditions, may make changes to their facilities and procedures as described in the final safety analysis report (FSAR) (as updated) (also referred to as the updated final safety analysis report (UFSAR)), and conduct tests or experiments not described in the FSAR (as updated) without obtaining a license amendment pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.90, "Application for amendment of license, construction permit, or early site permit."

Applicability

This RG applies to each holder of an operating license issued under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 1), or a combined license issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 2), including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under 10 CFR 50.82(a)(1) or 10 CFR 50.110 or a reactor licensee whose license has been amended to allow possession of nuclear fuel but not operation of the facility.

Applicable Regulations

- 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," provides regulations for licensing production and utilization facilities.

Written suggestions regarding this guide or development of new guides may be submitted through the NRC's public Web site in the NRC Library at https://nrcweb.nrc.gov/reading-rm/doc-collections/reg-guides/, under Document Collections, in Regulatory Guides, at https://nrcweb.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.

Electronic copies of this RG, previous versions of RGs, and other recently issued guides are also available through the NRC's public Web site in the NRC Library at https://nrcweb.nrc.gov/reading-rm/doc-collections/reg-guides/, under Document Collections, in Regulatory Guides. This RG is also available through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under ADAMS Accession Number (No.) ML21109A002. Revision 2 of RG 1.187 was issued in June 2020 with a post-promulgation comment period. The regulatory analysis for Revision 2 of RG 1.187 may be found in ADAMS under Accession No. ML19045A432. Draft guide DG-1356, associated with Revision 2 of RG 1.187, may be found in ADAMS under Accession No. ML19045A435, and the staff responses to the public comments on DG-1356 may be found under ADAMS Accession No. ML20125A729. The staff responses to the post-promulgation public comments on RG 1.187, Revision 2, may be found under ADAMS Accession No. ML21109A001.

- 10 CFR 50.59, "Changes, Tests, and Experiments," contains requirements for the process by which licensees, under certain conditions, may make changes to their facilities and procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated), without obtaining a license amendment pursuant to 10 CFR 50.90.

- 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit," contains the requirements for applicants requesting an amendment to a license or permit under 10 CFR Part 50 or 10 CFR Part 52.

- 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," in the Appendices containing certified designs, Section VIII.B, "Processes for Changes and Departures," provides the process by which applicants and holders of combined licenses may, under certain conditions, make changes to the Tier 2 information for their facilities and procedures as described in the plant-specific Design Control Document (as updated), without prior NRC approval. Under 10 CFR 52.98, FSAR (as updated) information not in Tier 2 is governed by 10 CFR 50.59.

- 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants" (Ref. 3), governs the issuance of renewed operating licenses and renewed combined licenses for nuclear power plants licensed pursuant to Sections 103 or 104b. of the Atomic Energy Act of 1954, as amended, and Title II of the Energy Reorganization Act of 1974.

Related Guidance

- Nuclear Energy Institute (NEI) 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation" (Ref. 4), provides industry guidance on the implementation of 10 CFR 50.59, as discussed in this RG. The appendices listed below provide additional guidance on implementation of 10 CFR 50.59 for selected topics.

  - Nuclear Energy Institute (NEI) 96-07, Appendix A, "Text of 10 CFR 50.59," dated November 2000 (Ref. 5). Appendix A is the text of the 10 CFR 50.59 rule as it existed in November 2000 and has not been updated for the revisions to 10 CFR 50.59 issued in 2001 and 2007.

  - NEI 96-07, Appendix B, "Guidelines for 10 CFR 72.48 Implementation," dated March 5, 2001 (Ref. 6). RG 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments" (Ref. 7), through its endorsement of NEI 96-07, Appendix B, provides guidance for licensees of independent spent fuel storage installations (ISFSIs) or spent fuel storage system design certificate holders in conducting changes, tests, and experiments to their facilities. On June 2, 2020, the NRC staff published draft guide (DG)-3054, "Guidance for Implementation of 10 CFR 72.48, "Changes, Tests, and Experiments," (Ref. 8) for comment that proposed the endorsement of NEI 12-04, Revision 2, "Guidelines for 10 CFR 72.48 Implementation," in place of Appendix B. On September 28, 2020, the NRC staff published RG 3.72, Revision 1 (final version of DG-3054), which endorsed NEI 12-04, Revision 2, in place of NEI 96-07, Appendix B.
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  - NEI 96-07, Appendix C, Revision 0 - Corrected, "Guideline for Implementation of Change Control Processes for New Nuclear Power Plants Licensed under 10 CFR Part 52," dated March 2014 (Ref. 9). NRC Letter to NEI Russell J. Bell, "Acceptance for Endorsement of Nuclear Energy Institute 96-07, Appendix C, Revision 0 - Corrected:

Guideline for Implementation of Change Control Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52," dated July 2, 2014 (Ref. 10), states that NRC finds NEI 96-07, Appendix C, "acceptable for use by licensees during formal NRC endorsement via the NRC's regulatory guide process."

- NEI 96-07, Appendix D, Revision 1, "Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications," May 2020 (Ref. 11). Appendix D provides focused application of the 10 CFR 50.59 guidance to activities involving digital instrumentation and control (I&C) modifications and is endorsed in this guide (RG 1.187 Revision 3), with clarifications.

- NEI 96-07, Appendix E, "User's Guide for NEI 96-07, Revision 1, 'Guidelines for 10 CFR 50.59 Implementation,'" October 2011 (Ref. 12). Appendix E was issued by NEI without request for NRC endorsement and provides focused guidance for specific 10 CFR 50.59 related topics that are commonly encountered. It is not publicly available in the NRC document control system.

Purpose of Regulatory Guides

The NRC issues RGs to describe methods that are acceptable to the staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses. Regulatory guides are not NRC regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 50, 52, and 54 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0011, 3150-0151, 3150-0155 respectively. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch, (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0011, 3150-0151, and 3150-0155), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov.

Public Protection Notification

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

B. DISCUSSION

Reason for Revision

Revision 2 of RG 1.187 (Ref. 13) was issued in June 2020 with a post-promulgation comment period. Revision 2 provided guidance on complying with the requirements of 10 CFR 50.59 when performing a digital I&C modification. Specifically, the revision found that NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations," Appendix D, Revision 1, "Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications," dated May 2020 (Ref. 11), provided an acceptable approach for complying with 10 CFR 50.59 when conducting digital I&C modifications, with certain clarifications. In response to the comments received in the revision 2 post-promulgation comment period, this revision of RG 1.187 (Revision 3) adds an additional clarification in section C.2.e related to the Human Factors Engineering (HFE) screening examples in NEI 96-07, Appendix D, Revision 1, that discuss an increase in response time.

Background

Under 10 CFR 50.59, licensees are allowed to make changes in the facility and procedures as described in the FSAR (as updated) and conduct tests or experiments not described in the FSAR (as updated), without obtaining a license amendment pursuant to § 50.90 provided specific criteria are met. Following the NRC issuance of a 1999 revised rule for 10 CFR 50.59 in Volume 64 of the *Federal Register* (64 FR 53582; October 4, 1999) (Ref. 14), NEI submitted a guidance document to the NRC for review for the implementation of 10 CFR 50.59. In November 2000, the NRC issued RG 1.187 (Revision 0), "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments" (Ref. 15), to endorse NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation."

Following issuance of RG 1.187, Revision 0, the NRC promulgated two rules that affected 10 CFR 50.59, in 2001 (66 FR 64737; December 14, 2001) (Ref. 16) and 2007 (72 FR 49352; August 28, 2007) (Ref. 17). The 2001 rulemaking revised Section 50.59(b) to correct minor errors in the regulatory text. The 2007 rulemaking amended 10 CFR Part 52 and made associated conforming changes to 10 CFR 50.59(b), and 50.59(d)(2) and (3). The rulemakings caused portions of NEI 96-07, Revision 1, to be obsolete. In particular, the text of 10 CFR 50.59 in Appendix A to NEI 96-07, Revision 1, "Text of 10 CFR 50.59" was no longer current, and NEI 96-07, Revision 1, pre-dates the current version of 10 CFR Part 52.

On May 30, 2019 (84 FR 25077), the NRC issued RG 1.187, Revision 1 (Ref. 18), that clarified certain statements in NEI 96-07, Revision 1, Section 4.3.5, regarding the meaning of "accidents of a different type," and Section 4.3.8 regarding the definition of "departure from a method of evaluation." In the same notice (84 FR 25077), the NRC also issued proposed Revision 2 of RG 1.187 as draft guide (DG)-1356, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests and Experiments'" (Ref. 19) to endorse, with certain exceptions and additions, NEI 96-07, Appendix D, Revision 0, dated January 8, 2019 (Ref. 20). A subsequent revision of NEI 96-07, Appendix D, Revision 1, "Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications," dated May 2020 (Ref. 11), resolved the issue addressed by the exception in DG-1356.

<u>Digital Modifications Background</u>

Modifications of I&C systems can involve installation of new systems or components that use digital technology, replacement of analog devices with digital technology, or updating existing digital equipment. Both the industry and the NRC have issued previous guidance, including the following, to

address a variety of issues that can arise from such modifications. By letter dated March 15, 2002, NEI submitted an Electric Power Research Institute (EPRI) report, "Guideline on Licensing Digital Upgrades EPRI TR-102348 Revision 1" (NEI 01-01) (Ref. 21), for the NRC staff's review. NEI 01-01 replaced the original version of EPRI TR-102348, issued December 1993 (Ref. 22), which the NRC endorsed in Generic Letter 1995-02, "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" (Ref. 23). On November 25, 2002, the NRC issued NRC Regulatory Issue Summary (RIS) 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'" (Ref. 24). RIS 2002-22 endorsed NEI 01-01 as guidance in designing and implementing digital upgrades to nuclear power plant I&C systems.

Following the NRC staff's 2002 endorsement of NEI 01-01 through RIS 2002-22, holders of operating licenses have used the guidance in support of digital I&C modifications in conjunction with RG 1.187, Revision 0, which endorses NEI 96-07, Revision 1. The NRC staff conducted inspection reviews of the documentation of digital I&C plant modifications prepared using the guidance in NEI 01-01 and identified inconsistencies in the performance and documentation of the engineering evaluations by some licensees. In addition, the NRC inspection reviews identified documentation issues with the written evaluations of the 10 CFR 50.59(c)(2) criteria.

In May 2018, the NRC issued RIS 2002-22, Supplement 1, "Clarification on Endorsement of Nuclear Energy Institute Guidance in Designing Digital Upgrades in Instrumentation and Control Systems" (Ref. 25), to clarify RIS 2002-22 and provide additional guidance in the areas that were the subject of the NRC inspection findings. The NRC continues to endorse NEI 01-01, as stated in RIS 2002-22, Supplement 1. The guidance in RIS 2002-22, Supplement 1 clarifies the NRC staff's endorsement of NEI 01-01, Sections 4 and 5, and Appendices A and B. Specifically, RIS 2002-22, Supplement 1 clarifies the guidance for preparing and documenting "qualitative assessments" that can be used to evaluate the likelihood of failure of a proposed digital modification, including the likelihood of failure due to a common cause (i.e., common-cause failure (CCF)).

Consideration of International Standards

The International Atomic Energy Agency (IAEA) works with member states and other partners to promote the safe, secure, and peaceful use of nuclear technologies. The IAEA develops Safety Requirements and Safety Guides for protecting people and the environment from harmful effects of ionizing radiation. This system of safety fundamentals, safety requirements, safety guides, and other relevant reports, reflects an international perspective on what constitutes a high level of safety. To inform its update of this RG, the NRC considered IAEA Safety Requirements and Safety Guides pursuant to the Commission's International Policy Statement (Ref. 26) and Management Directive and Handbook 6.6, "Regulatory Guides" (Ref. 27). The NRC staff did not identify any IAEA Safety Requirements or Guides with information related to the topic of this RG.

Documents Discussed in Staff Regulatory Guidance

This RG endorses the use of a third-party guidance document, NEI 96-07, Revision 1. This third-party guidance document may contain references to other codes, standards, or third-party guidance documents that the NRC refers to as secondary references. If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the

secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a RG, then the secondary reference is neither a legally binding requirement nor a generic, NRC-approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

1. NEI 96-07, Revision 1

The NRC staff endorses the guidance in NEI 96-07, Revision 1, as generally acceptable for use as a means for complying with the requirements in 10 CFR 50.59. However, the NRC staff provides clarification to certain statements in NEI 96-07, Revision 1 as discussed below.

a. Section 4.3.8 of NEI 96-07, Revision 1, provides the following as one of several examples of changes that "are not considered departures from a method of evaluation described in the UFSAR":

> Use of a methodology revision that is documented as providing results that are essentially the same as, or more conservative than, either the previous revision of the same methodology or another methodology previously accepted by NRC through issuance of an SER.

The regulation allows licensees to document a methodology revision either (1) as a change to any of the elements of the methodology described in the UFSAR (i.e., paragraph 50.59(a)(2)(i) of the departure definition), or (2) as a change from the methodology described in the UFSAR to another method (i.e., paragraph of the 10 CFR 50.59(a)(2)(ii) departure definition). If a methodology revision is documented as a change from the methodology described in the UFSAR to another method using paragraph 10 CFR 50.59(a)(2)(ii) of the departure definition, then paragraph 10 CFR 50.59(a)(2)(i) of the departure definition (i.e., "the results of the analysis are conservative or essentially the same") is not applicable.

b. Section 4.3.5 of NEI 96-07, Revision 1, states, in part:

> Certain accidents are not discussed in the UFSAR because their effects are bounded by other related events that are analyzed. For example, a postulated pipe break in a small line may not be specifically evaluated in the UFSAR because it has been determined to be less limiting than a pipe break in a larger line in the same area. Therefore, if a proposed design change would introduce a small high energy line break into this area, postulated breaks in the smaller line need not be considered an accident of a different type.

The last sentence of Section 4.3.5 of NEI 96-07, Revision 1, states, "Accidents of a different type are credible accidents that the proposed activity could create that are not bounded by UFSAR-evaluated accidents."

The UFSAR evaluates a broad spectrum of transients and accidents or initiating events. Accidents are categorized by type based on their effects on the plant. For example, one type of accident will cause the reactor coolant system (RCS) to pressurize and possibly jeopardize RCS integrity. Categorizing accidents by type provides a basis for comparison between events, which makes it possible to identify and evaluate the limiting cases (i.e., the cases that can challenge the analysis acceptance criteria) and eliminate non-limiting cases from further consideration. To assist in identifying accidents of a different type, consider that plant UFSAR analyses were based on credible failure modes of existing equipment and determine whether a proposed modification would change the basis for the most limiting scenario. Accidents that are not limiting cases are not discussed in the UFSAR.

An accident of a different type is any new accident, distinct from any previously evaluated in the UFSAR but of similar frequency and significance. A different accident analysis, not simply a revision of an existing analysis, would be needed for this different type of accident.

c. **Other Documents and Examples Referenced in NEI 96-07, Revision 1**

As stated above in Section B, "Documents Discussed in Staff Regulatory Guidance," Revision 1 of NEI 96-07 references other documents, but NRC's endorsement of Revision 1 of NEI 96-07 should not be considered an endorsement of the referenced documents. Additionally, Revision 1 of NEI 96-07 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in Revision 1 of NEI 96-07, the NRC's endorsement of Revision 1 should not be considered a determination that the examples are applicable for all licensees. A licensee should ensure that an example is applicable to its particular circumstances before implementing the guidance as described in an example.

d. **Guidance for FSAR Supplements for License Renewal**

The guidance in Revision 1 of NEI 96-07 and in this RG is applicable to changes to information added to the FSAR in accordance with 10 CFR 54.21(d) (i.e., for summary descriptions of the programs and activities for managing the effects of aging and the evaluation of time-limited aging analyses).

e. **Applicability to 10 CFR Part 50 Licensees other than Power Reactors**

While most of the examples and specific discussion focuses on power reactors, 10 CFR Part 50 licensees other than power reactors may use the guidance contained in Revision 1 of NEI 96-07. However, certain aspects of the guidance discuss regulatory requirements that may not fully apply to these licensees (e.g., Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants").

2. NEI 96-07, Appendix D, Revision 1

The NRC staff evaluated NEI 96-07, Appendix D, Revision 1, as applied to digital modifications only. The NRC has not reviewed Appendix D for generic application in the 10 CFR 50.59 process. In this context, the NRC staff endorses NEI 96-07, Appendix D, Revision 1, as a means for complying with the requirements of 10 CFR 50.59 when conducting digital I&C modifications, subject to the following clarifications:

a. **Relationship to NEI 01-01**

NEI 96-07, Appendix D, Revision 1, states: "The guidance in this appendix supersedes the 10 CFR 50.59-related guidance contained in NEI 01-01/EPRI TR-102348, Guideline on Licensing of Digital Upgrades, and incorporates the 10 CFR 50.59-related guidance contained in Regulatory Issue Summary (RIS) 2002-22, Supplement 1, Clarification on Endorsement of Nuclear Energy Institute Guidance in Designing Digital Upgrades in Instrumentation and Control Systems." However, the NRC continues to find NEI 01-01 acceptable for use by NRC licensees, as described in RIS 2002-22, Supplement 1.

The staff position is that licensees have the option to use the 10 CFR 50.59 guidance provided in either NEI 01-01 or in NEI 96-07, Appendix D, Revision 1. However, NEI 96-07, Appendix D, Revision 1, does not describe, and this revision to RG 1.187 (Revision 3) does not endorse, applying select portions from both NEI 96-07, Appendix D, Revision 1, and the 10 CFR 50.59 guidance of NEI 01-01.

b. **Changes from NEI 96-07, Revision 1**

i. **Human-System Interface**

NEI 96-07, Appendix D, Revision 1, includes screening guidance for the Human-System Interface (HSI). Under NEI 96-07, Revision 1, Section 4.2.1.2, changes to HSI (previously called "man-machine interface") should automatically be screened in because such changes "fundamentally alter (replace) the existing means of performing or controlling design functions." In RIS 2002-22, Supplement 1, the NRC endorsed guidance in NEI 01-01 that contradicts the guidance in NEI 96-07, Revision 1, Section 4.2.1.2, with the following statement, "not all changes to the human-system interface fundamentally alter the means of performing or controlling design functions." Therefore NEI 01-01 advises that not all changes to HSI should automatically screen in. NEI included similar guidance on screening for HSI in NEI 96-07, Appendix D. The NRC staff acknowledges that aspect of Appendix D is thus not a change from existing guidance on digital interfaces but notes that it is a change from the guidance in NEI 96-07, Revision 1. The NRC staff agrees that changes to HSI may be screened as described in NEI 96-07, Appendix D, Revision 1.

ii. **Use of Acceptance Criteria as Evaluation Results**

NEI 96-07, Appendix D, Section 4.3.6, states: "if any existing safety analysis is no longer bounding (e.g., the revised safety analysis no longer satisfies the acceptance criteria identified in the associated safety analysis), then the proposed activity creates the possibility for a malfunction of an SSC [structure, system, or component] important to safety with a different result." Appendix D, Example 4-18, illustrates this concept by using satisfaction of an acceptance criterion to conclude that the change in that example does not create a possibility for an SSC malfunction with a different result.

NEI 96-07, Revision 1, Section 4.3.6, in contrast to Appendix D, does not refer to "acceptance criteria" for the purpose of determining whether a change creates the possibility of a malfunction of an SSC important to safety with a different result. Rather, the previously endorsed guidance in NEI 96-07, Revision 1, Section 4.3.6, states that "the types and results of failure modes of SSCs…should be identified," and "[a]ttention must be given to whether the malfunction was evaluated in the accident analysis at the component level or the overall system level." The NRC has now determined that, in addition to the existing guidance in NEI 96-07, Revision 1, licensees may consider whether all applicable acceptance criteria remain satisfied after a proposed change to demonstrate that no possibility for a malfunction with a different result has been created. Accordingly, whether a proposed change to an SSC creates a malfunction with a different result can be determined for the purposes of 10 CFR 50.59(c)(2), criterion (vi), by comparison to the applicable acceptance criteria (see clarification 2.d).

c. **Sufficiently Low Likelihood of Software Common Cause Failure**

RIS 2002-22 Supplement 1 is currently the only guidance the NRC has reviewed or endorsed as providing an acceptable technical basis to determine that the likelihood of software CCF is sufficiently low for the purpose of 10 CFR 50.59 evaluations and may be used in conjunction with NEI 96-07, Appendix D, Revision 1.

d. **Appendix D, Section 4.3.6, Step 6: Basic Assumptions and Acceptance Criteria**

NEI 96-07, Appendix D, Section 4.3.6, Step 6 includes new guidance for a two-prong test for determining whether a proposed change would create the possibility for a malfunction of an SSC important to safety with a different result as follows:

> For those design functions placed into [categories 1.b, 2.b, or 3 in Step 2], if any of the previous evaluations of involved malfunctions of an SSC important to safety have become invalid due to their basic assumptions no longer being valid (e.g., single failure assumption is not maintained), **or** if any existing safety analysis is no longer bounding (e.g., the revised safety analysis no longer satisfies the acceptance criteria identified in the associated safety analysis), then the proposed activity creates the possibility for a malfunction of an SSC important to safety with a different result. [Emphasis added.]

Failure of either prong of the test results in the need for a licensee to seek a license amendment to authorize the proposed change. This guidance is not provided in NEI 96-07, Revision 1, which does not discuss "basic assumptions" or "acceptance criteria" in this context. The NRC staff agrees that conforming to this guidance will ensure compliance with the requirement in 10 CFR 50.59(c)(2)(vi). However, the licensee will need to ensure that the existing safety analysis results can correctly be compared to the results of the analysis of the proposed change. To that end, the NRC staff provides the following clarifications.

The first prong of the test fails if the change would invalidate "basic assumptions" of the existing evaluations of involved malfunctions of an SSC important to safety. But Appendix D does not define "basic assumptions." Therefore, the NRC believes clarification of the meaning of "basic assumptions" as used in this test is warranted. From the context of NEI 96-07, Appendix D, Section 4.3.6, the term "basic assumptions" appears to relate to the validity of evaluations of malfunctions of modified SSCs for comparison to existing evaluations of malfunctions. However, departures from methods of evaluation are evaluated solely under 10 CFR 50.59(c)(2), criterion (viii), for which guidance is provided in NEI 96-07, Revision 1, Section 4.3.8.

In the context of this test, the NRC staff understands "basic assumption" to refer to design functions of SSCs assumed to be performed in demonstrating the adequacy of design, including certain design functions that, although not specifically identified in the safety analysis, are credited in an indirect sense. The guidance in Section 4.3.6. lists the single failure assumption as an example of a "basic assumption," however, there are others. Additional examples of "basic assumptions" include the assumptions (1) that credited plant and reactor protection system functions will be performed, (2) that credited engineered safety system functions will be performed, and (3) that credited plant system functions and associated instrumentation and controls functions will be performed.

The second prong of the test fails if "the existing safety analysis is no longer bounding" after the proposed change. The parenthetical in the second prong of the test refers to "acceptance criteria." NEI 96-07, Revision 1, Section 3.12, states "[s]afety analyses are those analyses or evaluations that demonstrate that acceptance criteria for the facility's capability to withstand or respond to postulated events are met." Accordingly, if a safety analysis concludes that all applicable acceptance criteria are met, then satisfaction of the acceptance criteria constitutes the results of the safety analysis. If the FSAR identifies more than one acceptance criterion as applicable to an SSC function, all the identified applicable acceptance criteria must be satisfied to demonstrate that the existing safety analysis is bounding for the proposed change.

Applicable acceptance criteria must be found in the licensee's FSAR. As NEI 96-07, Revision 1, Section 3.7 states, "The scope of the UFSAR includes its text, tables, diagrams, etc., as well as supplemental information explicitly incorporated by reference." Nonetheless, some FSARs may not clearly identify or specify acceptance criteria for a particular analysis. Recognizing that, in contrast to Example 4-18, acceptance criteria may not be directly stated in a licensee's FSAR, licensees may need to refer to supporting documents referenced in the FSAR. Further, the safety analysis may simply

conclude that the analyzed result of a postulated event is acceptable without reference to any criteria or without specifically using the term "acceptance criteria." For that reason, licensees should ensure they have correctly identified all applicable acceptance criteria for the event being analyzed for purposes of Section 4.3.6, Step 6. Comparison to existing acceptance criteria is possible only if all applicable acceptance criteria can be clearly identified in the FSAR, as described above. However, licensees may not use NRC regulations or any other documents outside their FSAR or licensing basis as a source of applicable acceptance criteria for the event analyzed in their FSARs because 10 CFR 50.59 requires a comparison to results in the FSAR. Note, however, that licensees may use such documents for other purposes, such as identifying design functions, as indicated in Appendix D.

e. Screening Examples that Discuss an Increase in Response Time

The NRC staff has two clarifications on the use of HFE evaluations in screening in Appendix D, Section 4.2.1.2. First, in Example 4-7, although the HFE evaluation determined there was an increase in response time for that example, the example also indicates that the change did not affect any design function related to response time. Therefore, the increase in response time identified by the HFE evaluation is not relevant to Example 4-7 because it does not affect, adversely or otherwise, any design function in Example 4-7. Although it may be unrealistic for an operator response time not to be related to a design function, with that clarification, Example 4-7 is consistent with the guidance.

Second, in Example 4-8, the HFE evaluation concluded that there is an increase in operator response time but screened out the change's effects on operator response. That conclusion could be misunderstood to mean that an increase in response time can screen out so long as the HFE evaluation concludes that the response remains "timely and comparable," which is not necessarily correct. As Section 4.2.1.2 of Appendix D indicates, an increase in time to respond will generally screen in as adverse. However, NEI 96-07, Revision 1, Section 4.2.1 includes an example (involving diesel generators) that illustrates a case in which an increase in response time can screen out.

In that diesel generator example, the UFSAR-described design function specifies a response time, and although the proposed change would increase the equipment response time, it would not result in a response time exceeding the design function response time. Although Example 4-8 does not indicate that it relies on the diesel generator example in NEI 96-07, Revision 1, the NRC staff believes that Example 4-8 would be valid if understood as applying the concept illustrated by the example in NEI 96-07, Revision 1, Section 4.2.1. Nonetheless, an HFE evaluation cannot show that an increase in response time is not adverse (screens out) in the absence of other information in the FSAR.

Example 4-8 is acceptable if it illustrates a case in which an increase in response time is not adverse because the new response time to accomplish design function (b) falls within (i.e., is bounded by) a design function response time specified in the UFSAR. Example 4-8 includes a design function response time and states "a response time requirement of the operator is credited." Although, Example 4-8 does not explicitly state that the credited design function response time is the basis for the not adverse conclusion, with that understanding of the example, the NRC staff concludes that Example 4-8 is acceptable.

D. IMPLEMENTATION

The NRC staff may use this regulatory guide as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this regulatory guide to support NRC staff actions in a manner that would constitute backfitting as that term is defined in 10 CFR 50.109, "Backfitting," and as described in NRC Management Directive 8.4 (Ref. 28), "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," nor does the NRC staff intend to use the guidance to affect the issue finality of an approval under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in Management Directive 8.4. If a licensee believes that the NRC is using this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in Management Directive 8.4.

REFERENCES [1]

1. *U.S. Code of Federal Regulations* (CFR), "Domestic Licensing of Production and Utilization Facilities," Part 50, Chapter 1, Title 10, "Energy" (10 CFR Part 50).

2. CFR, "Licenses, Certifications, and Approvals of Nuclear Power Plants," Part 52, Chapter 1, Title 10, "Energy" (10 CFR Part 52).

3. CFR, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," Part 54, Chapter 1, Title 10, "Energy" (10 CFR Part 54).

4. Nuclear Energy Institute (NEI) 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," November 2000, Washington, DC (ADAMS Accession No. ML003771157)[2]

5. NEI 96-07, Appendix A, "Text of 10 CFR 50.59," dated November 2000, Washington, DC (ADAMS Accession No. ML003771157).

6. NEI 96-07, Appendix B, "Guidelines for 10 CFR 10 CFR 72.48 Implementation," dated March 5, 2001, Washington, DC (ADAMS Accession No. ML010670023).

7. U.S. Nuclear Regulatory Commission (NRC), Regulatory Guide (RG) 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments," Washington, DC.

8. NRC, Draft Guide 3054, "Guidance for Implementation of 10 CFR 72.48, "Changes, Tests, and Experiments," May 2020, Washington, DC (ADAMS Accession No. ML19269B763).

9. NEI 96-07, Appendix C, "Guideline for Implementation of Change Control Processes for New Nuclear Power Plants Licensed under 10 CFR Part 52," Revision 0 - Corrected, dated March 2014, Washington, DC (ADAMS Accession No. ML14091A739).

10. NRC Letter to NEI Russell J. Bell, "Acceptance for Endorsement of Nuclear Energy Institute 96-07, Appendix C, Draft Revision 0: Guideline for Implementation of Change Control Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52," dated July 2, 2014, Washington, DC (ADAMS Accession No. ML14113A529).

11. NEI 96-07, Appendix D, Revision 1, "Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications," dated May 2020, Washington, DC (ADAMS Accession No. ML20135H168).

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1 Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html. The documents can also be viewed on line or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.

2 Publications from the Nuclear Energy Institute (NEI) are available at their Web site: http://www.nei.org/home or by contacting the headquarters at Nuclear Energy Institute, 1776 I Street NW, Washington DC 20006-3708; telephone: 202-739-800; fax 202-785-4019.

12. NEI 96-07, Appendix E, "User's Guide for NEI 96-07, Revision 1, 'Guidelines for 10 CFR 50.59 Implementation,'" October 2011, Washington, DC (Not Publicly Available).

13. NRC, RG 1.187, Revision 2, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," June 2020, Washington, DC (ADAMS Accession No. ML20125A730).

14. 64 FR 53582, *Federal Register,* Volume 64, p. 53582, Washington, DC, October 4, 1999.

15. NRC, RG 1.187, Revision 0, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," November 2000, Washington, DC.

16. 66 FR 64737, *Federal Register*, Volume 66, p. 64737, Washington, DC, December 14, 2001.

17. 72 FR 49352, *Federal Register*, Volume 72, p. 49352, Washington, DC, August 28, 2007.

18. NRC, RG 1.187, Revision 1, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," May 2019, Washington, DC.

19. NRC, Draft Guide 1356, "Guidance for Implementation of 10 CFR 50.59, "Changes, Tests and Experiments," May 2019, Washington, DC (ADAMS Accession No. ML19045A417).

20. NEI 96-07, Appendix D, Revision 0, "Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications," dated January 2019, Washington, DC (ADAMS Accession No. ML19015A312).

21. NEI 01-01, Revision 0, "Electric Power Research Institute (EPRI) TR-102348, Revision 1, 'Guideline on Licensing Digital Upgrades,'" March 2002, Washington, DC (ADAMS Accession No. ML020860169).

22. Nuclear Utilities Management and Resource Council (NUMARC) and Electrical Power Research Institute (EPRI) NUMARC/EPRI Report TR-102348, "Guideline on Licensing Digital Upgrades," December 1993, Washington, DC (ADAMS Accession No. ML020860169).

23. NRC, Generic Letter 1995-02, "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," April 26, 1995, Washington, DC. (ADAM Accession No. ML031070081)

24. NRC, Regulatory Issue Summary (RIS) 2002-22, "Use of EPRI/NEI Joint Task Force Report, 'Guideline on Licensing Digital Upgrades'": EPRI TR-102348, Revision 1, NEI 01-01: A Revision of EPRI TR 102348 to Reflect Changes to the 10 CFR 50.59 Rule,'" November 25, 2002, Washington, DC (ADAMS Accession No. ML023160044).

25. NRC, RIS 2002-22, Supplement 1, "Clarification on Endorsement of Nuclear Energy Institute Guidance in Designing Digital Upgrades in Instrumentation and Control Systems," dated May 31, 2018, Washington, DC (ADAMS Accession No. ML18143B633).

26. NRC, "Nuclear Regulatory Commission International Policy Statement," Federal Register, Vol. 79, No. 132, July 10, 2014, pp. 39415-39418.

27. NRC, Management Directive (MD) 6.6, "Regulatory Guides," Washington, DC, May 2, 2016 (ADAMS Accession No. ML18073A170).

28. NRC, Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," Washington, DC.