U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE 1.187, Revision 2

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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 Commission'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 10 CFR 50.50.

Applicability

This RG applies to each holder of an operating license issued under Title 10 of the *Code of Federal Regulations* (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.
    - 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

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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.) ML20125A730. The regulatory analysis may be found in ADAMS under Accession No. ML19045A432. The associated draft guide DG-1356 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.

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.

  - 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. 8). 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. 9), 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. 10). 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 Rev. 2), with additions.

- NEI 96-07, Appendix E, "User's Guide for NEI 96-07, Revision 1, 'Guidelines for 10 CFR 50.59 Implementation,'" October 2011 (Ref. 11). 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 guidance for implementing the mandatory information collections in 10 CFR Parts 50 and 52 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), under control numbers 3150-0011 and 3150-0151. Send comments regarding this information collection to the Information Services 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 and 3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC20503; 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

This revision of RG 1.187 (Revision 2) provides guidance on complying with the requirements of 10 CFR 50.59 when performing a digital I&C modification. Specifically, this revision finds 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. 10), provides an acceptable approach for complying with 10 CFR 50.59 when conducting digital I&C modifications, with certain clarifications.

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. 12), 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. 13), to endorse NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," November 2000.

Following issuance of RG 1.187, Revision 0, the NRC promulgated two rules that affected 10 CFR 50.59, which were published in Volume 66 of the *Federal Register* (66 FR 64737; December 14, 2001) (Ref. 14), and Volume 72 of the *Federal Register* (72 FR 49352, August 28, 2007) (Ref. 15). 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), 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.

In May 2019, the NRC issued RG 1.187, Revision 1 (Ref. 16), 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 May 2019, 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. 17) to endorse, with certain exceptions, NEI 96-07, Appendix D, Revision 0, dated January 8, 2019 (Ref. 18). NEI submitted a final version of NEI 96-07, Appendix D, Revision 1, "Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications," dated May 2020 (Ref. 10), to the NRC that resolved the exceptions 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.

By letter dated March 15, 2002, NEI submitted the Electric Power Research Institute (EPRI) report, "Guideline on Licensing Digital Upgrades EPRI TR-102348 Revision 1," (NEI 01-01) (Ref. 19), for the NRC staff's review. NEI 01-01 replaced the original version of EPRI TR-102348, issued December 1993 (Ref. 20), which the NRC endorsed in Generic Letter 1995-02, "Use of NUMARC/EPRI Report TR-102348, 'Guideline of Licensing Digital Upgrades,' in Determining the Acceptability of Performing Analog-to-Digital Replacements under 10 CFR 50.59 (Ref. 21). 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 22). 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 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. 23), 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 that should be more consistently applied for documenting "qualitative assessments." The RIS Supplement also provides a technical basis that the NRC staff considers sufficient for concluding that a proposed digital modification will result in a "sufficiently low" likelihood of failure, including the likelihood of failure due to a common cause (i.e., common-cause failure (CCF)).

Harmonization with International Standards

The NRC has a goal of harmonizing its regulatory guidance with documents issued by the International Atomic Energy Agency (IAEA) to the extent practical. The NRC staff has reviewed the IAEA standards and guides and did not identify any documents with useful relevant information related to the topics in 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. 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. 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 2) does not endorse, applying select portions from both NEI 96-07, Appendix D, Revision 1 and 10 CFR 50.59 guidance of NEI 01-01. In addition, NEI 96-07, Appendix D, Revision 1 is applicable to digital modifications only and is not generically applicable to the 10 CFR 50.59 process.

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." The NRC has endorsed contradicting

guidance in NEI 01-01, which states, "not all changes to the human-system interface fundamentally alter the means of performing or controlling design functions," and therefore NEI 01-01 advises that not all changes to HSI should automatically screen in. NEI included similar guidance on screening for HSI in 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 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, Rev. 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, Rev. 1, provided that licensees should consider changes to SSCs at the same level at which malfunctions of the affected SSCs were previously evaluated in the FSAR (i.e., component- or system-level). The NRC has now determined that, in addition to consideration of component- and system-level effects, licensees may consider whether satisfaction of all applicable acceptance criteria are maintained 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 criterion (vi) by comparison to the applicable acceptance criteria (see clarification 2.d).

c. **Software Failure**

RIS 2002-22 Supplement 1, should be used in conjunction with NEI 96-07, Appendix D, Revision 1 to provide an acceptable technical basis to determine that the likelihood of software CCF is sufficiently low for the purpose of 10 CFR 50.59 evaluations.

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

Appendix D, Section 4.3.6, Step 6 includes a new 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:

> 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. As stated above, this is new guidance not already in NEI 96-07, Rev. 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). The NRC staff provides the following clarifications to assist licensees implementing this new guidance.

The primary concept behind this test is that if the existing safety analysis remains bounding of the proposed change, then a possibility for a different result would not be created. However, to ensure that the existing safety analysis can correctly be compared to the results of a new analysis for the proposed change, licensees will need to ensure that the existing methods of analysis remain valid, as approved by the NRC, both to conduct the new analysis and to compare the results.

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. This prong of the test addresses the applicability and validity of the methodology for the safety analysis in the existing FSAR as approved by the NRC. The guidance in Section 4.3.6. lists the single failure assumption as a type of "basic assumption," but does not otherwise define "basic assumption." NRC believes clarification of the meaning of this term is warranted.

In the context of this test, "basic assumption" refers to the assumptions delineating the scope of the method of evaluation for analyses in an FSAR (i.e., the range of applicability and validity of the methodology approved by the NRC), including all calculated inputs and uncertainties. To evaluate the proposed modification, the licensee needs to identify the methodology approved by the NRC in the existing FSAR and verify its applicability and validity. A "basic assumption" would no longer be valid if the malfunction resulted in a scenario beyond the scope of the method of evaluation, which could occur due to the introduction of a new phenomenon that was not previously modeled, or the use of the method of evaluation outside of the range of applicability approved by the NRC (e.g., the need to model a phenomenon in a different range than was considered during NRC approval). Further, for purposes of this guidance, "basic assumption" may include assumptions such as redundancy, diversity, and defense-in-depth in addition to the single failure assumption given in Section 4.3.6.

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, rev. 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. However, in many FSARs, acceptance criteria are not clearly identified or specified. 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. However, licensees may not use NRC regulations, the SRP, or any other documents outside their FSAR or licensing basis as a source of applicable acceptance criteria for the event analyzed in their FSAR because 10 CFR 50.59 requires a comparison to results in the FSAR.

Comparison to existing acceptance criteria is possible only if all applicable acceptance criteria can be clearly identified in the FSAR, as described above. Other methods remain available to complete a criterion (vi) evaluation, such as a component- or system-level evaluation. In any case, if the results of any existing safety analysis would not bound the results of a new malfunction, then the change creates the possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in an FSAR, and therefore would require a license amendment.

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. 24), "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. 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).

9. 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).

10. 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. ML 20129J857).

11. 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).

12. 64 FR 53582, *Federal Register,* Volume 64, p. 53582, Washington, DC, October 4, 1999.

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

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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.

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

15. 72 FR 49352, *Federal Register*, Volume 72, p. 49352, Washington, DC, August 28, 2007.

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