

U.S. NUCLEAR REGULATORY COMMISSION

DRAFT REGULATORY GUIDE DG-1356

Proposed Revision 2 to Regulatory Guide 1.187



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Technical Lead: Philip McKenna

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 prior NRC approval.

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

This RG is being issued in draft form to involve the public in the development of regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff position. Public comments are being solicited on this DG and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal rulemaking Web site, <http://www.regulations.gov>, by searching for draft regulatory guide DG-1356. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this DG, previous versions of DGs, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <https://nrcweb.nrc.gov/reading-rm/doc-collections/reg-guides/>. The DG is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML19045A435. The regulatory analysis may be found in ADAMS under Accession No. ML19045A432.

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). The 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, “Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications,” November 2018 (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 guidance, RG 1.187 Rev. 2, with exceptions and clarifications set forth below.

- 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 to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated events, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required 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: oir_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, the Nuclear Energy Institute (NEI) 96-07, “Guidelines for 10 CFR 50.59 Evaluations,” Appendix D, Revision 0, “Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications,” was submitted to the NRC on November 30, 2018. The NEI letter, “Request for NRC Endorsement of NEI 96-07, Appendix D, Rev. 0,” dated January 8, 2019 (Ref. 12) was received on January 8, 2019 requesting NRC staff endorsement. As discussed in Section C of this RG, the NRC staff concludes that Appendix D provides an acceptable approach for the application of 10 CFR 50.59 guidance when conducting digital instrumentation and control modifications, with certain exceptions and 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. 13), 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. 14), to endorse NEI 96-07, Revision 1, “Guidelines for 10 CFR 50.59 Implementation,” Washington, DC, 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. 15), and Volume 72 of the *Federal Register* (72 FR 49352, August 28, 2007) (Ref. 16). 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-dated the current version of 10 CFR Part 52.

In May 2019, the NRC issued RG 1.187, Revision 1 (Ref. 17), 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...”.

Digital Modifications Background

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. 18), for the NRC staff’s review. NEI 01-01 replaced the original version of EPRI TR-102348, issued December 1993 (Ref. 19), 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. 20). 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. 21). 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 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. 22), 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 Supplement 1 clarifies the NRC staff’s endorsement of NEI 01-01, Sections 4 and 5, and Appendices A and B. Specifically, Supplement 1 clarifies the guidance that should be more consistently applied for documenting “qualitative assessments.” It 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)).

NRC continues to endorse NEI 01-01 as stated in RIS 2002-22 and RIS 2002-22, Supplement 1, which remain in effect. NEI 96-07, Appendix D, does not replace or supersede NEI 01-01 either in whole or in part. Licensees have the option to use the 10 CFR 50.59 guidance *in total* in either NEI 01-01 or in NEI 96-07, Appendix D. However, NEI 96-07, Appendix D, 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 and the 10 CFR 50.59 guidance of NEI 01-01. In addition, NEI 96-07, Appendix D is applicable to digital modifications only and is not generically applicable to the 10 CFR 50.59 process.

Harmonization with International Standards

The NRC staff reviewed guidance from the International Atomic Energy Agency (IAEA) and International Organization for Standardization (ISO) and did not identify any standards that provided useful related guidance to NRC staff, applicants, or licensees.

Documents Discussed in Staff Regulatory Guidance

This RG endorses, in part, 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 is endorsing 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 is providing 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.

2. NEI 96-07, Appendix D

The NRC staff considers the guidance in NEI 96-07, Appendix D, acceptable for use in complying with the requirements in 10 CFR 50.59, subject to the following exceptions and additions:

a. NEI 96-07, Appendix D Use

NEI submitted NEI 96-07, Appendix D, to the NRC staff as a means of addressing 10 CFR 50.59 challenges pertaining to digital I&C implementation because of the unique challenges posed (e.g., introduction of software). The NRC staff evaluated NEI 96-07, Appendix D, as applied to digital modifications only, and therefore has not determined Appendix D to be acceptable for other uses.

b. Human-System Interface

Licensees should not apply the guidance in Appendix D in a way that would be inconsistent with the guidance in NEI 96-07, Rev. 1. However, including Human-System Interface (HSI) changes in the screening process is a change from the guidance contained in NEI 96-07, Revision 1, Section 4.2.1.2. The NRC staff agrees that HSI may be screened as described in Appendix D. Digital interfaces are fundamentally different than analog interfaces. The guidance in Appendix D, Section 4.2.1.2 takes this difference into account, whereas, the guidance in NEI 96-07, Revision 1 does not.

c. Examples Illustrate Guidance

Examples are meant to illustrate the guidance provided and should not be used to derive guidance. As noted in Appendix D, Section 1.5, examples may deliberately exclude other pertinent or related aspects that could potentially change the screening or evaluation conclusions. For example, the “Note” in example 4-19 of NEI 96-07, Appendix D states, “The acceptability of these new area radiation monitors will be dictated by their reliability, which is assessed as part of Criterion (ii), not Criterion (vi).” The NRC staff’s position is that this note is potentially misleading as it could be read to mean that CCF of a proposed digital I&C modification is solely a reliability issue, applicable to Criterion (ii) and not Criterion (vi), when read within the context of the entirety of example 4-19.

d. Software Common Cause Failures

The NRC staff’s position is that NEI 01-01, Section 5, as clarified by RIS 2002-22 Supplement 1, is 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. There is no consensus method for determining the likelihood of CCF of software (i.e., an industry consensus standard) that has been reviewed or endorsed by the NRC.

e. Section 4.3.6 of NEI 96-07, Appendix D

The NRC staff takes exception to the application of the term “safety analysis” to the criterion in section 10 CFR 50.59(c)(2)(vi) in lieu of the term “FSAR (as updated)” throughout NEI 96-07, Appendix D, Section 4.3.6. This exception includes the Introduction to Section 4.3.6 of NEI 96-07, Appendix D, which does not itself provide guidance on the application of 10 CFR 50.59(c)(2)(vi) to a DI&C modification. Nonetheless, the NRC staff takes exception to the rationale set forth in the Introduction for

limiting the matters considered under that criterion to safety analyses. In particular, the NRC staff takes exception to steps 5 and 6 in “Determination of Safety Analysis Result Impact,” Section 4.3.6 of NEI 96-07, Appendix D, because the determination of the safety analysis result impact is only made against the safety analysis sections of the FSAR (as updated) and not against the entire FSAR (as updated). The NRC staff’s position is that where the criteria in 10 CFR 50.59 uses the term “previously evaluated in the final safety analysis report,” it means the whole FSAR (as updated). Therefore, when applying the guidance in Appendix D, licenses should not limit their examination of the FSAR (as updated) to particular sections. For example, Section 4.3.6 of Appendix D instructs the licensee to consider malfunctions previously evaluated in the safety analysis in their FSAR (as updated). Licensees should instead consider malfunctions previously evaluated in any section of their FSAR (as updated).

The text in Section 4.3.6 of NEI 96-07, Appendix D, allows the user to answer the question: “Does the Activity Create a Possibility for a Malfunction of an SSC Important to Safety with a Different Result?” However, contrary to NRC staff’s interpretation of the guidance in NEI 96-07 and of 10 CFR 50.59, Section 4.3.6 of NEI 96-07, Appendix D, generally focuses on the impact of a malfunction on the results of the safety analysis rather than the impact on the results of the FSAR (as updated).

The NRC staff’s position is that Section 4.3.6 of NEI 96-07, Appendix D, should determine whether the impact of the “SSC malfunction” has a different result than any previously evaluated in the FSAR (as updated), instead of a different result than previously evaluated in the “safety analysis” (Appendix D expresses the latter concept as “safety analysis results impact.”). Therefore, Step 5 in Section 4.3.6 should be used to identify malfunctions previously evaluated in the FSAR (as updated) and the results of these malfunctions. Step 6 in Section 4.3.6 should be used to compare the projected/postulated results with the previously evaluated results to determine whether the effects are bounded by the results in the FSAR (as updated).

Examples 4-17 through 4-23 of NEI 96-07, Appendix D, use the term “safety analysis” based on the explanation in the introduction of NEI 96-07, Appendix D, Section 4.3.6, rather than using the UFSAR. This can result in an incorrect 10 CFR 50.59 evaluation. For instance, in example 4-19, which discusses an upgrade of area radiation monitors, the NRC staff takes exception to the text: “There are no safety analyses that directly or indirectly credit this design basis function. Namely, there are no considerations of malfunctions of single or multiple radiation monitors, or expected responses of the radiation monitors, in any safety analysis.” The NRC staff’s position on example 4-19 is that the user should identify area radiation monitor malfunctions previously evaluated in the FSAR (as updated) and the results of these malfunctions. The results should be compared with previously evaluated results to determine whether the effects are bounded by the results in the FSAR (as updated), and not solely the results in the safety analysis. Stating that there cannot be a different result when comparing to a preexisting safety analysis because none exists is not adequate to meet 10 CFR 50.59.

3. 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.

4. 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).

D. IMPLEMENTATION

The purpose of this section is to provide information on how licensees¹ may use this guide and information regarding the NRC's plans for using this RG. In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting," and any applicable finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

Use by Licensees

Licensees may voluntarily² use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this RG may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Licensees may use the information in this RG or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this RG. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this RG, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this RG to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this RG. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the RG, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this RG, generic communication, or promulgation of a rule requiring the use of this RG without further backfit consideration.

During regulatory discussions on plant specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this RG, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this RG are part of the licensing basis of the facility. However, unless this RG is part of the license for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this RG constitutes a violation.

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised RG and (2) the specific subject matter of this RG is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this RG or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

If a licensee believes that the NRC is either using this RG or requesting or requiring the licensee to implement the methods or processes in this RG in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the

¹ In this section, "licensees" refers to licensees of nuclear reactors under 10 CFR Parts 50 and 52; and the term "applicants," refers to applicants for licenses and permits for (or relating to) nuclear reactors under 10 CFR Parts 50 and 52, and applicants for standard design approvals and standard design certifications under 10 CFR Part 52.

² In this section, "voluntary" and "voluntarily" means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

guidance in NRC Management Directive 8.4, “Management of Facility-Specific Backfitting and Information Collection” (Ref. 23), and NUREG-1409, “Backfitting Guidelines” (Ref. 24).

REFERENCES³

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, Appendix A, “Text of 10 CFR 50.59,” dated November 2000 (ADAMS Accession No. ML003771157).⁴
5. NEI 96-07, Revision 1, “Guidelines for 10 CFR 50.59 Implementation,” Washington, DC, November 2000 (ADAMS Accession No. ML003771157).
6. NEI 96-07, Appendix B, “Guidelines for 10 CFR 10 CFR 72.48 Implementation,” dated March 5, 2001 (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 (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 (ADAMS Accession No. ML14113A529).
10. NEI 96-07, Appendix D, Revision 0, “Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications, dated November 2018” (ADAMS Accession No. ML18338A389).
11. NEI 96-07, Appendix E, “User’s Guide for NEI 96-07, Revision 1, ‘Guidelines for 10 CFR 50.59 Implementation,’” October 2011 (Not Publicly Available).
12. NEI letter, “Request for NRC Endorsement of NEI 96-07, Appendix D, Rev. 0,” January 8, 2019 (ADAMS Accession No. ML19015A312).

³ 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.

⁴ Publications from the Nuclear Energy Institute (NEI) are available at their Web site: <http://www.nei.org/> or by contacting the headquarters at Nuclear Energy Institute, 1776 I Street NW, Washington DC 20006-3708, Phone: 202-739-800, Fax 202-785-4019.

13. 64 FR 53582, *Federal Register*, Volume 64, p. 53582, Washington, DC, October 4, 1999.
14. NRC, RG 1.187, Revision 0, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," Washington, DC, November 2000.
15. 66 FR 64737, *Federal Register*, Volume 66, p. 64737, Washington, DC, December 14, 2001.
16. 72 FR 49352, *Federal Register*, Volume 72, p. 49352, Washington, DC, August 28, 2007.
17. NRC, RG 1.187, Revision 1, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," Washington, DC, April 2019.
18. NEI 01-01, Revision 0, "Electric Power Research Institute (EPRI) TR-102348, Revision 1, 'Guideline on Licensing Digital Upgrades,'" dated March 2002 (ADAMS Accession No. ML020860169).
19. Nuclear Utilities Management and Resource Council (NUMARC) and Electrical Power Research Institute, (EPRI) NUMARC/EPRI Report TR-102348, "Guideline on Licensing Digital Upgrades," dated December 1993 (ADAMS Accession No. ML020860169).
20. 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," dated April 26, 1995.
21. 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," dated November 25, 2002 (ADAMS Accession No. ML023160044).
22. 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 (ADAMS Accession No. ML18143B633).
23. NRC, Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection," Washington, DC.
24. NRC, NUREG-1409, "Backfitting Guidelines," Washington, DC.