

U.S. NUCLEAR REGULATORY COMMISSION

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Technical Lead: Duane Hardesty

GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59, “CHANGES, TESTS AND EXPERIMENTS,” AT NON-POWER PRODUCTION OR UTILIZATION FACILITIES

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes an approach that is acceptable to the staff of the U.S. Nuclear Regulatory Commission (NRC) to meet the regulatory requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.59, “Changes, tests and experiments” (Ref. 1), at a non-power production and utilization facility (NPUF), as defined in the Applicability section below. It endorses, with clarifications and an exception, Nuclear Energy Institute (NEI) 21-06, “Guidelines for 10 CFR 50.59 Implementation at Non-power Production and Utilization Facilities,” Revision 0, issued August 2021 (Ref. 2).

Applicability

This RG applies to NPUFs, which for the purposes of this RG includes, non-power reactors, research reactors, testing facilities (also referred to as test reactors), critical assemblies, and training reactors, as well as non-power production or utilization facilities whether or not they have a reactor (i.e., medical radioisotope irradiation and medical processing facilities) subject to 10 CFR Part 50. NPUFs, which for the purposes of this RG includes, collectively refer to non-power reactors and certain other production or utilization facilities that are licensed under 10 CFR 50.21(a) and (c) or 10 CFR 50.22, “Class 103 licenses; for commercial and industrial facilities.” This RG is not applicable to nuclear power reactors, fuel processing facilities, or the kinds of production facilities described in paragraphs (1) and (2) of the definition of “production facility” in 10 CFR 50.2, “Definitions.”

Applicable Regulations

The regulations in 10 CFR Part 50 establish criteria for the licensing of production and utilization facilities. To that end, the specific 10 CFR Part 50 regulations applicable to this RG include the following:

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-2007. Alternatively, comments may be submitted to the Office of Administration, Mailstop: TWFN 7A-60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff. 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. ML21243A103. The regulatory analysis may be found in ADAMS under Accession No. ML21243A104.

- 10 CFR 50.59 contains requirements 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 50.90, “Application for amendment of license, construction permit, or early site permit.”
- 10 CFR 50.90 contains requirements for applicants requesting an amendment to a license or construction permit issued under 10 CFR Part 50.

Related Guidance

- RG 1.187, Revision 3, “Guidance for Implementation of 10 CFR 50.59, “Changes, Tests, and Experiments,” issued June 2021 (Ref. 3), describes an approach that is acceptable to the NRC staff to meet the regulatory requirements of 10 CFR 50.59.
- NEI 96-07, Revision 1, “Guidelines for 10 CFR 50.59 Implementation,” issued November 2000 (Ref. 4). NEI 96-07, Revision 1, provides industry guidance on the implementation of 10 CFR 50.59 and is endorsed in RG 1.187, Revision 3, with clarifications. RG 1.187, Revision 3, Section A, “Related Guidance,” lists appendices to NEI 96-07 that provide additional guidance on implementing 10 CFR 50.59 for selected topics. The following appendix to NEI 96-07 is applicable to this RG:
 - NEI 96-07, Appendix D, Revision 1, “Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications,” issued May 2020 (Ref. 5), provides focused application of the 10 CFR 50.59 guidance to activities involving digital instrumentation and control modifications and is endorsed in RG 1.187, Revision 3, with clarifications.

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 Part 50 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 number 3150-0011. 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 Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0011) Office of Management and Budget, Washington, DC, 20503.

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 Issuance

The NRC staff is issuing this RG for the purpose of endorsing, with clarifications, NEI 21-06, Revision 0, as an acceptable approach for NPUF licensees to comply with the requirements of 10 CFR 50.59. The existing guidance (see related guidance above) focuses on power reactors.

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 10 CFR 50.90 provided specific criteria are met. These changes under 10 CFR 50.59(d) are required to be reported to the NRC at least every 24 months. However, all current NPUF licenses have technical specification requirements to report annually to the NRC: Tabulation of major changes in the reactor facility and procedures, and tabulation of new tests or experiments, or both, that are significantly different from those performed previously and are not described in the Safety Analysis Report, including a summary of safety evaluation leading to the conclusions that they are allowed without prior authorization by the NRC.

In August 2021, the NEI submitted NEI 21-06, Revision 0, to the NRC for review for the implementation of 10 CFR 50.59. The National Organization of Test, Research, and Training Reactors (TRTR) developed this document to provide guidance on implementing 10 CFR 50.59 at nuclear facilities other than power reactors, specifically NPUFs. NEI 21-06, Revision 0, was developed because most of the examples and specific discussion in NEI 96-07, Revision 1, (as endorsed in RG 1.187, Revision 3) focus on power reactors and some regulatory requirements that do not apply to NPUF licensees. In addition, NEI 21-06, Revision 0, was developed by adapting the guidance in NEI 96-07, Revision 1, to provide a consistent approach to applying 10 CFR 50.59 at power reactor licensees and NPUF licensees.

RG 1.187 also continues to provide guidance on implementing 10 CFR 50.59 for NPUF licensees. RG 1.187, Revision 3, Section C.1.e, “Applicability to 10 CFR Part 50 Licensees other than Power Reactors,” clarifies NEI 96-07, Revision 1, stating, “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 to Part 50, ‘Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants’).”

Consideration of 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 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. 6) and Management Directive and Handbook 6.6,

“Regulatory Guides” (Ref. 7). The following IAEA Safety Requirements and Guide was considered in the development of the Regulatory Guide:

- IAEA Safety Standards Series No. SSG-24, “Safety in the Utilization and Modification of Research Reactors,” issued 2012 (Ref. 8)

Although the NRC has an interest in facilitating the harmonization of standards used domestically and internationally, the agency does not specifically endorse the IAEA safety standard listed above and is only acknowledging that such documents may be a useful reference for general information.

Documents Discussed in Staff Regulatory Guidance

This RG endorses the use of a third-party guidance document, NEI 21-06, Revision 0. 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

The NRC staff endorses the guidance in NEI 21-06, Revision 0, for use as a means for NPUF licensees, described in the applicability section above, to comply with the requirements in 10 CFR 50.59. However, the NRC staff provides clarifications and an exception to certain statements in NEI 21-06, Revision 0, as discussed below:

a. Other Documents and Examples Referenced in NEI 21-06, Revision 0

As stated above in Section B, in the paragraph titled “Documents Discussed in Staff Regulatory Guidance,” NEI 21-06, Revision 0, references other documents, but the NRC’s endorsement of NEI 21-06, Revision 0, should not be considered an endorsement of the referenced documents. Additionally, NEI 21-06, Revision 0, includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in NEI 21-06, Revision 0, the NRC’s endorsement 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.

b. Relationship to NEI 96-07, Revision 1

While most of the examples and specific discussion contained in Revision 1 of NEI 96-07 focus on power reactors, the NRC staff position is that the licensees to which this RG applies have the option to use the guidance on 10 CFR 50.59 provided in either NEI 21-06, Revision 0, (as endorsed in this RG), or NEI 96-07, Revision 1 (as described in RG 1.187, Revision 3). However, NEI 21-06, Revision 0, does not describe, and this RG does not endorse, applying select portions from both NEI 96-07, Revision 1, and the guidance on 10 CFR 50.59 in NEI 21-06, Revision 0.

c. Relationship to NEI 96-07, Appendix D, Revision 1, and NEI 01-01

NEI 21-06, Revision 0, does not provide specific guidance on digital modifications under 10 CFR 50.59. Applicable guidance for NPUF licensees conducting digital modifications appears in RG 1.187, Revision 3 (endorsing, with clarifications, NEI 96-07, Appendix D, Revision 1), RIS 2002-22, dated Nov. 25, 2002 (endorsing, with qualifications, NEI 01-01, “Guideline on Licensing Digital Upgrades EPRI TR-102348 Revision 1,” dated March 15, 2002 (Ref. 9)), and Supplement 1 to RIS 2002-22, dated May 31, 2018. NEI 96-07, Appendix D, Revision 1, states the following:

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* (Ref. 10).

However, the NRC continues to find NEI 01-01 (as described in RIS 2002-22, Supplement 1) as well as NEI 96-07, Appendix D, Revision 1 (as described in RG 1.187, Revision 3), acceptable for use by NPUF licensees.

d. Exception from NEI 21-06, Revision 0, regarding changes that are not considered departures from a method of evaluation

The NRC staff identified an issue in NEI 21-06, Revision 0, Section 4.3.8, which states, in part:

- Use of a methodology revision that is documented 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.

The bulleted paragraph quoted above is not correct in the context of that list and could result in licensees misapplying 10 CFR 50.59. Therefore, in place of that paragraph, licensees should apply the following guidance “by way of contrast for changes 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 the previous revision of the same methodology described in the UFSAR.

e. Clarification of Guidance from NEI 96-07, Revision 1, as Reorganized and Partially Omitted in NEI 21-06, Revision 0

The NRC staff identified guidance needing clarification in NEI 21-06, Revision 0, Section 4.3.8.2, under the subheading, “Considerations for Determining if New Methods May be Considered ‘Approved by the NRC for the Intended Application.’” The guidance under this heading has been reorganized from the equivalent guidance on pages 67–68 in NEI 96-07, Revision 1, in ways that may cause confusion.

In addition, NEI 21-06, Revision 0, omits guidance from the equivalent portion of NEI 96-07, Revision 1, that is relevant to NPUFs. Therefore, licensees should consider the following questions from NEI 96-07, Revision 1, in addition to those presented on page 49 of NEI 21-06, Revision 0:

Is the facility for which the methodology has been approved designed and operated in the same manner as the facility to which the methodology is to be applied? Is the relevant equipment the same? ... Are the relevant existing UFSAR-described failure modes and effects analyses the same?

For clarity, the NRC staff provides the following guidance, which licensees may use in place of the information under the heading “Considerations for Determining if New Methods May be Considered ‘Approved by the NRC for the Intended Application.’” This is the same guidance as presented in NEI 21-06, Revision 0, but reorganized to be consistent with the guidance in NEI 96-07, Revision 1, and with the additional questions listed in the paragraph above:

Considerations for Determining if New Methods May be Considered “Approved by the NRC for the Intended Application”

The following questions highlight important considerations for determining that a particular application of a different method is technically appropriate for the intended application, within the bounds of what has been found acceptable by NRC, and does not require prior NRC approval.

- Is the application of the methodology consistent with the facility’s licensing basis (e.g., NUREG- 1537 or other facility-specific commitments)? Is the methodology consistent with relevant industry standards?

If application of the new methodology requires exemptions from regulations or facility-specific commitments, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with a facility’s licensing basis, then prior NRC approval may be required. The applicable change process must be followed to make the facility’s licensing basis consistent with the requirements of the new methodology.

- If a computer code is involved, has the code been installed in accordance with applicable software quality assurance requirements? Has the facility-specific model been adequately qualified through benchmark comparisons against test data, facility data or approved engineering analyses? Is the application consistent with the capabilities and limitations of the computer code? Has industry experience with the computer code been appropriately considered?

The computer code installation and facility-specific model qualification are not directly transferable from one organization to another. The installation and qualification should be in accordance with the licensee’s quality assurance program.

- Is the facility for which the methodology has been approved designed and operated in the same manner as the facility to which the methodology is to be applied? Is the relevant equipment the same? Are the relevant existing UFSAR-described failure modes and effects analyses the same? If the facility is designed and operated in a similar, but not identical, manner, the following types of considerations should be addressed to assess the applicability of the methodology:

- How could those differences affect the methodology?
- Are additional sensitivity studies required?
- Should additional single failure scenarios be considered?
- Are analyses of limiting scenarios, effects of equipment failures, etc., applicable for the specific facility design?
- Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?

- Differences in the facility configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage facilities may not include an analytical analysis of certain accidents that was performed in later vintage

facilities. Some facilities may be required to postulate a loss of off-site power or a maximum break size for certain events; others may have obtained exemptions to these requirements from the NRC. Some facilities may have emergency core cooling systems; other facilities do not. Facility specific failure modes and effects analyses may reveal new potential single failure scenarios that cannot be adequately assessed with the original methodology. The existence of these differences does not preclude application of a new methodology to a facility; however, differences must be identified, understood and the basis documented for concluding that the differences are not relevant to determining that the new application is technically appropriate.

D. IMPLEMENTATION

The NRC staff may use this RG 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 RG 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 (MD) 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests” (Ref. 11). However, the backfitting provisions in 10 CFR 50.109, “Backfitting,” do not apply to Part 50 licensees other than power reactors. The regulatory basis for 10 CFR 50.109 was expressed solely in terms of nuclear power reactors. The NRC’s Advanced Notice of Proposed Rulemaking, Policy Statement, Proposed Rules, and Final Rules for amendments to 10 CFR 50.109 in the 1980s involved only nuclear power reactors. As a result, the NRC has not applied 10 CFR 50.109 to research reactors, testing facilities, and other non-power facilities licensed under 10 CFR Part 50 (e.g., “Final Rule; Clarification of Physical Protection Requirements at Fixed Sites”) (Ref. 12). In a 2012 final rule concerning non-power reactors, the NRC stated, “The NRC has determined that the backfit provisions in 10 CFR 50.109 do not apply to test, research, or training reactors because the rulemaking record for 10 CFR 50.109 indicates that the Commission intended to apply this provision to only power reactors, and NRC practice has been consistent with this rulemaking record” (“Final Rule; Requirements for Fingerprint-Based Criminal History Records Checks for Individuals Seeking Unescorted Access to Non-Power Reactors”) (Ref. 13).

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 MD 8.4. If a licensee believes that the NRC is using this RG 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 MD 8.4.

REFERENCES¹

1. *U.S. Code of Federal Regulations* (CFR), “Domestic Licensing of Production and Utilization Facilities,” Part 50, Chapter 1, Title 10, “Energy”
2. Nuclear Energy Institute (NEI), NEI 21-06, “Guidelines for 10 CFR 50.59 Implementation at Non-power Production and Utilization Facilities,” Revision 0, August 2021.² (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21236A089)
3. U.S. Nuclear Regulatory Commission (NRC), Regulatory Guide (RG) 1.187, Revision 3, “Guidance for Implementation of 10 CFR 50.59, “Changes, Tests, and Experiments,” Washington, DC, June 2021. (ADAMS Accession No. ML21109A002)
4. NEI 96-07, Revision 1, “Guidelines for 10 CFR 50.59 Implementation,” Washington, DC, November 2000. (ADAMS Accession No. ML003771157)
5. NEI 96-07, Appendix D, Revision 1, “Supplemental Guidance for Application of 10 CFR 50.59 to Digital Modifications,” Washington, DC, May 2020. (ADAMS Accession No. ML20135H168)
6. U.S. NRC, “International Policy Statement,” Washington, DC, May 12, 2014. (ADAMS Accession No. ML14132A317)
7. U.S. NRC, Management Directive 6.6, “Regulatory Guides,” Washington, DC, May 2, 2016. (ADAMS Accession No. ML18073A170)
8. International Atomic Energy Agency, Safety Standards Series No. SSG-24, “Safety in the Utilization and Modification of Research Reactors,” Vienna, Austria, 2020.³
9. NEI 01-01, Revision 0, “Electric Power Research Institute (EPRI) TR-102348, Revision 1, ‘Guideline on Licensing Digital Upgrades,’” Washington, DC, March 2002. (ADAMS Accession No. ML020860169)
10. U.S. NRC, 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,” Washington, DC, May 31, 2018. (ADAMS Accession No. ML18143B633)

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 online 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> 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.

3 Copies of International Atomic Energy Agency (IAEA) documents may be obtained through their Web site: www.iaea.org or by writing the International Atomic Energy Agency, P.O. Box 100 Wagramer Strasse 5, A-1400 Vienna, Austria.

11. U.S. NRC, Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," Washington, DC, September 20, 2019, (ADAMS Accession No. ML18093B087).
12. U.S. NRC, Rules and Regulations: Clarification of Physical Protection Requirements at Fixed Sites, 58 Fed. Reg. 13699, Monday, March 15, 1993, pp 13699-13700.
13. U.S. NRC, Rules and Regulations: Requirements for Fingerprint-Based Criminal History Records Checks for Individuals Seeking Unescorted Access to Non-Power Reactors (Research or Test Reactors), 77 Fed. Reg. 27561, May 11, 2012, pp. 27561-27574.