

U.S. NUCLEAR REGULATORY COMMISSION

DRAFT REGULATORY GUIDE DG-1291

Proposed New Regulatory Guide RG 1.234

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EVALUATING DEVIATIONS AND REPORTING DEFECTS AND NONCOMPLIANCE UNDER 10 CFR PART 21

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for complying with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" (Ref. 1).

Applicability

This RG applies only to applicants, licensees, dedicating entities, and their suppliers associated with constructing, owning, operating, or supplying of nuclear power plants subject to 10 CFR Part 21, and regulated pursuant to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," (Ref. 2), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 3).

Applicable Regulations

- 10 CFR Part 21 establishes the requirements for procedures to evaluate and report in order to implement the requirements of Section 206, "Noncompliance," of the Energy Reorganization Act of 1974 (Ref. 4), which requires that the NRC receive immediate notification that a facility, activity, or basic component (1) fails to comply with the Atomic Energy Act of 1954 (Ref. 5), as amended, or any applicable NRC rule, regulation, order, or license of the Commission relating to substantial safety hazards or (2) contains a defect, which could create a "substantial safety hazard," as defined by NRC regulations..
- 10 CFR 50.55(e) requires procedures that evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable, and in all cases within 60 days of discovery. This requirement overlaps and supports the Part 21 requirements because both 10 CFR Part 21 and 10 CFR 50.55(e) require that deviations and failures are evaluated.

This regulatory guide 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 draft guide 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 **INSERT: DG-XXXX**. 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 draft regulatory guide, previous versions of this guide, 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 <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The draft regulatory guide 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. ML16165A298. The regulatory analysis may be found in ADAMS under Accession No. ML16165A301.

Related Guidance

- NUREG-0302, Revision 1, “Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance” (Ref. 6), provides the NRC’s remarks to explain the first proposed rule and responses to stakeholder questions.

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 Act¹

This RG contains and references information collections covered by 10 CFR Part 21 that is subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The information collections were approved by the Office of Management and Budget (OMB) under OMB control number 3150-0035.

Public Protection Notification

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

¹ Send comments regarding this information collection to the Information Services Branch, 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, (3150-0035) Office of Management and Budget, Washington, DC 20503.

B. DISCUSSION

Reason for Issuance

This new guide (Revision 0) provides licensees and applicants with formal guidance for an acceptable method of evaluating and reporting defects under 10 CFR Part 21. This new guidance will aid in minimizing compliance challenges to licensees and vendors that have been identified through inspection activities. This new guide endorses Nuclear Energy Institute (NEI) 14-09, “Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1 which was developed to incorporate previous guidance in NUREG-0302; to add additional clarity in the specific areas where issues have historically occurred; and to include experience gained from the nearly 40 years of complying with 10 CFR Part 21.

Background

Although the regulations in 10 CFR Part 21 have been in effect for many years, the NRC had not previously published a RG to provide licensees and applicants with formal guidance for an acceptable method of evaluating and reporting defects. The regulations in Part 21 establish the requirements for procedures to evaluate and report in order to implement the requirements of Section 206, “Noncompliance,” of the Energy Reorganization Act of 1974, which requires that the NRC receive immediate notification that a facility, activity, or basic component (1) fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable NRC rule, regulation, order, or license of the Commission relating to substantial safety hazards or (2) contains a defect, which could create a “substantial safety hazard,” as defined by NRC regulations.

The applicability of Part 21 is broader than most NRC regulations. The requirements in Part 21 impose obligations on certain officers of NRC licensees and on certain officers of nonlicensees that construct facilities for, or supply components to, licensed facilities or activities (i.e., vendors or suppliers). Consequently, developing programs that implement the requirements of the regulation poses different challenges for the licensees and vendors.

Since it was codified in 1977, Part 21 has presented compliance challenges to licensees and vendors. Furthermore, attempts to provide guidance for evaluating and reporting under Part 21 for power reactor licensees and vendors (e.g., presentations and questions and answers issued in conjunction with vendor workshops, generic communications) have been unable to reduce the incidence of NRC inspection findings associated with inadequate implementation of Part 21.

The purpose of the evaluation and reporting requirements in 10 CFR Part 21 is to enhance the NRC’s “defense in depth” measures for assuring the public’s health and safety. Reporting of defects and noncompliances, which could create a substantial safety hazard, ensures that the NRC receives prompt notification of such instances. NRC findings related to failures to report in accordance with Part 21 are important. The NRC considers noncompliances to be safety and security indicators potentially affecting the agency’s ability to carry out its statutory mission. Many of the surveillance, quality control, and auditing activities that both the NRC and its licensees rely on to monitor compliance with safety standards are based primarily on complete, accurate, and timely recordkeeping and reporting. Therefore, the NRC may consider a failure to make a required report that impedes its ability to take regulatory action to be significant, even if that failure was inadvertent or did not result in an actual consequence.

In addition, the statements of consideration that accompanied the final rule for 10 CFR Part 52 clarified the applicability of various requirements to each of the licensing processes in 10 CFR Part 52, including how Section 206 reporting requirements and, therefore, the provisions of 10 CFR Part 21, should be extended to early site permits, standard design certifications, and combined licenses.

Regulatory Issue Summary (RIS) 2010-05, “Applicability of 10 CFR Part 21 Requirements to Applicants for Standard Design Certifications” (Ref. 7), clarifies the NRC’s regulatory position regarding the applicability of 10 CFR Part 21 requirements to standard design certification or design certification rule (DCR) applicants (hereafter referred to as DCR applicants) before and after the DCR is issued by the NRC. Nuclear Energy Institute (NEI) 14 09, “Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1 (Ref. 8), incorporated all the information provided in RIS 2010-05.

Harmonization with International Standards

The NRC staff reviewed guidance from the International Atomic Energy Agency, International Organization for Standardization, and International Electrotechnical Commission and did not identify any standards that provided useful guidance to NRC staff, applicants, or licensees relative to 10 CFR Part 21 reporting requirements.

Documents Discussed in Staff Regulatory Guidance

This RG endorses the use of one or more codes or standards developed by external organizations, and other third-party guidance documents. These codes, standards, and third-party guidance documents may contain references to other codes, standards, or third-party guidance documents (“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 regulatory guide 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

Nuclear Energy Institute (NEI) 14-09, "Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1, is approved for use by the NRC staff and provides an adequate basis for complying with the requirements of 10 CFR Part 21, with the following clarification:

For the purposes of interactions between DCR applicants and combined operator license (COL) holders, the DCR applicant is considered to be the supplier and the COL holder the purchaser while using the guidance of NEI 14-09.

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees² may use this guide and information regarding the NRC's plans for using this regulatory guide. 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.

Use by Applicants and Licensees

Applicants and licensees may voluntarily³ use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide 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. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this regulatory guide for actions that do not require NRC review and approval, such as changes to a facility design under 10 CFR 50.59, "Changes, Tests, and Experiments." Licensees may use the information in this regulatory guide 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 regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, 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 regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this regulatory guide. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this regulatory guide, generic communication, and promulgation of a rule requiring the use of this regulatory guide 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 regulatory guide, 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 regulatory guide are part of the licensing basis of the facility. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

² In this section, "licensees" refers to licensees of nuclear power plants under 10 CFR Parts 50 and 52; and the term "applicants" refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52, and applicants for standard design approvals and standard design certifications under 10 CFR Part 52.

³ In this section, "voluntary" and "voluntarily" mean 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.

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 regulatory guide and (2) the specific subject matter of this regulatory guide 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 regulatory guide 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.

Additionally, an existing applicant may be required to comply with new rules, orders, or guidance if 10 CFR 50.109(a)(3) applies.

If a licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide 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 guidance in Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 9), and NUREG-1409, "Backfitting Guidelines" (Ref. 10) and the NRC.

REFERENCES ⁴

1. *U.S. Code of Federal Regulations* (CFR), “Reporting of Defects and Noncompliance,” Part 21, Chapter I, Title 10, “Energy.”
2. CFR, “Domestic Licensing of Production and Utilization Facilities,” Part 50, Chapter I, Title 10, “Energy.”
3. CFR, “Licenses, Certifications and Approvals for Nuclear power Plants,” Part 52, Chapter I, Title 10, “Energy.”
4. *Energy Reorganization Act of 1974*, Section 206, “Noncompliance.”
5. *Atomic Energy Act of 1954*, as amended, Title 42, United States Code (U.S.C.) § 2011 et seq.
6. U.S. Nuclear Regulatory Commission (NRC), “Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings To Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance”, NUREG-0302, Revision 1, Washington, DC, July 12–26, 1977. (Agencywide Documents Access and Management System (ADAMS) Accession No. ML062080399).
7. NRC, “Applicability of 10 CFR Part 21 Requirements to Applicants for Standard Design Certifications,” RIS 2010-05, Washington, DC, May 24, 2010.
8. Nuclear Energy Institute, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance,” NEI 14-09, Revision 1, Washington, DC, February 2016. (ADAMS Accession No. ML16054A825).
9. NRC, “Management of Facility-Specific Backfitting and Information Collection,” MD 8.4, October 9, 2013. (ADAMS Accession No. ML12059A460).
10. NRC, NUREG-1409, “Backfitting Guidelines,” Washington, DC, July 1990. (ADAMS Accession No. ML032230247).

⁴ 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.