

U.S. NUCLEAR REGULATORY COMMISSION

DRAFT REGULATORY GUIDE DG-1416

Proposed Revision 1 to Regulatory Guide 1.234



Issue Date: November 2023
Technical Lead: Deanna Zhang

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 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, as amended (Ref. 5), or any applicable NRC rule, regulation, order, or license of the Commission relating to substantial safety hazards or (2) contains a defect that could create a “substantial safety hazard,” as defined by NRC regulations.
- 10 CFR 50.55(e) requires, among other things, 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 for holders of facility construction permits under 10 CFR Part 50; and, for holders of combined licenses (until the Commission makes the finding under 10 CFR 52.103(g)) and manufacturing licenses under 10 CFR Part 52. This requirement overlaps and supports the 10 CFR Part 21 requirements because both 10 CFR Part 21 and 10 CFR 50.55(e) require that deviations and failures be evaluated.

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 website, <http://www.regulations.gov>, by searching for draft regulatory guide DG-1416. Alternatively, comments may be submitted to the Office of Administration, Mailstop: TWFN 7A-06M, 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 website under the Regulatory Guides document collection of the NRC Library at <https://nrc.gov/reading-rm/doc-collections/reg-guides/index.html>. 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. ML23187A549. The regulatory analysis may be found in ADAMS under Accession No. ML23187A550.

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, July 12–26, 1977,” dated October 1977 (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 methods that are acceptable to the staff for implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses. Regulatory guides are not NRC regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 21, 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 3150-0035, 3150-0011, and 3150-0151, respectively. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0035, 3150-0011, and 3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW, Washington, DC, 20503; email: oira_submissions@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 Issuance

Revision 0 of this guide was issued to provide licensees and applicants with an acceptable method of evaluating and reporting defects in compliance with 10 CFR Part 21. Specifically, this guide endorses Nuclear Energy Institute (NEI) 14-09, “Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1, issued February 2016 (Ref. 7), 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.

This revision of this guide (Revision 1) clarifies the NRC’s definition of counterfeit, fraudulent, and suspect items (CFSI). In addition, the staff made several editorial changes to conform to the current format and content of RGs.

Background

The regulations in 10 CFR Part 21 establish the requirements for procedures to evaluate and report in order to implement the requirements of Section 206 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 that could create a “substantial safety hazard,” as defined by NRC regulations.

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 non-compliances that 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 10 CFR Part 21 are important. The NRC considers non-compliances 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.

Since it was codified in 1977, 10 CFR Part 21 has presented compliance challenges to licensees and vendors. Furthermore, attempts to provide guidance for evaluating and reporting under 10 CFR 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 10 CFR Part 21. Since the issuance of RG 1.234, Revision 0, the number of NRC inspection findings have been reduced when the guidance in RG 1.234 was implemented correctly.

The applicability of 10 CFR Part 21 is broader than most NRC regulations. Its requirements impose obligations on certain officers of NRC licensees and on certain officers of non-licensees 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.

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 its licensing processes, 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 (COLs).

Finally, Regulatory Issue Summary (RIS) 2010-05, “Applicability of 10 CFR Part 21 Requirements to Applicants for Standard Design Certifications,” dated May 24, 2010 (Ref. 8), clarified 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 NRC issues the DCR. Subsequently, NEI 14-09, Revision 1, incorporated all the information provided in RIS 2010-05.

Consideration of International Standards

The International Atomic Energy Agency (IAEA) and Nuclear Energy Agency (NEA) work cooperatively with member states and other partners to promote the safe, secure, and peaceful use of nuclear technologies. This system of safety fundamentals, safety requirements, safety guides, and other relevant reports, reflect an international perspective on what constitutes a high level of safety. To inform its development of this RG, the NRC considered IAEA and NEA safety requirements and safety guides pursuant to the Commission’s International Policy Statement (Ref. 9) and Management Directive and Handbook 6.6, “Regulatory Guides” (Ref. 10).

The NRC staff did not identify any IAEA safety requirements or guides with information related to the topic of this RG. However, the staff has identified the NEA Committee on Nuclear Regulatory Activities (CNRA) Report NEA/CRNA/R (2012), “Regulatory Oversight of Non-Conforming, Counterfeit, Fraudulent, and Suspect Items (NCFSI),” dated February 13, 2013 (Ref. 11), as providing relevant information. This document discusses different approaches to managing NCFSI and notes that existing controls may need to be put in place throughout the supply chain. This RG incorporates quality assurance guidance and is generally consistent with the NEA’s basic safety principles.

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 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 NEI 14-09, Revision 1, which provides an adequate basis for complying with the requirements of 10 CFR Part 21, with the following clarifications:

1. In the context of using NEI 14-09 and for the purposes of interactions between standard design certification or design certification rule (DCR) applicants and combined operating license (COL) holders, the DCR applicant is considered to be the supplier and the COL holder the purchaser.
2. For types and location of postings, the NRC staff agrees that 10 CFR Part 21 allows postings to be hard copies, digital copies, or a combination of both. In addition, links to electronic postings may be identified on “sites,” that is, websites, commonly frequented by workers during the performance of work subject to 10 CFR Part 21. The NRC staff endorses those positions and clarifies that posting requirements of 10 CFR 21.6 may be met through electronic postings, regardless of the physical location of the workplace.
3. Regarding training guidance, NEI 14-09 states the following:

10 CFR part 21 does not establish requirements for training of personnel involved in 10 CFR part 21 activities. However, as a good practice, appropriate familiarization, and training in the requirements of 10 CFR part 21 should be provided initially, and as appropriate on an ongoing basis, as necessary. As another good practice, an organization should designate individuals capable of assisting the staff in part 21 evaluation, reporting requirements and training requirements.

The NRC’s position regarding training of personnel involved in 10 CFR Part 21 activities is that this training would be covered under 10 CFR 50.120, “Training and qualification of nuclear power plant personnel.” If an employee covered by 10 CFR 50.120 is required to perform tasks associated with 10 CFR Part 21, including the evaluation of a reportable condition under 10 CFR Part 21 training, the systems approach to training would evaluate and train covered employees on the related elements. The staff’s position on this point relates to the requirements of 10 CFR 50.120, rather than 10 CFR Part 21, and thus should not be understood to contradict the guidance in NEI 14-09.

4. Section 2.7, “Deviation,” of NEI 14-09 states that “Counterfeit and fraudulent items are considered to be deviations.” Section 7.4, “Deviation in a Delivered Basic Component,” of NEI 14-09, clarifies this and states that “A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to 10 CFR Part 21 must be evaluated.” Other than just referencing counterfeit and suspect items, NEI 14-09 does not formally define CFSI. To provide clarity and ensure consistency when addressing related NRC oversight activities, for the purposes of this guidance, the NRC staff understands CFSI to mean “Items that are intentionally manufactured or altered to imitate a legitimate product without the legal right to do so (Counterfeit); intentionally misrepresented with the intent to deceive (Fraudulent); or reasonably suspected of being Counterfeit or Fraudulent (Suspect).” The NRC staff considers CFSI to be a deviation to be treated according to the guidance in NEI 14-09.

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, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests” (Ref. 12), 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), “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, Section 42, United States Code (U.S.C.) § 2161, 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, July 12–26, 1977,” NUREG-0302, Revision 1, Washington, DC, October 1977. (Agencywide Documents Access and Management System (ADAMS) Accession No. ML062080399)
7. Nuclear Energy Institute (NEI), NEI 14-09, Revision 1, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Washington, DC, February 2016. (ML16054A825)²
8. NRC, Regulatory Issue Summary 2010-05, “Applicability of 10 CFR Part 21 Requirements to Applicants for Standard Design Certifications,” Washington, DC, May 24, 2010.
9. NRC, “Nuclear Regulatory Commission International Policy Statement,” *Federal Register*, Vol. 79, No. 132, pp. 39415–39418 (79 FR 39415), Washington, DC, July 10, 2014.
10. NRC, Management Directive (MD) 6.6, “Regulatory Guides,” Washington, DC.
11. Nuclear Energy Agency Committee on Nuclear Regulatory Activities, Report NEA/CRNA/R (2012)7, “Regulatory Oversight of Non-Conforming, Counterfeit, Fraudulent, and Suspect Items (NCFSI),” Paris, France, February 13, 2013.³

1 Publicly available NRC published documents are available electronically through the NRC Library on the NRC’s public website 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>. For problems with ADAMS, contact the Public Document Room staff at 301-415-4737 or (800) 397-4209, or email pdr.resource@nrc.gov. The NRC Public Document Room (PDR), where you may also examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

2 Publications from the Nuclear Energy Institute (NEI) are available at its website: <http://www.nei.org/> or by contacting the headquarters at Nuclear Energy Institute, 1776 I Street, NW, Washington, DC 20006-3708, telephone: 202-739-8000, fax 202-785-4019.

3 Publications from the Nuclear Energy Agency (NEA) are available at its website: <https://www.oecd-nea.org/> or by contacting the headquarters at Nuclear Energy Agency, 2, rue André Pascal, 75775 Paris Cedex 16, France, telephone: +33 1 73 21 28 19.

12. NRC, MD 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.”