

Navigating the Part 21 Regulations

June 13, 2024
Workshop on Vendor Oversight

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Topics

- Definitions, and Part 21 Language
- Important Practices for Navigating Part 21
- Reporting Responsibilities
- Reporting under Other Regulations
- Electronic Reporting Requirements

Definitions and Part 21 Process

- 10 CFR Part 21.3, “Definitions,” contains the definitions that should be used when discussing Part 21 issues.
- Guidance was clarified when the staff found that Nuclear Energy Institute (NEI) 14-09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1 provided a basis for meeting the requirements of Part 21 as recognize in Regulatory Guide (RG) 1.234, Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21,” Revision 1.
- Important Part 21 language
 - Discovery
 - Deviation
 - Evaluation
 - Substantial Safety Hazard
 - Defect
 - Notification

Definitions and Part 21 Process

A flow chart is available in the Appendix A, "Evaluation and Notification Flowchart" of NEI 14-09

- Part 21's flow is governed by timelines for each of the following parts of the regulation.
- Deviation => Discovery => Evaluations of a potential Substantial Safety Hazard (SSH) => Defect => Notification.
 - If no SSH exists, then the issue is not reportable.
 - Interim report is needed if more time is required to continue the evaluation per 21.21(a)(2).
 - The NRC will follow up on the status of interim reports and other information as necessary to meet the requirements in 21.21(d)(4).

Important Practices for Navigating Part 21

Communications between suppliers and purchasers

(NEI 14-09, Section 8.2, "COMMUNICATION BETWEEN SUPPLIERS AND PURCHASERS DURING THE EVALUATION AND NOTIFICATION PROCESS")

- 10 CFR Part 21 does not contain requirements for the communication of deviations and failures to comply between the purchaser and supplier.
- However, communication between suppliers and purchasers is strongly recommended as a good practice that can help ensure that entities involved in the nuclear supply chain are complying with regulations.
- Communications between purchasers and suppliers:
 - Allow[s] suppliers to perform assessments and determine if the supplier has delivered basic components with the same deviations to other purchasers.
 - Should be used to ensure clear commitments to compliance with Part 21 timeliness requirements.

Reporting Responsibilities

Who needs to report

- The entity that discovered the deviation or failure to comply has the responsibility to complete the evaluation within 60 days from discovery or submit an interim report if the evaluation cannot be completed within 60 days. The discovering entity also has the responsibility to make a Part 21 notification to the NRC.
- Suppliers that discover a deviation or failure to comply are responsible for performing the SSH evaluation and reporting:
 - Except if a supplier does not have the capability to perform the evaluation, the supplier must inform the purchaser(s) that the evaluation is being transferred to the purchaser so the purchaser can comply with the 60-day evaluation period.
 - 10 CFR 21.21(b) – “Once the Supplier has determined that they cannot complete an evaluation, then potentially affected Purchasers must be informed within five (5) working days of that determination.”

The supplier's determination shall be documented and available for review per Part 21.41, “Inspections” and Part 21.51, “Maintenance and inspection of records.”

Reporting Responsibilities

Who needs to report

- Purchasers (licensees) are ultimately responsible for the Part 21 requirements if the basic component is delivered and **may not delegate evaluation and reporting obligations**. The supplier may assist in the evaluation, but the purchaser will be responsible for meeting the Part 21 requirements.
- Purchasers are required to include identification of the supplier of the basic component that fails to comply or contains a defect in their written notification.
- Anyone can submit a Part 21 report, and voluntary reporting is not discouraged.

Reporting Under Other Regulations

Purchasers have the ability use other regulations to meet the Part 21 regulation.

- The reporting requirements of 10 CFR Part 21 apply to entities that are subject to the requirements of other regulations (e.g., Appendix B to 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 50.55(e), 10 CFR Part 50.72, 10 CFR Part 50.73, and 10 CFR 73.1200 and 73.1205)
- 10 CFR 21.2(c) states that the evaluation of deviations and appropriate reporting of defects under 10 CFR 50.72, and 10 CFR 50.73 satisfies each person's evaluation, notification and reporting obligation to report defects under 10 CFR Part 21.

Reporting Under Other Regulations

Purchasers have the ability use other regulations to meet the Part 21 regulation

If an issue that is being reported pursuant to 10 CFR 50.72/73 implicates Part 21 (e.g. the issue deals with a deviation in a basic component), then duplicate reporting may not be required. The licensee may satisfy the reporting requirements of Part 21 by providing the results of the SSH evaluation and all relevant information required by Part 21 in the Licensee Event Report (LER).

- To satisfy Part 21 reporting requirements, the report needs to identify that the Parts 50.72 and 50.73 intent is to meet the requirements of 10 CFR 21. (Check the Part 21 Box on the form).
- The must also include LER the information required by 10 CFR 21.21(d)(4). The regulation requires reporting information that the discoverer of the issue knows at the time.

Reporting Under Other Regulations

Purchasers have the ability use other regulations to meet the Part 21 regulation

- If the evaluation of an event associated with a deviation under the guidance for Parts 50.72 and 50.73 does not result in a report, licensees must ensure that the evaluation and reporting required by Part 21 is completely satisfied.
- Licensees may choose to REPORT information required by Part 21 in their LERs. The evaluation must still be accomplished in accordance with Part 21 and all information required by Part 21 must be reported.

Electronic Reporting Requirements

Regulatory guidance for electronic submittals.

- **§ 21.5 Communications** - Except where otherwise specified in this part, written communications and reports concerning the regulations in this part must be addressed to the **NRC's Document Control Desk, and sent by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001**; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by **electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time.**

Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to MSHD.Resource@nrc.gov; or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. In the case of a licensee or permit holder, a copy of the communication must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

Electronic Reporting Requirements

Regulatory guidance for electronic submittals.

- **Initial Notification** - The initial notification to the NRC Operations Center can be by facsimile at (301) 816-5151 or by telephone (301) 816-5100. The preferred method is by facsimile, and the director or responsible officer should call the NRC Operations Center to verify receipt of the facsimile. The initial notification should state that a 10 CFR Part 21 reportable item or condition was discovered.
- **Written Notification** - A written notification must be addressed to the NRC's Document Control Desk and mailed to the: U.S. Nuclear Regulatory Commission, Washington, DC 20555-001, or hand delivered at 11555 Rockville Pike, Rockville, MD. **Electronic submissions are also permissible provided it is in a manner that enables the NRC to receive, read, authenticate, distribute, and archive, and process and retrieve it a single page at a time.** The written notification must provide the following information...(Part 21 requirements form 21.21(b)(4) i through ix.).