



10 CFR Part 21

NQA-1 Committee Meeting

Richard McIntyre

Office of Nuclear Reactor Regulation
Division of Engineering
Quality and Vendor Branch A

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Agenda

- Requirements of 10 CFR Part 21
 - Purpose
 - Scope
 - Definitions
 - Posting
 - Procedures
 - Notification
 - Inspection
 - Records
- Rulemaking
- Examples

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Requirements of Part 21

- Purpose [10 CFR 21.1]
 - Notify the Commission of a defect in:
 - Basic Component
 - Activity/service
 - Facility
- Scope [10 CFR 21.2]
 - The regulations of this Part applies to:
 - Licensees
 - Suppliers of basic components for licensees

Requirements of Part 21

- Definitions [10 CFR 21.3]
 - Basic Component
 - Item with a safety function that assures
 - The integrity of the reactor coolant pressure boundary,
 - The capability to shutdown the reactor and maintain a safe shutdown condition, or
 - The capability to mitigate accidents that could result in offsite exposure comparable to those referenced in 10 CFR 50.34, 50.67 or 100.11, and
 - Item design and manufactured under 10 CFR 50 Appendix B, or
 - Commercial grade item successfully dedicated.



Requirements of Part 21

- Definitions (cont.)
 - Commercial Grade Item
 - A structure, system or component that was not designed and manufactured as a basic component.
 - Critical Characteristics
 - Those important design, material, and performance characteristics of a commercial grade item that once verified will provide reasonable assurance that the item will perform its intended safety function.

Requirements of Part 21

- Definitions (cont.)

- Dedication

- Acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as basic component will perform its intended safety function.
- Achieved by:
 - Identifying critical characteristics
 - Verifying acceptability
 - Inspection, tests or analyses
 - Commercial grade survey
 - Source verification
 - Performance history





Requirements of Part 21

- Definitions (cont.)
 - Deviation
 - A departure from the technical requirements included in a procurement document.
 - Discovery
 - Completion of the documentation first identifying a deviation.
 - Evaluation
 - Documented process of determining that a deviation could
 - create a substantial safety hazard, or
 - violate a license technical specification safety limit.



Requirements of Part 21

- Definitions (cont.)
 - Defects
 - Deviation in a delivered basic component that on a basis of an evaluation could
 - create a substantial safety hazard, or
 - violate license technical specifications safety limits.
 - Substantial Safety Hazard
 - Loss of safety function to the extent that creates a major reduction in the degree of protection provided to the public health and safety.



Requirements of Part 21

- Interpretations [10 CFR 21.4]
 - Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulation in this part by any officer or employee of the Commission other than a written interpretation by the General Council will be recognized to be binding upon the Commission.



Requirements of Part 21

- Posting Requirements [10 CFR 21.6]
 - Post documents [10 CFR 21.6(a)]
 - Most recent 10 CFR Part 21 Regulation,
 - Section 206 of the Energy Reorganization Act of 1974, and
 - Your procedures developed pursuant to Part 21.



Requirements of Part 21

- Notification Requirements
 - Develop procedures [10 CFR 21.21(a)]
 - Entities subject to this Part are required to adopt procedures to evaluate deviations and report defects:
 - Directions to acquire information sufficient to identify the deviation.
 - Directions to perform an evaluation.
 - Directions to reach a conclusion within 60 days of discovery of deviation, based on the analysis as to whether the deviation could create a substantial safety hazard.

Requirements of Part 21

- Notification Requirements (cont.)
 - Develop procedures (cont.)
 - Directions to create an interim report when the evaluation of the deviation can not be completed within 60 days of the discovery of deviation.
 - Directions to inform a director or responsible officer within 5 days after completion of evaluation.
 - Directions to notify all affected purchasers within 5 days, if the supplier does not have the capability to perform the evaluation. [10 CFR 21.21(b)]





Requirements of Part 21

- Notification Requirements (cont.)
 - Notification to the Commission of a defect must be performed by a director or responsible officer. [10 CFR 21.21(d)(1)]
 - Defect notification time period to Commission [10 CFR 21.21(d)(3)]
 - Initial Notification – within 2 days of notifying director or responsible officer.
 - Written Notification – within 30 days of notifying director or responsible officer.

Requirements of Part 21

- Notification Requirements (cont.)
 - Content of written defect reports [10 CFR 21.21(d)(4)]
 - Name and address of entity informing the Commission.
 - Identification of basic component that contains the defect.
 - Identification of the firm supplying the basic component.
 - Nature of the defect and the substantial safety hazard that could be or was created by the defect.

Requirements of Part 21

- Notification Requirements (cont.)
 - Content of written defect reports (cont.)
 - The date that the information of the defect was obtained.
 - The number and location of all such basic component in use or supplied to facilities subject to this regulation.
 - The corrective action,
 - Name of individual responsible for the action, and
 - Length of time taken to complete the action.
 - Advice given to purchasers (licensees) related to the defect.

Requirements of Part 21

- Procurement Documents [10 CFR 21.31]
 - Procurement documents issued for basic components must state that Part 21 applies to the item or service.

- Inspections [10 CFR 21.41]
 - Entities subject to this regulation must permit the Commission to inspect:
 - Records
 - Premises
 - Activities
 - Basic Components
 - Note: Licensees should make sure that foreign suppliers are aware of these inspection requirements.





Requirements of Part 21

- Maintenance of records [10 CFR 21.51]
 - Entities subject to this regulation must prepare and retain records for a minimum period:
 - Evaluations of deviations – 5 years
 - Notifications sent to purchasers – 5 years
 - Record of purchasers of basic components (procurement documents) – 10 years



Part 21 Rulemaking

- July 31, 1991 - Final Rule on Part 21 (56 FR 36089):
 - Eliminated duplicate reporting of defects under Part 21 and 50.55(e).
 - Reporting criteria of 50.55(e) the same as Part 21 - defects that could create a substantial safety hazard.
 - Established time limit for transfer of information when the supplier is not capable of evaluating a deviation - 5 days.
 - Established uniform time periods for reporting defects to Commission.
 - Established uniform requirements for content of reports.



Part 21 Rulemaking (cont.)

- Sept 19, 1995 - Final Rule (60 FR 48369)
 - Broaden definition of “commercial grade items” with a more inclusive definition, “any item that has not been dedicated for use as a basic component.”
 - Included a generic process for dedication of commercial grade items for safety-related use (EPRI-5652).
 - Clarified that the entity performing the dedication of a commercial grade item is responsible for evaluating deviations and reporting defects and failures to comply as required by 10 CFR Part 21.



Examples

- Example 1: Licensee rejects basic component during receipt inspection
 - Licensee responsibility
 - Licensee (as purchaser) may conduct a receipt inspection before taking a final acceptance of the component.
 - In that case, it is the staff's position that "delivery" would not occur, and therefore no notification to the NRC by the licensee would be required.



Examples

- Example 1 (cont.)
 - Supplier responsibility
 - Identify all such basic components with similar deviations delivered to facilities subject to this regulation.
 - If not capable of performing the evaluation, notify purchaser(s) in 5 working days.
 - Evaluate deviation.
 - If deviation is determined to be a defect:
 - Report to Commission.
 - Notify affected purchasers – good practice.



Examples

- Example 2: Operating component failure
 - Question 1:
 - Does a report under 10 CFR 50.72 (Event Notifications), or 10 CFR 50.73 (Licensee Event Report) satisfies responsibility to report under 10 CFR Part 21?
 - Question 2:
 - Should the licensee notify the supplier?

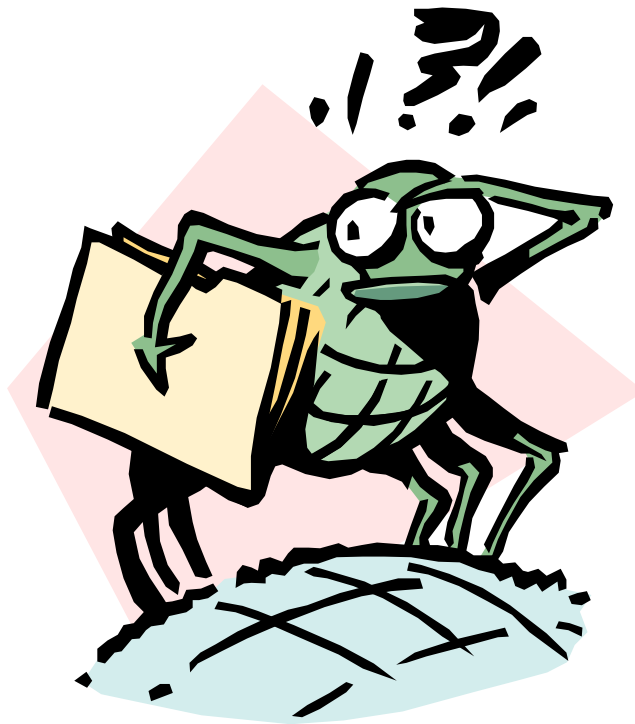


Examples

- Example 3: Supplier notified of material specification deviation by their authorized nuclear inspector
 - Material supplied by ASME certificate holder did not conform to ASME material specification requirements.
 - Supplier handled issue under corrective action program.
 - Root cause identified that subcontractor did not understand material specification requirements.
 - Material was supplied to multiple utilities purchasers.
 - Supplier notified their customers of material specification deviation.

- Does the example meet requirements of Part 21?

Questions



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