

10 CFR Part 21 Requirements

NUPIC Vendor Conference

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Agenda

- Inspection Procedure 36100
- Background
- 10 CFR Part 21 Process
- Requirements
- Information Notice 2007-40
- Interpretation

Inspection Procedure 36100



- IP36100, “Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance,” issued on October 3, 2007
- NRC Inspections verify that the vendor has established a program to effectively implement 10 CFR Part 21 requirements
- This IP is also used by NRC inspectors during observations of NUPIC audits (IP43005)

Background

- Purpose of the regulation is to notify the Commission of a defect in basic component.
 - Basic Component
 - Items that have been design and manufactured under 10 CFR 50 Appendix B, or
 - Commercial grade items that have successfully completed the dedication process.
- The regulations applies to:
 - NRC licensed facilities
 - Suppliers of basic components for NRC licensed facilities

Background (cont.)

- Deviation vs. Defect
 - Deviation
 - A departure from the technical requirements included in a procurement document
 - Defect
 - Deviation in a basic component delivered to a purchaser, that on a basis of an evaluation could
 - create a substantial safety hazard, or
 - violate license technical specifications safety limits

10 CFR Part 21 Process



- Discovery
- Evaluation
- Notification

10 CFR Part 21 Process

- Discovery –
 - Documented identification of the deviation
 - Consider potential deviations and failures to comply identified through the nonconformance and/or corrective action process that may require evaluation under the Part 21 process

10 CFR Part 21 Process

- Evaluation –
 - Determine, within 60 days of discovery, if deviation could create a substantial safety hazard
 - Issue an interim report when the evaluation can not be completed within 60 days of discovery
 - If the supplier does not have the capability to perform the evaluation, notify all affected purchasers within 5 days of discovery
[10 CFR 21.21(b)]

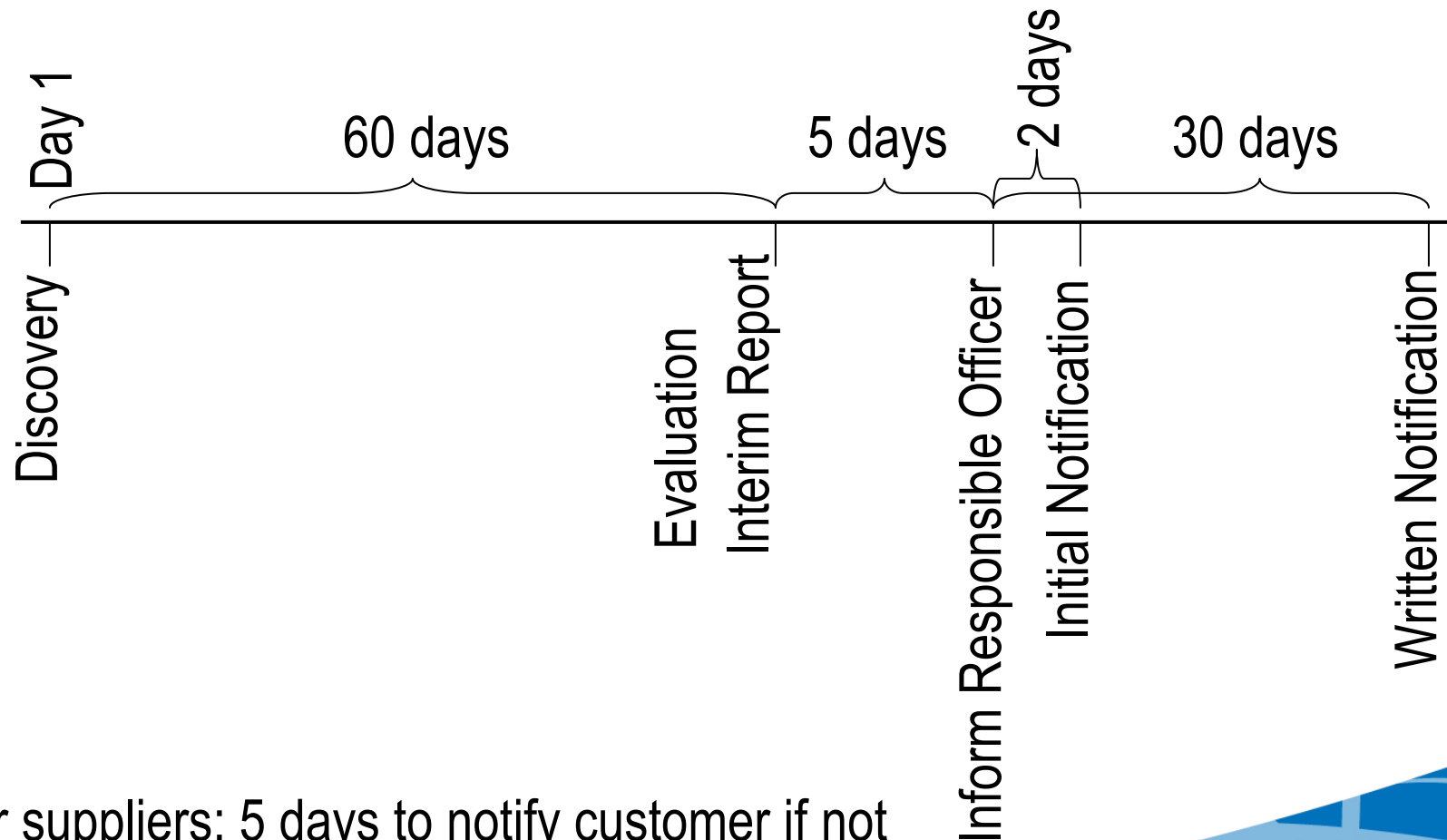
10 CFR Part 21 Process (cont.)

- Notification – [10 CFR 21.21(d)]
 - Inform a director or responsible officer, as soon as practicable and, in all cases, within 5 working days after completion of the evaluation
 - Notification to Commission
 - Initial notification by facsimile within 2 days of informing the responsible officer
 - Written notification within 30 days of informing the responsible officer

10 CFR Part 21 Process (cont.)

- Notification (cont.)
 - Content of written notification
 - Name and address of entity informing the Commission
 - Identification of basic component that contains the defect
 - Identification of the vendor
 - Nature of the defect
 - The substantial safety hazard that could be or was created by the defect
 - The date that the information of the defect was obtained
 - The number and location of all such basic components in use or supplied to facilities subject to this regulation
 - The corrective action
 - Advice given to purchasers

10 CFR Part 21 Timeline



For suppliers: 5 days to notify customer if not capable to perform evaluation

Part 21 Requirements

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

Part 21 Requirements as Verified in IP36100



- Posting Requirements [10 CFR 21.6]
 - Current 10 CFR Part 21 regulation,
 - Section 206 of the Energy Reorganization Act of 1974, and
 - Procedures implementing Part 21 requirements.

Part 21 Requirements as Verified in IP36100



- Procedure Requirements [10 CFR 21.21(a)]
 - Shall include measures to evaluate deviations and failures to comply
 - The procedure should describe the measures on how to comply with other Part 21 requirements.
For example:
 - A link to the QA processes (e.g., control nonconformance and corrective actions) to identify deviations and failures to comply
 - Accurately reflect the time frames of 10 CFR 21.21(d) for reporting identified defects

Part 21 Requirements as Verified in IP36100



- Procedure Requirements (cont.)
 - NRC inspectors sample Part 21 records :
 - **Evaluations** to verify that the evaluation and conclusion were developed in a reasonable manner.
 - **Notifications** (either to Commission or affected customers) to verify that notification was made at the required time frames.

Part 21 Requirements as Verified in IP36100



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

Information Notice 2007-40

- IN 2007-40, “Inadequate Implementation of 10 CFR Part 21 Requirements By Vendors Who Supply Basic Components to Nuclear Power Plant Licensees,” issued on December 21, 2007
- Examples of inadequate Part 21 implementation discussed in the IN:
 - Inadequate procedures
 - Inadequate evaluation
 - Failure to meet timeliness requirements
 - Failure to include Part 21 applicability in purchase orders

Interpretation

- 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. [10 CFR 21.4]