10 CFR Part 21 Requirements

NUPIC Vendor Conference

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United States Nuclear Regulatory Commission
Protecting People and the Environment

Agenda

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

Inspection Procedure 36100

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- 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

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- Discovery
- Evaluation
- Notification

10 CFR Part 21 Process

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- 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

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- 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.)

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- 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.)

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- 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

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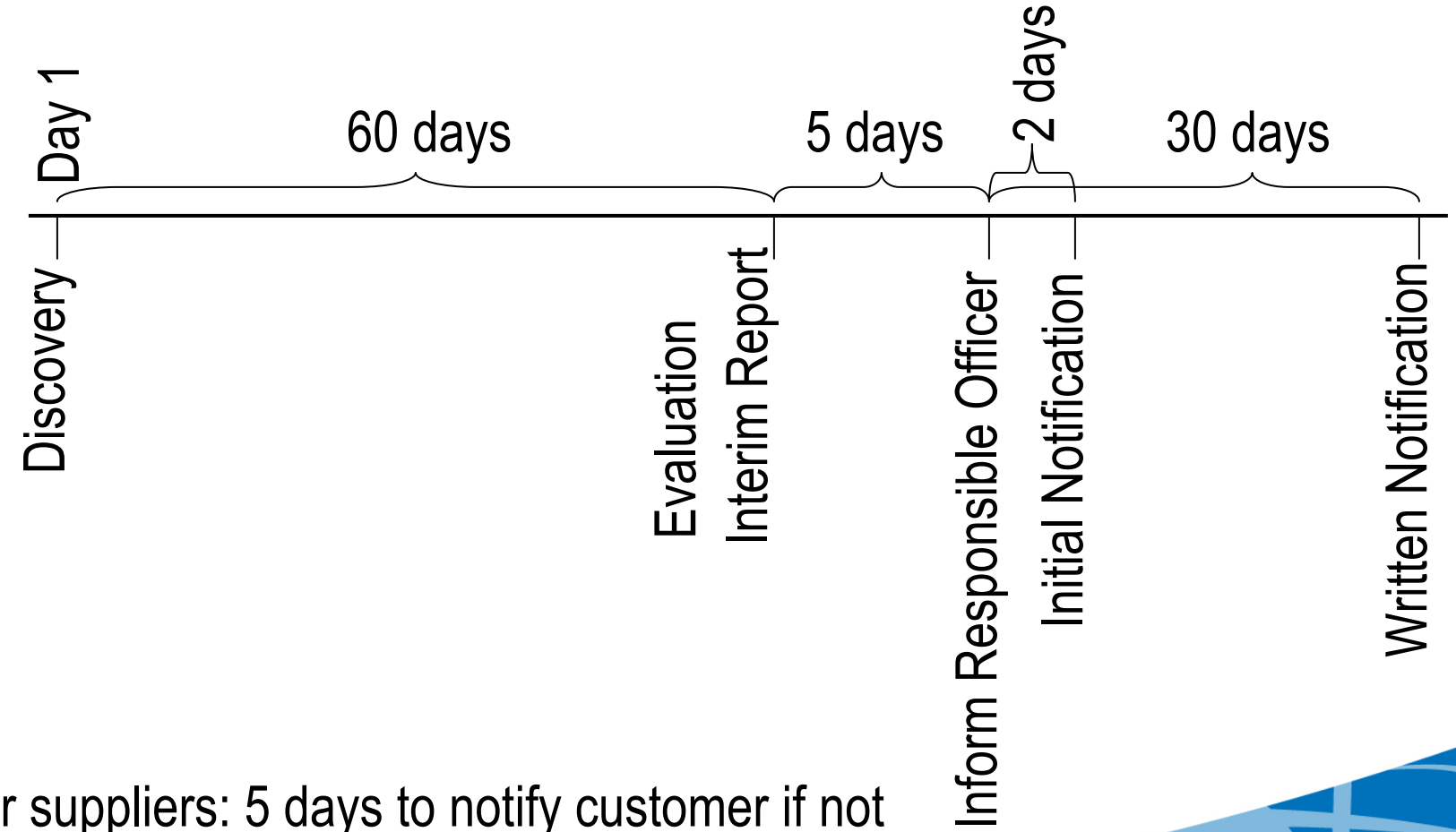

For suppliers: 5 days to notify customer if not capable to perform evaluation

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 reassonable 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

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- 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]