

**NUPIC Meeting**

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**Auditor Training**

**10 CFR Part 21 Requirements and Guidance**

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# Agenda

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

# Background

- The Energy Reorganization Act of 1974
  - Established the NRC
  - Is part of the principal statutory authorities that governs NRC's work
- The Energy Reorganization Act (ERA) of 1974, Section 206, “Noncompliance”
  - Link: <http://www.nrc.gov/reading-rm/doc/collections/nuregs/staff/sr0980/rev1/vol-1-sec-2-to-5.pdf> (on the NRC website)

# 10 CFR Part 21 Process

- Purpose of the regulation is to notify the Commission of a defect or a failure to comply in basic component.
- The regulation applies to:
  - NRC licensed facilities
  - Suppliers of basic components for NRC licensed facilities

# Part 21 Process

- Discovery
- Evaluation
- Notification

# Part 21 Process (cont'd)

- **Discovery** [10 CFR 21.3]

- Completion of the documentation first identifying the existence of a deviation or failure to comply

- **Deviations**

- A departure from the technical requirements included in a procurement document

A company shipped carbon steel bolts to customer, but the Purchase Order specified stainless steel bolts. The Company identified a deviation

# Part 21 Process (cont'd)

- **Deviations**

- A departure from the technical requirements included in a procurement document



**EXAMPLE**

A company shipped carbon steel bolts to customer, but the Purchase Order specified stainless steel bolts. The Company identified a deviation.

# Part 21 Process (cont'd)

- **Identifying Deviations**

- Strong Corrective Action Programs are VITAL for identifying potential deviations.



A vendor's corrective action program did not interface with the Part 21 program. The vendor did not have a programmatic way to identify deviations.



A vendor had numerous types of corrective action programs, some of which did not interface with the Part 21 program.

# Part 21 Process (cont'd)

- **Evaluation**

- The process within the Part 21 program used to determine whether a deviation is a defect.

- **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

# Part 21 Process (cont'd)

- **Evaluation (cont'd)**

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

# Part 21 Process (cont'd)



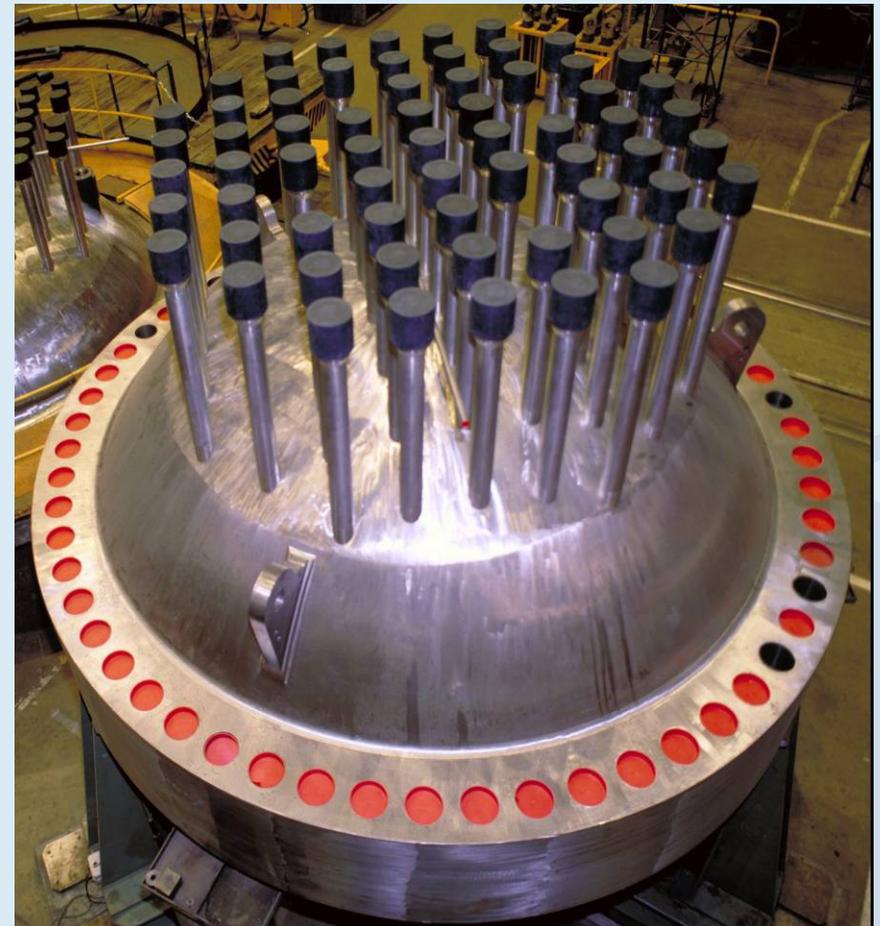
The company starts its Part 21 Evaluation. It contacts customer, that tells them that the safety-related bolts are welded to stainless steel flanges on the Reactor Coolant System.



The company continues its Evaluation. The carbon steel bolts have different material and welding properties that could cause the flanges to fail at the plant. The company has enough information to determine that the bolts could cause a substantial safety hazard. The company has identified a Defect.

# Part 21 Process (cont'd)

- A common misconception is that isolated deviations do not need to be evaluated. After all, if there's just one item...
- All Deviations must be evaluated.



# Part 21 Process (cont'd)

- **Evaluating for Defects (cont'd)**

- Evaluations must include a determination of whether a deviation could create a substantial safety hazard.

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Vendor evaluations focused on technical engineering aspects but did not address substantial safety hazard.

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Vendor evaluations of deviations were inadequate because the vendor did not know the specific application of the item at the affected licensee facility.

# Part 21 Process (cont'd)

- **Notification – [10 CFR 21.21(d)]**
  - Official communication from a director or responsible officer, to the NRC, of a defect.
  - 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 or telephone within **2 days** of informing the responsible officer
    - Written notification within **30 days** of informing the responsible officer

# Part 21 Process (cont'd)

- **Notification** (cont'd)

- 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

# Part 21 Process (cont'd)

- **Notification** (cont'd)

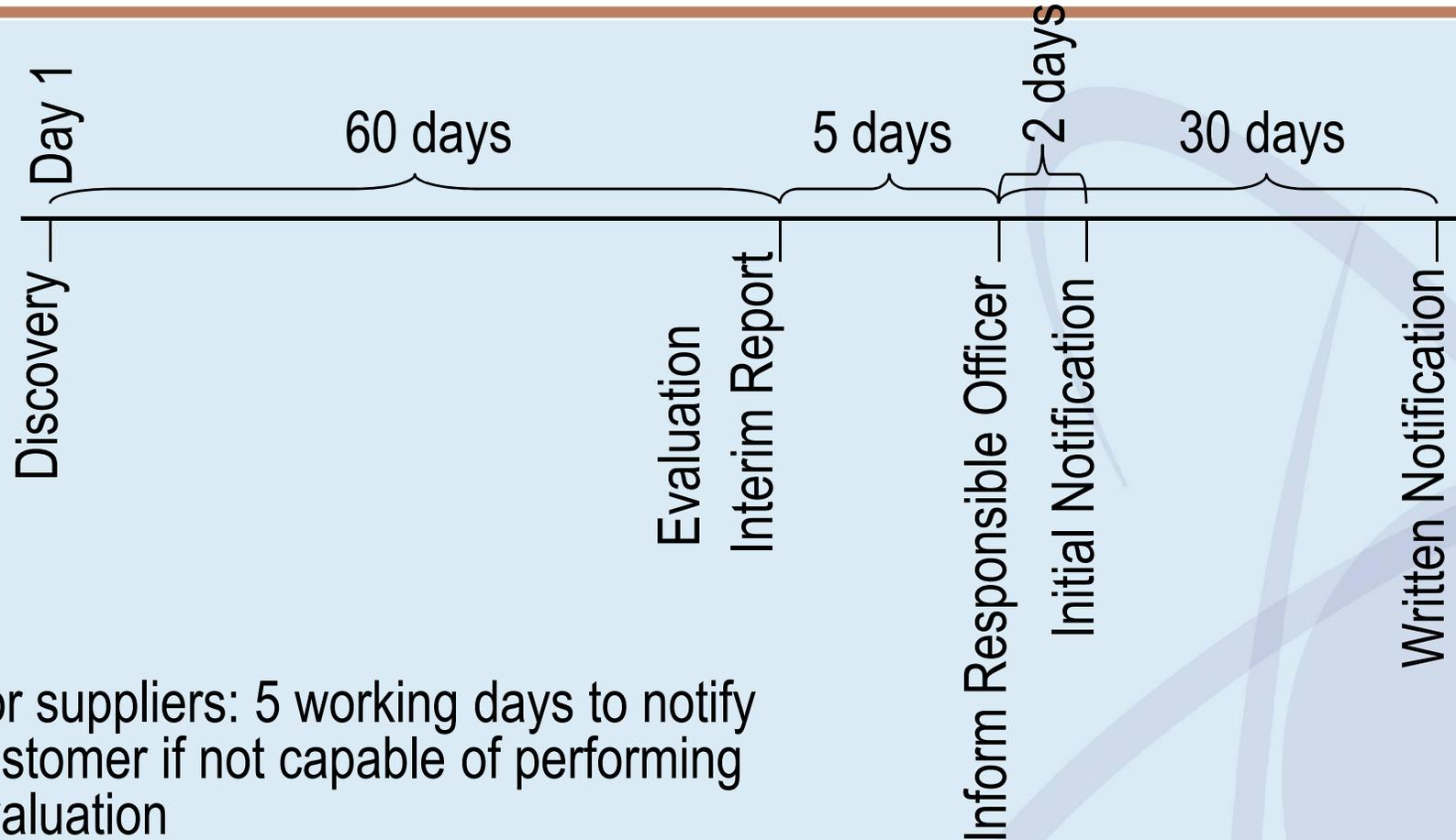


The President of the company notifies the NRC of the bolt defect by a complete Part 21 Notification.



If the company determined that it could not perform a Part 21 Evaluation, it would have to inform the customer of the Deviation within five days. This is different than Notification.

# Part 21 Timeline



For suppliers: 5 working days to notify customer if not capable of performing evaluation

# Part 21 Reports

- Located on the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/event-status/part21/>
- Website contains all Part 21 notifications from 1995 to present

# Part 21 Requirements

- **Inspections [10 CFR 21.41]**
  - Entities subject to Part 21 shall permit the Commission to inspect:
    - Records
    - Premises
    - Activities
    - Basic Components

# Inspection Procedure (IP) 36100

- IP 36100, “Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance,” issued on October 3, 2007
- NRC Inspectors 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 Nuclear Procurement Issues Committee (NUPIC) audits (IP 43005)

# Part 21 Requirements as Verified in IP 36100

- **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 Process (cont'd)

- **Procedure Requirements [10 CFR 21.21(a)]**
  - Vendors' procedures must have guidance to:
    - Evaluate deviations to identify defects

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FINDINGS**



Vendor did not have procedures in place to evaluate deviations.

- Inform their customers, within five days, if they determine that they do not have the capability to evaluate.

**NRC  
FINDINGS**



Vendor did not meet 5-day timeliness requirement to inform customers of deviations when the vendor was not capable of performing the evaluation.

# Part 21 Requirements as Verified in IP 36100 (cont'd)

- **Procedure Requirements (cont'd)**
  - The procedure should describe the measures on how to comply with other Part 21 requirements. For example:
    - A link to other 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 IP 36100 (cont'd)

- **Procedure Requirements** (cont'd)
  - NRC inspectors review a sample of 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 IP 36100 (cont'd)

- **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 Counsel will be recognized to be binding upon the Commission. [10 CFR 21.4]

# Questions