



**Inspecting Part 21
NUPIC Auditor Conference
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Agenda

- 10 CFR Part 21
- Inspection Preparation
- Inspection Procedure (IP) 36100
- Part 21 Requirements as verified in IP 36100
- IP 36100 vs. NUPIC Checklist
- Examples
- Questions

10 CFR Part 21

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

Inspection Preparation

- Part 21 Notifications
 - Located on the NRC website at <http://www.nrc.gov/reading-rm/doccollections/event-status/part21/>
 - Website contains all Part 21 notifications from 1995 to present
 - NRC inspectors should review the Part 21 notifications to identify any recent Part 21 reports from the vendor (supplier) or licensee/applicant being inspected.

Inspection Preparation

- Part 21 Questions & Answers
 - Revision 1 of NRC Responses to 10 CFR Part 21 and Fuel Cycle Facility Questions Received During the Vendor Workshop on New Reactor Construction in December, 2008.
<http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight.html>
 - Website contains all Part 21 questions and answers from the vendor workshop on new reactor construction during December 2008.

Inspection Preparation

- **Question 28:**

If a Part 21 procedure stating processes to be in accordance with §21.21(a) is not adequate, why doesn't the regulation state as such?

- **Answer:**

Section 21.21(a) states, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards. The regulation specifically states that the vendor must have a procedure in place that governs the conduct of Part 21 evaluations. A procedure that simply references the regulations instead of providing working level guidance on how to meet the regulations does not provide reasonable assurance that Part 21 is being met. The vendor must include in its procedure adequate guidance to ensure regulatory compliance, such as a description of specific steps that will be implemented to meet the requirements of Part 21.

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.
- Used by NRC Inspectors to verify that the vendor has established a program to effectively implement 10 CFR Part 21 requirements.
- It has been used by NRC inspectors during observations of NUPIC audits (IP 43005).

Part 21 Requirements as verified in IP 36100

- Covers five major areas
 - Controls for the evaluation of deviations and failures to comply [10 CFR 21.21 (a)].
 - Notification to the NRC of identified items or failures to comply associated with substantial safety hazards [10 CFR 21.21(d)].

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

- Implementation of procurement document controls as required by 10 CFR 21.31.
- Implementation maintenance of records [10 CFR 21.51]
- Posting Requirements [10 CFR 21.6]

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

- Control of evaluations
 - Procedure Requirements [10 CFR 21.21(a)]
 - The procedure shall include measures to evaluate deviations and failures to comply within specified timeframes.
 - 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)

- Evaluation timeliness
 - Determine, within **60 days** of discovery, if deviation could create a substantial safety hazard [10 CFR 21.21(a)]
 - If the evaluation can not be completed within **60 days** of discovery, issue an interim report [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 Requirements as verified in IP 36100 (cont'd)

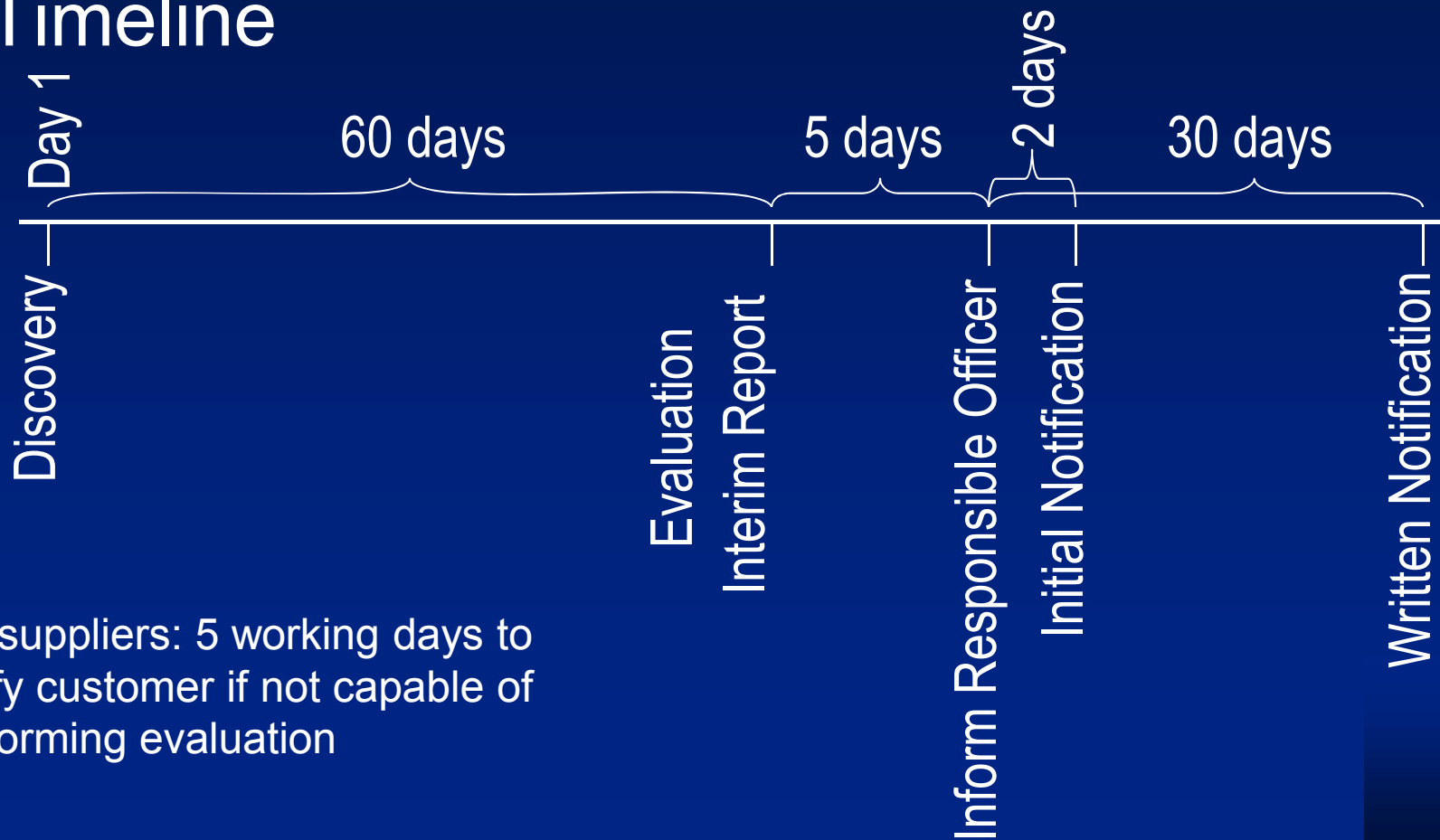
- Notification [10 CFR 21.21 (d)]
 - Inform a director or responsible officer
 - within **5 working days** after completion of the evaluation
 - Notification to NRC
 - Initial notification by facsimile or telephone within **2 days** of informing the responsible officer
 - Written notification within **30 days** of informing the responsible officer

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

- Notification (continued)
 - To purchasers
 - within **5 working** days if the vendor is not capable of performing the evaluation.

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

- Timeline



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

Part 21 Requirements as verified in IP 36100 (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 document controls
 - The NRC inspectors select a sample of procurement documents
 - to verify applicability of 10 CFR Part 21

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

- Maintenance of records [10 CFR 21.51]
 - Procedures and/or controls for maintenance of records that reflect the time according to regulations:
 - Evaluations of deviations – 5 years
 - Notifications sent to purchasers – 5 years
 - Record of purchasers of basic components (procurement documents) – 10 years

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

- Posting Requirements [10 CFR 21.6]
 - The NRC inspectors select at least one posting for inspection to verify:
 - Current 10 CFR Part 21 regulation,
 - Section 206 of the Energy Reorganization Act of 1974, and
 - Procedures implementing Part 21 requirements.

IP 36100 vs. NUPIC Checklist

NRC	NUPIC Checklist
1. Verification of timeliness of evaluations as required by 10 CFR 21.21 (a)	Does not appear to address timeframes as required by 10 CFR 21.21 (a)
2. NRC inspectors select samples of: <ul style="list-style-type: none"> a. Evaluated deviations that did not result in the identification of a defect or failure to comply. b. Notifications to the Commission to verify timeliness and completion. c. Identified deviations for which the vendor was not capable of performing the evaluation. 	Does not appear to address the selection of samples during audits.

IP 36100 vs. NUPIC Checklist

NRC	NUPIC Checklist
<p>3. Verification of procedures and/or controls for maintenance of records:</p> <ul style="list-style-type: none"> a. Evaluations of deviations – 5 years b. Notifications sent to purchasers – 5 years c. Record of purchasers of basic components (procurement documents) – 10 years 	<p>Does not appear to address the verification of maintenance of records time frame. Neither in Section 11 (Nonconforming items/Part 21) nor Section 16 (Records).</p>

Part 21 Procedure Examples

Procedure Example 1

- See handout 1

Procedure Example 2

- See handout 2

Linkage to Other QA Processes Example:

NRC inspectors identified that a vendor had sent out an advisory letter to its customers describing a safety issue related to a basic component manufactured by the vendor. Although there was a clear linkage between the vendor's corrective action program and its Part 21 program, the NRC inspectors could not find any evidence that the vendor had perform a Part 21 evaluation on the issue identified in the advisory letter. In addition, the vendor failed to enter the issue into its corrective action program.

Questions

