



Effective Auditing of 10CFR21 Programs

NUPIC Vendor Meeting

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Topics

- **Introduction**
- **Background**
- **Know the Regulations**
 - **Definitions**
 - **Postings**
 - **Requirements-Discovery, Evaluation, and Notification**
 - **Time Line**
 - **Procurement Documents**
 - **Record Requirements**
- **NUPIC Checklist – Section 11.4**
- **Subtle Points/Requirements**
- **Common Findings/Oversights**
- **Assessment Strategies**
- **Resources / Tools**
- **Summary**



Background

- Previous Method of Auditing Part 21
Included Verifying Postings
and existence of a procedure
- Checklist Revision- 13, effective October 1, 2007
Section 11, checklist question 11.4 added more detail
- NRC Information Notice 2007-40 issued December 2007, *“Inadequate Implementation of 10 CFR Part 21 Requirements By Vendors Who Supply Basic Components to Nuclear Power Plant Licensees”*



Background

Key Concerns from NRC IN 2007-040

- Vendor's 10 CFR Part 21 evaluation of a potentially defective basic component was inadequate because the vendor did not know the specific application for the component and, therefore, did not have the capability to determine if the potentially defective component represented a substantial safety hazard.
- Vendor was not meeting the 5-day timeframe requirement in 10 CFR 21.21(b) for informing licensees of deviations when the vendor was not capable of performing the 10 CFR Part 21 evaluation.



Background

Key Points from NRC IN 2007-040- (continued)

- Vendor's 10 CFR Part 21 evaluations, only focused on the technical engineering aspects of the deviation performed under its corrective action program.
- NRC inspections at two licensees identified examples of purchase orders issued to U.S.-based suppliers that did not meet 10 CFR 21.31 "Procurement Documents," that requires procurement documents to specify that the provisions of 10 CFR Part 21 apply.
- Subcontractors supplying basic components to a vendor were not performing 10 CFR Part 21 evaluations of deviations and/or failures to comply for determining 10 CFR Part 21 reportability of potential defects that could cause a substantial safety hazard.



Background

Key Points from NRC IN 2007-040 (continued)

- Several vendors' 10 CFR Part 21 programs did not have adequate procedural guidance to identify and evaluate deviations associated with a substantial safety hazard. In addition, several vendors did not have guidance to evaluate significant conditions adverse to quality that were identified in their corrective action programs to determine whether the requirements of 10 CFR Part 21 applied.
- During inspections and observation of several NUPIC joint utility audits at foreign vendor facilities, the NRC staff identified examples where these vendors were not adequately implementing the requirements of 10 CFR Part 21 in that some of these vendors did not adopt appropriate procedures to perform 10 CFR 21.21(a) evaluations.



Summary of IN 2007-40

- **Lack of Procedure**
- **Inadequate procedures**
- **Lack of Connection between Corrective Action/NCR and**
- **Part 21 process**
- **- Inadequate evaluations**
- **- Failure to meet timeliness requirements**
- **- Failure to include Part 21 applicability in purchase orders**



Know the Regulations

- General Provisions

 - **Purpose**

 - **Scope**

 - **Definitions**

 - Interpretations

 - Communications

 - **Posting requirements**

 - Exemptions

 - Information collection requirements; OMB approval

- **Notification**

- **Procurement Documents**

- **Inspections, Records**

- Enforcement

- Authority



Know the regulations

- **Scope and Purpose**

Purpose of the regulation is to notify the Commission of a defect in basic component.

- **Basic Component means a structure, system , or component, or part thereof that affects its safety function necessary to assure:**
 - a) The integrity of a reactor coolant pressure boundary**
 - b) The capability to shut down the reactor and maintain it in a safe shutdown condition**
 - c) The capability to prevent or mitigate the consequences of accidents which could result in a potential offsite exposures**

Items and (Services) that have been design and manufactured under 10 CFR 50 Appendix B, or

Commercial grade items and services that have successfully completed the dedication process.



Know the regulations

The regulations applies to:

- **NRC licensed facilities**
- **Suppliers of basic components for NRC licensed facilities**
- **Includes dedicating entities**



Know the Regulations

- **Definitions**

Defect-

- **deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations of Part 21 , on the basis of an evaluation, the deviation could create a substantial safety hazard**
- **The installation, use or operation of a basic component containing a defect as defined in this section;**
- **A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 or part 52**
- **A deviation in a portion of a facility subject to early site permit, standard design certification, standard approval, construction permit, combined license or manufacturing licensing requirements of part 50 or part 52, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance**
- **An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.**



Know the Regulations

Definitions (continued)

Substantial safety hazard- a loss of safety function to the extent that there is a major reduction in the degree of protection Provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72

Deviation – a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design certification or standard design approval



Know the Regulations

Discovery- the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures

Evaluation – the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard

Notification- the telephonic communication to the NRC Operations Center or written transmittal to the NRC Document Control Desk

Responsible officer- the president, vice president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to Part 21



Know the Regulations

Posting Requirements

Post current copies of :

- 1) Part 21 Regulations;**
- 2) Section 206 of the Energy Reorganization Act of 1974; and**
- 3) Procedures adopted pursuant to the regulations**

Documents must be posted in a conspicuous position on any premises within the US where the activities subject to this part are conducted

Or

If posting is not practical, the license or firm in addition to posting Section 206, post a notice which describes the regulation/procedures, including the name of the individual to whom reports may be made and states where they may be examined.



Know the Regulations

Requirements

Three Phases of Part 21

Discovery

Evaluation

Notification



Know the Regulations

- **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**



Know the Regulations

Evaluation

Proper procedures established and implemented for

- Evaluation of deviations and failure to comply to identify defects and failure to comply as soon as practical (in all cases within 60 days of discovery) that could create a substantial safety hazard or
- Complete an interim report if the evaluation cannot be completed within 60 days of discovery of deviation. The interim report should describe the deviation being evaluated and state when the evaluation be completed. The interim report must be submitted in writing within 60 days by the responsible officer.



Know the Regulations

Evaluation (continued)

- **Ensure responsible officer is informed as soon as practical, in all cases within *5 working days* after completion of the evaluation:**
 - 1) **fails to comply with the Atomic Energy Act of 1954, or any applicable rule, regulation, order, or license of the Commission or standard design approval under part 52. relating to a substantial safety hazard or**
 - 2) **contains a defect**

- **If the deviation is discovered by the supplier of basic components (or services), and the supplier determines that it does not have the capability to perform the evaluation, then the supplier must inform the purchasers of affected licensees within *5 working days* of this determination**



Know the Regulations

Notification

Responsible Officer must notify the Commission when:

He or she obtains information reasonably indicating a failure to comply or a defect affecting:

- 1) manufacture, construction or operation of a facility or an activity within the US that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 702, 71, or 72**
- 2) A basic component that is within his or her organization's responsibility and is supplied to a facility or an activity within the US that is subject to the licensing, design certification, or approval requirements under parts 30, 40, 50, 52, 60, 61, 1, or 72 of this chapter**

The notification to the NRC of a defect and the evaluation of a defect are not required if the responsible officer has actual knowledge that the Commission has been notified in writing of the defect

Notification – initial notification by fax (preferred) to the NRC Operations Center at 301-816-5151 (Follow-up phone call to verify receipt of fax) or telephone at 301-816-5100 with in *2 days* following receipt of information by the director; written notification within *30 days* following receipt of information by the responsible officer on the identification of a defect or a failure to comply.



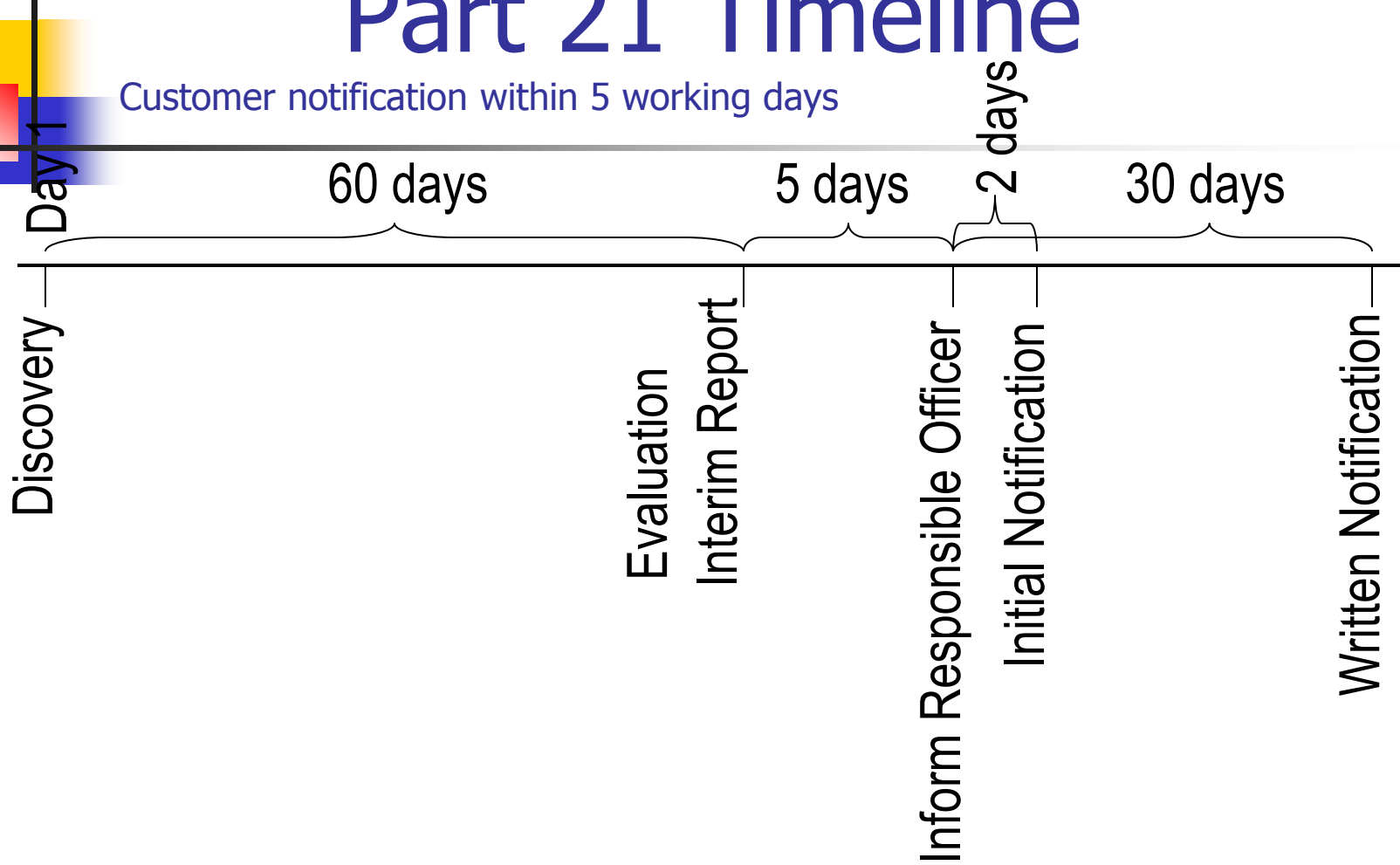
Know the Regulations

Notification (continued)

- **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 Timeline

Customer notification within 5 working days





Know the Regulations

Procurement Documents

- Procurement documents for basic components shall specify that the provisions of Part 21 Apply
- Applies to US and International Suppliers that supply basic components to US licensees



Know the Regulations

Maintenance of Records

- **Retain evaluations of all deviations and failure to comply for a minimum of five years**
- **Suppliers of basic components must retain notifications sent to purchasers and affected licenses for a minimum of five years after date of the notification**
- **Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic components or service associated with a basic component.**
- **Other record requirements for applicants for standard design certification under subpart of part 52**



Subtle Points/Requirements

- Definitions/ Difference between deviation and defect
- Calendar days versus working days
- 10CFR21 applies to all suppliers providing basic components including international suppliers
- Procurement documents for basic components must specify 10CFR21 applies
- Suppliers' audits of their subtiers must evaluate Part 21 program
- Procurement documents for commercial items (including those being dedicated) should not invoke 10CFR21
- Applies to suppliers performing dedication activities



Subtle Points/Requirements

- Distinct retention periods for records of deviations and customers
- Requirement to have direct links from the nonconformance and corrective action processes to the Part 21 process and vice versa
- The process must be adequately prescribed by procedure
- Computerized posting may not meet requirements
- 10CFR21 process can be documented separately from QA Manual
- Applies to services



Common Audit Findings/Oversights

- Definitions are not accurate
- Difference between deviation and defect
- Suppliers are not clearly documenting deviations
- Calendar days versus working days
- 10CFR21 applies to all suppliers providing basic components including international suppliers
- Procurement documents for basic components must specify 10CFR21 applies
- Suppliers' audits of their subtiers must evaluate Part 21 program



Common Audit Findings/Oversights

- Procurement documents for commercial items (including those being dedicated) should not invoke 10CFR21
- Applies to suppliers performing dedication activities
- Distinct retention periods for records of deviations and customers
- Requirement to have direct links from the nonconformance and corrective action processes to the Part 21 process and vice versa
- The process must be adequately prescribed by procedure
- Computerized posting may not meet requirements
- Apply process to services



Part 21 Assessments Strategies

- Ensure conditions identified in IN 2007-040 are not present
- Ensure common audit findings / oversights are considered
- Select sample of nonconformance/deficiencies for review to determine if conclusions are reasonable and well documented and procedure requirements are implemented
- Select sample of deviations to review evaluations on whether the deviation represented a defect
- Select sample of Part 21 notifications to evaluate implementation of Part 21 requirements, i.e. time and notification requirements



Resources/Tools

- 10CFR21 Regulation – Know the regulation
- Information Notice IN 2007-40

- NRC Inspection Procedure 36100, “Inspection of 10CFR Part 21 and 10CFR50.55(e) Programs for Reporting Defects and Noncompliance”
- Use Technical Specialist to help review Part 21 screening and evaluation process
- NRC Quality website: <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance.html>

- **NRC Quality website:** <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight/past/2008/index.html>



Summary

- Know the regulations
- Definitions
- Timeframes
- Understand the nuances and subtle points
- Use your resources/tools
- Knowing the background, regulations, common findings/oversights, assessment techniques, and using your resources will help facilitate an effective audit of internal and subtier suppliers Part 21 process.



Questions

- Questions ????????