



NRC Workshop on Vendor Oversight for New Reactor Construction

10 CFR Part 21: Requirements and Guidance

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Agenda

- Section 206 of ERA of 1974
- Back to Basics
- 10 CFR Part 21 Process
- Part 21 Requirements
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- Part 21 as Verified by IP 36100
- Part 21 vs 10 CFR 50.55(e)
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Energy Reorganization Act

Section 206

- The Energy Reorganization Act (ERA) of 1974, Section 206, “Noncompliance,” requires
 - (a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act (AEA) of 1954 as amended, or pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity—
 - (1) fails to comply with the AEA of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards, or
 - (2) contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate, shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

Energy Reorganization Act

Section 206 (cont.)

- (b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the AEA of 1954, as amended.
- (c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the AEA of 1954, as amended.

Energy Reorganization Act

Section 206 (cont'd)

- (d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section.

Energy Reorganization Act

Section 206 (cont'd)

- The text of Section 206 of the ERA of 1974 is contained in NUREG-0980, “Nuclear Regulatory Legislation: 109th Congress (Volume 1, No. 7, Rev. 1, 2nd Session, and Volume 2, No. 7, 1st Session)”
- <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0980/rev1/vol-1-sec-2-to-5.pdf> (on the NRC website)

Back to Basics

- Basic Component – as defined in 21.3 –
 - “(1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:
 - (A) The integrity of the reactor coolant pressure boundary;
 - (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
 - (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

Back to Basics (cont'd)

- (1)(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.”

10 CFR Part 21 Process

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

Part 21 Process (cont'd)

- 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

Part 21 Process (cont'd)

- Discovery
- Evaluation
- Notification

Part 21 Process (cont'd)

- Discovery –
 - “... completion of the documentation first identifying the existence of a deviation or failure to comply ...” [10 CFR 21.3]
 - Inputs to Part 21 process could be potential deviations and failures to comply identified through the nonconformance and/or corrective action process that may require evaluation under the Part 21 process

Part 21 Process (cont'd)

- Evaluation –
 - 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)]

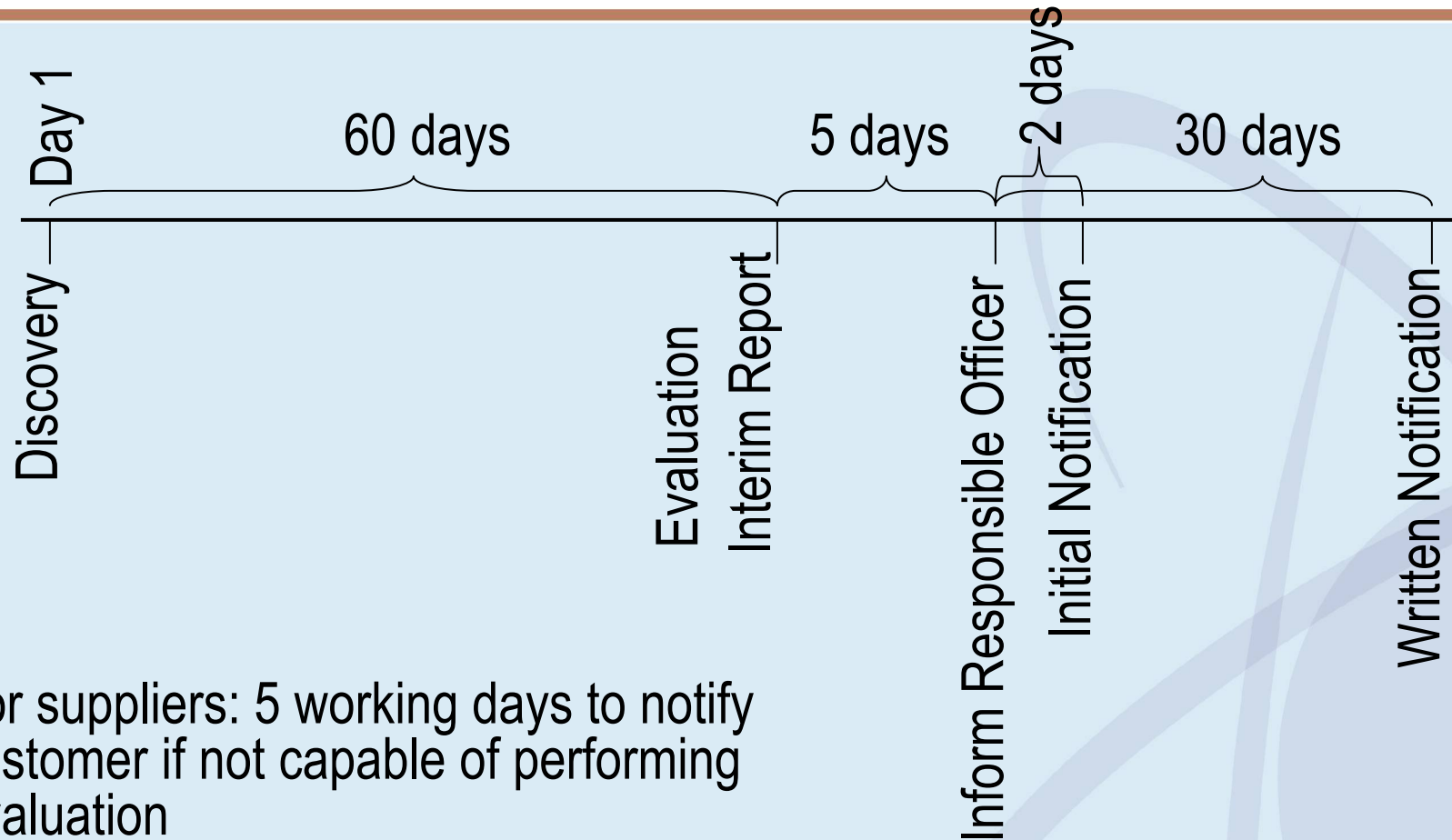
Part 21 Process (cont'd)

- 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 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 (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



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 Requirements as Verified in IP 36100 (cont'd)

- Procedure Requirements [10 CFR 21.21(a)]
 - The procedure 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 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 (continued)
 - 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

Part 21 vs. 10 CFR 50.55(e)

- 50.55 “Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses”
 - “...each combined license is subject to the terms and conditions in paragraphs (e) and (f) of this section until the date that the Commission makes the finding under §52.103(g) of this chapter:”

Part 21 vs. 10 CFR 50.55(e)

(cont'd)

- 50.55(e) has requirements for posting, procedures to evaluate deviations and failures to comply, notification to the NRC, procurement documents, and records retention.
- Differences exists in requirements of procedures, notification, and records retention.

Part 21 vs. 10 CFR 50.55(e)

(cont'd)

- 50.55(e)(3)(iii)(C) (procedures) requires notification of director or responsible officer if the construction of a facility or activity, or basic component supplied to such facility... undergoes any significant breakdown in any portion of the quality assurance program conducted under Appendix B which could have produced a defect in a basic component.

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

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