



10 CFR Part 21, “Reporting Of Defects and Non-compliance”

ASME NQA-1 EU / EMEA IWG

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US NUCLEAR REGULATORY COMMISSION (NRC)



Agenda



- 10 CFR Part 21 Purpose
- Definitions and Process
- Part 21 Timeline
- Part 21 Requirements
- Regulatory Guide RG 1.234 “Evaluating Deviations and Reporting Defects and Noncompliance”
- Questions & Comments



10 CFR Part 21

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- Purpose of the regulation is to notify the Nuclear Regulatory Commission of:
 - Defects in a basic components relating to substantial safety hazards or,
 - A failure to comply with any applicable rule, regulation, order, or license of the NRC relating to substantial safety hazards.
 - 10 CFR Part 21 applies to:
 - NRC licensed facilities
 - Suppliers of basic components for NRC licensed facilities



Definitions and Process

- Basic Component [as defined in 21.3]
 - Structure, system, or component or part thereof, that affects a safety function necessary to assure:
 1. Integrity of the RCS pressure boundary
 2. Capability to shutdown the reactor and maintain in safe shutdown condition, or
 3. The capability to prevent or mitigate the consequences of accidents which could result in offsite exposure [...]
 - Items designated and manufactured under:
 - An Appendix B to 10 CFR Part 50 quality assurance program, or
 - A Commercial-grade item which have successfully completed the dedication process



Part 21 Process

- Discovery
- Evaluation
- Notification





Part 21 Process

- 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

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

Strong Corrective Action Programs are
VITAL
for identifying potential deviations



Part 21 Process

- Evaluation –
 - The process within 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 specification safety limits, etc.

NRC NUREG-0302, contains the criteria to determine the existence of substantial safety hazard (SSH)



Part 21 Process

- Evaluation –
 - Determine, within **60 days** of discovery, if deviation could create a SSH [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 this determination [10 CFR 21.21(b)]



Part 21 Process

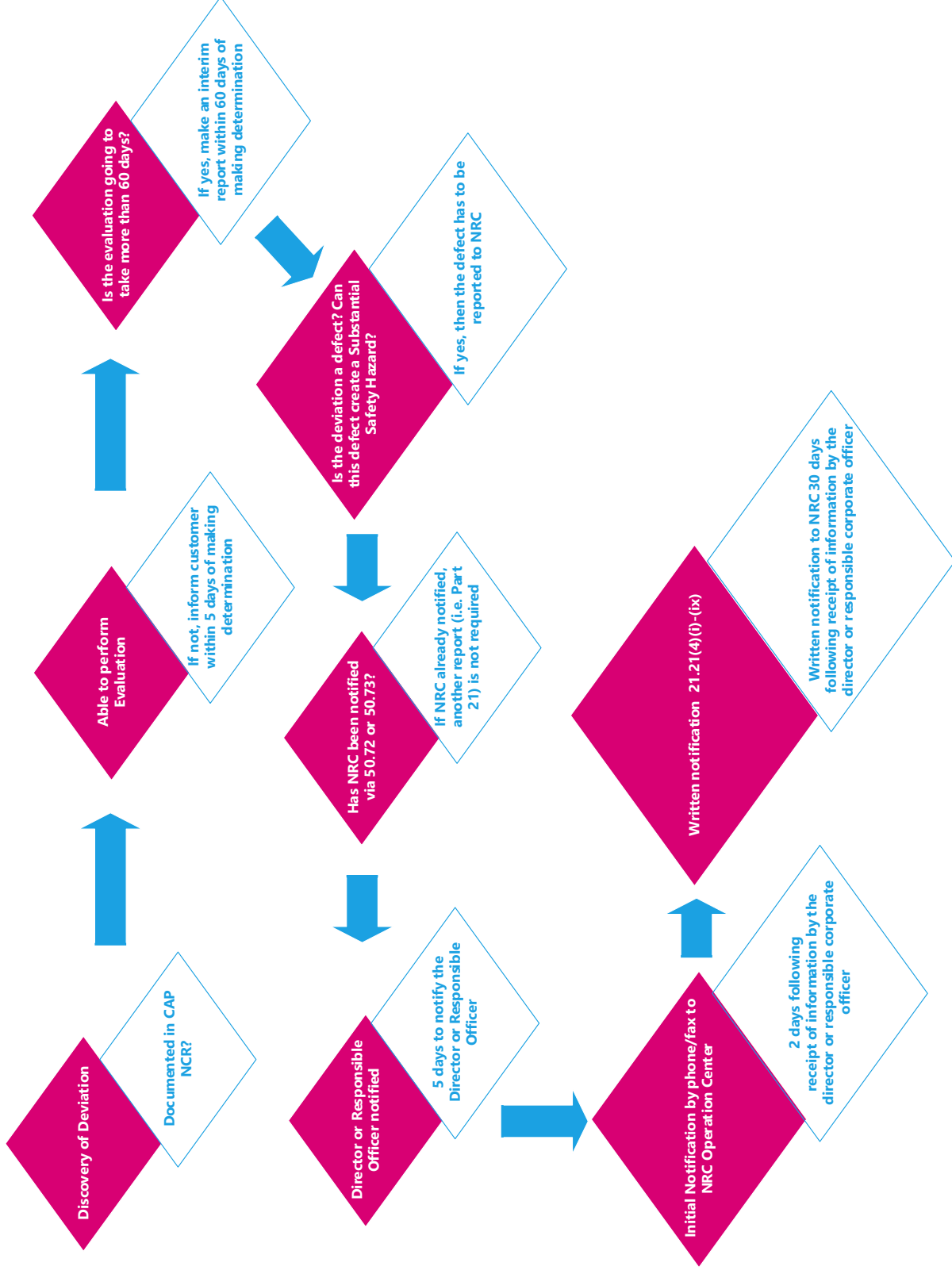
- Notification – [10 CFR 21.21(d)]
 - Inform a director or responsible officer, as soon as practicable and, in all cases, within **5** working days after completion of the evaluation
 - Notification to Commission
 - Initial notification by facsimile or telephone within **2** days of informing the responsible officer and written notification within **30 days** of informing the responsible officer



Part 21 Process

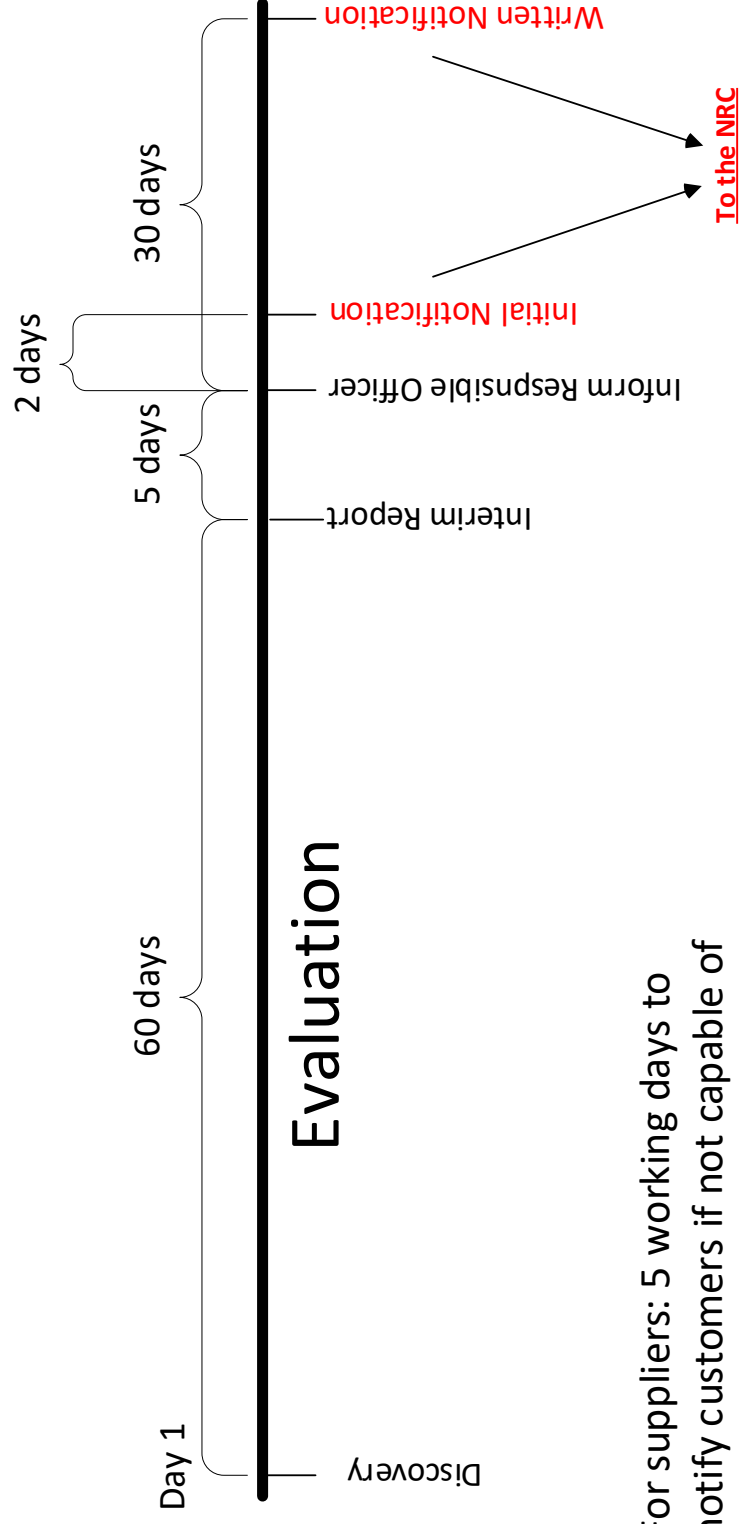
- Notification (continued)
 - Content of written notification
 - Name and address of entity informing the Commission
 - Identification of basic component that contains the defect
 - Identification of the vendor
 - Nature of the defect
 - The SSH that could be or was created by the defect
 - The date 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





Part 21 Timeline



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



Part 21 Requirements

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



Part 21 Requirements

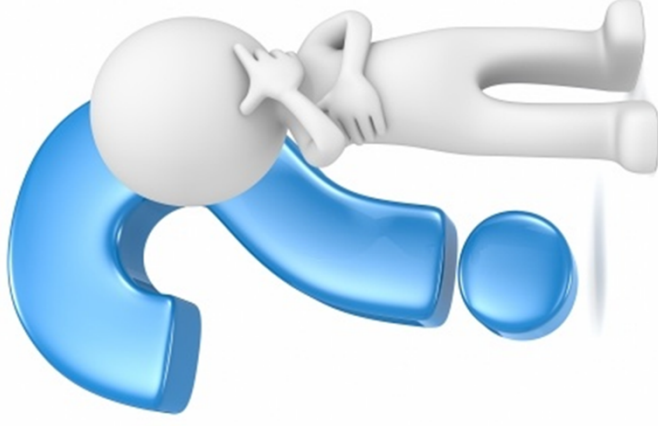
- Interpretation - Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulation in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission. [10 CFR 21.4]



RG 1.234 “Evaluating Deviations and Reporting Defects and Noncompliance”

- Endorses Revision 1 of NEI 14-09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance” (ML16054A825)
- Provides clarification on Part 21 requirements for reporting and evaluating
- **Efforts made by the staff as part of the Rule Making process to clarify Part 21 requirements are captured here**

Questions & Comments



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