



Industry Guidance on Part 21 Evaluation and Reporting

NRC Workshop on Vendor Oversight
June 23, 2016

Overview

- NEI 14-09 Rev 1 submitted in Feb. 2016
 - Intended for power reactor licensees and their suppliers
 - Request endorsement through Regulatory Guide
- Purpose
 - Comprehensive guidance on Part 21 evaluation and reporting
 - Address clarity issues identified by NRC
 - Incorporate experience and lessons learned

NEI 14-09, Revision 1

**GUIDELINES FOR
IMPLEMENTATION OF
10 CFR PART 21
REPORTING OF DEFECTS
AND NONCOMPLIANCE**

February 2016



June 23, 2016

NRC Workshop on Vendor Oversight

nuclear. clean air energy.

Sources of content

- NUREG-0302 – Q&A from 1977 rulemaking
- Statements of consideration from subsequent rulemakings
 - 1977: 40FR28893
 - 1978: 43FR48622
 - 1991: 56FR36081
- NRC Policy papers (e.g., SECY 91-150)
- NRC Regulatory Basis for Part 21 Clarifications

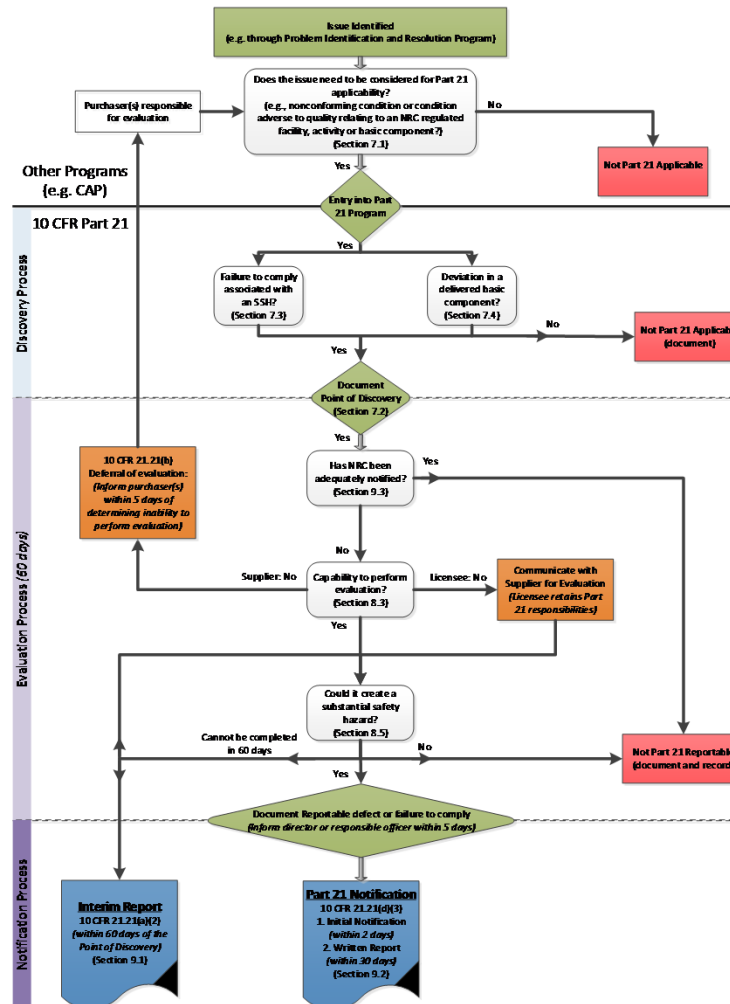
Issues identified by NRC

- SECY 11-0154 and Regulatory Basis identified issues that should be clarified
- Clarifications in NEI 14-09
 - Quality requirements in procurement documents
 - Point of discovery
 - Deviation and delivery
 - Evaluation and reporting responsibility
 - Deferral of evaluation
 - Use of licensee event reports (50.72/50.72)
 - Acceptable forms of written notification
 - Contemporary posting
 - Training

Outline

- Purpose and scope
- Definitions and acronyms
- Facilities, activities and organizations subject to Part 21
- Director and responsible officers
- Interfaces with other regulations
- Organization's controls (e.g. procedures, posting)
- Discovery process
- Evaluation process
- Notification process
- Appendices: flowchart and checklist template

Part 21 Evaluation and Reporting Process



Highlighted Areas for Supplier Awareness

- Discovery (Sections 2.8 and 7)
- Nexus between licensee evaluation report and Part 21 obligations (Section 5.2)
- Responsibility to establish procedures (Section 6.1)
- Maintaining Part 21 evaluations that do not result in reports to the NRC (Section 6.2)
- Significance of specifying Part 21 requirements in procurement documents (Section 6.5)
- Benefits of maintaining open dialog between licensee and vendor on a potential Part 21 evaluation (Section 8.2)

Discovery

- Part 21 definition:
 1. Completion of documentation first identifying,
 2. the existence of a deviation or failure to comply potentially associated with a substantial safety hazard
- SECY 91-150: Discusses that discovery is a process that requires some investigation
- Guidance clarification
 - Point of discovery does not always coincide with entry into corrective action program
 - Time for discovery depends on complexity of issue
 - Discovery should be timely and not unnecessarily delay the evaluation

Use of licensee event reports (50.72/50.73)

- Part 21 rule and statements of consideration
 - 50.72/50.73 evaluation and report satisfy Part 21
- NRC identified issues for clarification
 - LERs described Part 21 reportable conditions, but did not indicate Part 21 applicability
 - Examples in NRC letter to NEI (ML14232A816)
- Guidance clarification
 - If Part 21 is applicable, it should be identified in LER report
 - If Part 21 is applicable, LER should contain as much Part 21 information as possible

Path Forward

- Draft regulatory guide published for comment
 - Endorsement of NEI 14-09
 - Additional guidance for activities other than power reactors (e.g., fuel cycle facilities)
 - Anticipated in mid-2016
- Final Regulatory Guide
 - Anticipated in early 2017



June 23, 2016

NRC Workshop on Vendor Oversight

nuclear. clean air energy.