

NRC Public Meeting
Rulemaking to Revise
10 CFR Part 21
August 1, 2011

PART 21: EVALUATING AND REPORTING

PANEL DISCUSSION



■ EVALUATING & REPORTING

1. Lack of Regulatory Guidance

Problem statement:

- The NRC has never issued a Regulatory Guide on evaluating and reporting under Part 21

Potential recommendation:

- Issue the NRC's "How-To" on Part 21

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
		✓	

■ EVALUATING & REPORTING

2. Quality Requirements in Procurement Documents

Problem statement:

- Quality requirements are not always properly invoked

Potential recommendation:

- Require quality requirements (e.g. Appendix B for reactors) in purchase orders

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓	✓	✓	

■ EVALUATING & REPORTING

3. Lack of clarity in definition of Basic Component for non-reactor facilities

Problem statement:

- Definition of Basic Component for non-reactors is unclear
 - Many exemption requests requested and granted for Part 70 facilities
 - Problematic phrase “directly procured by the licensee” in definition of Basic Component

Potential recommendation:

- Consider need for more detailed definitions for certain applications
- Eliminate procurement language in definition of Basic Component

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓		✓	

■ EVALUATING & REPORTING

4. Clarify the Point of Discovery

Problem statement:

- “Completion of documentation” term in definition of discovery is subject to diverse interpretations

Potential recommendation:

- Strengthen link to Corrective Action Program
- Explicitly require that Conditions Adverse to Quality to be screened for Deviations

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓		✓	

■ EVALUATING & REPORTING

5. Evaluating and Reporting Responsibility

Problem statement:

- Regulation does address supplier and customer responsibilities for evaluating or reporting

Potential recommendation:

- Clarify expectations for each entity's responsibility
- Explore customer communication to a supplier when a deviation is discovered
- Clarify responsibilities with deferring evaluation (see next slide)

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓		✓	

■ EVALUATING & REPORTING

6. Deferral of Evaluations 21.21(b)

Problem statement:

- Deferral of Part 21 evaluations are not always adequately communicated to customers

Potential recommendation:

- Require formal customer notification when Part 21 evaluation cannot be performed

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓	✓	✓	

■ EVALUATING & REPORTING

7. Use of Licensee Event Reporting (50.72 and 50.73)

Problem statement:

- Lack of clarity as to when licensee event report evaluations satisfy Part 21 requirements

Potential recommendation:

- Offer guidance to clarify when licensee event reporting fulfills Part 21 responsibility.

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓		✓	

■ EVALUATING & REPORTING

8. Acceptable forms of written notification per 21.21(d)(2)

Problem statement:

- Statement can be misinterpreted to incorrectly allow other reporting to satisfy Part 21

Potential recommendation:

- Clarify that “other” reports must reference Part 21 and include the information required by 21.21(4)

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓		✓	

■ EVALUATING & REPORTING

9. 50.55(e) Redundancy

Problem statement:

- 50.55(e) is a redundant reporting requirement.

Potential recommendation:

- Move reporting of QA program breakdown during construction to Part 21

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓			

■ EVALUATING & REPORTING

10. Evaluation of Counterfeit Fraudulent and Suspect Items (CFSI) under Part 21

Problem statement:

- Since they are not explicitly addressed, it may not be immediately clear that delivered counterfeit and fraudulent items are deviations, per Part 21

Potential recommendation:

- Clarify that counterfeit and fraudulent items are Deviations, requiring evaluation

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
		✓	

■ EVALUATING & REPORTING

11. Clarify Deviation and delivery

Problem statement:

- Concept of delivery is not introduced until addressing Defects (in definition of Defect)

Potential recommendation:

- Move delivery to definition of deviation

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
✓		✓	

■ EVALUATING & REPORTING

12. Contemporary Posting Requirements

Problem statement:

- Interpretation of current posting requirements could prevent the use of more effective communication methods

Potential recommendation:

- Offer guidance that supports the use contemporary technologies to communicate Part 21 to employees

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
		✓	

■ EVALUATING & REPORTING

13. Training

Problem statement:

- The level of training required for Part 21 is not addressed

Potential recommendation:

- Offer guidance emphasizing that Part 21 is an activity affecting quality and therefore training must be adequately performed per the quality assurance program.

Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
		✓	