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

Rulemaking Overview and Update

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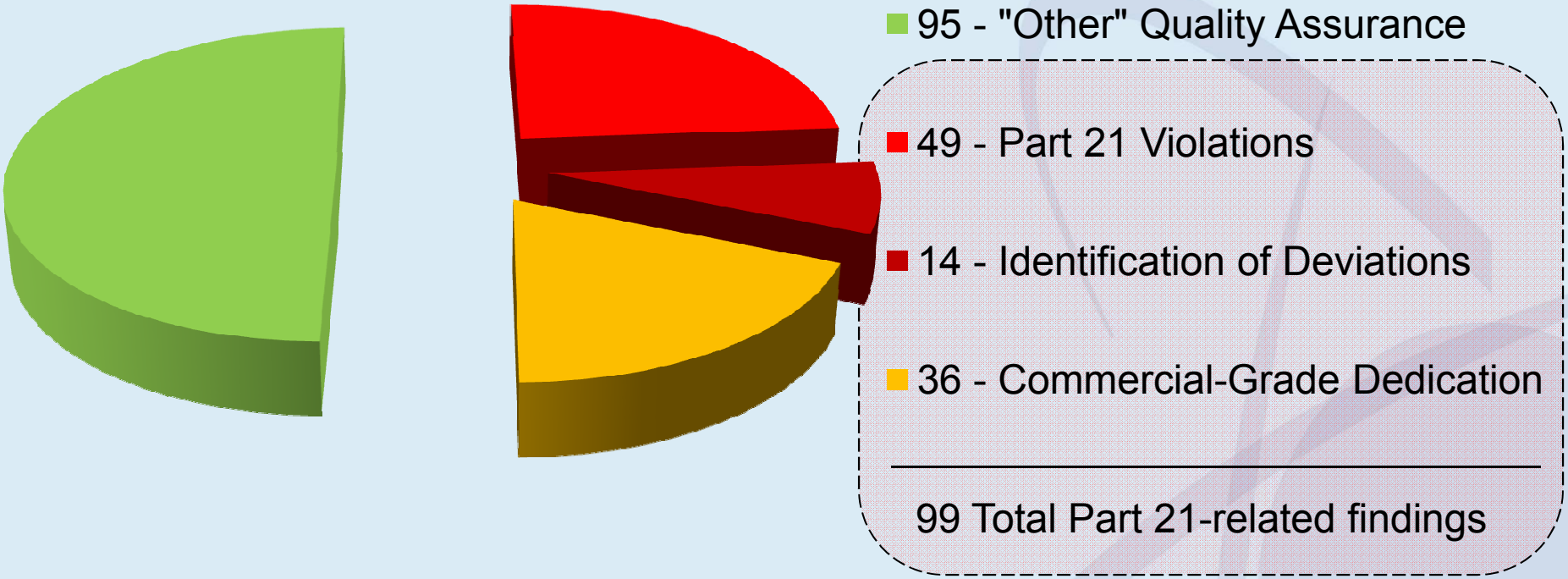
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Right Time for Change

- NRC believes changes to Part 21 and associated regulations are desirable
  - Many issues despite generic communications and outreach efforts
  - Recent audits by Office of the Inspector General reiterated issues
- New plant construction is the appropriate time to consolidate guidance and clarify the NRC's expectations
- Opportunity to clarify expectations for non-reactor facilities

"Even as the final rule was published on June 6, 1977, the Commission recognized that future experience and further information might warrant clarifying or other changes to the rule." (NUREG-0302)

Right Time for Change (cont'd)



Vendor Inspection Findings (2007 to 2011)

Build on Experience

EVALUATING AND REPORTING	Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
1. Lack of Regulatory Guidance			✔	
2. Quality Requirements in Procurement Documents	✔	✔	✔	
3. Procurement language in definition of Basic Component for non-reactor facilities	✔		✔	
4. Clarify point of discovery	✔		✔	
5. Evaluating and Reporting Responsibility	✔		✔	
6. Deferral of Evaluation - 21.21(a)	✔	✔	✔	
7. Use of Licensee Event Reporting (i.e. 50.72/73)	✔		✔	
8. Acceptable forms of written notification per 21.21(2) for non-reactor facilities	✔		✔	
9. 50.55e Redundancy	✔		✔	
10. Evaluation of Counterfeit Fraudulent and Suspect Item (CFSI) under Part 21			✔	
11. Clarify Deviation and delivery	✔		✔	
12. Contemporary posting requirements			✔	
13. Training			✔	

COMMERCIAL-GRADE DEDICATION	Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
A. Lack of Regulatory Guidance			✔	✔
B. Proper Place for Dedication	✔			
C. Definition of Dedication	✔			
D. Definition of Commercial-Grade Item	✔			
E. Clarify that Dedication is a Safety-Related activity			✔	
F. Dedication plans and the importance or safety function	✔	✔	✔	✔
G. Sampling Requirements			✔	✔
H. Use of Commercial Calibration (and Testing) Labs			✔	✔
I. Software Dedication			✔	✔

ADMINISTRATIVE CHANGES	Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
i. Add “Part 52” to definition of Dedication	✔			
ii. Definitions for Part 76 facilities (i.e. Basic Component, Substantial Safety Hazard)	✔			
iii. Definition of Critical Characteristics for non-reactor facilities	✔			

Build on Experience (cont'd)

- Clarify the Regulations
  - Simplify when possible
  - Revisit definitions in Part 21
  - Must comply with Section 206 "Noncompliance" of the Energy Reorganization Act of 1974
- Provide Updated Regulatory Guidance
  - Benefit from over 33 years of experience
  - Opportunity to consolidate existing guidance
- Use stakeholder input to improve the Part 21 process

Milestones

- Office of New Reactors began preliminary rulemaking activities in December 2009
- NRC agency-wide Part 21 working group formed in January 2011
  - Discussions on holistic approach to clarify Part 21
- Preliminary discussions at public meetings
  - 2011 NRC Regulatory Information Conference
  - Nuclear Procurement Issues Committee (NUPIC) Vendor Conference
  - Electric Power Research Institute Joint Utility Task Group (EPRI JUTG)

Milestones (cont'd)

- September 2011: Commission (SECY) paper
  - Communicate the staff's plan to develop the regulatory basis for rulemaking
- Rulemaking kickoff meeting in Fiscal Year 2012
- **Extensive stakeholder and public interaction throughout the rulemaking process**

Milestones (cont'd)

YOU ARE HERE

Identify need for rulemaking

NRC staff issued user need memo in 2009

Regulatory (Technical) Basis

- Foundation of effective rulemaking

- Public meetings
- Draft rule text

Proposed Rule

- Draft text & guidance

- 75 day public comment period (typically)

Final Rule

- Final text & guidance
- Implementation period (if needed)

- Public meetings on implementation

Opportunities for public participation

How to Get Involved

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