

NUPIC
20th Annual Vendor
Meeting
June 15 – 16, 2011

10 CFR Part 21 Rulemaking Update

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Office of New Reactors

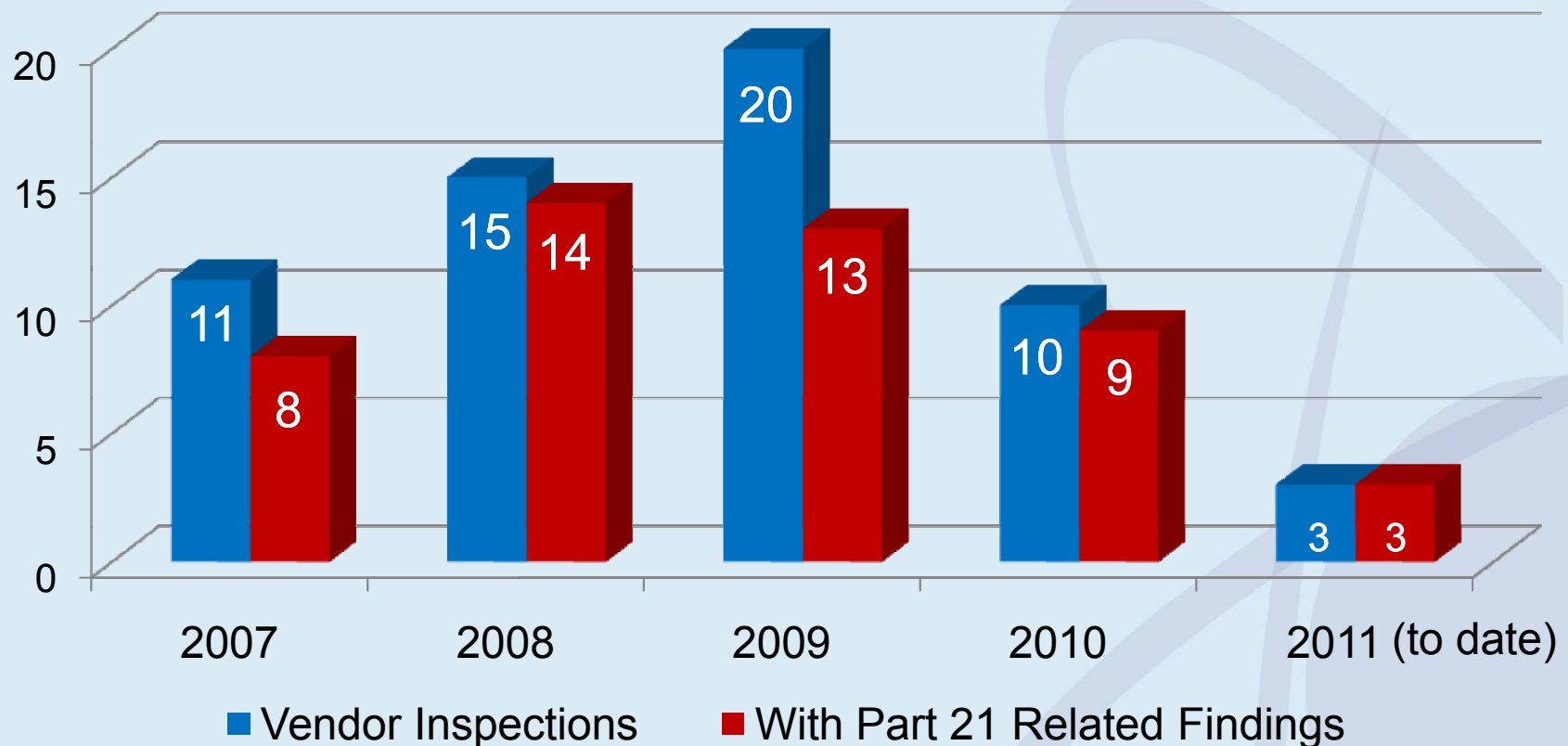


Right Time for Change

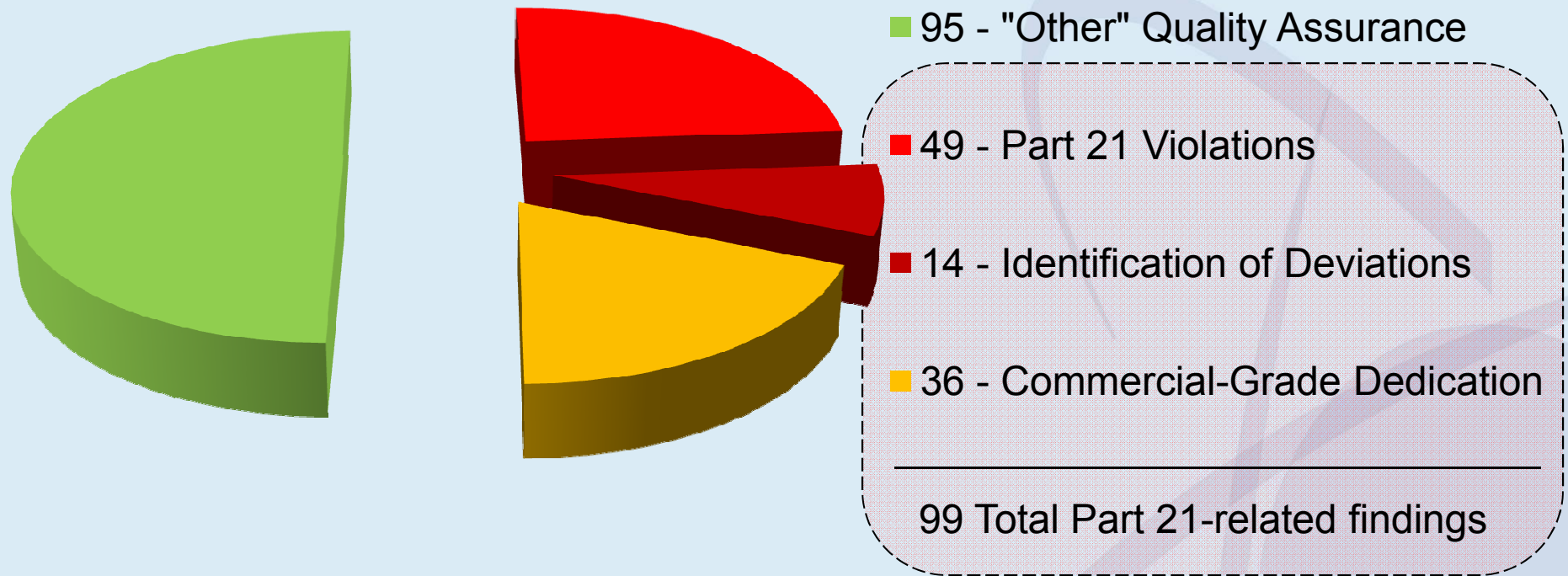
- NRC believes changes to Part 21 and associated regulations are desirable
 - Many issues despite generic communications and outreach efforts
 - Recent audits by Office of the Inspector General reiterated issues
- New plant construction is the appropriate time to consolidate guidance and clarify the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

“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)



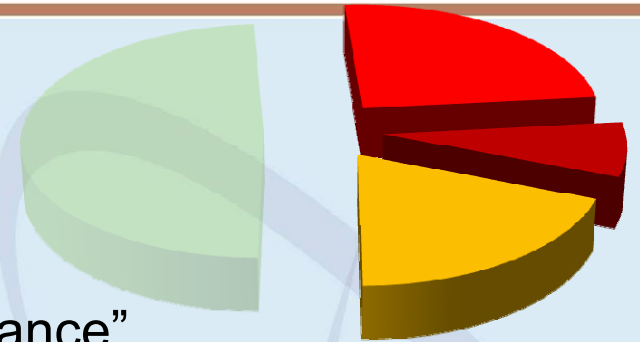
Right Time for Change (cont'd)



Vendor Inspection Findings (2007 to 2011)

Build on Experience

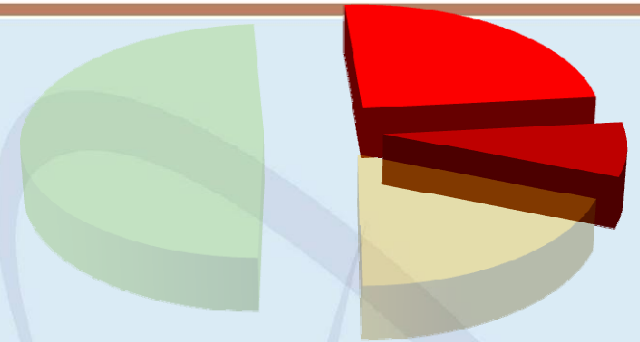
- Clarify the Regulations
 - Simplify when possible
 - Revisit definitions in Part 21
 - Must comply with Section 206 “Noncompliance” of the Energy Reorganization Act of 1974
- Provide Updated Regulatory Guidance
 - Benefit from over 33 years of experience
 - Opportunity to consolidate existing guidance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



Areas of Improvement

■ EVALUATING AND REPORTING

1. Issue Regulatory Guidance
 - Issue the NRC’s “How-To” on Part 21
2. Quality Requirements in Procurement Documents
 - Require quality requirements (i.e. Appendix B) in purchase orders
3. Clarify the Point of Discovery
 - Strengthen link to Corrective Action Program
 - Require Conditions Adverse to Quality to be screened for Deviations
4. Responsibility and Deferral of Evaluations: 21.21(b)
 - Require formal customer notification when Part 21 evaluation cannot be performed



Areas of Improvement (cont'd)

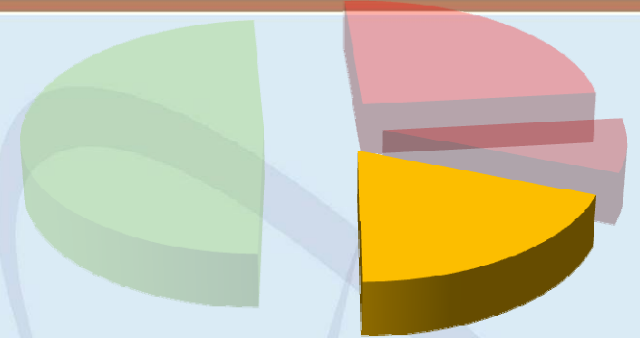
■ EVALUATING AND REPORTING (cont'd)

5. Examine 50.72 & 50.73 Licensee Event Reporting
 - 50.72 and 50.73 may not always fulfill Part 21 responsibility
6. 50.55(e) Redundancy
 - Move reporting of QA program breakdown during construction to Part 21
7. Counterfeit Fraudulent and Suspect Item Tie-In
 - Clarify that counterfeit and fraudulent items are Deviations
8. Update Posting Requirements
 - Make it easier to use contemporary technologies

Areas of Improvement (cont'd)

COMMERCIAL-GRADE DEDICATION

1. Issue Regulatory Guidance
 - Revisit and Endorse industry guidance
2. Proper Place for Dedication
 - Separate section for Dedication
3. Definition of Dedication
 - Focus on equivalency to Appendix B (for reactors)
4. Definition of Commercial-Grade Item
 - Provide contemporary definition
5. Clarify that Dedication is a Safety-Related Activity



Areas of Improvement (cont'd)

COMMERCIAL-GRADE DEDICATION (cont'd)

6. Knowledge of Safety Function

- Allow dedication without knowing safety function
- Require Dedication Plan

7. Sampling

- Clarify guidance on reduced sampling
- Endorse EPRI TR-017218

8. Clarify Use of Commercial Laboratories for Calibration and Testing

9. Establish Guidelines for Software Dedication

Milestones



- Office of New Reactors began preliminary rulemaking activities in December 2009
- Ongoing internal discussions on holistic approach to clarify Part 21
 - Internal Part 21 Working Group meetings
 - Preliminary discussions at public meetings
- Consider interim solutions such as Generic Communications

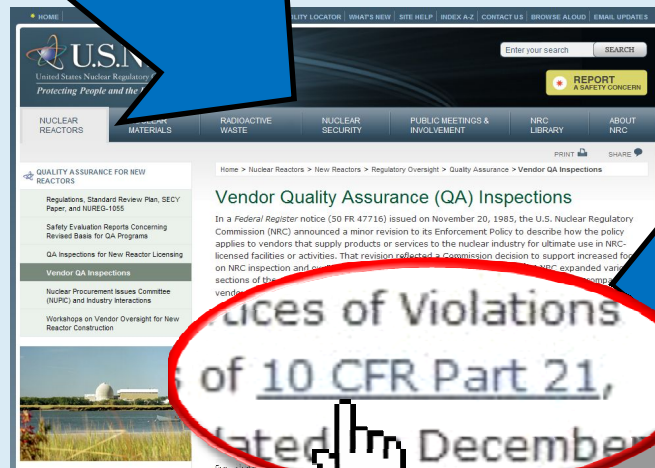
Milestones (cont'd)



- August 1, 2011: Category 3 Public Meeting to solicit early stakeholder feedback
- September 2011: Commission (SECY) paper to recommend options to clarify the requirements of Part 21
- Rulemaking kickoff meeting in Fiscal Year 2012

Extensive stakeholder and public interaction throughout the rulemaking process

How To Get Involved



How To Get Involved (cont'd)

PUBLIC MEETING: August 1, 2011

- Agenda under development
 - Part 21 Vision in greater detail
 - Open forum for discussion
 - Seek stakeholder input
- Logistics:
 - Half-Day event (afternoon)
 - Location near NRC Headquarters in Rockville, Maryland
 - Reminder will be sent to Part 21 subscribers



Thank you for your attention!

Victor Hall

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