



10 CFR PART 21 RULEMAKING UPDATE

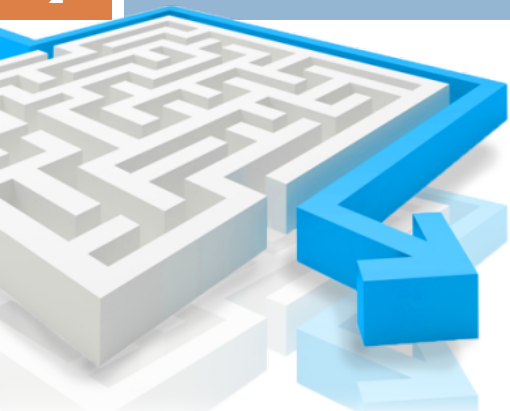


Victor Hall, Office of New Reactors



Part 21 Rulemaking – What is it?

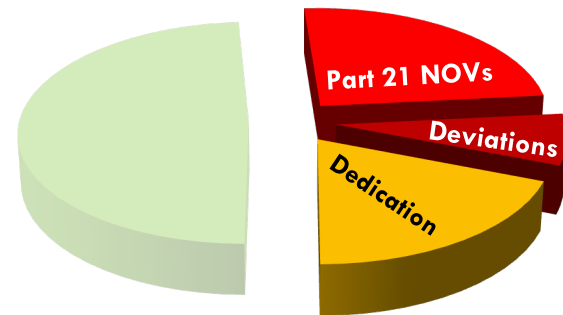
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- NRC staff's proposal to clarify 10 CFR Part 21
 - ▣ Simplify rule language when possible
 - ▣ Provide updated Regulatory Guidance

- Developed 25 Areas for Improvement in 3 categories:

- ▣ Evaluating & Reporting
- ▣ Commercial Grade Dedication
- ▣ Administrative Changes



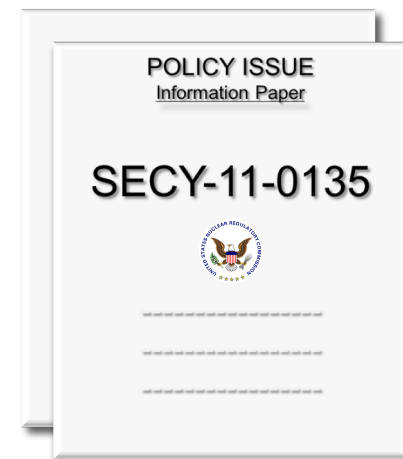
- Use stakeholder input to improve the Part 21 process
 - ▣ Additional areas for improvement identified at public meetings



Quick History

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- Recognized need for revisions during promulgation (1977)
 - ▣ 1991: Changes to eliminate duplicate reporting. More detail on reporting criteria, content, and timeline
 - ▣ 1995: Expanded on commercial grade dedication process
- 2009: Office of New Reactors User Needs Memorandum
- 2010: Inspector General audit of Vendor Program
- 2011: Commission Paper: SECY-11-0135
 - ▣ Informed the Commission of staff's plan to develop Regulatory Basis to clarify Part 21





Rulemaking Timeline

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**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





Regulatory Guidance



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- Regulatory Guidance development will be integral part of rulemaking process
 - ▣ Benefit from over 34 years of experience
 - ▣ Opportunity to consolidate existing guidance
- DG-1 291, Evaluating Deviations and Reporting Defects and Noncompliance
- DG-1 292, Dedication of Commercial Grade Items



Draft Regulatory Basis

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- ❑ Issued Revision 0 of the Draft Regulatory Basis for rulemaking (**ADAMS Accession No. ML12248A200**) in December 2012
- ❑ Discussed at January 24, 2013, public meeting
- ❑ Follow up discussion topics in meeting summary (ML13052A700)





Draft Regulatory Basis (cont'd)

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Anatomy of the Regulatory Basis (ML12248A200)

- Existing Regulatory Framework
- Definition of Regulatory Problem
- Options to Resolve Regulatory Problem
 - ▣ Proposed Changes to NRC Regulations
 - ▣ Guidance development
 - ▣ Generic Communications
 - ▣ Use Voluntary Programs
 - ▣ Take No Action





Draft Regulatory Basis (cont'd)

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EXAMPLE: Evaluating & Reporting

1. Lack of Regulatory Guidance

- Framework: No formal NRC guidance exists
- Problem: Not enough detail in regulations for many scenarios
- Options to Resolve Regulatory Problem:
 - ▣ No proposed changes to regulations
 - ▣ Develop Regulatory Guidance
 - ▣ Generic communications not a holistic solution
 - ▣ Voluntary programs not a viable solution
 - ▣ No action results in continued findings





Draft Regulatory Basis (cont'd)

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EXAMPLE: Dedication

G. Sampling Requirements

- Framework: No formal NRC sampling guidance
- Problem: Sampling being incorrectly performed
- Options to Resolve Regulatory Problem:
 - ▣ No proposed changes to regulations
 - ▣ Endorse industry standard through Regulatory Guide
 - ▣ Generic communications not as effective as Regulatory Guidance
 - ▣ Voluntary programs: Industry willing to revise guidance
 - ▣ No action results in continued findings





Outreach Activities

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- Public meetings and presentations to actively solicit early stakeholder feedback

- Latest follow-up topics from January 24th, 2013 meeting:
 - ▣ Quality Requirements in Procurement Documents
 - ▣ Definition of Basic Component for Non-Reactor facilities
 - ▣ Flow Chart of Part 21 process (Deviation and Delivery)
 - ▣ Use of 50.72/73 (LERs) to satisfy Part 21 requirements
 - ▣ Definition of Dedication
 - Impact on non-reactor facilities
 - Impact on DOE/NRC licensed facilities
 - What “proposed language” might look like



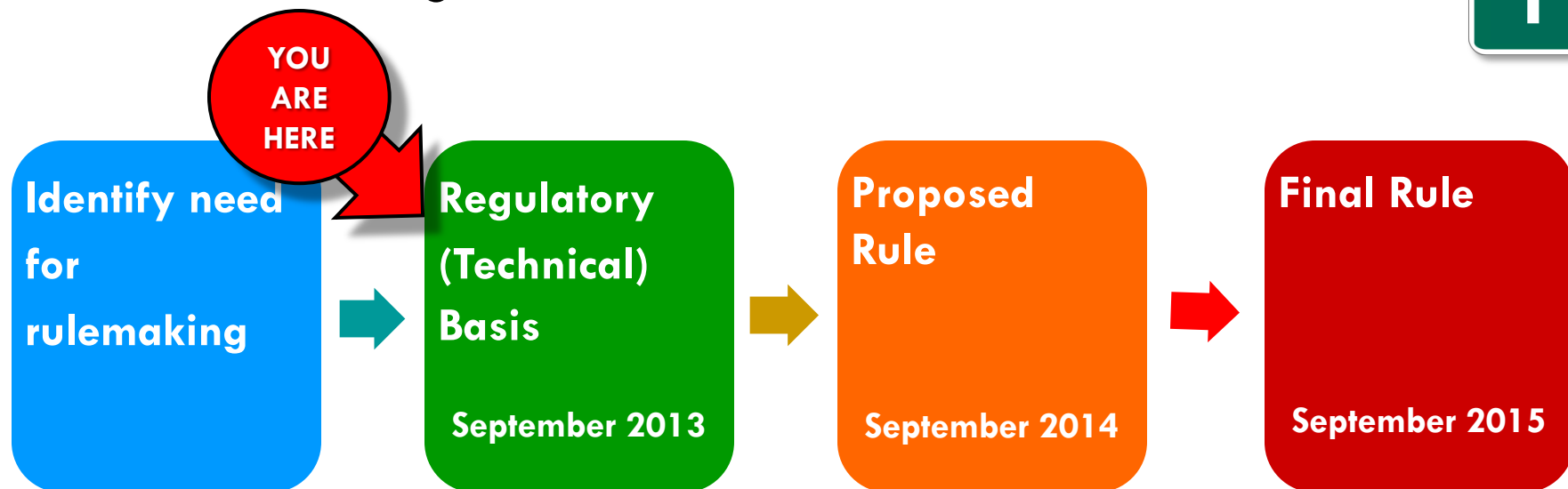
Next Steps

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- Upcoming Public Meeting on May 30, 2013, (tentatively scheduled) to discuss Evaluating & Reporting



- Rulemaking Process





How to Get Involved (cont'd)

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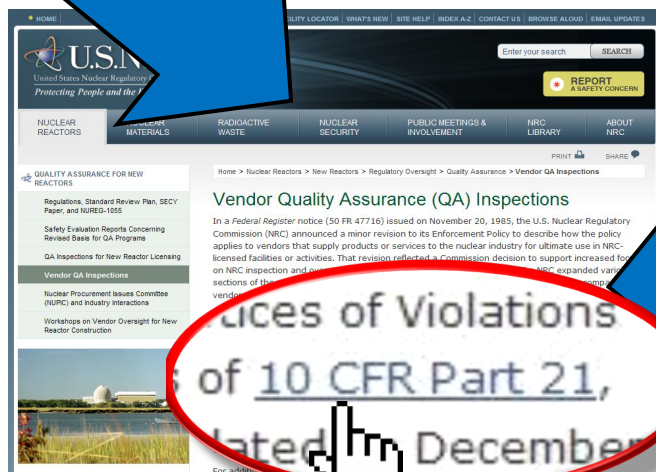
How to Get Involved (cont'd)

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Victor Hall
Office of New Reactors
Victor.Hall@nrc.gov
(301)415-2915

