



# 10 CFR PART 21 RULEMAKING UPDATE

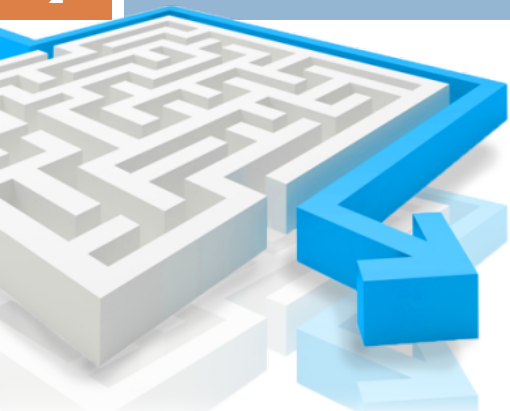


Victor Hall, Office of New Reactors



# Part 21 Rulemaking – What is it?

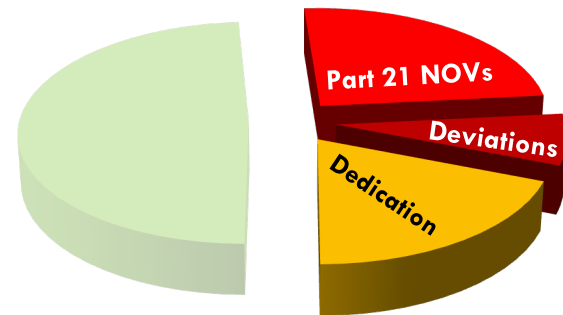
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- NRC staff's proposal to clarify 10 CFR Part 21
  - ▣ Simplify rule language when possible
  - ▣ Provide updated Regulatory Guidance

- Developed 25 Areas for Improvement in 3 categories:

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



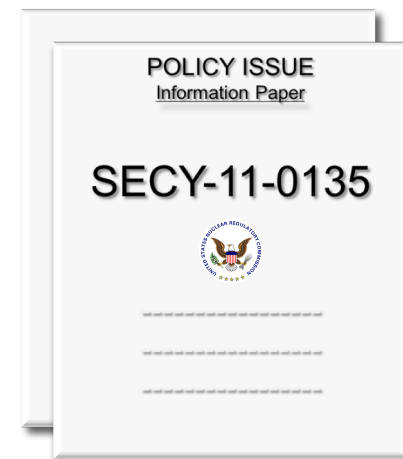
- Use stakeholder input to improve the Part 21 process
  - ▣ Additional areas for improvement identified at public meetings



# 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

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- Public meetings
- Draft rule text

## Proposed Rule

- Draft text & guidance

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- 75 day public comment period (typically)

## Final Rule

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

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- 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 24<sup>th</sup>, 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



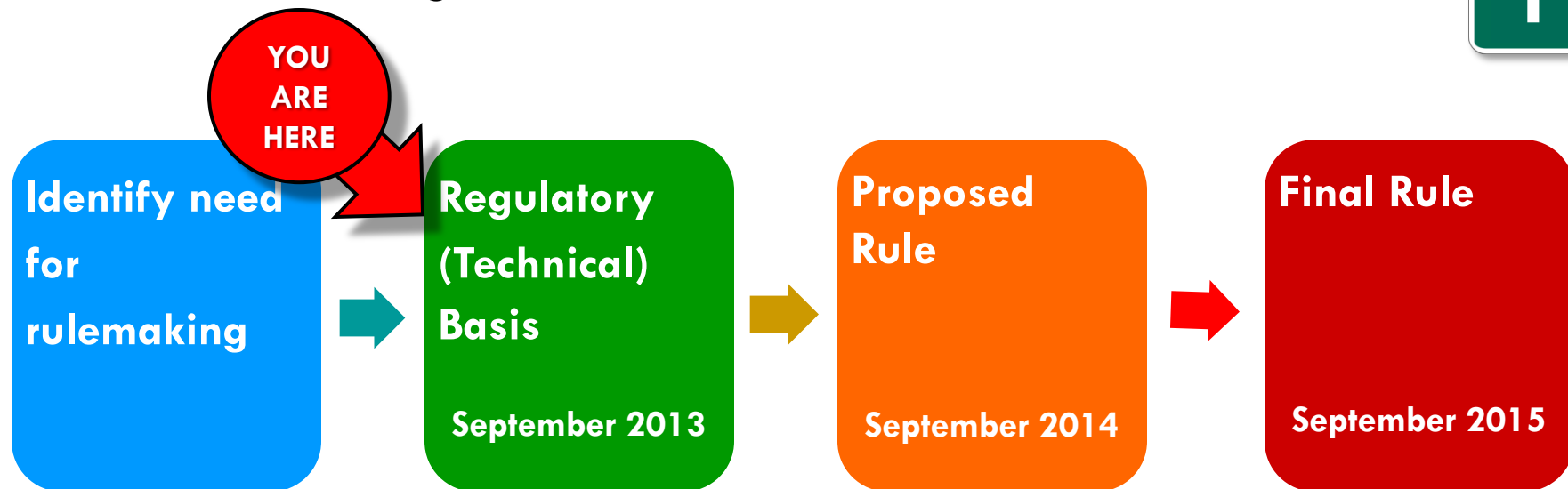
# Next Steps

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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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The screenshot shows the regulations.gov website. On the left, there is a banner with a group of diverse people and the text "let your voice be heard". Below this, it states: "Regulations.gov is your source for U.S. government regulations and related documents. On this site you can find, read and comment on documents. Share your knowledge and make your voice count."

On the right, there is a section titled "Begin a search by choosing a task or entering a keyword". It contains four buttons: "search for a proposed rule" (with a magnifying glass icon), "submit a comment" (with a play button icon), "read comments" (with a speech bubble icon), and "search for a final rule" (with a gavel icon).

Below these buttons, there is a "Select Document Type:" dropdown menu. To its right, there is a search bar labeled "Enter Keyword or ID:" containing the text "NRC-2012-0012". Below the search bar is an orange "Search" button. To the right of the "Search" button are two links: "» Advanced Search" and "» Browse By Topic".

A red circle highlights the search bar containing "NRC-2012-0012" and the "Search" button.

Search for NRO Docket **NRC-2012-0012**



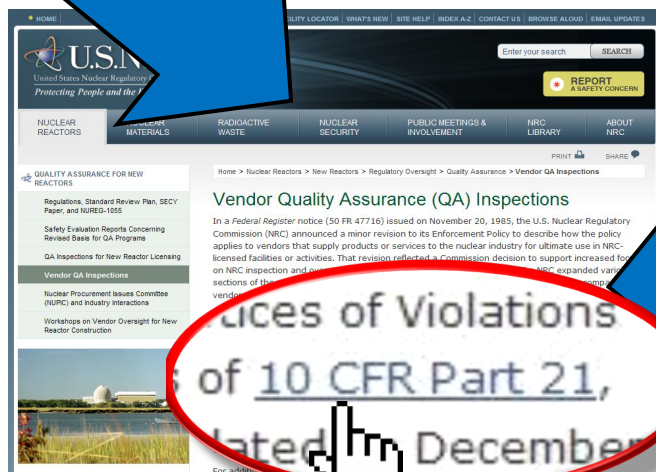
# How to Get Involved (cont'd)

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Google

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

