

10 CFR PART 21 RULEMAKING STATUS NOVEMBER 20, 2014



Jermaine Heath, Office of New Reactors



Rulemaking Timeline



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**YOU
ARE
STILL
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





Draft Regulatory Basis - Stat



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- Working with NRC Office of General Council to finalize Revision 1 of Draft Regulatory Basis
- Planning to include proposed rulemaking language in Revision 1 of Draft Regulatory Basis



Draft Regulatory Basis - Timeline

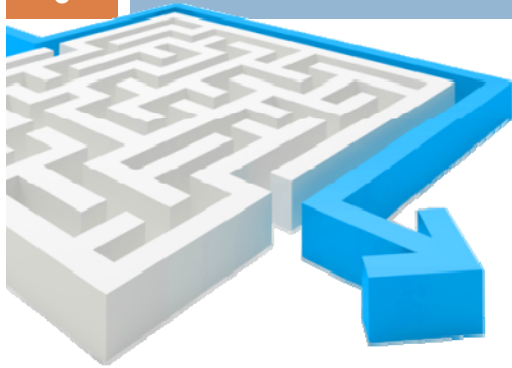
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- Revision 0: Published in December 2012.
 - ❖ Series of public meetings held in 2013
 - ❖ NRC vendor workshop in June 2014
- Revision 1: Plan to publish in ~~September 2014~~ Winter 2014
 - ❖ Will include draft rule language for discussion
 - ❖ Public meetings to follow
- Plan to finalize Revision 1 of the Regulatory Basis in ~~December 2014~~ Spring 2015

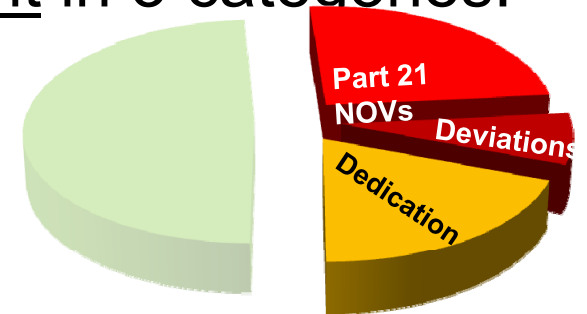


Part 21 Rulemaking – What is it?

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- NRC staff's proposal to clarify 10 CFR Part 21 as prescribed in SECY-11-0135
 - 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





Rulemaking-Proposed Areas of Focus

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EVALUATION AND REPORTING	Requires Regulation Change	New Requirement	NRC Guidance	Proposed Industry Guidance
Lack of Regulatory Guidance			x	x
Quality Requirements in Procurement Documents				
Lack of Clarity in Definition of Basic Component for Nonreactor Facilities and Activities	x			
Clarification of Point of Discovery	x			
Clarification of Defect	x	x		
Clarification of Delivery	x			
Evaluating and Reporting Responsibility			x	x
Deferral of Evaluation – 10 CFR 21.21(b)			x	x
Use of Licensee Event Reporting (§ 50.72 and § 50.73)	x	x	x	x
Acceptable Forms of Written Notification under 10 CFR 21.21(d)(2)			x	x
10 CFR 50.55(e) Redundancy	x	x		
Evaluation of Counterfeit, Fraudulent, and Suspect Items			x	x
Contemporary Posting Requirements			x	x
Training			x	x
Lack of Clarity in Evaluating and Reporting Requirements for Part 70 Licensees			x	x



Rulemaking-Proposed Areas of Focus

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COMMERCIAL-GRADE DEDICATION	Requires Regulation Change	New Requirement	NRC Guidance	Proposed Industry Guidance
Lack of Regulatory Guidance			x	x
Proper Place for Dedication	x			
Definition of Dedication	x			
Definition of Commercial-Grade Item	x			
Clarification of Dedication as Safety-Related Activity			x	
Dedication Plans and the Importance of Safety Function	x	x	x	x
Sampling Requirements			x	x
Use of Commercial Calibration (and Testing) Laboratories— International Laboratory Accreditation Cooperation Process			x	x
Software Dedication			x	x



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-1291, Evaluating Deviations and Reporting Defects and Noncompliance
- DG-1292, Dedication of Commercial Grade Items
- DG-1305, “Design and Analysis Computer program Commercial-Grade Dedication Requirements”



Regulatory Guidance



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Regulatory Guidance development underway, including NRC participation with industry groups and stakeholders

- DG-1291, “Evaluating Deviations and Reporting Defects and Noncompliance” could address:
 - ❖ NEI 14-09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance.”



Regulatory Guidance



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Regulatory Guidance development underway, including NRC participation with industry groups and stakeholders

- DG-1292, Dedication of commercial-grade Items could endorse:
 - ❖ EPRI 3002002982, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications,”



Regulatory Guidance



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Regulatory Guidance development underway, including NRC participation with industry groups and stakeholders

- DG-1305, “Design and Analysis Computer program Commercial-Grade Dedication Requirements” would address:
 - ❖ EPRI Technical Report 1025243, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications”



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 the text "let your voice be heard" and a description of the site's purpose. On the right, there is a search section titled "Begin a search by choosing a task or entering a keyword". Below this title are four icons representing different tasks: "search for a proposed rule", "submit a comment", "read comments", and "search for a final rule". Below these icons, there is a "Select Document Type:" dropdown menu and two checkboxes: "Open for Comment/Submission" and "View results by docket folder". To the right of these options is a search input field containing the text "NRC-2012-0012". Below the input field is an orange "Search" button. To the right of the "Search" button are two links: "» Advanced Search" and "» Browse By Topic". A red circle is drawn around the search input field and the "Search" button.

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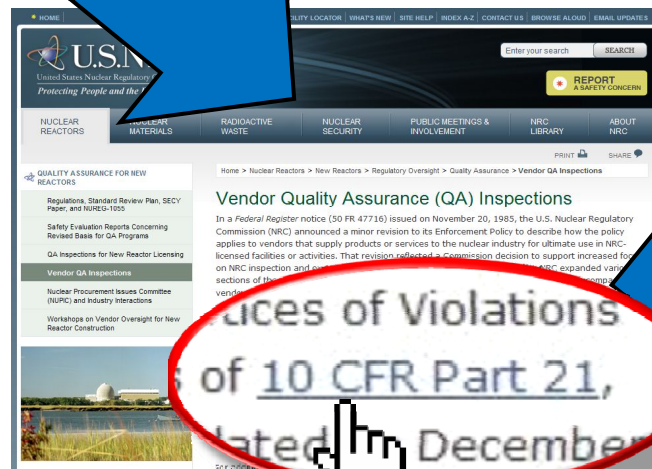
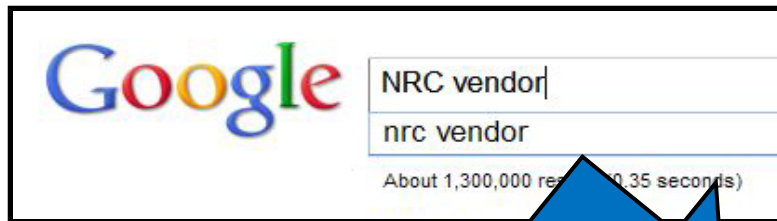
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Search for NRO Docket **NRC-2012-0012**



How to Get Involved (cont'd)

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10 CFR Part 21 Rulemaking Status

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QUESTIONS??