



# Workshop on Vendor Oversight

## 10 CFR PART 21 RULEMAKING UPDATE



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# Part 21 Rulemaking – What is it?

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- Proposal to clarify 10 CFR Part 21, as described in Commission Paper: SECY-11-0135
  - Evaluating & Reporting Process
  - Commercial Grade Dedication
  
- Simplify rule language
  
- Provide updated regulatory guidance
  - DG-1291, Evaluating Deviations and Reporting Defects and Noncompliance
  - DG-1292, Dedication of Commercial Grade Items
  
- Use stakeholder input to improve the Part 21 process



# 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

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- Revision 0 of Draft Regulatory Basis published in December 2012.
  - Series of public meeting held in 2013
  
- Revision 1 due out in June, 2014
  - Will include draft rule language for discussion
  - Public meetings to follow
  
- Plan to finalize Revision 1 of the Regulatory Basis in September 2014



# Regulatory Guidance



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- Regulatory Guidance development underway, including NRC participation with industry groups
- DG-1 291, Evaluating Deviations and Reporting Defects and Noncompliance could endorse:
  - ▣ NEI guidance on Evaluating and Reporting
- DG-1 292, Dedication of Commercial Grade Items could endorse:
  - ▣ EPRI guidance on dedication (Revision to 5652, and consolidation of supplemental guides)

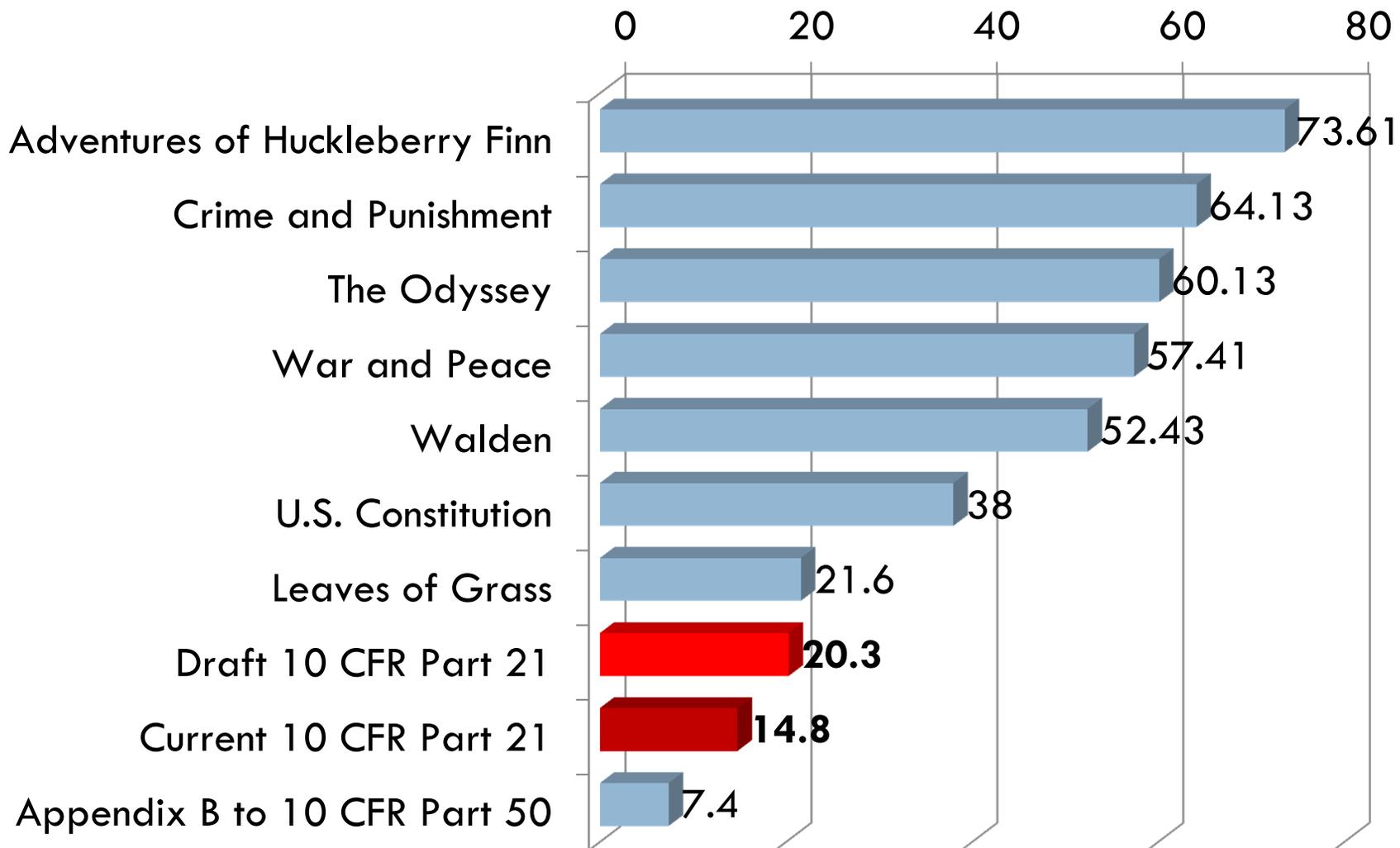
# Rule Language Changes: Less is More

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	<b>CURRENT PART 21</b>	<b>DRAFT PART 21</b>
Words	5488	4334
Words per sentence	29.7	25.3
Passive sentences	24.7%	24%
Flesch Reading Ease (Out of 100 Max)	14.8	20.3

# Flesch Reading Ease (out of 100)

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# Basic Component (Current)

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- Basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:
  - ▣ (A) The integrity of the reactor coolant pressure boundary;
  - ▣ (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
  - ▣ (C) The capability to prevent or mitigate the consequences of accidents...



# Basic Component (New Draft)

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- A basic component means a structure, system, component, or part thereof relied upon to remain functional during and following design basis events to assure:
  - ▣ (A) The integrity of the reactor coolant pressure boundary;
  - ▣ (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
  - ▣ (C) The capability to prevent or mitigate the consequences of accidents...



# Basic Component (Current)

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- (ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.



# Basic Component (New Draft)

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- (ii) Basic components are controlled under a quality assurance program complying with appendix B to part 50 of this chapter.



# Commercial Grade Item (Current)

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- (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).
- (2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:
  - (i) Not subject to design or specification requirements that are unique to those facilities or activities;
  - (ii) Used in applications other than those facilities or activities; and
  - (iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).



# Commercial Grade Item (New Draft)

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- *Commercial grade item* means an item that is not a basic component.



# Dedication (Current)

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- (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.



# Dedication (New Draft)

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- Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function.



# New Draft Section

## § 21.71 Commercial Grade Dedication

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- To dedicate an item, a dedicating entity must:
  - (1) Perform a technical evaluation that identifies the item's critical characteristics.
  - (2) Identify acceptance criteria for each critical characteristic.
  - (3) Verify acceptance of each critical characteristic using one or more of the (four) following acceptance methods...

# New Draft Section (cont'd)

## § 21.71 Commercial Grade Dedication

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- Dedication is complete when all of the item's critical characteristics have been verified and documented.
- Dedication must be conducted in accordance with the provisions of 10 CFR Part 50, appendix B.
- If any critical characteristic of the item cannot be verified then that item cannot be dedicated.



# How to Get Involved

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The screenshot shows the homepage of regulations.gov. The header includes the logo and the tagline "Your Voice in Federal Decision-Making". A navigation bar contains icons for "search for a proposed rule", "submit a comment", "read comments", and "search for a final rule". A large banner on the left features a group of diverse people and the text "let your voice be heard". Below this, a paragraph explains the site's purpose. On the right, a search section is highlighted with a red circle. It includes a "Select Document Type:" dropdown menu, two checkboxes for "Open for Comment/Submission" and "View results by docket folder", and a search bar containing the text "NRC-2012-0012". A red "Search" button and links for "Advanced Search" and "Browse By Topic" are also visible.

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



# How to Get Involved (cont'd)

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