

10 CFR PART 21 RULEMAKING UPDATE AND ITS EFFECT ON COMMERCIAL-GRADE DEDICATION

NUPIC VENDOR MEETING
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Part 21 Rulemaking – What is it?

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- NRC staff's proposal to clarify 10 CFR Part 21 as prescribed in Commission Paper 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



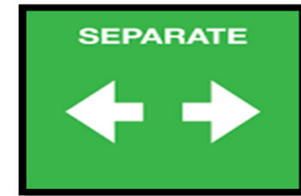
Part 21 Rulemaking – What is it?

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Proposed Changes to the Regulations

□ Restructure Part 21

- ▣ Separate evaluation & reporting from commercial-grade dedication



□ Create a new 10 CFR 21.71, “Commercial Grade Dedication Requirements”

- ▣ Define CGD process
- ▣ List basic steps
- ▣ Require documenting technical evaluations
- ▣ Dedication must be conducted in accordance with requirements of Appendix B



SECY-11-0135 - Commercial-grade Dedication

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COMMERCIAL-GRADE DEDICATION	Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
(A) Lack of Regulatory Guidance			✓	✓
(B) Proper Place for Dedication	✓			
(C) Definition of Dedication	✓			
(D) Definition of Commercial-Grade Item	✓			
(E) Clarification of Dedication as a Safety-Related Activity			✓	
(F) Dedication Plans and the Importance of Safety Function	✓	✓	✓	✓
(G) Sampling Requirements			✓	✓
(H) Use of Commercial Calibration (and Testing) Laboratories—International Laboratory Accreditation Cooperation Process			✓	✓
(I) Software Dedication			✓	✓



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.
 - ▣ Discussed at NRC vendor workshop in June 2014 in Portland OR
- Revision 1 of Draft Regulatory Basis was published in April 2015
 - ▣ Included draft rule language for discussion
 - ▣ Public meeting held on April 28, 2015



Draft Regulatory Basis

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- Issue Final Regulatory Basis by the end of July 2015
 - Provide updated regulatory guidance
- Includes new definitions for:
 - Basic component
 - commercial-grade item
 - Dedication





Draft Regulatory Basis

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- Regulatory Guidance development is integral to rulemaking process
 - ▣ 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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- DG-1291, “Evaluating Deviations and Reporting Defects and Noncompliance” could endorse:
 - ▣ NEI 14-09, NEI 14-09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance.”





Regulatory Guidance

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- 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” (Revision to 1988 EPRI NP-5652 and consolidation of 1994 EPRI supplemental guidance)



Regulatory Guidance

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- DG-1305, “Design and Analysis Computer program Commercial-Grade Dedication Requirements” will endorse:
 - ▣ EPRI Technical Report 1025243, revision 1, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications”



NRC Licensing Actions

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- On September 17, 2014, NRC received the NEI Submittal of EPRI “*Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260*”
- NRC Staff members participated in development of this new EPRI Guideline to help coordinate ongoing NRC actions as part of Rulemaking related to dedication requirements within 10 CFR Part 21.



NRC Licensing Actions

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- NRC staff has begun review of the September 2014 EPRI Guideline for potential NRC endorsement *outside* of Part 21 rulemaking through issue of a draft NRC Regulatory Guide DG-1292.
- We expect this document will provide much needed industry guidance in the area of commercial-grade dedication and aligns very well with the proposed Part 21 rulemaking actions related to commercial-grade dedication included in revision 1 of the Draft Regulatory Basis.



Basic Component (New Draft)

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- (i) ... 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 (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 (New Draft)

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- Commercial-grade item means an item that is not 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 Proposed 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) acceptance methods described in EPRI guidance document.



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.



Commercial-grade Dedication (Post Part 21 Rulemaking Implementation)

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- ❑ What does this mean for commercial-grade dedication activities when the 10 CFR Part 21 Rulemaking is implemented??
- ❑ Dedication has continued to evolve, while 10 CFR Part 50 Appendix B has remained the same.
- ❑ Quality Process – commercial-grade dedication must be conducted in accordance with the provisions of a 10 CFR Part 50, Appendix B quality program.



Commercial-grade Dedication (Post Part 21 Rulemaking Implementation)

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Positions in Revision 1 of the regulatory basis:

- Dedication
 - ▣ Provides reasonable assurance that the commercial-grade item will perform its intended safety function (adopted from 10 CFR Part 21)
- Basic components are controlled under 10 CFR Part 50, Appendix B Quality Assurance Program
 - ▣ Provides adequate confidence that a structure, system, or component will perform satisfactorily in service (adopted from the introduction to 10 CFR Part 50, Appendix B)



Important Final Thoughts

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- Both approaches are legitimate
 - ▣ Control (through design and manufacture process) the important design, material, and performance characteristics of the item under a Part 50, Appendix B Quality Assurance Program
 - ▣ Perform commercial-grade dedication
- Suppliers can provide items as basic components in accordance with the requirements of 10 CFR Part 50, Appendix B **without** performing commercial-grade dedication.
- 10 CFR 50, Appendix B controls are still effective. In fact, Criterion VII of Appendix B is the basis for the four commercial-grade dedication methods.



Part 21 Rulemaking Update and Commercial-grade Dedication

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QUESTIONS

