



Overview of Potential Changes to Commercial Grade Dedication from 10 CFR Part 21 Rulemaking

EPRI Meeting – February 2013

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Topics

- Update on Part 21 rulemaking
- Overview of Proposed Changes
- Specific Changes related to Commercial Grade Dedication



Update on Part 21 Rulemaking

- Issued Draft Regulatory Basis in December 2012 (ADAMS No. ML12248A200)
- Details Regulatory Problems:
 - Evaluating and Reporting
 - Commercial Grade Dedication
 - Administrative Changes
- Examines Options to Resolve Regulatory Problems

Update on Part 21 Rulemaking (cont'd)

- NRC hosted public meeting to solicit feedback on January 24, 2013
- Planning follow-up meetings for areas needing more discussion
- NRC plans to issue final regulatory basis in 2013

Overview of Proposed Changes

- Evaluating and Reporting
- Provide NRC Guidance (How-to)
 - Strengthen link to Appendix B Quality Assurance
- Will seek to clarify key definitions (i.e. Defect, Deviation, Delivery, Discovery)

Commercial-Grade Dedication

- Lack of Regulatory Guidance
- Proper Place for Commercial-Grade Dedication Requirements
- Definition of Dedication
- Definition of Commercial-Grade Item
- Clarification of Dedication as Safety-Related Activity for Reactor Facilities

Commercial-Grade Dedication

- Dedication Plans and the Importance of Safety Function
- Sampling Requirements
- Use of Commercial Calibration and Testing Laboratories – ILAC Process
- Software Dedication

Lack of Regulatory Guidance

- NRC's guidance on commercial-grade dedication is scattered throughout different generic communications (i.e. GL-89-02, GL-91-05, IN 2011-01) and endorsed industry documents (i.e., EPRI N 5652 and ASME NQA-1-2008/2009 Addenda Subpart 2.14)
- NRC staff is proposing issuing a regulatory guide on CGD to provide guidance in the following areas:
 - NRC's regulations
 - Techniques used by the NRC staff in evaluating specific problems
 - Endorsement of the new industry guidance.

Proper Place for Dedication

- The regulatory framework for dedication resides solely in 10 CFR 21.3, “Definitions” and is not discussed in the body of the regulation.
- As such, the regulation is difficult to apply and it is open to inadequate licensee and vendor interpretation of the dedication process.
- NRC staff is proposing to
 - Modify Part 21 to create a stand-alone section for Dedication.

Definition of Dedication

- The definition of dedication describes implementation details, which go beyond the fundamental intent of dedication.
- NRC staff is proposing to:
 - Maintain the fundamental principle of dedication in the definitions
 - Move the implementing details to a separate section and expanded, as necessary.

Definition of Commercial Grade Item

- The definition of commercial-grade item in 10 CFR 21.3 is not consistent with contemporary uses of dedication.
- The definition of commercial-grade item contains the concept that certain items cannot be dedicated.
- NRC staff is proposing to:
 - Simplify the definition and include all items as commercial-grade items
 - Specify what can be dedicated in the proposed new section, part, or appendix on dedication discussed before.

Clarification of Dedication as a Safety-Related Activity

- The definition of dedication for reactor facilities in 10 CFR 21.3 and the definition of safety-related in 10 CFR 50.2 are very similar.
- Dedication is often performed with inadequate QA controls.
- NRC staff is proposing to:
 - Emphasize that dedication is a safety-related activity conducted under applicability of 10 CFR 50 Appendix B.
 - Move the dedication process from the definitions to the proposed new section, part, or appendix.
 - Provide Regulatory Guidance endorsing industry standards.

Dedication Plans and the Importance of Safety Function

- Dedication is not always adequately documented.
- Technical evaluations are not adequately performed.
- NRC staff is proposing:
 - Modify 10 CFR 21 to require dedication plans
 - Provide Regulatory Guidance endorsing industry standards.



Sampling Requirements

- NRC has not formal guidance on sampling.
- NRC staff is proposing:
 - Define sampling in 10 CFR 21.
 - Provide Regulatory Guidance endorsing industry guidance. (new revision to EPRI TR-017218)



Use of Commercial Calibration and Testing Laboratories—ILAC Process

- NRC approved the use of commercial calibration laboratories under ILAC Process through a Safety Evaluation.
- Licensees and suppliers need to dedicate commercial calibration services, which should include surveys or in-process surveillances.
- NRC staff is proposing:
 - Consolidate guidance in a regulatory guide on dedication.

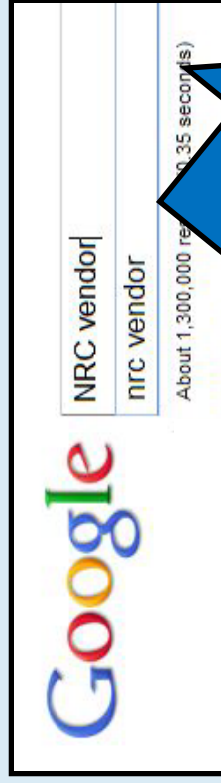
Software Dedication

- Software can be safety-related and can be dedicated.
- NRC staff is proposing:
 - Defining the requirements of software dedication in the 10 CFR 21.





Part 21 Subscribers



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Questions or Comments?

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