



# **Public Meeting on Modernization Plan #3: Commercial Grade Dedication of Digital Equipment**

NRC MP#3 Working Group

July 12, 2018

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## NRC Staff Criteria for Inspections

- NRC staff criteria for observations and audits of 3<sup>rd</sup> party SIL certifying entities would be determined on the basis of response to questions raised during February 16, 2017 meeting
- Based on progress made by EPRI on research of SIL certification process, NEI may be in a better position to respond to the NRC staff questions on SIL process evaluation
- Process used for endorsing NEI 14-05 may serve as an example to follow

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# NRC Staff Questions on SIL Process Evaluation\*

- What entity will submit a request to the NRC for conducting an evaluation on the adequacy of the proposed third-party certification process?
- What entity will conduct an evaluation of the International Electrotechnical Commission's (IEC) third-party audit certification process?
- What entity will provide membership access to the third-party certification audit records?
- What entity will provide membership access to the results of evaluations conducted by the third-party organizations?
- What entity will maintain ongoing oversight of the third-party certification process?
- What entity will ensure Part 21 responsibilities for evaluating and reporting are satisfied?
- What entity will evaluate the adequacy of the IEC 61508 standard?

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\* From February 16, 2017 Public Meeting

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# Example

NRC Safety Evaluation for Technical Report NEI 14-05, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1.

ADAMS Accession No.: [ML14322A535](#)

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# Backup Slides

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## Compliance with Part 21

- *Dedication - ... 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... In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B.*

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## Compliance with Part 21

- *Dedicating entity - ... dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a **third-party** dedicating entity, or the licensee itself.*
- *§ 21.21(c) - A dedicating entity is responsible for --  
(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and  
(2) Maintaining auditable records for the dedication process.*

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## Appendix B to 10 CFR 50

- *VII. Control of Purchased Material, Equipment, and Services – Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. ... The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.*



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# Commercial Grade Dedication Process

- Technical Evaluation
  - Identification of Critical Characteristics
  - Development/Selection of Acceptance Process
- Implementation Commercial Grade Dedication
  - Licensee
  - Contractor/Sub-contractor (Third Party)
    - Qualification of their Quality Assurance Program to meet the requirements of Appendix B and their capabilities to implement such program.