



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

NRC MP #3 Working Group
Office of New Reactors
February 16, 2017

Purpose and Agenda

The purpose of this meeting is to discuss aspects of the Modernization Plan #3 of the Integrated Action Plan to Modernize Digital Instrumentation & Controls Regulatory Infrastructure. The meeting will continue discussions on the proposed use of standards and third party process “certifiers” for dedication of commercial grade digital equipment.

1:00pm	Introduction	NRC
	Summary of November 3 Meeting	
	Purpose and Scope of MP #3	
1:30pm	Update to NEI submittal – Appendix C	NEI
2:30pm	Compliance with Part 21	NRC
3:30pm	Update on EPRI research – Status and Schedule	NEI/EPRI
4:00pm	Discussion of Referenced Documents	NEI/NRC
4:15pm	Opportunity for Public Comment	ALL
4:45pm	Summary of Actions, Next Steps	NRC/NEI
5:00pm	Adjourn	NRC

Summary of November 3 Meeting

- Meeting information found in ADAMS package:
ADAMS Accession No. [ML16312A380](#)
 - Agenda, Presentation Materials, Summary and Transcript.
- Action items resolved:
 - The comment resolution table for DG-1292 will be available upon issuance of the final regulatory guide.
 - NEI provided feedback and comments for staff consideration for the MP #3 activities and schedule.
 - NRC staff continues to clarify objectives of MP #3.

Purpose and Scope of MP #3

- Evaluate domestic and international standards on commercial grade dedication (CGD) of digital equipment for improving agency guidance in support of this modernization plan.
- Explore the use of independent, third-party “certification” of digital equipment for use in nuclear safety applications. This process is being effectively used in some other industries.

Compliance with 10 CFR 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.*

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.*

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.*

Commercial Grade Dedication Process

- Technical Evaluation
 - Identification of Critical Characteristics
 - Development/Selection of Acceptance Process
- Implementation of Commercial Grade Dedication
 - Licensee
 - Contractor/Sub-contractor (Third Party)
 - Qualification of their Quality Assurance Program to meet the requirements of 10 CFR Part 50, Appendix B and their capabilities to implement such program.

Considerations for Industry Proposal*

- 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?

* See November 3 2016 Meeting Summary

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](#)

NEI Presentation Update to Appendix C

Break
Will return in 10 minutes

EPRI Presentation Update on Research

Discussion of EPRI NP-5652, Rev. 1, Section 14.1

- The NRC reviewed and endorsed the following as an acceptable approach for meeting an NRC requirement:
 - EPRI TR-106439, “Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications”
 - EPRI TR-107330, “Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants”
- The following documents have not been evaluated by the NRC:
 - EPRI 1025283, “Commercial-Grade Digital Equipment for High-Integrity Applications: Oversight and Review of Evaluation and Acceptance Activities”
 - EPRI TR-107339, “Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439” (Ref. 19)
 - EPRI 1011710, “Handbook for Evaluating Critical Digital Equipment and Systems”
 - EPRI TR-103291 “Handbook for Verification and Validation of Digital Systems”

Opportunity for Public Comment

Summary of Action Items

Conclusion of Meeting

Acronyms and References

- ADAMS: Agencywide Document Access and Management System
- NEI: Nuclear Energy Institute
- EPRI: Electric Power Research Institute
- DG-1292: Draft Regulatory Guide-1292, “Dedication of Commercial-Grade items for Use in Nuclear Power Plants”
- EPRI NP-5652, Rev. 1: “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications ”