NUPIC General Membership Meeting and Vendor Conference June 2015

NRC Vendor Inspection Update

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OUTLINE

- ✓ Update on Current initiatives
- ✓ 2015 NRC Vendor Inspections
- ✓ Recent Inspection Results
- ✓ A plug for Safety Culture





What has been covered 10 CFR Part 21 Rulemaking Activities Update

http://www.nrc.gov/reactors/newreactors/oversight/quality-assurance/part-21rulemaking.html



http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=00000003002002982







What will be covered

- Procurement Initiative
- Commercial Calibration Services (and Testing)
 http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/qual-assure-safety.html#calibr
- Software Dedication
 http://www.nrc.gov/reading-rm/doc-collections/reg-guides/power-reactors/draft-index.html
- Counterfeit, Fraudulent and Suspect Items (CFSI)
 http://www.nrc.gov/about-nrc/cfsi.html
- Ongoing Communication Initiatives







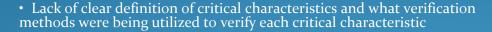
More on the Procurement Initiative

NRC Vendor Inspections identify commercial grade dedication (CGD) issues at many of the vendors inspected

During Feb meeting we noted two additional inspections

June 23-26, 2014 - RiverBend Station, Entergy Nuclear, Issued Integrated inspection Report May 12, 2015 http://adamswebsearch.nrc.gov/webSearch2/view?AccessionNumber=ML15127A5

August 25th–29th, 2014^r Duane Arnold, NextEra Energy Issued 4Q integrated resident report: http://adamswebsearch.nrc.gov/webSearch2/view?AccessionNumber=ML15037Ao



- Confusion over previous EPRI guidance with respect to critical characteristics for design versus critical characteristics for verification (being revised in new EPRI guidance).
- Issues in demonstrating similarity when trying to credit previous testing as a basis for establishing environmental and/or seismic qualification
- Ir proper use of reverse engineering methods









Commercial Calibration Services

By letter dated February 9, 2015, the NRC issued its safety evaluation report on NEI 14-05, Revision 1. http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/qual-assure-safety.html#calibr

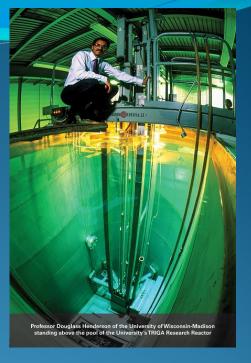
NRC's endorsement of NEI 14-05, Revision 1 expands the acceptance of the ILAC accreditation process and now includes domestic and international calibration and testing laboratories accredited by signatories to the ILAC Mutual Recognition Arrangement.

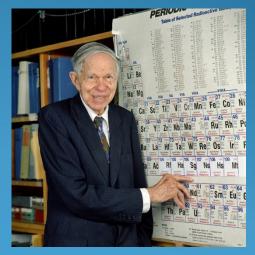
Regulatory Issue Summary expected to be issued during the fall of 2015 to communicate and clarify NRC's technical position on the use of the ILAC accreditation process as part of the commercial-grade dedication process.



Suppliers of basic components may begin to use the ILAC accreditation process and do not have to wait for the NRC to approve the QA program change for a licensee.







Use of National Metrology Institutes

June 4, 2014, NEI requested clarification on the NRC's position on the QA program requirements for international National Metrology Institutes (NMIs) as suppliers of primary reference standards and calibration services. (ML14170A683)

August 24, 1983, the NRC had clarified that for the U.S. NMI, which is the National Institutes of Standards and Technology (NIST) (formerly known as the National Bureau of Standards), it is not necessary for the purchaser to assure that NIST has a QA program that meets the applicable requirements of 10 CFR Part 50, Appendix B. However, this letter was silent on the applicability of the NRC position to NMIs in other countries. (ML15134A458)

April 30, 2015, the NRC clarified its position with regards to the use of domestic and international NMIs as suppliers of primary reference standards and calibration services. (ML15111A477)

The NRC's position is as follows:



Licensees and suppliers of basic components may procure primary reference standards and calibration services from NMI's that are signatories to the Committee for Weights and Measures Mutual Recognition Agreement without the need to perform an audit or a commercial-grade survey as the NMIs are organizations with proven abilities and disciplines.

Licensees and suppliers of basic components are still responsible for: (1) ensuring that the appropriate technical requirements are included in the procurement documents, and (2) performing receipt inspections to ensure that the procurement document requirements are met.

It is not necessary for licensees and suppliers of basic components to invoke the requirements of Appendix B to 10 CFR Part 50 or 10 CFR Part 21 in the procurement documents for primary reference standards and calibration services.







EPRI-5652 Commercial Grade Dedication Update*

Milestones	Target Date
EPRI Report 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial- Grade Items in Nuclear Safety-Related Applications," Revision 1 to EPRI NP-5652 and TR-102260, was completed and posted on EPRI's Web site at: http://www.epri.com/abstracts/Pages/Product Abstract.aspx?ProductId=000000003002002982	September 8, 2014
This document was also submitted to NRC for review by NEI in Fall 2014	Fall 2014
NRC participated in the Rollout Meeting, "Commercial Grade Dedication Guidance Update Workshop," November 5-6, 2014 in Charlotte, NC at EPRI's Headquarter Offices.	November 2014
NRC participated in NUPIC Lead Auditor Training Conference on CGD guidance	February 2015
NRC has completing a review of the Technical report for endorsement through the Regulatory Guide process (DRG-1292)	2015









EPRI 1025243 Software Dedication

Milestones	Target Date
Received NEI letter and submittal of EPRI 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-related Applications"	July 18, 2012
NRC issued 6 RAIs related to EPRI 1025243 to NEI	February 27, 2013
NRC meets with NEI/EPRI to discuss status of Document	May 2013
NRC received formal response from NEI and Revision 1 of document	January 22, 2014
NRC completed development of Draft RG 1305 and associated regulatory analysis to endorse guideline	May 2014
Internal NRC review	Completed
Draft RG 1305 to be released in the Federal Registry Notice for public comment	Expected JULY 2015





http://www.nrc.gov/reading-rm/doc-collections/reg-guides/power-reactors/draft-index.html



Counterfeit, Fraudulent and Suspect Items (CFSI)

Milestones	Target Date
The CFSI SECY-15-0003 (ML14240A629)	January 2015
The ML for the draft RIS is (ML14192B407) Final to be issued shortly	June 2015
CFSI website is live http://www.nrc.gov/about-nrc/cfsi.html	February 2015







Ongoing Communication Outreach

http://pbadupws.nrc.gov/docs/ML1435/ML14357A586.pdf

2014 Annual Vendor Newsletter is now available on our public website at the below link. Topics of interest include news on Commercial Grade Dedication Activities, Commercial Calibration Services, MDEP /VICWG Inspection Activities, Part 21 Rulemaking, Software CGD, RIS 2014-07, and The 2014 NRC Vendor Workshop.

http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/qual-assure-faqs.html

The Frequently Asked Questions FAQ page addresses Quality Assurance for New Reactors and currently has three main categories: 10 CFR Part 21 FAQs, Commercial Grade Dedication FAQs, and Enforcement FAQs.

http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/nonconformances-violations.htm

This page is to serve as a categorization tool and provides a list of all applicable QA Inspections for New Reactor Licensing and Vendor QA Inspection reports that have either a Notice of Nonconformance (NON) or Notice of Violation (NOV) within a specific criterion of 10 CFR 50 Appendix B or 10 CFR Part 21 related issue.

http://pbadupws.nrc.gov/docs/ML1508/ML15084A432.pdf This link describes the vendor inspection program (VIP)



http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/vendor-reg-form.html

These Links provide access to the Recent NRC RIS 2014-07, "ENHANCEMENTS TO THE VENDOR INSPECTION PROGRAM - VENDOR INFORMATION REQUEST" and the Vendor Registration Form.

http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendoroversight/past/2014/index.html 2014 NRC Workshop in Portland, Oregon

ML15138A347 – May 2015, NRC reviewed and approved QATR to reference 2011 NIRMA standard for management of electronic records.









Recent Audit Results



NRC Observation of NUPIC Audits and Findings

Conducted one Audit Observation week of February 2, 2015, at Tyco-Electronics Raychem (ML15056Ao86)

Additional Audit Observation planned for 3rd or 4th Quarter 2015 – May observe an LSA







Recent NRC Vendor Inspections

- CB&I, Lake Charles, LA Jan 2015*
- GE Reuter-Stokes, Twinsburg, OH Jan 2015
- General Cable, Willimantic, CT March 2015*
- National Testing Services, Huntsville, AL March 2015*
- Pentas Controls, Phoenix, AZ April 2015
- Westinghouse Electric Co., Cranberry Twp , PA April 2015
- ATC Nuclear Oak Ridge, TN April 2015
- Crane Nuclear Inc, Boilingbrook, IL May 2015*
- Westinghouse Electric Co., Warrendale, PA May 2015*
- CB&I, Laurens, SC May 2015*
- Fisher Controls Int., Marshalltown, IA May 2015*
- Premier Technologies, Blackfoot, ID June 2015*
- SPX Copes Vulcan ongoing*
- Kinetrics, Toronto, CAN June 2015*
- NTS, Huntsville, AL May 2015*
- Engine Systems Inc. Rocky Mount, NC May 2015
- · ABB, Coral Springs, FL May 2015
- Thermo-Fisher Scientific, San Diego, CA June 2015
- Westinghouse Electric Co, Cranberry Tnp, PA June 2015
- * AP-1000 testing, design, or fabrication RELEASED REPORTS







Recent Inspection Results







Findings

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- I: "Organization"
- III: "Design Control"
- VII: "Control of Purchased Material Equipment and Services"
- IX: "Special Processes"
- XI: "Test Control"

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- XV: "Nonconforming Materials, Parts or Components"
- XVI: "Corrective Action"
- 10CFR PART 21

Recent Inspection Results







Most Common issues:

- 1. Design Control
- 2. Corrective Action program
- 3. Control of Purchased Material Equipment and Services

Important Insights

- Recent observations from NRC inspections identified a general lack of rigor in oversight of suppliers
 - Ensuring procurement (design and testing) requirements are being fulfilled including adequate qualification testing
 - Ensuring suppliers and sub-suppliers are suitably qualified for and capable of performing PO requirements (i.e., scope of supply)
- Lack of rigor in the development, implementation and assessment of qualification testing to establish or ensure adequate component design
- Lack of Identification, evaluation, or completion of Corrective Action requirements for SCAC
 - Untimely corrective actions
 - Incomplete implementation of CAs
 - Failure to address and prevent recurrence

Recent Inspection Results







Summary:

- NRC continues to perform technically-focused inspections of vendors that evaluate the detailed design, procurement, fabrication, and testing of SR SSCs.
- Staff focus is on the design, testing, and fabrication of key components (rather than broad quality process evaluations) such as
 - SR Pumps
 - SR Valves
 - Plant Protection and Safety Monitoring systems
 - Structural Modules
- Findings reflect concerns with supplier oversight activities and the lack of rigor regarding CA evaluation and implementation.
- as well as the assessing the adequacy of meeting technical and quality requirements specified in procurement and detailed design documents related to those products.
- Findings also emphasize the importance of rigorous selfassessment activities that are comprehensive and intrusive in nature.

Future Inspection Activities





NRC will continue to perform technicallyfocused inspections of vendors that evaluate the detailed design, procurement, fabrication, and testing of SR SSCs.

- AP1000 modular construction
- AP1000 mechanical and electrical qualification test programs
- Digital Instrumentation and Control for AP1000
- Replacement steam generators and major components
- Valve and pump manufacturing
- Commercial-grade dedication organizations



A Plug for Safety Culture

The Commission defines **Nuclear Safety Culture** as the core values and behaviors resulting from a collective commitment by leaders and individuals to <u>emphasize safety</u> over competing goals to ensure protection of people and the environment.⁽¹⁾



NRC has issued Rev. 3 March 2015

(1) http://pbadupws.nrc.gov/docs/ML1506/ML15062A478.pdf





Questions



