



**NUPIC**

**20<sup>th</sup> Annual Vendor Meeting**

**Oak Brook, IL**

**June 15 - 16, 2011**

***NRC Report***

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Office of New Reactors



# Topic Areas

- Fukushima Event and NRC Response
- Vendor Inspection Activities
- NRC Information Notice IN 2011-01
- NUPIC Audit Observations
- ILAC Calibration Services Update
- 10 CFR Part 21 Rulemaking
- Dedication of Commercial Grade Software
- Counterfeit, Fraudulent & Substandard Items
- Nuclear Safety Culture

# Fukushima Daiichi Event

- Following the March 11 earthquake and tsunami in Japan, the NRC established a management level Task Force with expectations to develop recommendations for Commission consideration.
- The task force will identify potential actions that affect U.S. power reactors, including spent fuel pools. Areas to be reviewed include station blackout , prolonged loss of cooling due to external events, and emergency preparedness. The task force will gather information through ongoing inspections, and from domestic and international sources while remaining independent of any industry initiatives.
- <http://www.nrc.gov/japan/japan-info.html>

# Vendor Inspection Activities

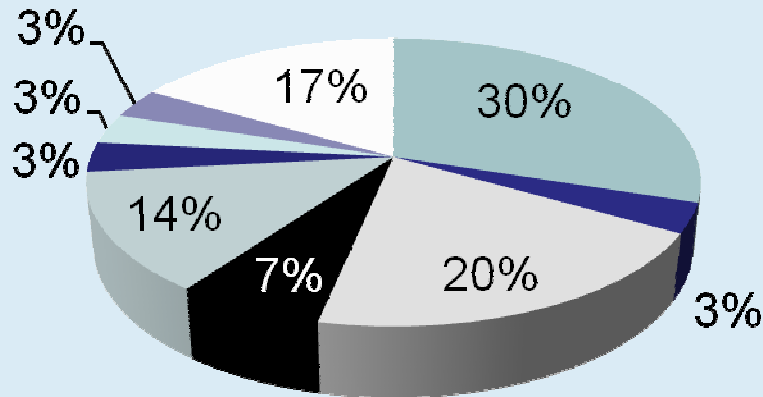
- Vendor Inspections completed since June 2010  
NUPIC Vendor Meeting (Report Issue Date)
  - International Quality Consultants, Inc. (July 8, 2010)
  - Sandvik Materials Technology (July 15, 2010)
  - Westinghouse / Purdue University (July 16, 2010)
  - Areva NP, Inc. (August 12, 2010)
  - Bechtel Power Corporation (August 30, 2010)
  - Mangiarotti S.p.A, Italy (September 29, 2010)
  - Tyco Electronics (October 6, 2010)

# Vendor Inspection Activities

- Black & Veatch (October 14, 2010)
- IHI Corporation, Japan (October 26, 2010)
- Consolidated Power Supply (January 3, 2011)
- GE Hitachi Nuclear Energy (January 20, 2011)
- Mitsubishi Heavy Industries, Ltd., Japan (February 2, 2011)
- Flowserve Limatorque (April 22, 2011)
- Available at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html>

# Vendor Inspection Findings

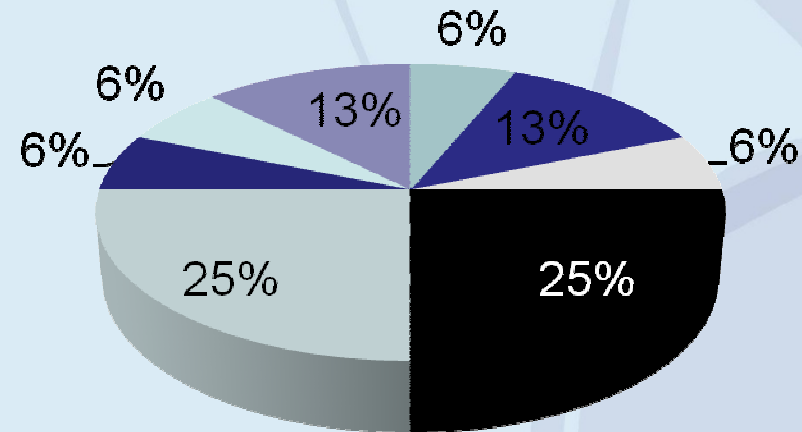
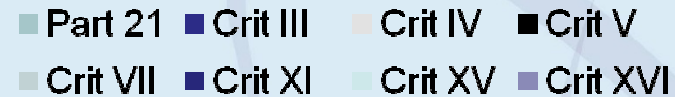
## 2010 Findings (30 total)



- Criterion II Quality Assurance Program
- Criterion V Instr./Procedures, & Drawings
- Criterion XI Test Control
- Criterion XVI Corrective Action

- Criterion III Design Control
- Criterion VII Control Purchased Mat.
- Criterion XII Control Test Equipment

## 2011 Findings (16 total)



- Criterion IV Procurement Document Control
- Criterion VIII Control of Materials
- Criterion XV Nonconformance of Materials

# Part 21 Violations

- Six vendors inspected during the last year have received NOVs related to this issue.
- NRC inspections continue to identify failure of vendors to adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards.

# CGI Dedication Findings

- Six vendors inspected during the last year have received NONs related to this issue.
- Westinghouse Electric Company testing performed at Purdue University, West Lafayette, Indiana for inplane shear testing in support of the AP1000 shield building
- Inspection identified findings related to the dedication of the test specimen, test equipment, and the test procedure

# Nonconformance & Corrective Action Findings

- Five vendors inspected during the last year have received NONs related to nonconformance and corrective action process deficiencies.
- A common program implementation weakness is that there is no procedural process in the corrective action program such as: a screening process to identify significant conditions adverse to quality; identifying and verifying timely corrective actions; and ensuring issues identified in the corrective action program that may create a substantial safety hazard are evaluated for Part 21 applicability.

# Control of Purchased Material, Equipment and Services

- Five vendors inspected during the last year received NONs related to Control of Purchased Material, Equipment, and Services and Audits
- A common program problem identified during inspections is the failure to perform an adequate external audit for a supplier on the Approved Vendors List for safety related components and services

# QA Program Weaknesses

- Flowserve Limitorque, Lynchburg, VA (April 11, 2011)
- The NRC inspection team identified three violations, and six nonconformances. One additional area of concern identified during the NRC inspection was Limitorque's reliance on multiple standards to define the QA requirements in the QMSM Quality Manual.

# NUPIC Audit Observation

- EDSA Micro Corporation - San Diego, CA  
(October 26-29, 2010)
- Nine NUPIC findings (including two Part 21) identified by the audit team
- NUPIC Findings captured supplier problem areas
  - No Part 21 evaluations conducted (referred to customers)
  - Software maintenance agreement required for error reporting
  - Older design-basis records irretrievable

# NUPIC Audit Observation

## Conclusions

- Good use of NUPIC immediate notifications:
  - User information notice (non-finding) - technical product literature did not clearly outline the verification requirements for the software user library
  - Notification of significant finding - ineffective QA program
- Significant finding used as NUPIC “missed opportunity”
- NRC inspectors concluded that, with the exception of the PBSA Worksheet preparation and usage, the NUPIC audit team effectively implemented the NUPIC audit process and thoroughly reviewed the areas covered by the audit.

# NUPIC Audit Observation

## Areas for Improvement

- More inclusive Performance Based Supplier Audit (PBSA) worksheet input from NUPIC users (only 1 of 8 responded)
- Programmatic “Technical Characteristics” and “Acceptance Criteria” listed on PBSA worksheet
  - EPRI guidance and PBSA Worksheet should not include generic programmatic attributes that are specifically addressed in the audit checklist.

# NUPIC Audit Observation

- Cameron Measurement Systems – City of Industry, CA (April 4-8, 2011)
- 5 NUPIC findings (including one Part 21) identified by the audit team
- This was the second NRC observation of a NUPIC joint utility audit at Cameron. The previous observation was conducted in August 2007 and resulted in NUPIC issuing an Immediate Notification of Significant Condition at the conclusion of the audit.

# NUPIC Audit Observation

- Summary
  - Audit team leader conducted adequate daily briefings with the audit team and the Cameron management team on issues and potential findings.
  - The auditors supported their identified five findings with comprehensive objective evidence and went to sufficient depth in their respective areas of focus.
  - NRC staff concluded, based on the review of the audit areas covered, that the joint utility audit process was effectively implemented by the audit team and the team identified appropriate performance-based findings for failure to adequately implement the Appendix B and Part 21 requirements.

# NUPIC Audit Observation

- Kinectrics Inc, Toronto, Canada (April 11-15, 2011)
- Observed by the Canadian Regulator CNSC
- 3 NUPIC findings and several recommendations identified by the audit team
  - Commercial grade dedication. Kinectrics was not consistently identifying and documenting the safety functions of the items that they were dedicating.
  - Procedural development and compliance. Kinectrics was not consistently documenting nonconformances in accordance with their quality assurance manual and operating procedures.
  - Software. Kinectrics was not meeting their quality assurance manual, specifically their commitment to ASME NQA-1 2008, in the area of software life cycle management and methods of evaluating, reviewing, and documenting software problems.

# NUPIC Audit Observation

- Conclusions
  - The NRC concluded that the NUPIC audit process was effectively implemented by the audit team and resulted in a reliable performance based review of the areas covered.

# Information Notice 2011-01

- NRC issued IN 2011-01 on February 15, 2011, to summarize the staff's observations and findings in the area of commercial grade dedication (CGD) for vendor inspections performed over the past 2 years. The following areas of concern were discussed.
  - Lack of Engineering Justification during the CGD dedication process
  - Documentation of the CGD process
  - Vendor Audit versus Commercial-Grade Survey
  - Sampling Plans for Commercial-Grade Item Dedication

# International Laboratory Accreditation Cooperation (ILAC)

- NRC continues to recognize the ILAC accreditation process for domestic commercial calibration laboratories as part of a commercial grade dedication process
- Moving forward, the nuclear industry's is developing process on how to provide oversight of the ILAC process
- Expand NRC's recognition of the ILAC accreditation process to include calibration and testing laboratories as well as the recognition of international calibration and testing laboratories.

# 10 CFR Part 21 Rulemaking

- Initiate rulemaking and issue regulatory guidance to clarify 10 CFR Part 21 requirements
  - Clarify evaluating and reporting requirements
  - Clarify expectations for commercial-grade dedication
    - Sampling
    - Use of commercial calibration laboratories
  - Extensive stakeholders cooperation
- NRC Public meeting on August 1, 2011 in Rockville, MD

# Commercial Grade Software Dedication

- NRC is evaluating options to expand guidance and regulations on dedicating software as part of Part 21 rulemaking
- ASME NQA-1 Software QA Subcommittee has developed dedication guidance to supplement NQA-1 Part II, Subparts 2.7 (software QA) and Subpart 2.14 (QA for Commercial grade items)
- EPRI Technical Advisory Group actions include the development of Draft guideline for utilization of Commercial Software in Nuclear Safety-Related Applications

# Counterfeit, Fraudulent, and Suspect Items (CFSI)

- NRC Internal Task Force to provide the Commission with a SECY paper in late October 2011.
- Increase across all industries of CFSI activity worldwide.
- NRC to Hold Public meeting on June 30, 2011, to discuss NRC assessment of regulations and guidance for the prevention of CFSI from entering the nuclear supply chain.

# Safety Culture

- The Commission defines **Nuclear Safety Culture** as *the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over, competing goals to ensure protection of people and the environment.*
- Consider safety culture at vendor facilities and throughout the supply chain

# Bottom Line

- Licensees should work with their vendors to ensure that vendor Appendix B and 10 CFR Part 21 programs adequately implement the requirements imposed in the procurement documents
- Vendors should be fully knowledgeable of all regulatory requirements and technical specifications imposed by licensees in procurement documents



**Questions?**