



NUPIC

Vendor Meeting

New Orleans, LA

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NRC Report

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Office of New Reactors



Topic Areas

- Vendor Inspection Activities
- NUPIC Audit Observation
- Combined License COL Applicant QA Implementation Inspections
- Regulatory Issue Summary on 10 CFR Part 21
- Commercial Calibration Services update
- NQA-1/Regulatory Guide 1.28 Revision 4
- 2nd Workshop on Vendor Oversight for New Reactor construction

Vendor Inspection Activities

- Vendor Inspections completed (Report Issue Dates)
 - Sargent & Lundy (October 27, 2009)
 - Sumitomo Metal Industries (November 13, 2009)
 - Curtis Wright Flow Control Corp (December 4, 2009)
 - Dubose – Part 21 Inspection only (February 22, 2010)
 - Shaw Nuclear Services (April 22, 2010)
 - Sulzer Pumps Inc (May 3, 2010)

Vendor Inspection Activities

- Sandvik Materials Technology, Sweden (May 2010 -- inspection completed)
- Westinghouse AP1000 Shield Building Test Program at Purdue University (May 2010 – inspection completed)
- All vendor inspection reports are available at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html>

Vendor Inspection Activities

- **Sargent & Lundy - Chicago, IL
(October 2009)**
 - **Summary of Finding**
 - **Design Control**
 - Failure to include the full range of intended applications during soil structural interaction (SSI) analysis software verification and validation

Vendor Inspection Activities

- **Sumitomo Metal Industries, Higashi-Mukojima, Amagasaki, Japan (November 2009)**
 - **Summary of Finding**
 - **Control of Purchased Material, Equipment, and Services**
 - Failure to verify that a supplier implemented controls needed to demonstrate that the prohibited materials listed in an EPRI technical report did not come in contact with tube material as specified by the purchase order

Vendor Inspection Activities

- **Curtis Wright Flow Control Corp (December 4, 2009)**
 - **Summary of Part 21 Violation**
 - Failure to provide adequate procedural guidance to evaluate deviations and failures to comply associated with substantial safety hazards and failed to make an interim report regarding a Part 21 evaluation that was ongoing for more than 60 days.
 - » Evaluation outside 60 days allowed
 - » Definitions differed from 10 CFR 21.3
 - **Summary of Nonconformances**
 - **Design control**
 - Failure to reference the design bases and other appropriate documents which specify operating requirements in the reactor coolant pump external heat exchanger design specification.
 - failure to provide documented evidence that the technical review activities required by their design review process had been performed.

Vendor Inspection Activities

- **Shaw – Charlotte, NC (April 2010)**
 - **Summary of Part 21 Violation**
 - Failure to provide adequate procedural guidance to evaluate deviations and failures to comply associated with substantial safety hazards
 - » Evaluation outside 60 days allowed
 - » Definitions differed from 10 CFR 21.3
 - **Summary of Nonconformances**
 - **Design control**
 - Failure to utilize the design change process to obtain prior Westinghouse approval for the use of the different revisions of the industry standards and the regulatory guide in design specifications and calculations.
 - Failure to specify the correct revisions or editions of industry standards and a regulatory guide in design documents.

Vendor Inspection Activities

- **Shaw – Charlotte, NC (April 2010)**
 - **Summary of Nonconformances (cont.)**
 - **Control of Purchased Material, Equipment, and Services**
 - Failure to perform a supplier qualification audit when placing a safety-related purchase order for commercial calibration services of measuring and test equipment
 - **Instructions, Procedures, and Drawings**
 - Failure to have implementing procedures governing the scheduling and processing of internal and external audits, including the tracking of audit open items to closure
 - **Corrective Action**
 - Failure to ensure the corrective action program has measures to:
 - » classify and evaluate issues identified through the internal audit process
 - » receive and promptly correct internal audit findings
 - Failure to implement effective corrective actions identified in two different internal audits

Vendor Inspection Activities

- **Dubose – Clinton, NC (February 2010)**
 - **Summary of Part 21 Violation**
 - Failure to provide a direct connection to the 10 CFR Part 21 program and/or implementing procedures when deviations related to “drop-shipped” material from sub-suppliers are identified at receiving by licensee
 - Failure to perform evaluations of deviations in basic components delivered to purchasers to assure these deviations were not substantial safety hazards, for seven identified Complaint Reports

Vendor Inspection Activities

- **Sulzer Pumps Inc – Chattanooga, TN (March 2010)**
 - **Summary of Part 21 Violation**
 - Failure to adopt an appropriate procedure to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard.
 - Failure to establish proper Part 21 record retention requirements.

Vendor Inspection Activities

- **Sulzer Pumps Inc – Chattanooga, TN (2010)**
 - **Summary of Nonconformances**
 - **Design Control**
 - Failure to evaluate and classify the coating process performed on a safety-related component (shaft) in a Service Water pump.
 - Failure to provide evaluations for deviations from the approved design inputs, through design change control measures or approvals and control of associated documentation for the change.
 - Failure to adequately verify by commercial survey or receipt inspection, the rubber material (a critical characteristic) used in bearings made by commercial-grade supplier during the dedication process.

Vendor Inspection Activities

- **Sulzer Pumps Inc – Chattanooga, TN (2010)**
 - **Summary of Nonconformances**
 - **Control of Purchased Material, Equipment, and Services**
 - Failure to perform commercial grade surveys instead of programmatic audits for several commercial grade suppliers.
 - **Corrective Action**
 - Failure to provide a systematic method for the review and follow-up of corrective actions to determine if they are being completed in a timely fashion and are effective in precluding recurrence of the deficiencies.

NUPIC Audit Observation

- **Engine Systems, Inc. – Rocky Mount, NC (March 2010)**
 - 1st NRC observation of a NUPIC audit of 10 CFR Part 21
 - Previously used IP 43005 which required NRC to perform Part 21 inspection using IP 36100
 - Smooth audit execution by NUPIC team during a difficult audit
 - Audit team leader dedicated to leadership – no assigned audit sections to facilitate the day to day actions
 - Diversity in scope at ESI
 - ESI performs extensive commercial grade dedication including Mechanical/Electrical/Electronics and Services
 - Parts include new/refurbished/repaired
 - Projects include design/modification/fabrication/testing
 - On-site Field Services

NUPIC Audit Observation

- **Engine Systems, Inc. – Rocky Mount, NC (March 2010)**
 - Conclusions
 - Audit team failed to conclude that ESI's internal audit process was ineffective, even though, at the conclusion of the audit, 28 issues had been identified resulting in 10 potential findings.
 - Discrepancies existed between the scope of supply listed in the Audit Notification letter, the Audit Plan, the Audit Report, the PBSAs, and what was actually audited by the NUPIC team while at ESI.
 - It was unclear from the issued audit report which of the supplier's products were evaluated by the audit.

NUPIC Audit Observation

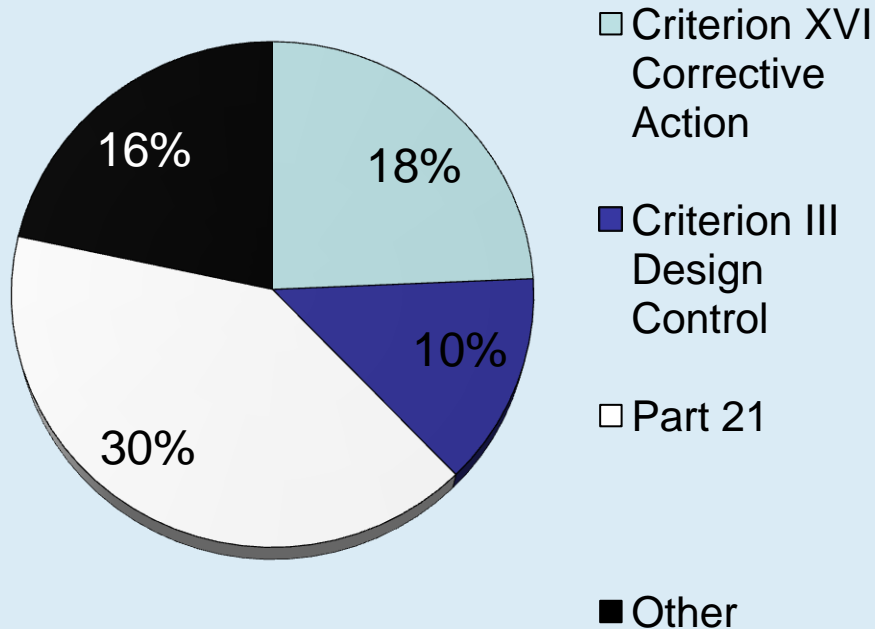
- **Areas For NUPIC Improvement**
 - Audit of supplier's QA program implementation should address all aspects of the facility's safety-related scope of supply
 - Technical Characteristics or Acceptance Criteria should be listed on the PBSA to evaluate Field Services
 - Effective vendor internal audits will provide accurate reflection of quality program health & status

Fermi Combined License COL Inspection Activities

- **Detroit Edison/Fermi 3 QA Implementation Inspection Scope**
 - Assess the implementation of the quality assurance program to support the Fermi Unit 3 COL application in accordance with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21
- **Summary of Findings**
 - **NRC Response and Revised NOVs (April 2010)**
 - **Control of Purchased Materials, Equipment, and Services (New)**
 - Failure to perform an evaluation of the B&V quality assurance program and adequately document the basis for the qualification of B&V to perform safety-related Fermi 3 COL activities after COL application
 - **Instructions Procedures and Drawings (Valid, Revised)**
 - Failure to complete any internal audits of QA programmatic areas implemented for Fermi 3 COL application activities performed to date
 - Failure to document trending of corrective actions to identify recurring conditions adverse to quality since the beginning of Fermi 3 project in March 2007

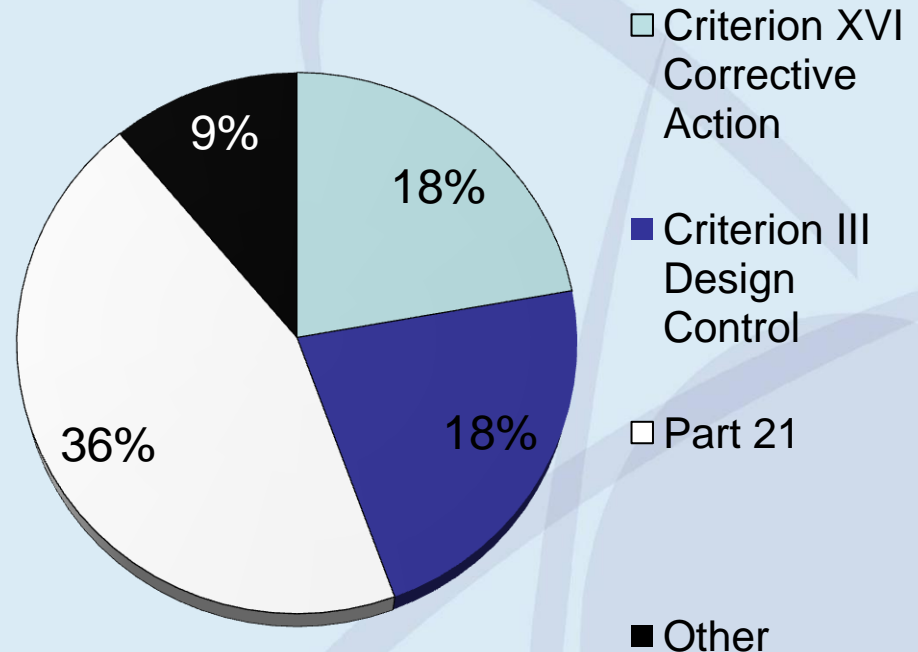
Vendor Inspection Findings

FY 2009



**Total – 57 (18 Inspections)
Inspection Findings (3.0)**

FY 2010



**Total – 11 (6 Inspections)
Inspection Findings (1.8)**

10 CFR Part 21 Regulatory Issue Summary (RIS)

- RIS 2010-05 issued May 24, 2010, to clarify the NRC's regulatory position regarding the applicability of 10 CFR Part 21 reporting requirements to standard design certification or design certification rule (DCR) applicants before and after the DCR is issued by the NRC.
- Part 21 Reporting requirements are applicable to 10 CFR Part 52 licensing and approval processes consistent with certain key principles.

Proposed 10 CFR Part 21 Rulemaking

- Staff is evaluating the benefits of amending 10 CFR Part 21 to include the necessary language to allow commercial-grade dedication in connection with early site permits, design certifications, combined licenses, and manufacturing licenses.
- The staff is also considering revising the requirements contained in 10 CFR Part 21 and 10 CFR 50.55(e) in a more comprehensive rulemaking.
- The staff intends to prepare new regulatory guidance in parallel with the rulemaking to add further clarification on the NRC's expectations regarding the implementation of 10 CFR Part 21 and 10 CFR 50.55(e) requirements.

Calibration Services Update

- In a letter dated February 26, 2009, Equipos Nucleares, S.A. (ENSA) requested the NRC to evaluate acceptance of international accrediting bodies belonging to ILAC as third party accreditation for commercial grade calibration services.
- NRC is evaluating options to expand our recognition of the ILAC MRA process to international ABs for calibration and testing laboratories.
 - Observed the APLAC & ILAC evaluation of A2LA on February 28 to March 5, 2010
 - 3 more NRC observations of accrediting bodies (ABs) planned for 2010: LAB, IAS and ACLASS
- Enhancement of licensee/NUPIC oversight would be needed.

NQA-1/Regulatory Guide 1.28 Revision 4

- On June 7th, NRC staff issued Revision 4 to Regulatory Guide 1.28, “Quality Assurance Program Criteria (Design and Construction)” for acceptance of the NQA-1-2008 Edition and the NQA-1a-2009 Addenda.
 - Includes Part I and II Requirements
 - Identifies specific Regulatory Positions
- http://adamswebsearch2.nrc.gov/idmws/doccontent.dll?library=PU_ADAMS^PBNTAD01&ID=101550202

NQA-1/Regulatory Guide 1.28 Revision 4

- ASME/NRC working on revision to Section III, Subsection NCA-4000 to incorporate the NQA-1-2008 Edition/2009-1a Addenda for N-type certificate holder activities.
- NRC continues interactions in ASME NQA-1 standardization activities
 - Subpart 2.7, “Quality Assurance Requirements for Computer Software for Nuclear Facilities,” task group is addressing commercial grade software dedication

2nd NRC Vendor Oversight Workshop

- Tomorrow, Thursday, June 17th
 - Registration will begin this afternoon and go for one hour after conclusion of the NUPIC meeting
 - Registration begins at 7:00 am on the 17th.
 - Opening remarks start at 8:00 a.m.
- Topics include:
 - Perspectives on Vendor Oversight
 - SCWE and Safety Culture
 - Counterfeit, Fraudulent, and Suspect Items
 - ASME Survey Process
 - NRC Enforcement Policy

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?