

Memo

- Document Date: March 23, 2010
 - Attached: Are slides for meeting with

NUPIC

General Membership Meeting

On February 8-11



NUPIC

**General Membership
Meeting**

Jupiter, FL

February 8 – 11, 2010

NRC Report

Richard McIntyre

Sr. Reactor Engineer
Office of New Reactors



Topic Areas

- Vendor Inspection Activities
- Combined License Applicant QA Inspections
- December 2008 NRC Vendor Workshop
- Calibration Services update
- International Cooperation
- NRC/NQA-1 Interaction update
- Counterfeit, Fraudulent and Substandard Items
- Proposed Regulatory Issue Summary on 10 CFR Part 21

Vendor Inspection Activities

- Recent Vendor Inspections completed (Report Issue Dates)
 - Sargent & Lundy (October 2009)
 - C & D Technologies (October 2009)
 - Sumitomo Metal Industries (November 2009)
 - Curtiss Wright (December 2009)
 - Energy Steel Follow-up (December 2009)
 - Namco Follow-up (December 2009)
 - Dubose – Part 21 inspection only (pending)

Vendor Inspection Activities

- 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

- **C & D Technologies – Blue Bell, PA (October 2009)**
 - **Summary of Findings**
 - **10 CFR Part 21 Program**
 - NOV for failure to adequately prescribe the process to perform an evaluation and meet timeliness requirements as specified in Part 21
 - NOV for failure to perform a Part 21 evaluations within 60 days of discovery of a deviation
 - **Corrective Action**
 - Failure to identify the root causes for quality problems and prevent their recurrence
 - **Design Control**
 - Failure to justify engineering change in a dedication package when a component's safety-related function was down-graded

Vendor Inspection Activities

- **C & D Technologies – Blue Bell, PA (October 2009) (Cont.)**
 - **Summary of Findings**
 - **Instructions, Procedures, and Drawings**
 - Failure to follow the dedication procedure and failure to prescribe an adequate procedure for the corrective action process of Customer Complaints
 - **Audits**
 - Failure to perform a survey instead of an audit for a commercial-grade supplier and failure to failure to adequately categorize audit observations as findings

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

- **Curtiss Wright – Cheswick, PA (December 2009)**
 - **Summary of Findings**
 - **10 CFR Part 21 Program**
 - NOV for failure to provide adequate procedural guidance to evaluate deviations and failures to comply associated with substantial safety hazards and failure to make an interim report regarding a Part 21 evaluation that was ongoing for more than 60 days
 - **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

- **Energy Steel and Supply – Lapeer, MI (December 2009)**
 - **Summary of Finding**
 - **Corrective Action**
 - Failure to implement the appropriate measures to process corrective actions within the timeframe specified by procedural requirements. ESSC had 24 corrective action reports that exceeded the due date without adequate justification to extend the completion date as allowed by the QA program

Vendor Inspection Activities

- **Namco Controls – Elizabethtown, NC (December 2009)**
 - **Summary of Finding**
 - **Measuring and Test Equipment**
 - Failure for the inspector to properly document nuclear M&TE that went beyond its re-calibration date, as required by procedures

Vendor Inspection Activities

- **Dubose – Clinton, NC 10 CFR part 21 inspection W/ NUPIC audit Observation (December 2009)**
 - **Summary of Finding**
 - **10 CFR Part 21 Program**
 - **The Part 21 procedure and the procedure for customer returns did not provide appropriate guidance for the Dubose evaluation of deviations and failures to comply for products “dropped shipped” from a sub-supplier’s facility to a licensee and rejected during the licensee’s receipt inspection activities.**

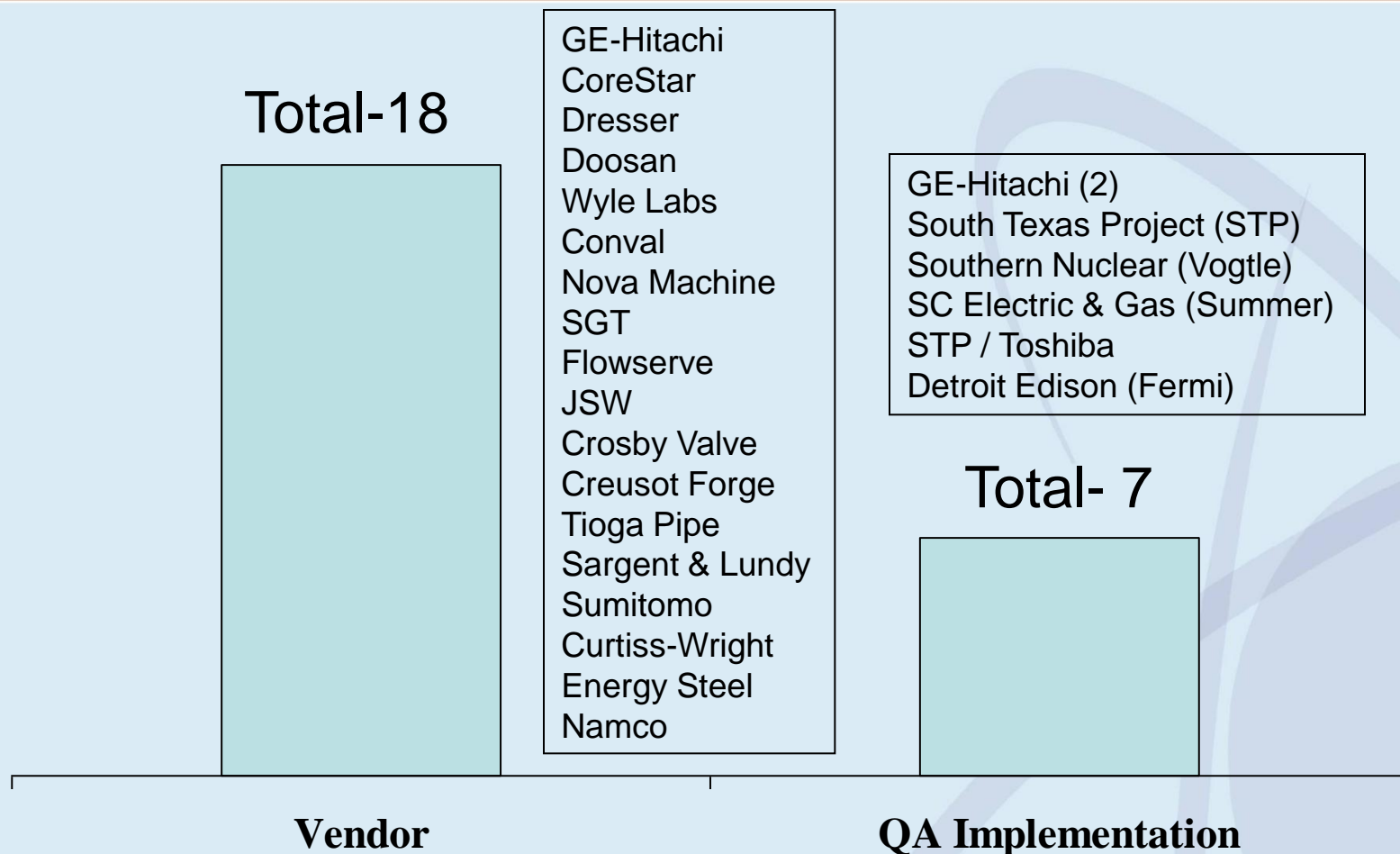
NUPIC Audit Observation

- **Dubose – Clinton, NC (December 2009)**
 - **NRC Observations**
 - **Technically competent Audit team**
 - **Effective communications within audit team and between Dubose and NRC**
 - **Dubose customer returns program for “dropped shipped” items not adequately reviewed by audit team**
 - **Team resources**
 - **Emphasis on completing checklist vs. performance-based auditing**
 - **Lead Auditor overburdened with balancing auditing activities and team lead activities**

Fermi Combined License Inspection Activities

- **Detroit Edison/Fermi 3 (August 2009)**
 - **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**
 - **QA Program**
 - NOV for failure to establish and implement a Fermi 3 QA program between March 2007, when the initial contract was placed with B&V for the conduct of safety-related COL activities, until February 2008, and retain overall control of these activities as required by Criterion II, “Quality Assurance Program,” of Appendix B
 - **Audits**
 - NOV for failure to complete any internal audits of QA programmatic areas implemented for Fermi 3 COL application activities performed to date
 - **Corrective Action**
 - NOV for failure to document trending of corrective actions to identify recurring conditions adverse to quality since the beginning of Fermi 3 project in March 2007

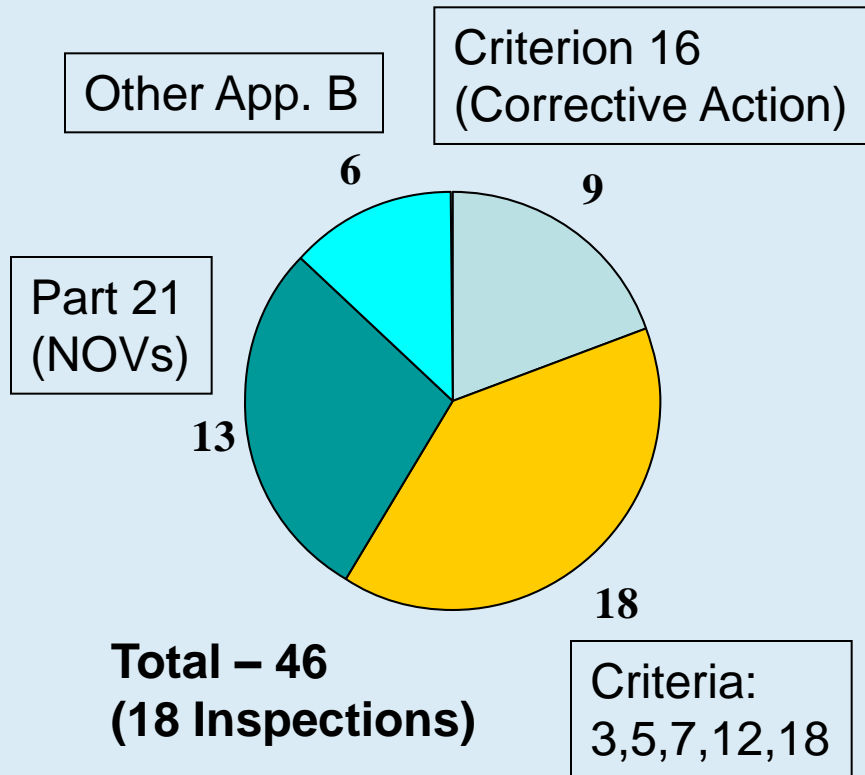
2009 Vendor Inspection Activities



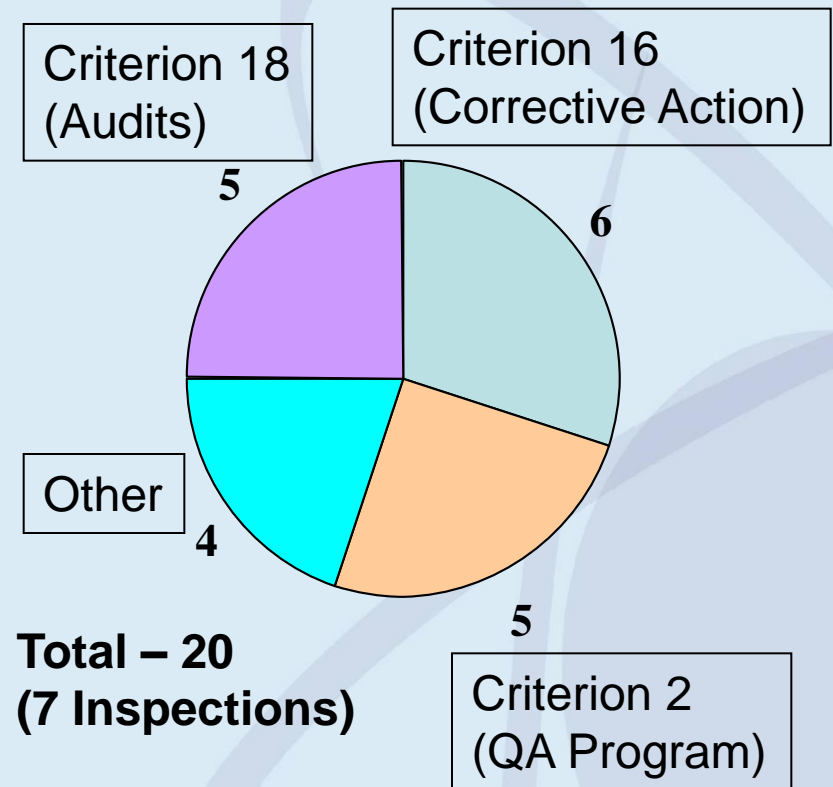
* Does not include observations with foreign regulators

2009 Vendor Inspection Activities

Vendor



QA Implementation



Future Vendor Inspections

- Shaw Group North Carolina – March
- Areva EPR DCD QA Implementation, Virginia
- Magiarotti (Ansaldo)-Italy
- Sandvik Materials, Sweden
- IHI – Yokohama Japan
- Shaw Group Modular construction, Lake Charles, LA

NRC Vendor Oversight Workshop

- Revised responses to Part 21 workshop questions were published in October 5, 2009.
 - <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight.html>
- Staff is in initial planning stages for another vendor workshop in conjunction with the June 2010 NUPIC vendor meeting in New Orleans.

Proposed Regulatory Issue Summary on 10 CFR Part 21

- This RIS is intended to clarify the NRC's regulatory position regarding the applicability of 10 CFR Part 21 requirements to standard design certification or design certification rule (DCR) applicants before and after the DCR is issued by the NRC.
 - RIS content is consistent with the 2007 conforming changes to 10 CFR Part 52.
 - Public comments will be solicited in the near future via a Federal Register Notice.

Calibration Services Update

- In a letter dated September 5, 2004, Arizona Public Service (APS) requested NRC to provide acceptance of the NVLAP (National Voluntary Laboratory Accreditation Program) accreditation of suppliers of commercial-grade calibration services in lieu of supplier audit, commercial-grade survey, or in-process surveillance.
- In a letter dated September 28, 2005, NRC approved APS's request in a Safety Evaluation Report based on the review of the NVLAP and American Association of Laboratory Accreditation (A2LA) programs recognized through the Mutual Recognition Arrangement (MRA) of International Laboratory Accreditation (ILAC). NRC has subsequently recognized other U.S. based Accrediting Bodies (ABs) also under the ILAC MRA : ACLASS, LAB, IAS and Perry Johnson
- NVLAP is described in 15 CFR Part 285, "National Voluntary Laboratory Accreditation Program."
- 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.
- NRC believes that some form of licensee/NUPIC oversight would be needed.

International Cooperation



International Cooperation

- MDEP Vendor Inspection Cooperation Working Group (VICWG) Meeting (NRC Office - October 2009)
 - 6 of 10 countries in attendance
 - Continue to pursue joint inspection
 - Member countries will continue to witness each others' inspection activities in 2010
- Resident and Vendor Inspector Exchanges with Finland, France, Taiwan and China

ASME NQA-1/NRC interactions

- NRR staff has developed Revision 4 to Regulatory Guide 1.28 for potential endorsement of the NQA-1-2008 Edition and the NQA-1a-2009 addenda.
- The NRC has completed review of the 33 public comments received on the draft RG and incorporated as necessary.
- RG 1.28, Revision 4, is expected to be issued in the near future.
- ASME/NRC working on revisions to Section III Subsection NCA-4000 to incorporate the NQA-1-2008 Edition/2009-1a addenda.

Counterfeit, Substandard, and Fraudulent Items

- NRC Issued IN 2008-04, “Counterfeit Parts Supplied To Nuclear Power Plants” (April 2008)
- Launched the NRC’s internal CSFI community (June 2009) Enhancing the NRC’s Vendor Inspection program (in-progress)
- Working with NUPIC to enhance their audit process (since February 2008)
- Improving communications and sharing information with the nuclear community (on-going)
- Working with EPRI’s Technical Advisory Group (TAG) on CSFI (on-going)
- Attended EPRI CFSI Report rollout and training (January 2010)



Questions