NUPIC

General Membership Meeting

San Antonio, Texas

February 2012

NRC Report

Richard McIntyre

Office of New Reactors

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Topics

- NRC Vendor Inspection Activities
- Part 21 Rulemaking Update
- Computer Software Dedication
- Calibration Services (ILAC) Update
- Counterfeit, Fraudulent, and Substandard Items (CFSI) Update
- NRO Reorganization and Vendor Center of Expertise

NRC Inspection Insights

- Continued observation of weaknesses in implementation of aspects of Vendor QA programs
  - Design control, control of suppliers, corrective action, and Part 21
- NRC Concerned with apparent lack of oversight of vendors by Suppliers/licensees
  - Need to maintain rigorous evaluation of implementation of programs
  - Observed lack fundamental conformance to 10 CFR Part 50 Appendix B and endorsed regulatory guidance
  - NRC Presentation on Monday's NUPIC Auditor conference related to supplier oversight weaknesses

Vendor Inspection Program Plan

- The vendor inspection program (VIP) verifies that reactor applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain. It accomplishes this through a number of activities, including: performing vendor inspections that will verify the effective implementation of the vendor's quality assurance program, establishing a strategy for vendor identification and selection criteria, and; ensuring vendor inspectors obtain necessary knowledge and skills to perform inspections. In addition, the VIP addresses interactions with nuclear consensus standards organizations, industry and external stakeholders, and international constituents.
- **http://pbadupws.nrc.gov/docs/ML1200/ML12006A008.pdf**

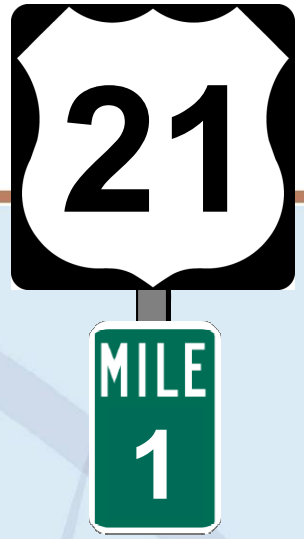
Rosemount Nuclear Inspection

- NUPIC audit performed in June 2010 led by STP identified 3 deficiencies
- NRC Inspection conducted last week of January 2012
  - Identified issues with Part 21 and Appendix B implementation
- Indentified potential Part 21 issues (NOVs)
  - Late reporting on 3 occasions due to incorrect Discovery definition in Part 21 procedure
  - Failure to complete a deviation evaluation

2012 Rosemount Inspection

- Potential Findings/Notice of Nonconformances (NONs)
  - Criterion III – identified examples where Rosemount performed inadequate dedication of commercial grade items (such as for a printed circuit board, pressure transmitter and resistor)
  - Criterion VII – inadequate controls of purchased material (QA involvement in PO issuance and PO controls on supplier)
  - Criterion XVII - inadequate access control to quality/design records
  - Criterion XIII – inadequate controls of chemical use in the production area (ammonium chloride)

Part 21 Summary



- Part 21 Rulemaking is underway
  - Clarify Evaluating and Reporting
  - Clarify Commercial-Grade Dedication
  - Address Administrative Changes
- Recent Milestones:
  - January 26, 2012: Public Meeting for early stakeholder feedback
  - September 29, 2011: Issued Commission paper (SECY-11-0135) to communicate the staff's plan to develop the regulatory basis for rulemaking
- Regulatory Basis development

Part 21 Rulemaking

- January 26, 2012
  - The purpose of the meeting was to discuss the NRC's rulemaking process, schedule, and allow industry and interested stakeholders the opportunity to participate in the regulatory basis and guidance development to clarify the requirements
  - Included presentations from the NRC, licensee, vendors, NEI and EPRI
  - Meeting Summary: ADAMS ML12027A133

Part 21 Rulemaking

- SECY-11-0135, September 29, 2011, describes the staff's plans to develop a regulatory basis, contained an enclosure that listed the 25 areas identified for improvement:
  - Administrative Changes
  - Evaluating and Reporting
  - Commercial-Grade Dedication

Regulatory Basis Status

- Based on each area for improvement , the working group will be identifying:
  - Definition of the Regulatory Problem
  - Existing Regulatory Framework
  - Options Considered to Resolve the Problem
    - Take No Action
    - Use Voluntary Programs
    - Implement Proposed Regulation
  - Proposed Changes to NRC Regulations

Regulatory Basis Status

- Development of Regulatory Guides
  - DG-1291, “Evaluating Deviations and Reporting Defects and Noncompliance
  - DG-1292, “Sampling and Dedication of Commercial Grade Items

Dedication of Software

- NRC following industry initiatives
  - EPRI JUTG meeting February 2012
    - discussions regarding software QA issues such as defining critical characteristics and identifying safety function
    - vendor presentation on dedication of commercial grade software
    - presentation on Software dedication using NQA-1 approach
  - EPRI guideline development for Acceptance of Computer Programs
    - TAG Review of final draft December 21, 2011
    - Currently incorporating comments and tweaking critical characteristic tables
    - Scope targeted at design and analysis software

Dedication of Software

- NRC following industry initiatives (Con't)
  - ASME NQA-1 Software Quality Assurance Subcommittee
    - Guidance for dedicating design & analysis commercial computer programs completed. Reconsideration ballot closed.
    - Non mandatory Guidance will be included in NQA-1-2012 edition.
    - Active Task Proposal Notices (TPNs) to consider further guidance on Quality Assurance Requirements for Computer Software used in both real-time and non real-time applications.
  - Continue to gain insights from inspections of vendors and applicants of COLs and DCs

Calibration Services / ILAC

- On September 16, 2011, NEI submitted an "Industry Proposal for Expanded Use of Internationally Accredited Calibration and Testing Laboratories."
- On October 4, 2011, NRC responded to the NEI letter and stated support, in principle, of an expansion of the of third-party accreditation to include both domestic and international calibration and testing laboratories accredited under ILAC.
- NEI has been accepted as ILAC Member for Calibration and Testing Laboratories (International and Domestic). A meeting with the ILAC Executive Committee will be scheduled in 1st quarter 2012 to discuss NEI options and oversight schedule.
- The NRC plans to hold a public meeting in the near future with NEI to continue ongoing dialogue related to plans for industry oversight of the ILAC MRA process.

CSFI

DEVELOPMENT OF AN AGENCYWIDE CFSI RESPONSE STRATEGY

CFSI TASK LEAD:
Dan Pasquale
(301) 415-2498

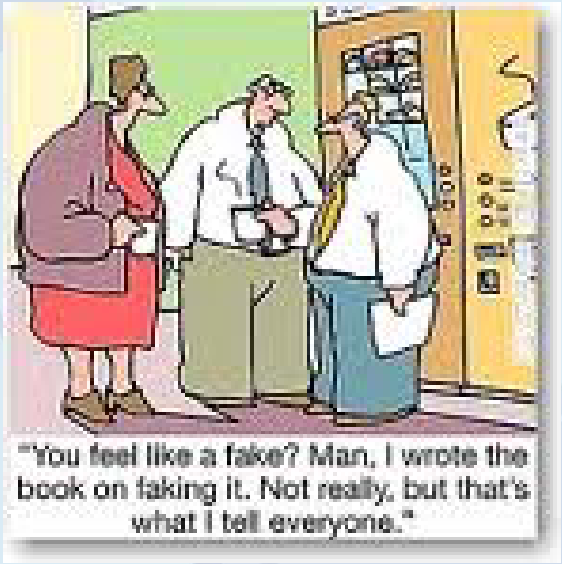
MISSION STATEMENT

"To coordinate the diverse staff resources within the agency to improve the agency's abilities to respond to challenges associated with counterfeit, fraudulent, and suspect items. This effort shall include agency-wide assessments of the following key areas: 1.) supply chain oversight, 2.) communications (both internal and external), 3.) Agency response protocols, and 4.) Cyber security supply chain oversight "

WORKING GROUP ON SUPPLY CHAIN OVERSIGHT	WORKING GROUP ON CFSI COMMUNICATIONS	WORKING GROUP ON CFSI RESPONSE PROTOCOLS	WORKING GROUP ON CYBER SECURITY SUPPLY CHAIN OVERSIGHT
WG Leader: ***Eugene Huang*** *Includes conventional supply chain processes*	*WG Leader:* ***Garrett Newman*** *Includes how CFSI information should be shared*	*WG Leader:* ***Doug Bollock*** *Includes how the various organizations need to interact*	*WG Leader:* ***Jeff Jacobson*** *(Stacy Smith)* *Relationships between security & sabotage including cybersecurity*

CSFI

Staff Actions to date



- SECY-11-0154 issued October 28, 2011
  NRC Working groups identified 24 issues with 19 planned actions for improvement to address the 24 issues - ML112200150
- "Staff Review of CFSI" issued November 18, 2011
  Provides a recommendation for each issue
  - ML1121130293
- February 16, 2012 public meeting
  - Conveyed to stakeholders the NRC's expectations for completing the 19 planned actions, including industry participation
- Next Public meeting in approximately 6 weeks

CSFI Possibilities

1. Incorporate Industry Actions and Initiatives
2. Enhance NRC Business Practices
   - New/revised internal NRC policies, practices, procedures
   - NRC coordination with Federal agencies and international governments
3. NRC Regulatory Activities
   - Regulatory guidance and communications
   - Inspections, audits and licensing reviews
   - New/revised regulations
   - Legislation recommendations

NRO Reorganization

- Effective February 2012
  - To re-align critical resources based on evolving NRO workload and responsibilities

Quality & Vendor Inspection Branch 1	Quality & Vendor Inspection Branch 2	Quality Assurance Branch
Rick Rasmussen *Includes Digital I&C and Electrical disciplines*	*Edward Roach* *Includes Mechanical, Structural, and Civil disciplines*	*Kerri Kavanagh (Acting)* *Includes COL and DCD Licensing*

NRO Reorganization

- The Vendor Inspection Center of Expertise (COE)
  - Streamline management chain for vendor inspections
  - Formalize coordination and serve in a support role to Allegations and Operating Experience / Construction Experience to strengthen vendor program and ensure uniform enforcement
  - Evaluate the need to integrate efforts with the reactor oversight program for a limited assessment of licensees' procurement programs, a proactive strategy identified in the agency wide staff assessment of counterfeit, fraudulent, and suspect items (CFSI).
  - Determine what information to capture and share on the Vendor Inspection Webpage including contact process for external stakeholders
  - To re-align critical resources based on evolving NRO workload and responsibilities

Safety Culture for Vendors

- The Commission's "Policy Statement on the Conduct of Nuclear Power Plant Operations," *Federal Register* notice, January 24, 1989, refers to safety culture as "the necessary full attention to safety matters" and the "personal dedication and accountability of all individuals engaged in any activity which has a bearing on the safety of nuclear power plants. A strong safety culture is one that has a strong safety-first focus."
- For vendors this means that all employees keep the safety function of their products in mind when making decisions during all of the procurement, manufacturing and testing stages associated with the product. This would include procedure adherence to assure key steps or processes are properly completed, the use of the corrective action and Part 21 reporting processes to assure issues that could impact the performance of the products are identified, appropriately resolved and reported, and keep the ultimate impact on safety function in mind when making decisions at all levels.

Questions