



# NUPIC

## General Membership Meeting

Chattanooga, TN  
October 6 - 8, 2009

### **NRC Report**

**Kerri Kavanagh**

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

# Vendor Inspection Activities

- Recent Vendor Inspections completed (Report Issue Dates)
  - Steam Generating Team (July 2009)
  - Anderson Greenwood Crosby (September 2009)
  - Flowserve Flow Control Division (August 2009)
  - Japan Steel Works (August 2009)
  - Creusot Forge (August 2009)
  - Tioga Pipe (September 2009)
  - Prime Technology (September 2009)

# Vendor Inspection Activities

- Recent Vendor Inspections completed (Inspection Report Under Development)
  - Sargent and Lundy LLC (Conducted September 2009)
  - C & D Technologies (Conducted September 2009)
  - Sumitomo Metals (Conducted September 2009)
- All vendor inspection reports are available at <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html>

# Vendor Inspection Activities

- **Steam Generating Team - Charlotte, NC (July 2009)**
  - **Summary of Findings**
    - **10 CFR Part 21 Program**
      - NOV for failure to adequately prescribe the procedures to evaluate deviations within 60 days and failure to perform a 10 CFR Part 21 evaluation
    - **Instructions, Procedures, and Drawings**
      - Failure to provide sufficient independence on deficiency reports
    - **Corrective Action Program**
      - Failure to initiate corrective action to prevent recurrence of a significant condition adverse to quality
    - **Audit**
      - Failure to address audit findings and observations in a timely manner

# Vendor Inspection Activities

- **Anderson Greenwood Crosby - Wrentham, MA (Sept. 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
    - **Design Control**
      - Failure to implement procedures for design control as described in the Quality Assurance Manual, like evaluation of conditions in Regulatory Guides to ASME Codes, completion of design check list, and determining the relieving capacity of the relief valves
    - **Control of Measuring and Test Equipment**
      - Failure to implement procedures for control of measuring and test equipment

# Vendor Inspection Activities

- **Anderson Greenwood Crosby - Wrentham, MA**  
(Sept. 2009) Cont.
  - **Summary of Findings**
    - **Corrective Action**
      - Failure to provide a mechanism to ensure that conditions adverse to quality which are identified by AGC's customers are systematically reviewed, documented, and addressed
      - Failure to identify or document any corrective action taken, actions to prevent recurrence, a proposed completion date, or follow up actions to be taken as required by the quality assurance manual

# Vendor Inspection Activities

- **Flowserve, Flow Control Division, Raleigh, NC (August 2009)**
  - **Summary of Findings**
    - **10 CFR Part 21 Program**
      - NOV for failure to meet the requirements set forth in 10 CFR Part 21 for the timely evaluation of deviations or failures to comply, and for the timely submittal of interim reports to the NRC
    - **Nonconforming Materials, Parts, or Components**
      - Failure to rework nonconforming items in accordance with documented procedures



# Vendor Inspection Activities

- **Japan Steel Works – Muroran, Japan (August 2009)**
  - **Summary of Finding**
    - **10 CFR Part 21 Program**
      - NOV for failure to provide sufficient guidance to meet the requirements to ensure that deviations and failures to comply would be evaluated to determine whether they were associated with substantial safety hazards

# Vendor Inspection Activities

- **Creusot Forge - Le Creusot, France (August 2009)**
  - **Summary of Findings**
    - **10 CFR Part 21 Program**
      - NOV for failure to meet the requirements for implementing a procedure to evaluate deviations and failures to comply, and for imposing Part 21 in procurement documents
    - **Control of Measuring and Test Equipment**
      - Failure to require the calibration of the temperature measuring thermocouples for the temperature baths for the impact tests to conform to ASME Code, Section III, Subsection NB-2360

# Vendor Inspection Activities

- **Tioga Pipe - Easton, PA (September 2009)**
  - **Summary of Finding**
    - **Quality Assurance Records**
      - **Failure to document controls for quality assurance record retention requirements (i.e., duration, location, and assigned responsibility) including the types of QA records that shall be stored in 2 hour fire rated cabinets**

# Vendor Inspection Activities

- **Prime Technology – North Branford, CT**  
(September 2009)
  - **Summary of Findings**
    - **10 CFR Part 21**
      - **NOV for inappropriate procedure to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard (i.e., procedure did not contain appropriate guidance on how to evaluate deviations)**
    - **Corrective Actions**
      - **Failure to enter the findings from the last NUPIC audit performed in February 2009 into corrective action process**
      - **Failure to complete corrective actions in timely manner**

# Vendor Inspection Activities

- **Prime Technology – North Branford, CT**  
(September 2009) Cont.
  - **Summary of Findings**
    - **Corrective Actions**
      - Failure of corrective action procedures to establish measures for the identification of deviations
    - **Design Control**
      - Failure to define dedication process under the Quality Assurance Manual as a controlled activity under Appendix B to 10 CFR Part 50
      - Failure to include measures in the dedication program to provide reasonable assurance that the materials, parts, equipment, and processes evaluated under the dedication program will perform their intended safety-related functions

# Vendor Inspection Activities

- **Prime Technology – North Branford, CT**  
(September 2009) Cont.
  - **Summary of Findings**
    - **Design Control**
      - Failure to document technical justification for design process changes
    - **Quality Assurance Program**
      - Failure to establish a documented personnel training/certification program for skills that required specialized training/experience
    - **Document Control**
      - Failure to establish controls in the Quality Assurance Manual for the issuance and revision of instructions, procedures and documents for activities affecting quality

# Vendor Inspection Activities (18 NRC Inspections Since 10/2008)

\*Totals do not include vendor inspections conducted in September 2009

Code	Description	# Findings
A	Commercial Dedication	10
B	Measure and Test Equipment	4
C	Software	2
D	Design Control/Change	10
E	Special Processes	2
F	Procurement	15
G	Fabrication/Assembly/Shop Floor Operation	0
H	Testing/Inspection	4
I	Non-conformance/Corrective Action Program	17
J	Part 21 Program & Other	27

# Future Vendor Inspections

- Curtiss-Wright EMD, PA - October
- Namco Controls, SC - October
- Energy Steel & Supply, MI - October



# Combined License Inspection Activities

- **South Texas Project Nuclear Operating Company (January 2009)**
  - **Summary of Findings**
    - **Quality Assurance Program**
      - NOV for failure to adequately control and identify the procedures that had been developed and implemented under the Quality Assurance Program for Unit 3 and 4 COL activities
    - **Document Control**
      - NOV for failure to provide document control practices to maintain the guidance document for procedure and document numbering as a controlled document

# Combined License Inspection Activities

- **South Texas Project Nuclear Operating Company (January 2009) Cont.**
  - **Summary of Findings**
    - **Corrective Action Program**
      - NOV for failure to include instructions for notification of appropriate levels of management in the event that a significant condition adverse to quality is identified or specify the requirement to implement corrective actions to preclude repetition, not just to address the root cause
    - **Audit**
      - NOV for failure to capture internal audit recommendations in the Action Tracking System, as required by STP Procedures

# Combined License Inspection Activities

- **South Texas Project Nuclear Operating Company (July 2009)**
  - **Inspection Scope**
    - Assess the basis upon which STPNOC determined that Toshiba is capable of providing the certified Advance Boiling Water Reactor. The inspection team examined Toshiba's compliance with the provisions of 10 CFR Part 21 and selected portions of Appendix B to 10 CFR Part 50.
  - **Summary of Findings**
    - **Training**
      - Failure to implement procedures for a new training record database
    - **Corrective Action program**
      - Failure to close corrective actions on a timely manner
    - **Control of Purchased Material, Equipment, and Services**
      - Failure to implement the appropriate procedure to perform internal audits

# Combined License Inspection Activities

- **Southern Nuclear Operating Company Vogtle Units 3 and 4 Combined License Application (March 2009)**
  - **Summary of Findings**
    - **Document Control**
      - NOV for failure to accurately reflect the correct definitions of 10 CFR Part 21, failure to address all the requirements of 10 CFR 50.55, and failure to use the correct terminology throughout the procedure
    - **Corrective Action Program**
      - NOV for failure to adequately provide procedural guidance to screen new condition reports for the potential applicability of 10 CFR Part 21 and does not provide a clear link to the 10 CFR Part 21.

# Combined License Inspection Activities

- **South Carolina Electric & Gas Company V. C. Summer Units 2 and 3 Combined License Application (June 2009)**
  - **Summary of Findings**
    - **Quality Assurance Program**
      - SCE&G New Nuclear Deployment (NND) implemented 12 NND procedures and guidelines that rely on ASME NQA-1 to describe how the quality assurance requirements in Appendix B to 10 CFR Part 50 are being satisfied rather than on ANSI N45.2, as described in the NRC accepted QAP for VCSNS Unit 1.

# Combined License Inspection Activities

- **Fermi 3 Combined License Application**
  - Inspection completed on August 21, 2009
  - Inspection report has not been issued

# NRC Vendor Oversight Workshop

- December 10 & 11, 2008, at the North Bethesda Maryland Marriott. Presentations made by NRC, NEI, NUPIC, NIAC, Licensees, and Vendors.
- Received over 300 written comments and questions
  - Part 21 (200)
  - Sampling (50-75)
  - Critical Characteristics (50-75)
  - General QA Topic (50-75)
  - Part 72 NMSS (50)
- All presentations have been placed on NRC website along with the answers to questions and comments.
  - <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight.html>
- Staff is in initial planning stages for another vendor workshop in April 2010.

# SOON TO BE RELEASED REGULATORY ISSUE SUMMARY ON 10 CFR PART 21

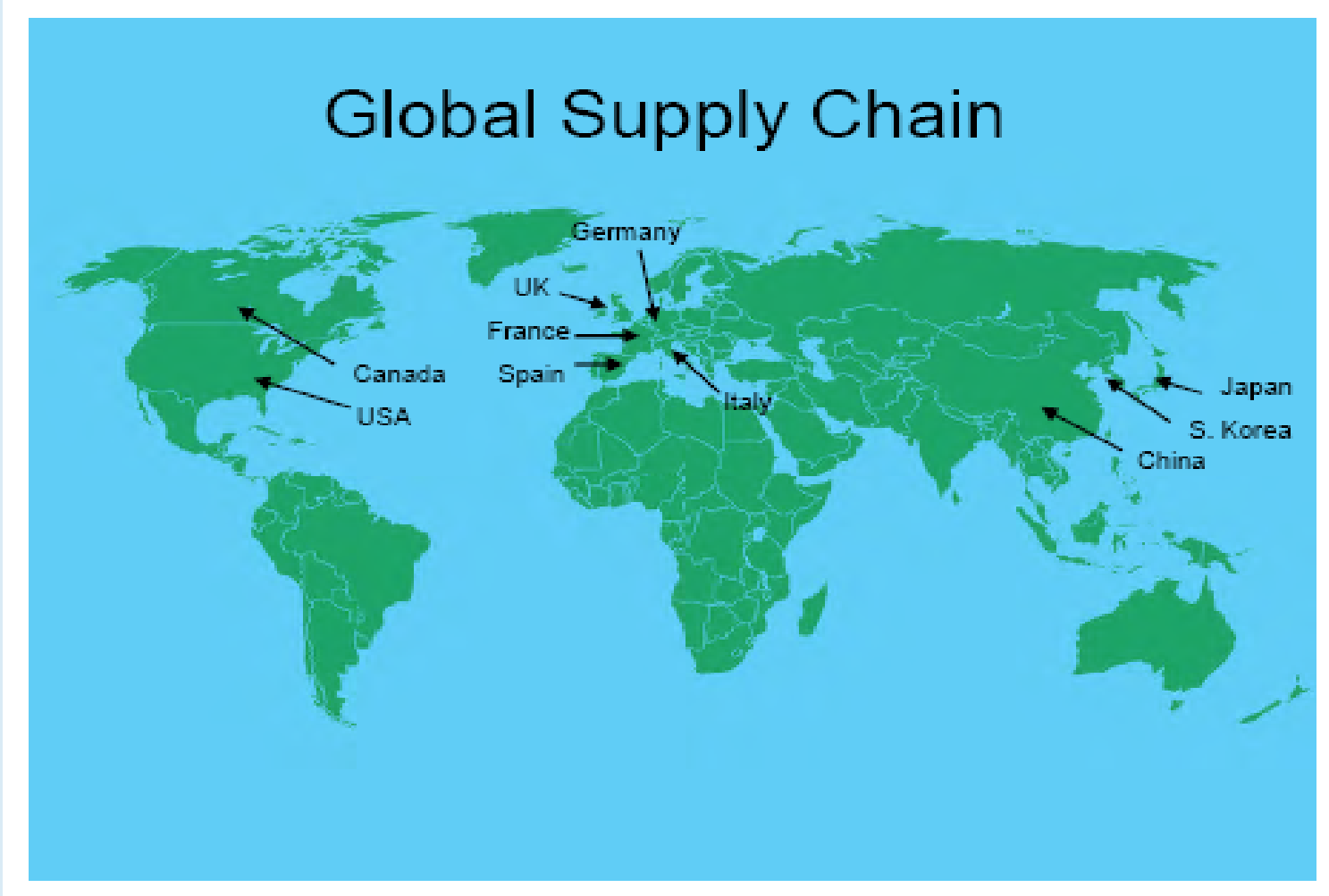
- RIS clarifies the NRC's regulatory position regarding the applicability of 10 CFR Part 21 requirements to standard design certification or design certification rule (DCR) applicants before and after the DCR is issued by the NRC.
  - RIS contents are consistent with the 2007 conforming changes to 10 CFR Part 52.
  - Public comments will be solicited in late October 2009.
  - Final RIS expected to be published in late December 2009.



# Calibration Services Update

- NRC has accepted accreditation bodies (AB) NVLAP, A2LA, ACLASS, L-A-B, and IAS calibration services as an alternative method for qualifying suppliers in lieu of supplier audit, commercial-grade survey, or in-process surveillance for commercial-grade suppliers of calibrations services.
- Staff met with NVLAP on May 28, 2009 to discuss potential methods for recognition of ILAC MRA beyond current 5 domestic ABs.
- Staff met with ILAC on August 26, 2009 to discuss the commercial calibration and testing laboratory accreditation process through the ILAC MRA. Specifically, the staff discussed the possibility of 1) expanding NRC's recognition to include international ABs that are full signatories to the ILAC MRA and 2) including testing services under ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
- Staff plans to meet with ILAC's Executive Committee during the joint annual meeting of ILAC and IAF in October 2009.

# International Cooperation



# International Cooperation

- Active member of newly-formed Vendor Inspection Cooperation Working Group (VICWG) - Part of Multinational Design Evaluation Program (MDEP)
- Overview of Recent Activities
  - Next VICWG Meeting is October 13-15, 2009, in Rockville, MD
  - July 2009 - French Regulator Autorité de Sûreté Nucléaire (ASN) observed NRC inspection at Creusot Forge, Le Creusot, France
  - July 2009 – Korean Regulator Korean Institute of Nuclear Safety (KINS) observed NRC inspection at Crosby Valve
  - July 2009 – Japanese Regulatory Authority (JNES) observed NRC inspection at Japan Steel Works, Muroran, Japan
  - September 2009 - JNES and Radiation and Nuclear Safety Authority Finland (STUK) observed NRC inspection at Sumitomo Metals, Japan

# ASME NQA-1/NRC interactions

- NRR staff has developed Revision 4 to Regulatory Guide 1.28 for potential endorsement of the NQA-1a-2009 addenda and the NQA-1-2008 Edition
- Public comment period for Draft RG DG-1215 (1.28) concluded September 8, 2009. Comments have been positive.
- ASME/NRC working on revisions to Section III Subsection NCA-4000 to incorporate the NQA-1-2008 Edition.



## Questions