NUPIC

Vendor Meeting

St. Louis, MO

June 17-18, 2009

NRC Report

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

Topic Areas

- Counterfeit, Suspect, Fraudulent Items
- Vendor Inspection Activities
- NUPIC Audit Observation
- December 2008 NRC Vendor Workshop
- Calibration Services Update
- International Cooperation
- NRC/NQA-1 Interaction update

Counterfeit, Suspect, Fraudulent Items (CSFI)

- GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products”
- Information Notice 2008-04, “Counterfeit Parts Supplied to Nuclear Power Plants,” issued April 2008
- Potential inspection focus areas:
  - Procurement and commercial-grade dedication programs to ensure the quality of procured vendor products
  - Industry practices for identifying counterfeit or fraudulent parts
  - Documents that provide traceability for quality-related components
  - Supply chain for a sample of specific components provided to each new reactor project
- Licensees are held accountable for the quality of parts used in the construction of new reactors

FY09 NRO Vendor Inspection Plans

- Commercial Grade Dedication organizations
- Forgings suppliers for ABWR, AP1000, EPR
- Manufacturing for SG tubes AP1000 and Areva EPR
- Manufacturing for valves (all Design Centers)
- STP COL alternate vendor (Toshiba) & ABWR component fabrication
- Follow-up Corrective Actions for previous NRO Vendor inspections

Vendor Inspection Activities

- Recent Vendor Inspections completed (Report Issue Dates)
  - Fairbanks Morse Engine (October 2008)
  - Babcock and Wilcox (B&W) Nuclear Operations Group, Inc. (October 2008)
  - Energy Steel and Supply (November 2008)
  - Enertech (December 2008)
  - Weir Valves & Controls (December 2008)
  - CoreStar International Corporation (CoreStar) (March 2009)

Vendor Inspection Activities

- Recent Vendor Inspections completed (Report Issue Dates)
  - GE Hitachi (GEH) Nuclear Energy, NC (March 2009)
  - Dresser Industries Incorporated (Dresser), LA (April 2009)
  - Doosan Heavy Industries, South Korea (May 2009)
  - Conval Inc., CT (May 2009)
  - Wiley Laboratories (June 2009)
  - Nova Machine Products Inc., OH (June 2009)

Vendor Inspection Activities

- General Electric Hitachi (GEH) Nuclear Energy (March 13, 2009)
  - **Inspection Scope:**
    - Review selected portions of GEH's QA and 10 CFR Part 21 programs focused on replacement parts to NRC licensed facilities.
  - **Summary of Findings**
    - **10 CFR Part 21 Program**:
      - NOV for failure to adequately prescribe the process to perform an evaluation within 60 days as specified in Part 21.
    - **Commercial Grade Dedication**:
      - Two findings to 10 CFR Part 50, Appendix B for the lack of documentation for links to environmental and seismic qualification, and for lack of justification for taking credit for Underwriters Laboratory certification.

Vendor Inspection Activities

- **CoreStar - Irwin, PA (March 2009)**
  - **Summary of Findings**
    - **10 CFR Part 21 Program**
      - Failure to adequately prescribe the process to perform an evaluation, as specified in Part 21.
    - **Corrective Action Program**
      - Failure to establish adequate measures for the identification of deviations and inadequate and untimely corrective actions, respectively.
    - **Audits**
      - Failure to adequately categorize audit observations as findings.
    - **Procurement**
      - Failure to prescribe in implementing procedures a certification system for safety-related products or services provided by CoreStar.

Vendor Inspection Activities

- **Dresser, LA – (April 2009)**
  - **Summary of Findings**
    - **10 CFR Part 21 Program**
      - Failure to adopt QA procedures that ensure compliance with 10 CFR Part 21 evaluation and reporting requirements
      - Failure to complete initial notification to the NRC within the required time frame.
    - **Commercial Grade Dedication Program**
      - Failure to adopt effective commercial grade dedication procedures.
    - **Design Control**
      - Failure to include the dynamic valve discharge actuation load in the Dresser design report as required by design specification for a North Anna pressurizer safety valve (PSV).

Vendor Inspection Activities

- **Dresser, LA (Cont.)**
  - **Summary of Findings**
    - **Procurement Document Control**
      - Failure to control procurement documents sent to suppliers on the Dresser Approved Nuclear Supplier List (ANSL).
    - **Instructions, Procedures, and Drawings**
      - Failure to provide adequate and consistent procedural guidance for interfaces among Dresser's 10 CFR Part 21 reporting process, the corrective and preventive action program, the control of nonconforming items process, and the repair/replacement activities processes.
    - **Corrective Action**
      - Failure to follow procedure steps taken to ensure that criteria within a quality procedure are satisfactorily accomplished.
      - Failure to have a documented procedure that reflects its process for corrective action.
    - **Audits**
      - Failure to maintain accurate audit documents (e.g., multiple examples Supplier Audit Assessment Checklists not filled out correctly).

Vendor Inspection Activities

- **Doosan Heavy Industries (DHI) – South Korea (May 2009)**
  - **Inspection Scope:**
    - Verify the implementation of the DHI quality assurance program for previous NRC inspection findings
  - **Summary of Findings:**
    - **Corrective Action**

      Doosan repeatedly failed to record pre-heat data for welding on the Sequoyah nuclear power plant replacement steam generator project. Corrective actions, including measures associated with a Root Cause Analysis, failed to determine the cause of the condition and preclude repetition of this significant condition adverse to quality.

Vendor Inspection Activities

- **Conval Inc., CT (May 2009)**
  - **Inspection Scope:**
    - To perform a follow-up inspection of the implementation of Conval's corrective actions for previous NRC identified inspection findings.
  - **Summary of Findings:**
    - **Inadequate Part 21 Procedure and Implementation**
      - Misuse of the terms defect and deviation
      - Did not include "failures to comply" in the guidance for implementing Part 21
      - No documented evidence that Part 21 applicability review is conducted for nonconformances
    - **Design Control / Instructions, Procedures, and Drawings**:
      Inadequate Commercial Grade Dedication Procedure
      - Wrong definition for CGI in the dedication procedure (included definition for facilities OTHER THAN nuclear power plants
      - Inconsistencies between scope and body of procedure for applying Part 21 to CGIs undergoing dedication
    - **Nonconforming Materials, Parts, or Components**:
      Inadequate procedure for Control of Nonconformances (no implementing guidance for the identification, documentation, evaluation, or disposition of nonconforming processes or activities)
    - **Corrective Action**
      Failure to effectively implement corrective actions for findings identified in NRC Inspection Report 99901367/2007-201. Inadequate Corrective Action procedure (procedure stated that the QA Manager is responsible for generating all CARs, leaving no method for other employees to identify, report, or document conditions adverse to quality).

Vendor Inspection Activities

- **Nova Machine Products Inc., OH (June 2009)**
  - **Summary of Findings**
    - **Corrective Action**
      Nova failed to identify deviations despite describing nonconformances that departed from the technical requirements included in the purchasers' procurement documents.
    - **Commercial Grade Dedication**
      Nova failed to establish measures to assure that purchased material conformed to licensees' safety-related procurement documents. Specifically, Nova's certified material test reports supplied to the purchaser were generated from chemical test data provided by commercial vendors.
    - **Supplier Audits**
      Nova's audit of PMC Lone Star failed to verify compliance of the sub-supplier's quality assurance program with specific criteria of Appendix B to 10 CFR Part 50.

Vendor Inspection Activities

- **Wyle Laboratories (June 2009)**
  - **Inspection Scope:**
    - To perform an of inspection of the implementation of Wyle Laboratories quality assurance program for testing activities for AP1000 squib valves.
  - **Summary of Findings:**
    - **Control of Measuring and Test Equipment**

      Wyle's records for out-of-tolerance instrumentation provided no objective evidence that the required evaluations had been performed for all tests in which out-of-tolerance instrumentation was used.

      Wyle failed to perform and record verification of equipment lighting at bench top and working levels in the calibration laboratory at six-month intervals. Wyle also failed to identify and segregate a lighting meter, with an "out-of-calibration" sticker as required.

Design Certification Inspection Activities

- **GEH ESBWR Design Certification Application (March 25, 2009)**
  - **Inspection Scope:**
    - The inspection reviewed GEH implementation of the software QA program for the design, development and use of software programs in support of the ESBWR design certification in accordance with the requirements of Appendix B to 10 CFR Part 50.
  - **Summary of Findings**
    - **10 CFR Part 21**
      - Failure to perform a Part 21 evaluation when another GEH organization indicated that a software problem had impacted their use of the code.
    - **Design Control**
      - Failed to document the justification or rationale for the use a particular version of a non-Level 2 code during an alternate calculation to verify original calculations and developer's assumptions.

Design Certification Inspection Activities

- **GEH ESBWR Design Certification (cont.)**
  - **Summary of Findings**
    - **Corrective Actions**
      - Failure to have an adequate corrective action program for Level 1 software code errors.
      - Failure to report problems under the Global Nuclear Fuel (GNF) Common Procedure for “Engineering Computer Programs”
    - **Audits**
      - Failure to have the GEH NQA audit plans for 2006 and 2007.
      - Failure to adequately document the basis of the audit findings to support the audit conclusions.

NUPIC Audit Observation

- **Global Nuclear Fuel (GNF) - Wilmington, NC (September 2008)**
  - The NUPIC audit team identified findings and recommendations for failure of GNF to adequately implement QA program requirements related to the following criterion of Appendix B: Design control; Commercial Grade Dedication; Procurement; Test Control, Inspections, Calibration; Document Control/Adequacy; Internal Audits; Corrective Action and Records.
  - NRC concluded that NUPIC audit process was effectively implemented by the audit team and the team identified appropriate performance-based findings for failure to adequately implement QA program requirements.

NUPIC Audit / NRC Inspection

- **GNF - Wilmington, NC** (cont.)
  - **Summary of NRC Findings**
    - The NRC identified one finding for GNF's failure to maintain 10 CFR Part 21 implementing procedures consistent with the requirements for notification letter content and the current definitions of 10 CFR Part 21.

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

Code	Description	# Findings
A	Commercial Dedication	10
B	Measure and Test Equipment	2
C	Software	2
D	Design Control/Change	6
E	Special Processes	2
F	Procurement	15
G	Fabrication/Assembly/Shop Floor Operation	0
H	Testing/Inspection	4
I	Non-conformance/Corrective Action Program	12
J	Part 21 Program & Other	16

Future Vendor Inspections

- Flowserve Valve, Raleigh, NC – July
- Crosby Valve, MA – July
- Japan Steel Works, Sapporo, Japan - July
- Toshiba, Yokohama, Japan – July
- SFAR Steel, Le Creuset, France – July
- Curtiss-Wright EMD, PA - August
- Sargent & Lundy, IL - September

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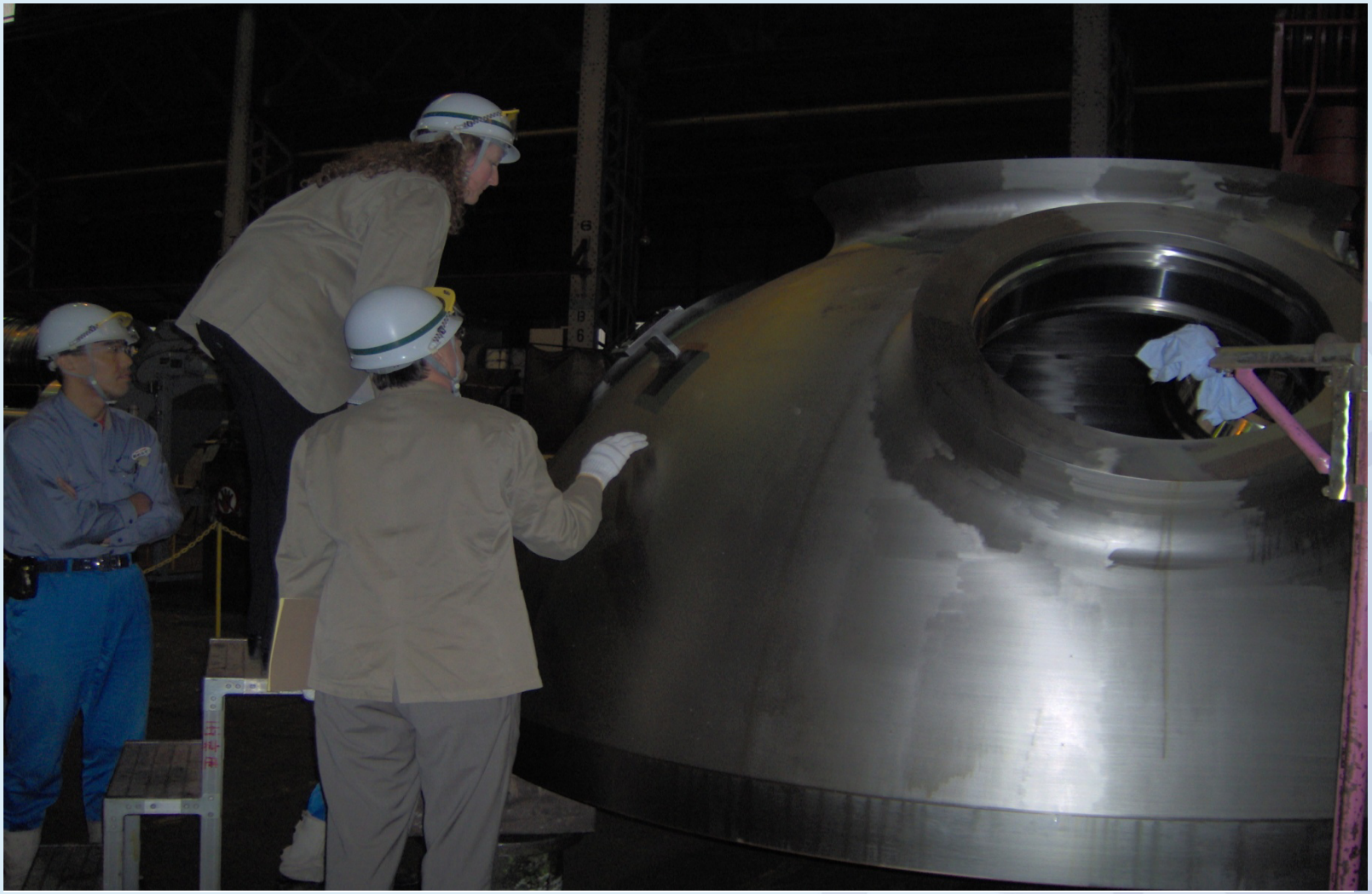

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NRC Vendor Oversight Workshop

- December 10 & 11, 2008, at the North Bethesda Maryland Marriott. Presentations made by NRC, NEI, NUPIC, NIAC, Licensees, and Vendors.
- Main topic areas
  - Commercial Grade Dedication
  - Part 21
- Nearly 600 participants
  - 162 vendors
  - 11 new plant applicants
  - 10 plant owners/operators
  - 8 reactor design companies
  - 11 construction companies
  - 7 U.S. government organizations
  - 2 foreign regulators
  - 6 nuclear fuel suppliers/processors/disposers
  - 2 news organizations

NRC Vendor Oversight Workshop

- Received over 300 written comments and questions
  - Part 21 (200)
  - Sampling (50-75)
  - Critical Characteristics (50-75)
  - General QA Topic (50-75)
  - Part 72 MNSS (50)

- Answers will be posted to website in groups. http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance.html

- All presentations have been placed on NRC website.
  - http://www.nrc.gov/public-involve/conference-symposia/vendor-oversight/index.html

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Calibration Services Update

- NRC Letters to:
  - ACLASS Accreditation Services dated December 19, 2007 (ML073440472)
  - Laboratory Accreditation Bureau (L-A-B) dated April 22, 2008 (ML081140564)
  - International Accreditation Services (IAS) dated May 14, 2008 (ML081330253)
- Bases for NRC approval for accepting 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.
- Similar to Arizona Public Services safety evaluation report dated September 28, 2005, for NVLAP and A2LA. (ML052710224)
- Met with NVLAP on May 28th to discuss potential methods for recognition of ILAC MRA beyond current 5 domestic ABs

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
  - Last VICWG Meeting held April 21-22, 2009, in Paris
  - April 2009 - Observed Korean Institute of Nuclear Safety (KINS) inspections at U.S. vendors: Flowserve Corporation (Valve division) and Curtiss-Wright, Target Rock Division
  - A NRO Inspector will be assigned for one term at the French Regulator Autorité de Sûrete Nucléaire ASN in Dijon, France in August 2009
  - June 2009 - NRO inspector participated as an observer on a QA audit by ASN at Mitsubishi Heavy Industries, in Japan
  - July 2009 - Japanese Regulatory authority JNES will observe vendor inspection at Japan Steel Works (JSW)

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
- Draft RG DG-1215 (1.28) should be released for public comment in near term.
- ASME/NRC working on revisions to Section III Subsection NCA-4000 to incorporate the NQA-1-2008 Edition.

Reminder

- Vendors should be fully knowledgeable of all regulatory requirements and technical specifications imposed by licensees in purchase orders
- Licensees should work with their vendors to ensure that the vendor quality programs adequately implement the requirements imposed in the purchase orders

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Questions