



NRC/NUPIC INTERFACE

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Quality and Vendor Branch, NRR

- NRR Reorganization in October 2005
 - 2 Quality and Vendor Branches in Division of Engineering
- Key Areas of Review:
 - Quality Assurance Program Descriptions
 - Extended Power Uprate Testing Programs
 - New Reactor Licensing Reviews and Inspections
 - Early Site Permits
 - Design Certifications
 - Combined License Applications
 - Vendor Inspections
 - NUPIC Audit Process Oversight
 - 10 CFR Part 21 Program Evaluations

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NRC Vendor Oversight

- NRC/NUPIK Interface
 - Draft Protocol for Observation of NUPIK Audits - Status with NEI??
 - ENSA Westinghouse/NUPIK Audit, Santander, Spain, September 2005
- Quality and Vendor Branch Inspections
 - General Electric Nuclear Energy (GENE), Wilmington, NC, November 2005
 - Flowserve, Raleigh, NC, January 2006





NRC Vendor Oversight

NRC Vendor Oversight cont.

- Commercial-Grade Calibration Suppliers
- Future NRC Activities

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NRC/NUPIC Interface

- **Equipos Nucleares, SA (ENSA)**

- 3 NRC Inspectors Observed the Westinghouse led/NUPIC (TXU & PGE) joint audit.
- Audit team identified 12 findings with ENSA QA program implementation:
 - Indoctrination and Training
 - Design control
 - Document control
 - Control of Special Processes (welding)
 - Control of Measuring & Test Equipment
 - Corrective Action
 - Quality Assurance Records
 - Internal Audits and Supplier Audits
 - Nonconforming, Materials, Parts ,and Components (including 10 CFR Part 21)



NRC/NUPIC Interface

ENSA Part 21 procedure for “Reporting Defects and Noncompliance” did not document or implement Part 21.21 requirements for evaluation of defects and failures to comply

- NRC issued Trip Report Dated October 28, 2005 in ADAMS (ML053010311)
 - Comprehensive Performance Based Audit at ENSA
 - Identified Numerous Findings in Program Implementation
 - Team Leader Efficiently Managed the Large Audit Team



NRC/NUPIC Interface

- Team Leader Established Effective Lines of Communications and Methods for Identifying the Findings.
- Areas for Continued Improvement
 - Audit of suppliers Part 21 Program and procedures for evaluating deviations and reporting needs to be expanded.
 - Use of Technical Specialists for areas such as commercial grade item dedication.
- NRC plans to Observe NUPIC Audit at Framatome ANP in France
- NRC Staff Preparing for New Construction Supplier Inspections
- NRC/NUPIC Interface Protocol with NEI - Where do we Stand??

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NRC/NUPIC Interface

- Issues Identified with 10 CRF Part 21 implementation during Recent NUPIC Audits
 - ENSA Part 21 procedure did not implement requirements of 21.21 for evaluation of defects and failures to comply
 - Enertech and ENSA invoking Part 21 on commercial grade suppliers
 - Appears that Supplier Audits are becoming a all-for-one and one-for-all to cover commercial, ISO, and Appendix B type QA programs



NRC Vendor Inspections

- GENE - ESBWR Design Certification
- Design Control Inspection Report w/Findings Issued January 11, 2006 (ML053560155)
 - GENE did not implement the ESBWR design control process.
 - External supplier audits performed by GENE did not identify and audit against the appropriate quality assurance program requirements.
 - GENE did not document or maintain training records.
 - GENE did not perform internal self-audits of the ESBWR program.
 - GENE did not complete the acceptance reviews associated with several ESBWR corrective action reports within the 30 day period.



NRC Vendor Inspections

- Flowserve - Raleigh - ASME Code & Safety Related Valves
- Inspection Report with Findings Issued February 8, 2006 (ML060310185)
 - Flowserve did not adequately implement their corrective action process.
 - Flowserve did not have procedures in place to perform 10 CFR Part 21 evaluations of significant conditions adverse to quality identified in their corrective action process.
 - Flowserve failed to implement appropriate procedural guidance.



NRC Vendor Inspections

- NRC will be verifying implementation of 10 CFR 21 program and procedures during NUPIC observations and NRC vendor inspections.
- Recent Inspection/NUPIC Audit Findings
 - Misunderstanding of Part 21 passed down to on procurement documents.
 - Inadequate Part 21 evaluation procedure.
 - Inadequate Appendix B procedural control to tie corrective action process into Part 21 evaluation process when applicable.



Commercial-Grade Calibration Suppliers

- Arizona Public Services – Bases of NRC approval documented in safety evaluation report (ML052710224).
- Alternative method for qualifying suppliers in lieu of supplier audit, commercial-grade survey, or in-process surveillance for commercial-grade suppliers of calibrations services.
- NRC staff has received inquiries regarding the applicability of SER to vendors.



Commercial-Grade Calibration Suppliers

- 3rd party accreditation is to ANSI/ISO/IEC 17025.
- NRC review and approval limited to NVLAP and A2LA, as recognized as ILAC signatories (applies to domestic suppliers only).
- Scope of accreditation covers contracted services.
- Purchase documents impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements.
- Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
- Purchase document shall require identification of the laboratory equipment/standards used.



Future NRC Activities

- Continue Observation of NUPIC audits.
- Perform Vendor Inspections
- Development of Quality and Vendor Branch Website.
- Continue ASME/NQA-1 Interface Activities.
- Continue Reviews and Inspections of Design Certifications, Early Site Permits, and Combined Licenses.



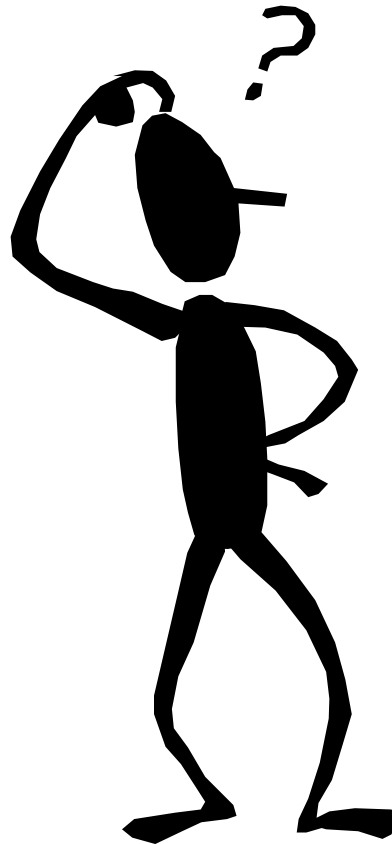
Future NRC Activities

- Draft NUREG-0800, Section 17.5, is available on NRC website
 - “Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants”
 - ADAMS - ML060180622
- This NUREG publication has been issued for public comment. Comments will be accepted 60 days from 2/10/06 date in the *Federal Register*.
 - ADAMS FRN - ML060260057



The Last Slide

- Questions?



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