



# NUPIC VENDOR MEETING

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Quality and Vendor Branch A

**June 15, 2006**



# Quality and Vendor Branch, NRR

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- NRR Reorganization in October 2005
  - 2 Quality and Vendor Branches in Division of Engineering (EQVA & EQVB)
- 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



# Presentation Topics

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- NRC Vendor Oversight
- NRC/NUPIC Interface
- NRC Vendor Inspections
- Commercial-Grade Calibration Services
- Future NRC Activities
- NRR Quality Assurance Website



# NRC Vendor Oversight

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- Quality and Vendor Branch A and Branch B Inspections
  - Areva Framatome ANP, Electrical Products Group, Cranberry Township, PA, May 2005
  - General Electric Nuclear Energy (GENE), Wilmington, NC, November 2005
  - Flowserve, Raleigh, NC, January 2006
  - Invensys/Triconex, Irvine, CA, March 2006
  - GENE, Wilmington, NC, (ESBWR follow-up inspection), April 2006
  - Crane Nuclear, Inc., Kennesaw, GA, April 2006



# NRC Vendor Oversight

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- NRC Observation of NUPIC Audits
  - ENSA Westinghouse/NUPIC joint utility audit, Santander, Spain, September 2005
  - Areva NP NUPIC Audit at Paris offices & Chalon/Saint Marcel Plant, May 2006
  - Mitsubishi Heavy Industries NUPIC audit at Kobe Japan plants, May 2006



# NRC/NUPIC Interface

- **Equipos Nucleares, SA (ENSA), Spain**
  - 3 NRC Inspectors Observed the Westinghouse led/NUPIC (TXU & PGE) joint audit in September 2005.
  - NRC issued Trip Report Dated October 28, 2005 in ADAMS (ML053010311)
  - 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

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- Areva NP NUPIC audit at Paris offices and Chalon/Saint Marcel manufacturing facility, May 2006
  - 3 NRC inspectors observed the Exelon led NUPIC (PSEG, FP&L, Ringhals AB, and NEK) joint utility audit
  - NRC issued Trip Report Dated June 7, 2006 in ADAMS (ML061510646)
  - Audit team identified 9 preliminary findings with the Areva NP QA programs implementation:
    - Design control
    - Instructions, procedures and drawings
    - Report of nonconforming materials, parts, or components (10 CFR Part 21)
    - Corrective action
    - Quality assurance records

# NRC/NUPIC Interface

- Mitsubishi Heavy Industries (MHI) NUPIC audit at Kobe Japan plants, May 2006
  - 2 NRC Inspectors Observed the Southern California Edison led NUPIC (STP & OPPD) joint utility audit.
  - NRC issued Trip Report Dated June 7, 2006 in ADAMS (ML061570442)
  - Audit team identified 4 preliminary findings with MHI QA program implementation:
    - Design control
    - Nonconforming Materials, Parts ,and Components
    - Corrective Action
    - Internal Audits and Supplier Audits
    - Inadequate 10 CFR Part 21 Posting and procedure for Evaluating and Reporting Defects and Noncompliance







# NRC/NUPIC Interface

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- Staff concluded that the 3 NUPIC audit teams conducted a thorough performance-based review of the implementation of the QA programs.
- Areas for Continued NUPIC 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 design and commercial grade item dedication.



# NRC/NUPIC Interface

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- Issues Identified with 10 CFR Part 21 implementation during Recent NUPIC Audits
  - Inadequate Part 21 evaluation procedure.
  - ENSA, Areva NP and Mitsubishi Heavy Industries (MHI) Part 21 procedures did not implement requirements of 21.21 for evaluation of defects and failures to comply.
  - Misunderstanding of Part 21 passed down on procurement documents.
  - Enertech and ENSA invoking Part 21 on commercial grade suppliers.



# NRC/NUPIC Interface

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- Continued.....Part 21 Issues identified during Recent NUPIC Audits
  - Inadequate Appendix B procedural control to tie corrective action process into Part 21 evaluation process when applicable.
  - Appears that Supplier Audits are becoming a all-for-one and one-for-all to cover commercial grade surveys, ISO, and Appendix B type QA programs.
- NRC will be verifying implementation of 10 CFR Part 21 program and procedures during NUPIC observations and NRC vendor inspections.



# NRC Vendor Inspections

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- Areva Framatome ANP, Electrical Products Group
- Inspection report with Findings Issued June 2, 2005 (ML051530438)
- Three Violations of 10 CFR Part 21
  - Failed to adopt appropriate procedures to evaluate deviations and failures to comply.
  - Failed to perform the required evaluation of an identified deviation.
  - Failed to provide an interim Part 21 report, within 60 days of discovery, to the NRC of an identified deviation.



# NRC Vendor Inspections

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- GENE - ESBWR Design Certification
- QA program & 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

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- 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 failed to implement appropriate procedural guidance.
  - 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.



# NRC Vendor Inspections

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- Invensys/Triconex – Safety Related Control Systems
- Inspection Report with one Nonconformance Issued April 13, 2006 (ML061100401)
- Invensys/Triconex Corrective Action Program did not meet the requirements of Appendix B to 10 CFR Part 50.
- Identified weakness with Part 21 procedure use of definitions consistent with Part 21



# NRC Vendor Inspections

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- GENE – ESBWR Design Certification
- Design Control Follow-Up Inspection
- Two Additional Preliminary Findings Identified:
  - GENE Corrective Action Process
  - Documentation reference quality standards not committed to in Chapter 17, Quality Assurance, of the ESBWR Design Control Document.





# NRC Vendor Inspections

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- Crane Nuclear Inc. - Valve Products and Services
  - Inspection Report with Findings Issued May 25, 2006 (ML061460006)
    - One Violation of 10 CFR Part 21
      - Failure to perform the required evaluation of an identified deviation.
    - One Nonconformance of Appendix B to 10 CFR Part 50
      - Training services were not in compliance with imposed safety-related contractual 10 CFR 50 Appendix B requirement.



# Commercial-Grade Calibration Services

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- Arizona Public Services – Bases of NRC approval documented in NRC 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 received March 15, 2006 letter from NUPIC regarding the applicability of APS SER to suppliers.



# Commercial-Grade Calibration Services

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- Alternate method is documented in the QA program description
- 3<sup>rd</sup> 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.





# Commercial-Grade Calibration Services

## 3<sup>rd</sup> Party Accreditation – Guidance to Suppliers

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Clarification requested by NUPIC letter, dated March 15, 2006  
NRC response dated June 6, 2006, in ADAMS (ML061580386)

- Question #1

Can suppliers maintaining a 10CFR50, Appendix B Program utilize the Safety Evaluation for the qualification of sub-suppliers, who provide commercial-grade calibration services, if the provisions of the Safety Evaluation are incorporated into the supplier's QA Program?

- Clarification

Appendix B suppliers may use the alternative for the qualification of commercial-grade calibration sub-suppliers. The conclusions of the Safety Evaluation with regard to the quality of supplier programs should also apply to sub-suppliers if the bases of the Safety Evaluation are maintained.



# Commercial-Grade Calibration Services

## 3<sup>rd</sup> Party Accreditation – Guidance to Suppliers

- Question #2

With respect to Question #1, are licensees required to impose the provisions of the Safety Evaluation in procurement documents before the supplier can implement those provisions? If yes, what is the basis for such a requirement

- Clarification

It is not necessary for a supplier to have a contract to implement the provisions of the alternative. In fact several suppliers that provide calibration services to the nuclear industry already have implemented the alternative to meet the requirements of other industrial customers. Licensees implementing the alternative should follow the guidelines of the Safety Evaluation to ensure that the bases of NRC approval are maintained.

Licensee choosing not to implement the alternative would procure calibration services as always and continue to conduct audits, commercial-grade surveys and/or in process surveillances as they did before the alternative was available.



# Future NRC Activities

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- Continue NRC/NUPIC interface
- Vendor Inspections led by EQVA & B
- Continue ASME/NQA-1 Interface Activities.
- Continue Reviews and Inspections of Design Certifications, Early Site Permits, and Combined Licenses.
- Revise SRP 17.5 (QA Program) to incorporate public comments (ongoing)



# NRR Quality Assurance Website

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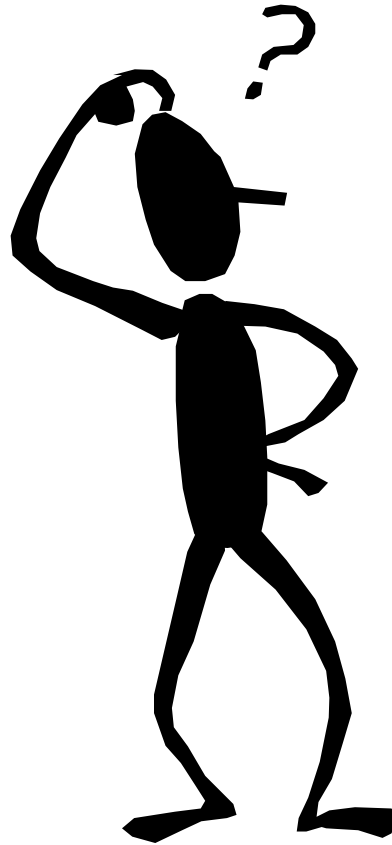
- NRR EQVA/B Quality Assurance Website available at <http://www.nrc.gov/reactors/new-licensing/quality-assurance.html>
- Links to all information presented is available on websites.
  - Will post all EQVA/B inspection reports, presentations, and correspondence on the website when it becomes publicly available in ADAMS.



# The Last Slide

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- Questions?



June 15, 2006

NUPIC Vendor Meeting

