



**NUPIC**

**General Membership Meeting**

**Charleston, SC**

**February 9-10, 2011**

**NRC Report**

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# Topic Areas

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- Vendor Inspection Activities
- Counterfeit, Fraudulent, Suspect Item (CFSI) Working Group Development
- NUPIC Audit Observation, EDSA Micro Corporation - October 2010
- Future of 10 CFR Part 21

# Vendor Inspection Activities

Shaw Modular Solutions, Lake Charles, LA  
January 2011-- Fabrication of AP1000  
modules for Vogtle and VC Summer

All vendor inspection reports are available at  
<http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html>

# Counterfeit, Fraudulent, Suspect Item (CFSI) Working Group Development

Working to coordinate the diverse NRC staff resources within the agency to improve the agencies abilities to respond to challenges associated with counterfeit, suspect, and fraudulent items. This effort shall include agency-wide assessments of the following key areas:

- Supply Chain Oversight;
- Communications (both internal and external);
- Agency response protocols

# NUPIC Audit Observation

- EDSA Micro Corporation - San Diego, CA (October 26-29, 2010)
- 2 NRC Inspectors participated
- NRC trip Report issued December 21, 2010
- 9 NUPIC findings (including two Part 21) identified by team

# EDSA Micro Corp.

## Unique Attributes:

1. Specialty scope of supply: electrical system design and modeling software
2. Only maintenance agreements since original POs issued 15+ years ago
3. EDSA QAP based on NQA-1a-1989 and NQA-2a-1990
4. No nuclear software in production (only maintenance activities)
5. EDSA ownership change without NUPIC notification

# EDSA Micro Corp.

## NRC Observations:

1. Efficient audit execution by NUPIC
2. Findings captured supplier implementation issues
  - No Part 21 evaluations (referred to customers)
  - Software maintenance agreement required for error reporting
  - Older design-basis records irretrievable
3. Good use of immediate notifications:
  - User information notice (non-finding) - technical product literature did not clearly outline the verification requirements for the software user library
  - Notification of significant finding - ineffective QA program
4. Significant finding used as a NUPIC “missed opportunity”

# EDSA Micro Corp.

## Areas For NUPIC Improvement:

- Better PBSA worksheet input from utility users (only 1 of 8 responded).
- Include the “Technical Characteristics” and “Acceptance Criteria” on PBSA worksheet
- The NUPIC Audit team prepared the “Technical Characteristics” section of PBSA worksheet with generic programmatic attributes from ASME NQA-1-1994, Subpart 2.7. These attributes were specifically addressed in other areas of the NUPIC Audit Checklist.

# Past and Present of Part 21

- NRC recognizes the need to clarify 10 CFR Part 21
  - Many issues exist despite generic communications and NRC staff outreach efforts
- NRO began preliminary rulemaking activities in December 2009
- Recent audits by the Office of the Inspector General reiterated issues
  - Vendor inspection programs (September 2010)
  - Implementation of 10 CFR Part 21 (early 2011)

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*“Even as the final rule was published on June 6, 1977, the Commission recognized that future experience and further information might warrant clarifying or other changes to the rule.” (NUREG-0302)*

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# Short Term Milestones

- Ongoing internal discussions on holistic solution to fix Part 21
  - Interim solutions as needed (Generic Communications)
- Presentation at the Regulatory Information Conference (RIC): *March 8 – 10, 2011*
- Commission paper (SECY) to recommend options to clarify the requirements of Part 21: *September 30, 2011*
  - Address need and priority for rulemaking, guidance, and outreach efforts.

# Vision for Part 21

- Stay true to Section 206 of the Energy Reorganization Act
- Fix problem areas
  - Clarify licensee and vendor responsibilities
  - Revisit definitions (i.e. Discovery)
  - Find a proper place for commercial-grade dedication
- Issue Guidance (i.e. Regulatory Guides)
  - Provide detailed expectations for a Part 21 program
  - Offer contemporary dedication guidance
  - Consider endorsing industry guidance (i.e. EPRI TR-017218 for Sampling)
- Stakeholder and public interaction throughout the rulemaking process

# New Part 21 Email Contact

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part021/>

Added a button in upper right hand corner “Subscribe to Updates “ to subscribe to email that updates you personally when Part 21 is revised

# Contact

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