

10CFR21 Update (NRC Initiatives)

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NRC / Industry Interaction

- Public Meeting on 8/1/11 reported results of NRC Part 21 Task Force efforts.
 - Team lead by Mr. Victor Hall
 - 25 “gaps” were identified comprised of the following:
 - *Perceived regulatory process deficiencies*
 - *Perceived licensee and supplier implementation*
- Industry position included acknowledgement of issues; however, need for rulemaking not evident . Strong preference for enhanced guidance
- This presentation addresses primarily Commercial Grade Dedication and CFSI issues

NRC Identified “Gaps”

EVALUATING AND REPORTING

- Lack of Regulatory Guidance – From NRC
- Quality Requirements in Procurement Documents – No requirement
- Clarify point of discovery – Based on inspection Findings
- Evaluating and Reporting Responsibility - Based on inspection Findings
- Deferral of Evaluation - 21.21(a) - Based on inspection Findings
- Use of 50.72/73 Event Reporting – Part 21 if not an LER
- 50.55e Redundancy – Additional requirement for Construction
- Counterfeit Fraudulent and Suspect Item (CFSI) Tie-in
- Clarify of Deviation and Delivery – Based on inspection Findings
- Contemporary posting requirements – Web postings
- Training – Inconsistency in implementation

NRC Identified “Gaps”

COMMERCIAL-GRADE DEDICATION

- Lack of Regulatory Guidance – From NRC
- Proper Place for Dedication – Is Part 21 the right place?
- Definition of Dedication – Based on inspection Findings
- Definition of Commercial Grade Item – Based on inspection Findings
- Clarify Dedication is a Safety-Related activity – Individual assessment
- Knowledge of Safety Function – Based on inspection Findings
- Sampling Requirements – Interviews and inspection Findings
- Use of Commercial Calibration (and Testing) Labs – Industry Guidance
- Software Dedication – Industry Guidance

Status

- NEI has established a team to facilitate industry engagement in activities going forward.
- Development of or revision to industry guidance in the following areas is ongoing:
 - Commercial Grade Dedication of Engineering Design Software
 - Commercial Grade Dedication of Calibration and Testing Laboratories (International and Domestic)

Status

- Commercial Grade Dedication of Engineering Design Software
 - EPRI Document developed – Waiting on response from NRC regarding endorsement via SER approach.
 - EPRI to address specifics

- Commercial Grade Dedication of Calibration and Testing Laboratories (International and Domestic)
 - NEI has been accepted as ILAC Member
 - Meeting with ILAC Executive Committee in 1st quarter 2012 to discuss options and schedule
 - Need NRC Feedback on proposal provided
 - Ongoing dialogue with NRC



Status

- Specific areas of interest to all stakeholders includes the following:
 - Relationship and reporting responsibilities with regard to 10CFR50.72 / 10CFR50.73 and 10CFR21
 - Redundancy between 10CFR50.55(e) and 10CFR21
- NEI is aligned to provide support to NRC effort – Mr. Chris Earls is Primary NEI Point of Contact

