



HISTORY OF VENDOR INSPECTION

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27th NUPIC Vendor Meeting

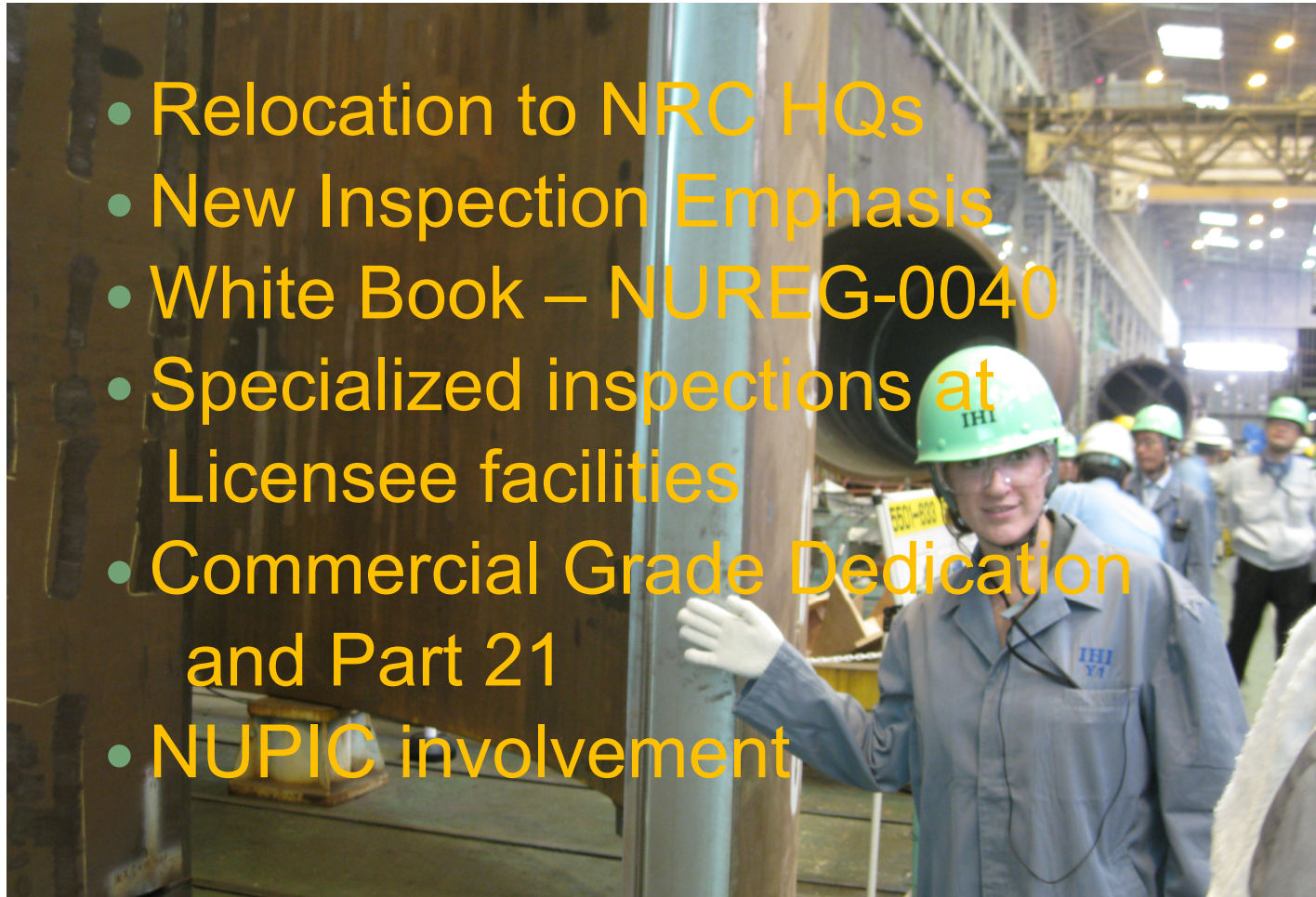
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Cleveland, Ohio



Topics

- Relocation to NRC HQs
- New Inspection Emphasis
- White Book – NUREG-0040
- Specialized inspections at Licensee facilities
- Commercial Grade Dedication and Part 21
- NUPIC involvement



Topics (cont'd)

- Office of New Reactors in 2007
- Audits by Office of Inspector General
- NRC Workshops on Vendor Oversight
- 10 CFR Part 21 Rulemaking
- ILAC ISO -17025 Endorsement
- EPRI Commercial-Grade
Dedication Guidance Endorsement
- Significant Generic Communications
- What we do!!





1984 Relocation to HQs

- Vendor Program Branch (VPB) moved from Region IV to NRC HQs Office of Inspection and Enforcement (I&E) in 1984
- New Staffing with inspectors with industry experience in design, construction, and quality assurance and quality control.
- Focus no longer on programmatic, but on performance based technical inspections



Original VPB Structure

- 3 VPB Inspection Sections
 - Equipment Qualification Inspection Section
 - Special Projects Inspection Section
 - Reactive Inspection section
- I&E disbanded in April 1987 and VPB inspection function moved to NRR as the Vendor Inspection Branch



NUREG-0040

- The “White Book”
- VPB and VIB regularly Issued NUREG-0040, “Licensee Contractor and Vendor Inspection Status Quarterly Report”
- Included NRC Inspection Reports for inspections of NSSS, Architect Engineers, and other licensee contractors, sub-tier contractors or suppliers
- Included a list of “Contractors with NRC Letters Confirming QA Program Implementation”

NUREG-0040 (cont'd)

- Information Notice No. 86-36: Change in NRC Practice Regarding Issuance of Confirming Letters to Principal Contractors
- As of May 16, 1986, NRC no longer issued confirming letters to principal contractors for NRC review of implementation of QA program reviewed and accepted by NRC.
- 1999 last year of Issue for NUREG-0040



Specialized Inspections at Licensees and Vendors

- Equipment Qualification for licensee electrical equipment for 10 CFR 50.49 implementation (1984 – 1988)
- Vendor – Utility Interface Inspections for compliance with NRC GLs 83-28 and 90-03 for licensee “Vendor Interface for Safety-related Components” (1985 – 1986)
- Licensee Safety-Related Procurement Inspections (1986 – 1988)



Specialized Inspections at Licensees and Vendors (cont'd)

- Commercial Grade Dedication (CGD)
Inspections at Licensees (1986 to 1992)
- Counterfeit, Fraudulent and Suspect Items
Inspections CFSI (items & materials)
- Issued multiple generic communications
related to fraudulent and suspect mechanical,
electrical and metallic material sent to NPPs



Commercial Grade Dedication (CGD) Inspections

- HQs Vendor Branch led 13 Inspections at licensees with Regional inspector participation
- Inspection NOVs resulted in issuing level 3 Civil Penalties to Licensees
- Issued GLs 89-02 and 91-05 specific to CGD and inspection results
- GL 91-05 outlined pause in NRC inspections while licensees implemented the October 1990 NUMARC 90-13 CGD improvements



CGD Inspections (cont'd)

- NRC conducted 8 assessments and 5 pilot inspections of licensee procurement and CG dedication programs between February 1991 and June 1992
- Weaknesses were observed BUT, staff noted that generally, licensees procurement and dedication programs had improved
- Draft IP 38703 for CG dedication issued in 1993



CGD Inspections (cont'd)

- April 1993 – conducted a 2-day NRC Commercial-Grade Procurement and Dedication Workshop in Dallas, TX
 - Included NRC regional , licensee and NUMARC participants
 - Introduced draft IP 38703
 - Discussed continuing dedication issues
- March 1994 - conducted a 2 day NRC Commercial-Grade Procurement and Dedication Training for regional inspectors in Rockville, MD



1995 Part 21 Rulemaking

- Effective October 15, 1995
 - Vendor inspection personnel involved in rulemaking activities
- Definitions with significant changes
 - Commercial Grade Item
 - Dedication
 - Critical Characteristics
- NEI expressed concerns the codification of several definitions and that these definitions may be ambiguous.



Reduction in Vendor Inspection

- During 1990s NRC identified:
 - Increased effectiveness of licensee commercial-grade dedication and procurement programs
 - A maturing of the supplier industry and
 - The evolution of NUPIC supplier audits
- Based on the above factors, NRC management reduced NRC vendor inspection effort to support inspections at vendors related to operating reactor events



Reduction in Vendor Inspection (cont'd)

- Vendor Inspection Branch disbanded at the end of 1994 and integrated as 2 reactive inspection sections in the Special Inspection Branch
- Vendor inspection ultimately integrated as a section within the QA, Vendor Inspection, and Maintenance Branch in 1997
- Inspection now limited to mainly allegation support and significant reactive inspections such as replacement of the North Anna 2 RPV head with an Areva EDF head fabricated for a French reactor pressure vessel.



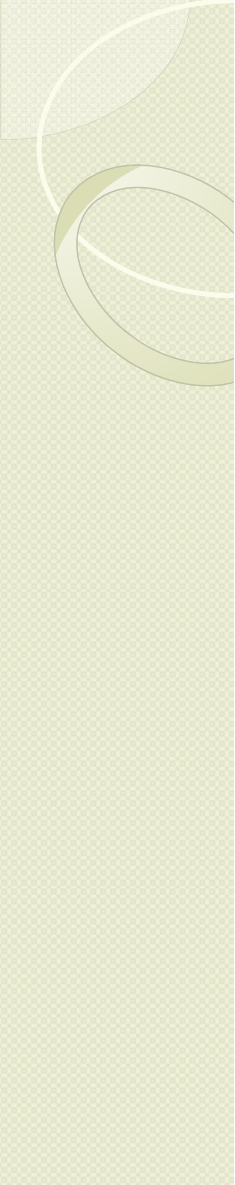
NUPIC Engagement

- Several NRC Information Notices issued in mid-late 80s related to ineffective licensee audits at suppliers
- NUPIC formed in 1989 by merging:
 - CASE - (Coordinated Agency for Supplier Evaluation)
 - NSQAC - (Nuclear Supplier Quality Assurance Committee)
- 1990: 1st NRR meeting with NUPIC to discuss the revised joint utility audit program



NUPIC Engagement (cont'd)

- 2003: began discussions with NUPIC to formally attend /observe NUPIC general member meetings and observe joint utility audits
- January 2004: NRC observed the 1st NUPIC joint utility audit at B&W Canada
- June 2005: NRR began presenting NRC vendor inspection issues at the NUPIC Vendor Meeting



NUPIC Engagement (cont'd)

- 2004: began process of observing at least two NUPIC joint utility audits per year
- 2007: developed IP 43005 to support NRC oversight of third-party organizations to qualify vendors in accordance with 10 CFR Part 50, Appendix B.
- 2007: began presenting NRC vendor inspection feedback at the annual NUPIC June vendor meeting

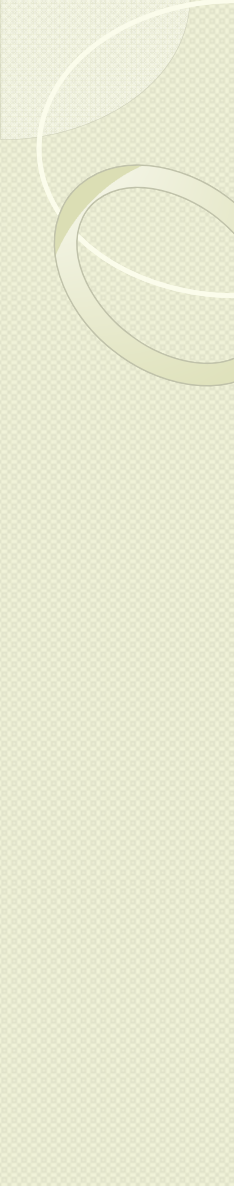
NUPIC Engagement (cont'd)





Early – Mid 2000s

- NRR recognized the need to prepare for potential new reactor construction and vendor oversight
- NRR specifically considered:
 - New suppliers entering the marketplace
 - Increased role of foreign suppliers
 - NUPIC's increased role in oversight
 - The expected extensive use of commercial-grade dedication
- Began process of preparing for future licensing (FLIRA) and revising construction inspection program developed during the 1970s



Early – Mid 2000s (cont'd)

- Industry Interface Participation
 - NUPIC
 - ASME Section III & XI committees
 - ASME NQA-1 committees
 - Electronic records (NIRMA Guidelines)
 - ANS & IEEE committees
- NQA-1 vs ISO-9001 evaluation
 - Requested by Commissioner Merrifield
 - SECY-03-0117 - “Approaches for Adopting More Widely Accepted International Quality Standards” issued in July 2003



Office of New Reactors (NRO)

- In 2007, NRO was established with Vendor Inspection activities as a key component to support licensing
- SECY 07-0105, “Enhancements to the Vendor Inspection Program within the Office of New Reactors” issued in June 2007
- Majority of qualified vendor inspectors moved from the NRR Quality & Vendor Branches to NRO
- NRR still maintained a small “Quality and Vendor Branch” focused on reactive inspections of nuclear vendors to support the allegation program and very limited operating experience issues



Office of New Reactors (cont'd)

- Two vendor inspection branches within the NRO Division of Construction Inspection and Operational Programs (DCIP) were established to inspect vendors to support new reactor licensing, design, & fabrication activities.



Office of New Reactors ((cont'd))

- New Reactor Vendor Inspections performed from 2007 to the present
- Both domestic and international suppliers inspected in the following countries: Japan, Korea, Italy, France, Spain, Sweden, Switzerland, and Canada
- Verified QA Program implementation for qualification test programs and fabrication activities to support ITAAC closure

New Reactor Design & Fabrication





New Reactor Design & Fabrication

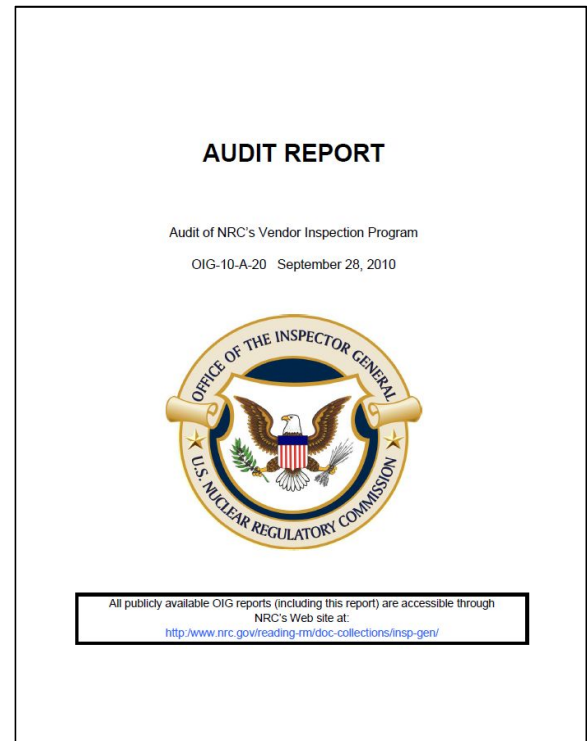
- AP1000 modular construction (structural and mechanical)
- AP1000 mechanical and electrical qualification test programs
- Digital Instrumentation and Control for AP1000
- ASME Section III and safety-related valve, pump and piping manufacturing
- Commercial-grade dedication organizations
- Reverse engineering activities

New Reactor Design & Fabrication



Audits by Inspector General (OIG)

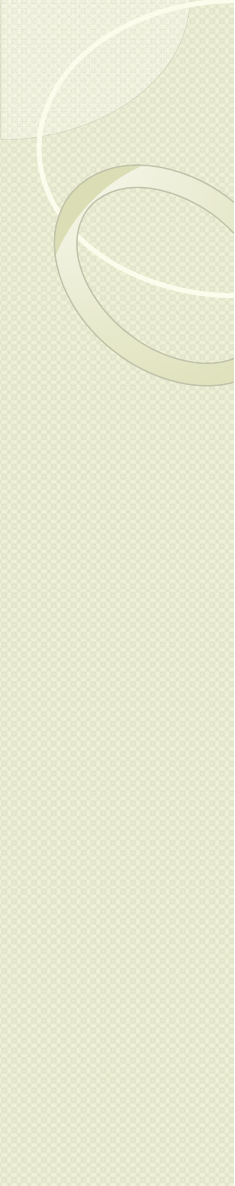
- 2009 - Quality Assurance Planning for New reactors
 - 2 Findings
- 2010 - Vendor Inspection Program
 - 10 Recommendations
- 2011 - 10 CFR Part 21
 - 5 Recommendations





Audits by OIG (cont'd)

- The OIG audit resulted in major DCIP staff actions including:
 - Proposed 10 CFR Part 21 Rulemaking
 - Developed Counterfeit Fraudulent and Suspect Item (CFSI) Strategy and issued generic communications
 - Expanded Stakeholder Outreach and supplier Communications
 - Implemented Vendor Inspection Program Plan (VIPP)



Vendor Center of Expertise (COE)

- 2012: COE was formed within NRO
- Combined NRO & NRR in the areas of vendor inspection programs, allegations, electrical engineering, and operating experience /construction experience (OpE/ConE).
- Perform reactive and routine inspections for operating and new reactor vendors

Vendor Center of Expertise (cont'd)



Vendor Center of Expertise (COE)





Workshops on Vendor Oversight

- First Vendor workshop held in December 2008 in Rockville MD
- Workshops' bring together NRC staff, regulated utilities, vendors of nuclear components, and other interested stakeholders to discuss technical and quality assurance vendor oversight issues
- Last one in 2016 was held in St Louis, MO



Workshops on Vendor Oversight (cont'd)

- Workshops have continued to be held every 2 years in conjunction with annual NUPIC June Vendor conference
- Tomorrow will be the 5th Vendor Workshop held in conjunction with NUPIC Vendor Conference and 6th all together
- A very important piece of NRC supplier oversight process is the continued success of NUPIC joint utility audits

Workshops on Vendor Oversight (cont'd)





2011 Part 21 Rulemaking

- On September 29, 2011, the staff issued SECY 2011-0135, "Staff Plans to Develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the Code of Federal Regulations Part 21 "Reporting of Defects and Noncompliance."
- In August 2015, the staff issued the Final Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliances." The regulatory basis justified amending the relevant regulations through the development of a proposed rule, and developing associated regulatory guidance documents.



2011 Part 21 Rulemaking (cont'd)

- In the January 2016, SECY-16-0009, Part 21 rulemaking was eliminated based on Project AIM recommendations and rebalancing of agency's work load.
- The NRC decided to develop regulatory guidance and to evaluate and endorse EPRI and NEI guidance documents related to commercial-grade dedication of design and analysis software, the dedication of CG items and services and for evaluating and reporting defects and failures to comply.



NRC Regulatory Guide 1.231

- In January 2017, the NRC issued Regulatory Guide 1.231, “Acceptance of Commercial Grade Design and Analysis Computer Programs for Nuclear Power Plants.”
- This RG endorses Revision 1 of EPRI 1025243, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications, with respect to acceptance of commercial-grade design and analysis computer programs associated with basic components for nuclear power plants.



NRC Regulatory Guide 1.164,

- In June 2017, the NRC issued Regulatory Guide 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants.”
- This RG endorses Revision 1 to EPRI NP-5652 and TR-102260 with respect to acceptance of commercial-grade dedication of items used as basic components for nuclear power plants.
- Included two staff regulatory positions: (1) 2 EPRI Seismic technical documents not endorsed (EPRI NP-7484 & TR 105849): and (2) only 2 of 6 EPRI digital I&C documents mentioned were endorsed by NRC (EPRI TR-106439 & TR-107330).



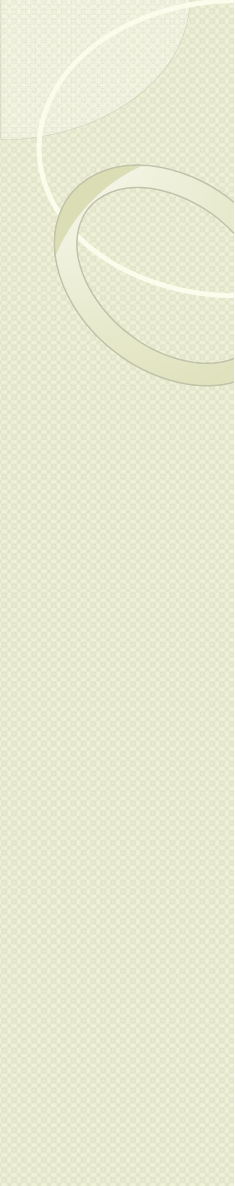
Counterfeit, Fraudulent and Suspect Items (CFSI)

- On January 8, 2015, the NRC staff published SECY Paper SECY-15-0003, “Staff Activities Related to Counterfeit, Fraudulent, and Suspect Items.”
- On June 24, 2015, the NRC issued Regulatory Issue Summary (RIS) 2015-08, “Oversight of Counterfeit, Fraudulent, and Suspect Items in the Nuclear Industry.” The RIS was issued to heighten awareness of the existing NRC regulations and how they apply to CFSI within the scope of NRC’s regulatory jurisdiction.



ILAC 17025 Endorsement

- On March 16, 2016, the NRC issued Regulatory Issue Summary (RIS), 2016-01, “Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services.”
- On April 1, 2016, the NRC staff approved the license amendment request submitted by Union Electric Company (dba, Ameren Missouri, the licensee) to change the operating quality assurance program revision 31, for Callaway Plant, Unit 1, to adopt NEI 14-05. Revision 1.



NRC Regulatory Guide 1.28

- ASME NQA-1 Endorsement
- In October 2017, NRC staff issued RG 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 5.
- Revision 5 updates the RG guidance to endorse the 2012 & 2015 editions of the ASME standard NQA-1, “Quality Assurance Requirements for Nuclear Facility Applications.”



NRC Regulatory Guide 1.33

- On June 25, 2013, the NRC issued Revision 3 of RG 1.33, “Quality Assurance Program Requirements (Operation)”
- Endorsed the 2012, edition of ANSI/ANS-3.2-2012, “Managerial, Administrative, and Quality Assurance Controls for Operational Phase of Nuclear Power Plants.”



Significant Generic Communications

- On February 15, 2011, NRC Information Notice (IN) 2011-01, “Commercial-Grade Dedication Issues Identified During NRC Inspections,” was issued.
- This IN summarizes the NRC staff’s observations and findings identified during vendor inspections in the area of commercial-grade dedication, as it applies to operating reactors, over the previous 2 years.



Significant Generic Communications

- On September 19, 2014, NRC Information Notice 2014-11: “Recent Issues Related To The Qualification And Commercial Grade Dedication Of Safety-Related Components,” was issued.
- This IN informed licensees of issues identified during NRC vendor inspections related to the qualification and commercial-grade dedication of safety-related replacement components. During vendor inspections, the NRC identified deficiencies in certain aspects of vendors’ commercial-grade dedication programs for safety-related equipment.



Significant Generic Communications

- On February 17, 2016, NRC Information Notice 2016-01: “Recent Issues related to the Commercial Grade Dedication of Allen Bradley 700-RTC Relays” was issued.
- This IN informed licensees about recent issues related to the commercial grade dedication (CGD) of Allen Bradley 700-RTC time delay relays, which the manufacturer redesigned to use a complex programmable logic device (CPLD).



Significant Generic Communications

- On July 15, 2016, NRC Information Notice 2016-09: “Recent Issues Identified when using Reverse Engineering Techniques in the Procurement of Safety-Related Components,” was issued.
- This IN informed licensees of issues that the NRC staff has identified concerning the supply of replacement safety-related components. Specifically, this IN describes instances where reverse engineering techniques were used to manufacture replacement components, and where the components were supplied without first verifying the supplied components met all safety-related design requirements.

2018 - What We Do

- The world's most elite nuclear vendor inspection program
- Conduct a targeted sample of routine and reactive vendor inspections (25 in FY18)
 - Direct technical vendor oversight
 - Support for construction
 - Technical support for allegation program



2018 - What We Do (cont'd)

- Licensing reviews for new plants
- QA reviews and implementation inspections
 - KHNP Design Certification
 - Vogtle & VC Summer COL
 - NuScale SMR Design Certification
- Involvement with Consensus Standards
 - ASME NQA-1
 - ASME Section III
 - ANS & IEEE



2018 - What We Do (cont'd)



QUESTIONS ??

