

Regulatory Update

Nuclear Oversight Committee

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Clearwater, FL



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Topics

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- ❑ NRC Vendor Inspections during COVID-19
- ❑ NRC review of EPRI Technical Report 3002020796
- ❑ Commercial-Grade Dedication Inspections at Licensees
- ❑ NRC Meeting with NEI on ISO 9001
- ❑ Regulatory Guide 1.28 Update
- ❑ Industry Outreach – NRC Town Hall on Vendor Oversight and 8th NRC Workshop on Vendor Oversight
- ❑ Questions

NRC Vendor Inspections During COVID-19

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- In 2020 - Vendor Inspection Program goal of 20 vendor inspections per fiscal year (Oct – Sept)
 - ▣ FY 2020 – 14 vendor inspections completed
- FY 2021 – Vendor Inspection Program goal revised to include licensing audits and observations (i.e., NUPIC or other regulators) – 20 per fiscal year
 - ▣ FY 2021 - 21 inspections/audits/observations: 10 vendor inspections, 4 observations of NUPIC audits, 1 observation of an ASN inspection, 1 parallel vendor inspection with ASN, 1 multinational vendor inspection, 3 licensing audits, and 1 Region 2 assist.
- FY 2022 – 9 inspections/audits/observations completed to date

Vendor Inspection Program Changes due to COVID 19 Pandemic

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- Revised inspection strategy
 - Established exigent inspection criteria to prioritize the safety of our inspectors and the vendor employees
 - Criteria includes safe mode of transportation, mandatory travel restrictions (state/county), available accommodations (hotels/restaurants etc)
 - Lead inspector tracks COVID transmission and positivity rates at vendor locations prior to final decision to travel and conduct onsite inspections
 - Remote and hybrid vendor inspections to supplement onsite inspections

NRC review of EPRI Technical Report 3002020796

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- EPRI's Technical Report 3002020796 "Remote Assessment Techniques Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions"
- May 7, 2021, and May 26, 2021, Southern Nuclear Operating Company (SNC) requested approval of a proposed change to the SNC Quality Assurance Topical Report (QATR)(ADAMS Accession No. ML21127A184 and ML21147A077)
- NRC Safety Evaluation completed on June 22, 2021 (ML21161A201) – 46 days from submittal



Commercial-Grade Dedication Inspections at Licensees

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- ❑ Commercial-grade dedication chosen to replace POV design engineering inspection, part of inspection procedure (IP) 71111.21
- ❑ Update to IP expected to be completed in the Spring of 2022
- ❑ Public meetings planned for the Fall of 2022 to discuss preparation and implementation

NEI proposal to utilize ISO 9001

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- The Nuclear Energy Institute (NEI) requested a public meeting with the NRC to discuss proposal.
 - ▣ Meeting held on Nov. 30, 2021
 - NEI presentation slides - ADAMS Accession Number ML21327A263.
 - Observation meeting summary - ML21348A313
 - ▣ Purpose – to discuss alternative approach to use suppliers with a commercial quality program (ISO 9001)
 - *Addresses necessary growth of the AR supplier community*
 - *Drives innovation for emergent AR technologies*
 - *Reduces economic challenges to small suppliers posed by development of Appendix B Program*



Meeting with NEI on ISO 9001

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- Discuss planned proposal to use ISO 9001 to satisfy Appendix B to 10 CFR Part 50 requirements to support 10 CFR Part 53 and the operating fleet
- NRC staff's perspective:
 - Scope of safety-related components for advance reactors needs to be defined and understood
 - Beneficial to focus on advance reactors and not on operating reactors
- NEI to submit a white paper with a more detailed proposal sometime in 2022

NEI proposal to utilize ISO 9001

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- Observation meeting conclusions
 - The staff stated that SECY-03-0117 already provides options on approaches for adopting more widely accepted international quality standards such as ISO-9001.
 - Approach 1: Acceptance of ISO 9001 as an Alternative to Appendix B
 - Approach 2: Nuclear Sector-Specific ISO Program
 - Approach 3: Licensee-Specific Controls for ISO 9001 Certified Suppliers
 - Approach 4: ISO 9001 Certified Suppliers for Commercial-Grade Item Procurement
 - NEI proposed:
 - To address gaps between the requirements of ISO-9001 and the requirements of Appendix B, such as special processes like welding, the licensee procuring the safety-related item or service and the ISO-9001 supplier supplying the item or service would have to address these gaps through procurement specifications and contractual agreements.
 - 10 CFR Part 21 requirements would be contractually passed down from the licensee procuring an item to the ISO-9001 supplier supplying the item through the procurement specifications.
 - To provide oversight of an ISO-9001 supplier, the licensee would extend their Appendix B QA program requirements to the ISO-9001 supplier.



Regulatory Guide (RG) 1.28 Update

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- ❑ Draft RG currently in development
- ❑ Revision 6 of RG 1.28 will endorse NQA-1 2017 and 2019 editions with conditions
- ❑ Draft RG to be issued for public comment in 2022

NRC Town Hall on Vendor Oversight

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- 1st Town Hall Meeting on Vendor Oversight held on June 24, 2021, virtually
- Approximately 220 attendees representing companies and organizations from 10 countries including vendors, industry groups, and government regulatory agencies.
 - ▣ Importance of Adhering to Procurement Specifications
 - ▣ Regulatory Alternatives for Supplier Oversight During Exigent Conditions
 - ▣ NRC's recognition of the ILAC accreditation process
- Plan to continue town halls in during non-NRC workshop years
- <https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/town-hall-meetings/past/2021.html>



8th NRC Workshop on Vendor Oversight

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- Workshop will be held virtually – date TBD
- Proposed topics:
 - Implementation of 50.69
 - Inspecting During a Pandemic - Lessons Learned
 - Commercial-Grade Dedication Inspections at Licensees
 - NRC's Position on the Use of ISO 9001 (SECY-03-0117)
 - Counterfeit, Suspect & Fraudulent Items
 - Implementation of EPRI Guidance on Hybrid & Remote Assessments
 - Licensee and/or Vendor's Perspective on Implementing the EPRI Guidance
- Registration will open in the Spring of 2022



Questions

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