



NRC UPDATE

February 9-11, 2021

EPRI Joint Utility Task Group (JUTG)
Procurement Virtual Forum



Aaron Armstrong and Paul Prescott

Quality Assurance Vendor Inspection Branch, Office of Nuclear Reactor
Regulation



Topics

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- Vendor Inspection Status
- 2021 NRC Virtual Town Hall
- COVID-19 Challenges
 - Licensing
 - Revision to Callaway's OQAP
 - Revision to Columbia Generating Station's Operational Quality Assurance Program (OQAP)
 - Public Meeting - Discuss Licensees' Plans for Supplier Oversight Beyond Frequency Extension Limits Allowed During the Current Exigent Condition
- Electric Power Research Institute's (EPRI)
 - Use of Remote Assessment Techniques (Draft Guidance)
- Update - ISO 17025:2017



Vendor Inspection Status

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- Since the last update there has been 14 inspections.
- Six were done on site and before the lock down of Covid-19 pandemic.
- After the pandemic there were 3 virtual inspections.
- There have been 5 on site inspections during the Covid-19 pandemic.
- The difference between the onsite and virtual inspections was based on the inspection's scope, risk to inspectors, and risk to supporting plant personnel.



2021 Virtual Town Hall Meeting

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- The purpose of a virtual town hall is for IQVB staff to engage with external stakeholders to discuss any current issues of importance to the nuclear industry, and to provide guidance and clarification as necessary. The goal of the virtual town hall meeting is to keep the external stakeholders informed on activities related to vendor inspection, QA, etc.
- The virtual town hall will be a Category 3 public meeting, and will not exceed more than 4 hours.
- The information on the virtual town hall will be announced on the NRC public meeting website.
- The virtual town hall is free to attend; however, attendees will be required to register prior to the virtual town hall.



COVID-19 Challenges

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Licensing

- The current COVID-19 pandemic emergency limits on domestic and international travel, has resulted in licensees and their suppliers having significant challenges meeting their regulatory commitments.
- The regulatory requirement for quality assurance program audits of suppliers is set forth in Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50.
- NRC regulatory guidance and nuclear industry quality standards: A typical supplier audit or commercial-grade survey is conducted on a triennial basis with a 90-day grace period afforded for unforeseen administrative issues.
- However, as a result of COVID-19 issues in the first quarter of 2020, licensees and suppliers became increasingly concerned that they might need to extend the grace period beyond the existing regulatory allowance in order to complete their oversight activities within an acceptable time frame.



Revision to Callaway's OQAPD

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- ❑ Ameren proposed to adopt a 25 percent grace period (i.e., 9 months) for audits and commercial-grade surveys to address the current public health emergency situation, as well as any similar situation in the future.
- ❑ Callaway's existing 90-day grace period for completing triennial vendor audits and commercial-grade surveys were set to expire for some of its suppliers on August 2020. Without a further extension, the affected suppliers would have to be removed from Callaway's Qualified Suppliers List within 90-days of the triennial audit or commercial-grade survey expiration date, which would adversely impact their ability to procure safety-related items and services.
- ❑ As the duration of the current national emergency is unknown, the NRC staff agreed that an overall extension of 25 percent to the triennial audit frequency for supplier audits and commercial-grade surveys may be implemented for exigent circumstances. The NRC staff found that the proposed changes continue to meet the requirements of Criterion VII of Appendix B to 10 CFR Part 50.



Revision to Columbia Generating Station's OQAPD

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- Energy Northwest requested to implement guidance found in EPRI's Technical Report 3002019436, "Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance," for performing **remote source verification**.
- The proposed change does not apply to vendor **audits** or **commercial-grade surveys**.
- The NRC staff reviewed the alternative screening criteria developed in the EPRI Report and determined that it provides licensees and vendors with acceptable guidance for using remote communication and video capabilities to perform remote source verification in exigent circumstances where it is not possible to perform on-site source verification due to conditions that threaten the health and safety of individuals performing the verification.



Public Meeting- Licensee Plans to Address Exigent Conditions

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- Purpose:
 - Discuss the licensees' approach for performing supplier oversight when the 25 percent audit or commercial-grade survey frequency extension limit is exceeded.
- Meeting was conducted virtually on November 2, 2020.



Public Meeting- Licensee Plans to Address Exigent Conditions

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- Industry presented four paths for future NRC staff consideration:
 - ▣ Path A – Develop guidance which allows audit Team Leader the flexibility to determine the team size required to conduct the audit or commercial-grade survey on-site while other members support remotely.
 - ▣ Path B –Develop more comprehensive guidance to support a hybrid or fully remote audit and commercial-grade survey approach should extensive travel and vendor restrictions not support any on-site presence. (The draft document is nearing completion)
 - ▣ Path C – Use a decision tree to explore procurement alternatives to accomplish each licensees' needs should a supplier approach or go beyond the 25 percent grace period allowance.
 - ▣ Path D – Use of the corrective action program (CAP) to document an evaluation for provisional authorization of the supplier, item, or service as the method of last resort.



Public Meeting- Licensee Plans to Address Exigent Conditions

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- Meeting Results
- NRC provided feedback by stating the NRC staff has considered the industry's proposals. The NRC staff did not have any issues with the proposed approach and the use of the CAP as a last resort. Licensees use of the CAP for conditions adverse to quality is within the regulatory framework. The NRC staff understands that this approach is intended to be temporary while industry stakeholders develop a methodology to perform remote supplier audits and commercial-grade surveys



EPRI Guideline

“Use of Remote Assessment Techniques”

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- The NRC staff continues to participate in the joint EPRI working group on the draft document for the conduct of hybrid and remote audits of suppliers.
 - ▣ The staff’s goal of participating on the working group is to expedite the NRC’s acceptance process, should the industry submit it for review.
- The scope of the document would be limited to use during exigent conditions, such as the current pandemic or other such warranted conditions where licensees and vendors could not safely conduct audits of suppliers.



Provisional Recognition of ISO/IEC No.17025: 2017

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- The Nuclear Energy Institute (NEI) submitted an update to Revision 1 of NEI 14-05A, which has been updated to recognize the 2017 edition of ISO/IEC 17025 as the basis for the International Laboratory Accreditation Cooperation (ILAC) accreditation process and to address other minor editorial changes, clarifications, and adjustments based on operating experience identified subsequent to the NRC's initial endorsement in February, 2015 (ADAMS Accession No. ML20259C391)
- As result of the ongoing COVID-19 pandemic, ILAC extended the transition period to the 2017 edition of ISO/IEC 17025 from November 30, 2020, to June 1, 2021. In light of ILAC's extension of the transition period, Revision 1 of NEI 14-05A also recognizes June 1, 2021, as an acceptable date for laboratories to transition to the 2017 edition of ISO/IEC 17025.
- While the NRC finalizes its review and approval of the safety evaluation report endorsing Revision 1 of NEI 14-05A, the NRC extended its provisional recognition of the 2017 edition of ISO/IEC 17025 from November 30, 2020 to June 1, 2021 in a letter dated November 20, 2020 (ADAMS Accession No. ML20325A192).



Key Takeaways

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- NRC continues to perform inspections activities virtually, onsite and the hybrid approach.
- NRC is making plans to hold a Virtual Town Hall Meeting.
- NRC continues to work with industry to develop guidance related to the Covid-19 pandemic.
- NRC will continue to update Stakeholders on the status of ISO/IEC 17025:2017 approval.



References

- Meeting Summary: ADAMS Accession No. ML20324A216, “Summary of the Public Meeting to Discuss Licensees' Plans for Supplier Oversight Beyond Frequency Extension Limits Allowed During the Current Exigent Condition”
- Meeting Summary: ADAMS Accession No. ML20203M179, “June 23-25, 2020, Summary of the Nuclear Regulatory Commission Workshop on Vendor Oversight”
- ADAMS Accession No. ML20216A681, “Callaway Plant, Unit No. 1 - Operating Quality Assurance Manual Change Revision 34B (EPID L-2020-LLQ-0004 [COVID-19])”
- ADAMS Accession No. ML20203K876, “Columbia Generating Station - Correction to Reduction in Commitment to the Operational Quality Assurance Program Description (EPID L-2020-LLQ-0003 [COVID-19])”