



# Town Hall Meeting on Vendor Oversight

## NRC's Updated Recognition of the International Laboratory Accreditation Cooperation (ILAC) Accreditation Process



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# Agenda

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- NRC's Safety Evaluation Report (SER)
- What's New?
  - ▣ Limitations of Use
  - ▣ Clarification
  - ▣ New Conditions
- Applicability
- Questions



# Important Distinction

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# NRC's Safety Evaluation Report

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- By letter dated February 20, 2020, the Nuclear Energy Institute (NEI) submitted for NRC's review and endorsement Revision 1 to NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services."
- NEI 14-05A was updated to recognize the 2017 edition of the International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17025 and to address other areas based on operating experience.
- By letter dated November 23, 2020, the NRC issued its SER on Revision 1 to NEI 14-05A.



# But 1<sup>st</sup>, a few reminders...

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- NRC's approval for using the International Laboratory Accreditation Cooperation (ILAC) accreditation process in lieu of performing commercial-grade surveys can only be implemented by a supplier who has a quality assurance (QA) program that meets the applicable requirements of Appendix B to 10 CFR Part 50.
- When commercial-grade surveys are utilized as an acceptance method, the commercial-grade survey report must document:
  - ▣ the commercial supplier's control over the identified critical characteristics and,
  - ▣ the associated quality controls that affect the critical characteristics, such as calibration of measuring and test equipment, when applicable.



# What's New?

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- Limitations of Use:
  - ▣ **Use of the ILAC accreditation process by commercial sub-suppliers is not appropriate.**
  - Commercial-grade survey reports must:
    - Document the acceptability of the commercial sub-supplier's control over calibration.
    - Address the selection and approval of suppliers and the overall procurement controls for such suppliers, as applicable.



# What's New?

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- Limitations of Use (cont.):
  - ▣ **ILAC accreditation process cannot be used as part of the commercial-grade dedication process of non-destructive examination (NDE) services.**
  - NRC's recognition of the ILAC accreditation process does not include the commercial-grade dedication of NDE services based on a laboratory's accreditation to the 2017 edition of ISO/IEC 17025.
  - Specific personnel qualification and certification requirements for NDE personnel performing safety-related activities not addressed by the ILAC accreditation process.



# What's New?

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## □ Clarification:

- Commercial-grade dedication requires the performance of a technical evaluation to ensure the correct technical requirements are specified in the procurement documents.
- NRC's recognition of the ILAC accreditation process is in lieu of performing a commercial-grade survey.
- As such, licensees and suppliers must follow the commercial-grade dedication process which includes performing and documenting a technical evaluation for the calibration and testing services being procured.





# What's New?

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## □ New Conditions:

### ▣ **Subcontracting of services is prohibited.**

- Procurement documents must prohibit the accredited calibration or testing laboratory from subcontracting the services being procured.
- The procurement document for accredited services must be submitted directly to the entity performing the calibration or testing.



# What's New?

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- New Conditions (cont.):
  - ▣ **Use of laboratories with accreditations based on two consecutive remote accreditation assessments cannot be used.**
    - During the documented review of a laboratory's accreditation, the dedicating entity must verify that the laboratory has achieved accreditation based on an on-site accreditation assessment by the selected accrediting body (AB) within the past 48 months.
- Procurement documents invoke:
  - ▣ **Performance of the services are contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months.**



# Applicability

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- For licensees, the use of ISO/IEC 17025:2017 as part of the ILAC accreditation process represents a QA alternative to the previously accepted QA program. As such, licensees may adopt the QA alternative of using ISO/IEC 17025:2017 provided that the bases of the NRC's approval are applicable to the licensee's facility pursuant to the requirements of 10 CFR 50.54(a)(3)(ii).
- On June 1, 2021, ISO/IEC 17025:2005 became invalid and only accreditation to ISO/IEC 17025:2017 is recognized under the ILAC accreditation process.



# Questions

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