

U.S. NRC'S RECOGNITION OF THE INTERNATIONAL LABORATORY ACCREDITATION COOPERATION (ILAC) PROCESS

CONSTRUCTION INSPECTION PROGRAM
PUBLIC MEETING
NOVEMBER 18, 2015



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NRO/DCIP/MVIB



Agenda

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- Safety Evaluation Report (SER)
 - ▣ NRC Conditions
- Regulatory Information Summary (RIS)
- Use of National Metrology Institutes (NMIs)
- Questions



NRC Safety Evaluation Report

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- By letter dated April 29, 2014, NEI submitted for NRC's review and endorsement NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services.
- By letter dated August 28, 2014, NEI submitted Revision 1 to NEI 14-05 in response to NRC's request for additional information.
- By letter dated February 9, 2015, the NRC issued its safety evaluation report (SER) on NEI 14-05.



NRC CONDITIONS

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- Method to use accreditation by an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory is documented in the Quality Assurance program.
- A documented review of the supplier's accreditation is performed and includes verification of the following:
 - ▣ Calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA and encompasses ISO 17025.
 - ▣ For procurement of calibration services, the published scope of accreditation covers the needed measurement parameters, ranges, and uncertainties.
 - ▣ For procurement of testing services, the published scope of accreditation covers the needed testing services including test methodology and tolerances/uncertainty.



NRC CONDITIONS

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- The purchase documents require that:
 - ▣ Service must be provided in accordance with the ISO 17025 program and scope of accreditation.
 - ▣ As found calibration data must be reported in the certificate of calibration when items are found to be out-of-tolerance.
 - ▣ Equipment/standards used to perform the calibration must be identified in the certificate of calibration.
 - ▣ Customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - ▣ Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services.



NRC CONDITIONS

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- It is validated, at receipt inspection, that the laboratory's documentation certifies that :
 - ▣ Service was performed in accordance with the ISO 17025 program and within the scope of accreditation.
 - ▣ Purchase order's requirements are met.



NRC Regulatory Information Summary

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- Purpose of the Regulatory Information Summary (RIS) is to announce and clarify NRC's technical position on the use of the ILAC accreditation process in lieu of performing a commercial-grade survey.
- Currently addressing public comments received.
- Suppliers of basic components may begin to use the ILAC accreditation process and do not have to wait for NRC's approval of a QA program change for a licensee.



NRC RIS

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- NRC continues to find Arizona Public Service's (APS) SER to be acceptable as an alternative method for using the ILAC accreditation process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process.
- APS's SER provides the NRC's original acceptance of the ILAC accreditation process.



Use of National Metrology Institutes

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- By letter June 4, 2014, NEI requested clarification on the NRC's position on the QA program requirements for international National Metrology Institutes (NMIs) as suppliers of primary reference standards and calibration services.
- In a letter dated August 23, 1983, the NRC had clarified that for the domestic NMI (NIST), it is not necessary for the purchaser to assure that NIST has a QA program that meets the applicable requirements of Appendix B to 10 CFR Part 50.
- By letter dated April 30, 2015, the NRC clarified its position with regards to the use of domestic and international NMIs as suppliers of primary reference standards and calibration services.



USE OF NMIs

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- The NRC position is as follows:
 - ▣ Licensees and suppliers of basic components may procure primary reference standards and calibration services from NMIs that are signatories to the Committee for Weights and Measures Mutual Recognition Arrangement without the need to perform an audit or a commercial-grade survey as the NMIs are organizations with proven abilities and disciplines.
 - ▣ Licensees and suppliers are still responsible for (1) ensuring that the appropriate technical requirements are included in the procurement documents, and (2) performing receipt inspection to ensure that the procurement document requirements are met.
 - ▣ It is not necessary for licensees and suppliers to invoke the requirements of Appendix B 10 10 CFR Part 50 or 10 CFR Part 21 in the procurement documents for primary reference standards and calibration services.



QUESTIONS

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□ Contact Information

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