



Workshop on Vendor Oversight

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



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Agenda

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



IMPORTANT DISTINCTION

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vs.





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 testing laboratory holds accreditation by an accrediting body recognized by the ILAC MRA and encompasses ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."
 - ▣ 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 17025:2005 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:
 - ▣ The calibration and testing service was performed in accordance with the ISO 17025:2005 program and within the scope of accreditation.
 - ▣ Purchase order requirements are met.



NRC'S EXPECTATIONS

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- Licensees and vendors must follow their commercial-grade dedication process when using the ILAC accreditation alternative for procurement of commercial calibration and testing services.
- Licensees and vendors may use the alternative method in lieu of performing a commercial-grade survey **as part of the dedication process** if the alternative method is documented in the quality assurance program and the following is performed:
 - ▣ Technical evaluation must be performed and documented:
 - Verify that the calibration and/or testing laboratory is accredited by an ILAC accrediting body and the scope of accreditation covers the contracted services.
 - A single technical evaluation may be performed provided the scope of accreditation has not changed.



NRC'S EXPECTATIONS

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- Section 4.3.2 of the SER states, in part, that “...all of the critical characteristics for calibration and testing services are already included in ISO/IEC-17025:2005 and are verified to be properly controlled by a laboratory as part of the ILAC accreditation process. The NRC staff verified this as part of its initial recognition of the ILAC accreditation process. As such, it is not expected that licensees and suppliers need to perform a technical evaluation to identify additional technical requirements. Therefore, a documented review of the calibration or testing laboratory’s accreditation is equivalent to the technical evaluation.”
- The above paragraph should not be interpreted to indicate that a technical evaluation as part of dedication of the service should not be performed.



NRC'S EXPECTATIONS

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- Critical characteristics for calibration and testing services are already included in ISO 17025:2005 and are verified to be properly controlled by the laboratory as part of the accreditation process.
 - NRC Conditions shall be imposed in the purchase order.
- Acceptance of critical characteristics
 - Review calibration and testing records to verify that all of the purchase order requirements have been met.



NRC Regulatory Information Summary

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- Regulatory Issue Summary (RIS) 2016-01 was issued on March 16, 2016.
- Purpose of the 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.
- Licensees and suppliers of basic components may begin to use the ILAC accreditation process.
 - On a letter dated April 1, 2016, the NRC approved a license amendment for Callaway Plant Unit 1 to incorporate the provisions of the SER into their Operating Quality Assurance Program.



NRC RIS

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- NRC continues to find the September 2005 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's 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 to 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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