

The Use of Accreditation in Commercial Grade Dedication of Laboratory Services

NRC Vendor Workshop

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NUCLEAR ENERGY INSTITUTE

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Overview

- Industry guidance
 - NEI 14-05
 - Submitted to NRC on April 29, 2014
- Purpose
 - Reduce duplication of surveys
 - Expand NRC acceptance of ILAC process
 - Calibration and testing services
 - Domestic and international laboratories

Industry Assessment of ILAC Process

- Evaluation of ILAC standards and procedures
- Observation of peer evaluations and assessments
 - Japan Accreditation Board in November 2013
 - American Association for Laboratory Accreditation in March 2014
- Evaluation of training
- Observation of Mutual Recognition Arrangement meeting

Industry Assessment of ILAC Process - Conclusions

- ILAC process is equivalent to survey
- Five differences between ILAC and NUPIC
 - Three are addressed by procurement requirements
 - As-found calibration data
 - Identifying the standards used
 - Notification of conditions adverse to quality
 - Two determined to be acceptable as-is
 - Compliance with procurement requirements
 - Counterfeit and fraudulent items

Purchaser's QA Program

- Address approach to use accreditation
 - Control of Purchased Material, Equipment, and Services
 - Control of Measuring and Test Equipment
 - Corrective Action
- Guidance contains a template for QA program

Procurement Requirements

- Service provided according to ISO/IEC-17025 program and scope of accreditation
- Include as-found calibration data when found to be out of tolerance (*for calibration services only*)
- Identify the standards and equipment used to perform the calibration (*for calibration services only*)
- Notification of any condition that adversely impacts the laboratory's scope of accreditation
- Any other technical and quality requirements related to the scope of supply

Commercial Grade Dedication

- Verify the laboratory is accredited to ISO/IEC-17025 by an ILAC signatory
- Verify the procured services are included in the scope of accreditation
 - For calibration services: measurement parameters, ranges, and uncertainties
 - For testing services: test methodology and tolerances/uncertainty
- Identify additional requirements for the scope of supply
- Verify that lab has certified the service was performed per the ISO/IEC-17025 program and scope of accreditation, and compliance with procurement requirements

Industry Oversight

- NEI Team, including NUPIC members
- ILAC standards and procedures
 - Monitor potential changes
 - Notify ILAC if potential changes may impact nuclear industry use of accreditation
 - Notify NRC of ILAC changes impacting guidance
- ILAC implementation of process
 - Observation of peer evaluations, including assessments, every 3 years
 - Led by NUPIC member

Path Forward

- Respond to NRC questions and feedback
- Notify industry when NRC endorses guidance
 - Estimated: 3Q2014