

Use of the International Laboratory Accreditation Cooperation Agreement

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NRC Workshop
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Scope

- **Commercial Grade Calibration and Testing Services**
 - **US Domestic facilities**
 - **International facilities**
- **Commercial Grade Dedication required for Safety Related applications**

Commercial Grade Dedication

Acceptance Methods of Dedication

- Method 1 – Special Tests and Inspections
- Method 2 – Commercial Grade Survey
- Method 3 – Source Verification
- Method 4 – Acceptable Supplier/Item Performance Record

Method 2 – Commercial Grade Survey

- **Ensure critical characteristics to be verified are documented**
- **Acceptance based on established quality controls**
- **Surveys should be specific to the item and the critical characteristics**
- **A Certificate of Conformance or Certified Material Test Report (CMTR) may be accepted under certain circumstances**

Qualification Process

- Commercial Grade Calibration & Testing
- Commercial Grade Dedication Package
- Commercial Grade Survey
 - **Access prohibited**
 - **Acceptable Alternative – ILAC Accreditation**
- Commercial Grade Dedication
- Safety Related Calibration & Testing

Or

Current Situation

- **Use of international commercial grade calibration and testing facilities is challenged for safety related applications due to:**
 - **NRC does not recognize laboratory accreditation under the ILAC Mutual Recognition Arrangement (MRA)**
 - **Inability of licensees and suppliers to access facilities preventing qualification through audit or survey process.**
- **Use of domestic commercial grade testing facilities for safety related applications is challenged due to:**
 - **NRC guidance addressing domestic certified calibration laboratories did not address “testing”, even though addressed by the approved certification process**

Regulatory Position

- **NRC Position**
 - Industry requests ILAC Process endorsement from 2008 – 2010
 - NRC states that supplier qualification is an industry issue – NRC is not in the business of qualifying suppliers – June 2010
 - The NRC does not procure services – (Difference with others)

- **OIG Audit of NRC Vendor Inspection Program - 9/28/10**
 - Calibration Laboratories Approval Guidance Must Be Clarified
 - Approving Accredited Commercial-Grade Calibration Laboratories Is Confusing
 - Calibration Laboratories Approval Process Guidance Is Disparate
 - Vendor Confusion Might **Lead To Inadequate Implementation of Appendix B and Part 21 Requirements**

Status

- **Action Plan from NEI to NRC seeking concurrence with approach submitted 9/19/11 – Positive feedback**
 - **ILAC process and procedure evaluation**
 - **Training and Qualification of evaluators**
 - **Approval Process for Accrediting Bodies**
 - **Accrediting Body evaluations and laboratory certification**
 - **Continuous Monitoring**
 - **Coordination with EPRI on dedication process**
- **December 2011 - NEI accepted as an ILAC Stakeholder enabling assessment of ILAC process.**

Status

- **Attended ILAC Meeting May 2012 (European Union)**
 - **AMC Meeting**
 - Observed process of Peer Evaluation Report Review
 - Reviewed completed reports from 3 EA Accreditation Bodies
 - Reviewed schedule of Peer Evaluations 2012/2013
 - **Arrangement Committee (ARC)**
 - Nuclear Industry / Regulator History
 - Review Action Plan with ILAC Membership
 - Discussed Observation Opportunities - Ongoing
 - “This engagement was envisioned when ILAC was formed” - Recognition that processes need to be revised to encourage this type of interaction

Status

- **Attended ILAC Meeting June 2012 (Asia-Pacific)**
 - **AMC Meeting**
 - **Observed process of Peer Evaluation Report Review**
 - **Reviewed completed reports from 3 APLAC Accreditation Bodies**
 - **Reviewed schedule of Peer Evaluations 2012/2013 – Schedule to be developed**
 - **Evaluator Training**
 - **Observed/Assessed 3 day Evaluator Training course**
 - **Observed/Assessed Instructor Training capabilities**
 - **Discussed Observation Opportunities**

Status

- **Action Plan Status**
 - ILAC process and procedure evaluation - **TBD**
 - Training and Qualification of evaluators - **Complete**
 - Approval Process for Accrediting Bodies - **Complete**
 - Accrediting Body evaluations and laboratory certification - **TBD**
 - Continuous Monitoring – **Process Being Developed**
 - Coordination with EPRI on dedication process - **TBD**
- **Report drafted for completed activities**
 - Stakeholder review of preliminary results to be scheduled

Proposal

- **NEI to issue final document including the following:**
 - **Results of process assessment**
 - **Results of Accrediting Body and Laboratory Certification observations**
 - **Definition of continuous monitoring process for end users**
 - **Potential for guidance on dedication process (NEI or EPRI documentation)**
- **NRC endorse NEI guideline for qualification of ILAC MRA certified calibration and testing laboratories**
- **Timeline contingent on completion of necessary observations**

Benefits

Regulatory

Establishes regulatory precedent and method for accepting world-wide accreditation

Quality

Highly trained and skilled technical professionals

Modification of ILAC Accreditation Body survey checklists

Access to laboratories in event additional oversight is warranted

Access to ongoing assessment results of certified laboratories

Approval process passed down supply chain – Nuclear industry solution

Cost

Allows utilization of testing data obtained on standard designs

Eliminate surveys of accredited facilities (domestic and international)

Enables use of local laboratories

Questions?



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