Implementation of the ILAC Process

5th NRC Workshop on Vendor Oversight

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Discussion Topics

- Industry guidance, NEI 14-05A
- Industry on-going monitoring of ILAC
- Industry implementation
- NUPIC checklist
- Procurement Issues / Operating Experience
- Questions

Industry Guidance, NEI 14-05A Revision 0

Main Points

- Expands scope of APS safety evaluation
- Domestic and international labs
- Calibration and test services
- Laboratories which are Accredited to ISO/IEC 17025 by ILAC MRA signatories
- In lieu of surveys as part of commercial grade dedication

MRA = Mutual Recognition Agreement

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Industry Ongoing Monitoring of ILAC

- NEI 14-05A, Revision 0, includes commitments for NEI and the industry to provide continued oversight of the International Laboratory Accreditation Cooperation (ILAC) process.

- The purpose of industry oversight is to confirm that the ILAC process continues to be consistent with NRC-accepted practices. Fulfillment of these commitments is necessary in order for the industry to credit accreditation under the ILAC process in the dedication of commercial grade laboratory services.

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Industry Ongoing Monitoring of ILAC

1. Review of ILAC requirements and procedures
   - Annually
   - For consistency of process and NRC approval
2. Observation of peer evaluations
   - Every three years, next one in 2017
   - For verification of implementation of process

- Issue an annual report on results of industry monitoring
- Review and Comment on revisions to ISO/IEC 17025 and ISO/IEC 17011
- Other optional activities

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Industry Implementation of NEI 14-05A

Supplier/Vendor Implementation

- Suppliers can implement immediately after making appropriate QA program changes
  - QA Manual and/or procedures – NEI 14-05A includes an acceptable QA program template

- Implementation must be in conjunction with Commercial Grade Dedication program
  - **Rules for Dedication Apply – EPRI TR 3002002982**

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Industry Implementation of NEI 14-05A

- This means the laboratory service must be procured commercially and dedicated for safety related use.
- Technical evaluation must be documented to identify the critical characteristics of the service.
- NEI 14-05A identifies the critical characteristics for calibration and testing services.
- NRC has endorsed these critical characteristics through their endorsement of NEI 14-05A.
- In lieu of utilizing a commercial grade survey to document the acceptability of the laboratory's control of the CC's, the laboratory's accreditation to ISO/IEC 17025 can be used, provided the conditions of NEI 14-05A are met.

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NUPIC Checklist

Changes to Section 3 - Commercial Grade Dedication- Added Checklist Item 3.5

- Verification that process is properly proceduralized
- Verification that technical evaluation has been performed to document the critical characteristics.
- Recognize Implementation of APS SER as an option
- Recognize Implementation of NEI 14-05A SER as an option
- Verification that Receiving Inspections are performed

Changes to Section 5 – Procurement

- Verification appropriate requirements are specified in PO's

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Procurement Issues/Operating Experience

- Interpretation of Laboratory's scope of Accreditation
  - This is not always easy
  - May require technical resources
- The Laboratory was accredited but an accredited service was not obtained
- Commercial Grade of the process is also required for international suppliers when 10CFR50, Appendix is invoked

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Procurement Issues/Operating Experience

Examples have been identified where PO's did not require:

1. The services to be provided in accordance with the lab's accredited ISO/IEC 17025:2005 program and scope of accreditation. (The service being provided must be accredited.)
2. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
3. Additional technical/quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

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Procurement Issues/Operating Experience

Examples where it was not validated at receipt inspection that the laboratory's documentation certifies that:

1. The contracted calibration or test service was performed in accordance with the laboratory's ISO/IEC-17025:2005 program and within the laboratory's scope of accreditation;

2. The purchase order's requirements were met.

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Procurement Issues/Operating Experience

Subcontracting by the Laboratory

1. ISO/IEC 17025 requires the laboratory to notify the customer in writing and recommends gaining approval.
2. The certification must document where the testing/calibration was performed.
3. The laboratory cannot indicate an accredited service was performed unless the subcontracted lab is accredited.
4. Certificate must identify any portions of the testing/calibration which is not accredited.

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Procurement Issues/Operating Experience

Use of Accreditation Logos/Symbols

- The use of Accreditation Logo is not required by ISO/IEC 17025 for Accredited Test/Calibration
- Each Accreditation Body can define requirements for use of Accreditation Logo
- Laboratories are allowed to use the symbol on reports within the scope of accreditation.
- New revision to ISO 17011 will strength this requirement to include use of symbol for specific services covered by the scope of accreditation
- Problems can be reported to the Accreditation Bodies

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Procurement Issues/Operating Experience

Fields of Accreditation

- Acoustics and Vibration
- Biological
- Calibration
- Chemical
- Construction Materials
- Electrical
- Environmental
- Forensic Examination
- Geotechnical
- Information Technology
- Mechanical;
- Nondestructive
- Sustainable Energy Testing
- Thermal

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Procurement Issues/Operating Experience

Accreditation Programs Not addressed by NEI 14-05A:

ISO/IEC 17020 Inspection Bodies

ISO/IEC 17043 Proficiency Testing Providers

ISO/IEC 17065 Product Certification Bodies

Clinical Testing Laboratories

ISO Guide 34 – Reference Material Producers

Visit www.nupic.com/NUPIC/Home/HotTopics.aspx for information regarding ILAC process

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QUESTIONS?

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