Implementation of the ILAC Process

Earl Mayhorn

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Discussion Topics

- Industry guidance, NEI 14-05A, “Guidelines For the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement Laboratory Calibration and Test Services”
- Industry on-going monitoring of ILAC
- Industry implementation
- Procurement Issues
- Receipt of NRC’s Provisional Endorsement of ISO/IEC 17025:2017
- Required Program Changes
- Required NUPIC Audit Checklist / Implementation Guideline
- Dialogue with NRC Relative to Revision to NEI 14-05A
- Submittal of Revision to NEI 14-05A to NRC

Industry Guidance, NEI 14-05A Revision 0

Main Points

- Expands scope of APS safety evaluation
- Domestic and international labs
- Calibration and test services
- Accredited to ISO/IEC 17025:2005, “General requirements for the competence of testing and calibration laboratories” 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, makes 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, last one was 2017
   - For verification of implementation of process

- Issue an annual report on results of industry monitoring

- Other optional activities

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Industry Implementation of NEI 14-05A

Supplier/Vendor Implementation

- Suppliers can implement 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**

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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 17025:2005 can be used, provided the conditions of NEI 14-05A are met as follows:

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Common Issues Identified During Audits

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.

Common Issues Identified During Audits

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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Common Issues Identified During Audits

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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Common Procurement Issues/Challenges

Use of Accreditation Logos/Symbols

- The use of Accreditation Logo is not required by ISO/IEC 17025:2005 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.
- Problems can be reported to the Accreditation Bodies

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Common Issues Identified During Audits

Fields of Accreditation

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

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Common Issues Identified During Audits

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 17034 – Reference Material Producers

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

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What has Changed?

NRC's Provisional Endorsement of ISO/IEC 17025:2017

- Endorsement Letter was transmitted to NUPIC/NEI on 4/22/19

- The letter dated 4/16/19 included the following:

  - NRC agreed with NUPIC's conclusion in Gap Analysis that ISO/IEC 17025:2017 does not present a reduction in technical or quality requirements

  - NRC confirmed that a technical evaluation is needed to implement the ILAC Process (CG Dedication)

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NRC's Provisional Endorsement of ISO/IEC 17025:2017

- - NRC's Endorsement is good through 11/30/2020

  - Licensees can adopt ISO/IEC 17025:2017 without NRC approval of QA program changes

  - Suppliers can adopt ISO/IEC 17025:2017 immediately after making the necessary program changes

  - Industry must submit a revision to NEI 14-05A for NRC Endorsement

  - Additional provisions for use of ILAC Process through changes to NEI 14-05A can be expected

  - Example - Prohibit Subcontracting

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Required Program Changes

When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), commercial grade surveys need not be performed provided each of the following conditions are met:

1. *A documented review of the supplier's accreditation is performed and includes a verification of the following:*

    a. *The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC 17025:2005 or ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."*

    b. *For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.*

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Required Program Changes

a. *For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.*

2. *The purchase documents require that:*

   a. *The service must be provided in accordance with their accredited ISO/IEC 17025:2005 or ISO/IEC- 17025:2017 program and scope of accreditation.*

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Required Program Changes

a. *As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance. (for calibration services only)*

b. *The equipment/standards used to perform the calibration must be identified in the certificate of calibration. (for calibration services only)*

c. *The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.*

d. *Additional technical and 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.*

2. *It is validated, at receipt inspection, that the laboratory's documentation certifies that:*

a. *The contracted calibration or test service has been performed in accordance with their ISO/IEC 17025:2005 or ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and*

b. *The purchase order's requirements are met.*

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Required Changes to the NUPIC Audit Checklist

- Implementation Guideline Section 3 – Add ISO/IEC 17025:2017

- Checklist Question 5.2 – Add ISO/IEC 17025:2017

- Implementation Guideline Section 5 – Add ISO/IEC 17025:2017

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Communication to Stakeholders

- Published Article in NUPIC Newsletter for Vendors and Stakeholders
- Email was sent to all suppliers listed in the NUPIC Database
- Posted the NRC letter on the NUPIC Website under Supplier Information Hot Topics tab
- Provide Presentation during June 2019 NUPIC Vendor Meeting

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Dialogue With NRC

- Concerns with lab subcontracting testing or calibration services
- Concerns with use of ISO/IEC 17025:2017 to accredit NDE Suppliers
- Recognition by suppliers that ILAC Process is a part of the commercial grade dedication process

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Revision to NEI 14-05A

- Change all references to ISO/IEC 17025:2005 to ISO/IEC 17025:2017
- Clarify the need for a technical evaluation documenting the critical characteristics for calibration and testing services
- Include sample technical (calibration and testing) evals
- Potentially include verbiage prohibiting subcontracting services
- Potentially include verbiage prohibiting use of NEI 14-05A to approve NDE suppliers

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Revision to NEI 14-05A

- NUPIC/NEI will meet again in July 2019 to discuss and resolve concerns
- Will request NRC endorsement without considering this a reduction of commitment per 10CFR50.54(a).
- Submittal of revision by August 1st.

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QUESTIONS?

Contact Information:

Earl Mayhorn

Email: emayhorn@ameren.com

Visit www.nupic.com/NUPIC/Home/HotTopics.aspx

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