Ameren MISSOURI | Callaway Energy Center

ILAC Accreditation Process Implementation
NUPIC Vendor Meeting

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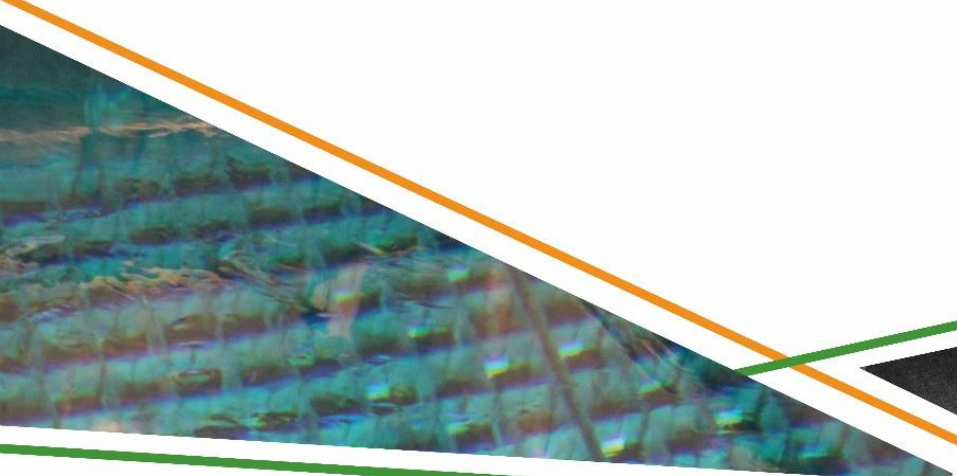
E. Mayhorn

EMayhorn@ameren.com



Discussion Topics

- Status of revision to NEI 14-05A
- Summary of Changes to NEI 14-05A, Rev. 1
- Actions Required
- Recently Asked Questions
- Main Points
- Audit Readiness
- References
- Questions

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Status of Revision to NEI 14-05A

- NEI 14-05A, Rev. 1 submitted to NRC – 2/20/2020
- Received One Request for Additional Information (RAI) from NRC - 5/1/2020

- NUPIC/NEI Responded to RAI - 5/13/2020
- ILAC Extended the ISO/IEC 17025:2005/2017 Transition Period – 6/2020

- Received Second Round of RAI's from NRC – 7/6/2020
- NUPIC/NEI Responded to RAI's – 9/11/2020

- Received Second Provisional Letter *11/30/2020*

- *Received NRC Safety Evaluation Report (SER) accepting NEI 14-05A, Rev. 1 on 2/19/2021. ADAMS ACCESS ML20322A019*

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Changes implemented in NEI 14-05A, Rev. 1

- References to ISO/IEC 17025:2005 have been replaced with references to ISO/IEC 17025:2017, with the understanding that ISO/IEC 17025:2005 was valid through June 1, 2021

- Clarifications on limits of use have been added to indicate the ILAC Accreditation process is not intended to be utilized for the commercial grade dedication of Nondestructive Examination (NDE) services.

- Subcontracting of accredited services is prohibited. The laboratory that is contracted to perform the required accredited calibration or testing must perform the service and cannot subcontract the services to another accredited laboratory.

Changes implemented in NEI 14-05A, Rev. 1

- The ILAC process is intended for use by licensees and suppliers of basic components as a part of the commercial grade dedication process and must be used in conjunction with other NRC-endorsed commercial grade dedication guidance such as EPRI TR 3002002982.

- A limitation has been placed on the use of remote accreditation assessments to maintain accreditation. Accredited testing or calibration services performed on behalf of licensees and suppliers of basic components cannot be accepted from laboratories who have not undergone an on-site accreditation assessment within the past 48 months of the date of services. Accreditation cannot be not be maintained based on consecutive remote accreditation assessments.

Changes implemented in NEI 14-05A, Rev. 1

- Sample technical evaluations for both calibration and testing services have been included as attachments to NEI 14-05A, Rev. 1. Use of these examples is not required.

- These changes represent clarifications and conservative adjustments and the ILAC process that was endorsed by the NRC in NEI 14-05A, Revision 0 remains fundamentally unchanged.

Required Actions

- Starting June 2, 2021, NEI 14-05A, rev. 0 becomes obsolete and users of the process must have the provisions of NEI 14-05A, Rev. 1 in place. ISO/IEC 17025:2005 will also be invalid for accreditation purposes

- Prior to changing from NEI 14-05A, Rev.0 to Rev. 1, verify your labs have completed the transition to ISO/IEC 17025:2017

- Add New Caveats to QAPD and/or Procedures and Procurement Documents

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NEI 14-05A, Rev. 1 Verbiage

The method the purchaser needs to follow, and document in their QA program, consists of:

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-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
   b. For procurement of calibration services, the published scope of accreditation for the lab covers the needed measurement parameters, ranges, and uncertainties.
   c. For procurement of testing services, the published scope of accreditation for the lab covers the needed testing services including test methodology and tolerances/uncertainty.
   d. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.
2. The purchase documents require that:
   a. The service must be provided in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.

NEI 14-05A, Rev. 1 Verbiage

b. 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)

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

d. *Subcontracting of these accredited services is prohibited.*

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

f. Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months.

g. Any 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.

3. 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-17025:2017 program, and has been performed within their scope of accreditation, and

b. The purchase order's requirements are met.

Recently Asked Questions

Is the ILAC accreditation process required to be prescribed in my QA Manual?

No, the process is not required to be prescribed in your QA manual unless your company have a topical report that has been approved by the NRC. Otherwise, the process can be prescribed in procedures.

What is required to be verified at receipt?

That the laboratory's documentation certifies that:

a. An ISO/IEC 17025:2017 accredited calibration or test was provided.

b. The purchase order's requirements are met.

Why can't the ILAC accreditation process be used to dedicate Nondestructive Examination Services? The nuclear industry has special personnel qualification and certification requirements that are not included in the accreditation process.

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Recently Asked Questions

The calibration lab that I use has multiple facilities. Can the main facility that I issue my PO to, subcontract the work to one of their other locations?

The general rule is contracting of accredited services is not allow. Some accredited laboratories have multiple locations and multiple accreditation certificates. The facility that you have evaluated and approved for the specific scope must performed the work. This may require one to have multiple listings for a given laboratory on their approved suppliers list. If a laboratory has multiple facilities under the same certificate, this would not be considered subcontracting.

Can one use the ILAC accreditation process to approved laboratories accredited by Accreditation Bodies that are not signatory to the ILAC MRA?

No, Laboratory must be accredited by an Accreditation Body that is signatory to the ILAC MRA.

Is Brammer (supplier of reference materials) the same as NIST?

No, while Brammer is a supplier of reference standards, they are a commercial supplier and Brammer would need to be surveyed or have their standards independently verified.

Recently Asked Questions

How does one verify a laboratory has received an onsite assessment within the past 48 months?

By contacting the laboratory similar to an annual contact made during annual evaluations. Remember, a documented review of the lab's capabilities is already required.

What can I do if the laboratory's scope of accreditation does not include all of my needs?

One can contact the laboratory and request consideration of getting their scope expanded to include the needed calibration or test. In addition, one can search for specific scope of accreditation's AB's websites

When does NEI 14-05A, revision 1 go into effect?

June 2, 2021

Why is a technical evaluation/dedication plan required?

Use of the ILAC accreditation process is a part of the dedication process; only the survey is not needed but the other steps of the dedication process are required.

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Review

Main Points

- Domestic and International Labs accredited to ISO/IEC 17025:2017
- Accredited by Domestic and International Accreditation Bodies
- Accredited to ISO/IEC 17025:2017 by ILAC MRA signatories
- In lieu of surveys as part of commercial grade dedication
- Technical Evaluations /Dedication Plans are required
- Accredited service can not be subcontracted
- Process can not be used to dedicate NDE services
- Laboratories must be accredited via an onsite assessment with past 48 months

Items in blue are new

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Audit Readiness

- **Verification that process is properly proceduralized per NEI 14-05A, rev. 1**
- **Verification that technical evaluation has been performed.**
- **Verification that evaluation of laboratories have been documented.**
- **Verification that procurement documents include the applicable requirements.**
- **Verification that the correct attributes are verified during receiving inspection.**

References

- https://www.nupic.com/NUPIC/Home/HotTopics.aspx
- NEI 14-05A, Revision 1
- NRC February 2021 SER – ADAMS Accession Number ML20322A019
- NRC 2020 Provisional Letter – ADAMS Accession Number ML20325A192
- NRC 2019 Provisional Letter - ADAMS Accession Number ML19056A451

Questions ??????