

Use of Laboratory Accreditation in Commercial Grade Dedication

NUPIC Vendor Meeting
June 17-18, 2015

Agenda

1. Industry guidance, NEI 14-05A
2. Industry on-going monitoring of ILAC
3. Industry implementation
4. NUPIC checklist
5. National Metrology Institutes (NMIs)

ILAC = International Laboratory Accreditation Cooperation

NRC Endorsement of Industry Guidance

- NEI 14-05, Revision 0 submitted April 29, 2014
- NRC RAIs received July 22, 2014
- NEI 14-05, Revision 1 submitted August 28, 2014
- NRC SER received February 9, 2015
- NEI 14-05A, Revision 0 issued March 4, 2015
 - NEI 14-05, Revision 1
 - NRC RAIs and NEI responses
 - NRC Safety Evaluation Report (SER)
- NEI 14-05A, Revision 0 is the approved version
- ML15075A434

Industry Guidance, NEI 14-05A Revision 0

- Expands scope of APS safety evaluation
- Domestic and international labs
- Calibration and test services
- Accredited by ILAC MRA signatories
- In lieu of surveys as part of commercial grade dedication

NEI 14-05A, Revision 0

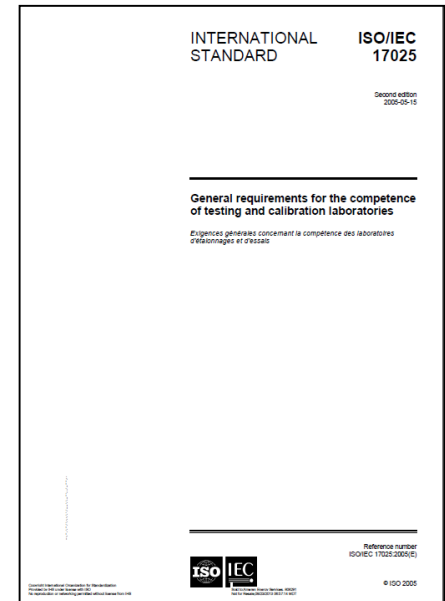
**GUIDELINES FOR THE USE
OF ACCREDITATION IN
LIEU OF COMMERCIAL
GRADE SURVEYS FOR
PROCUREMENT OF
LABORATORY
CALIBRATION AND TEST
SERVICES**

March 2015

MRA = Mutual Recognition Agreement

Industry Ongoing Monitoring of ILAC

- Commitment to NRC in NEI 14-05A
 - Review of ILAC requirements and procedures
 - Annually
 - Consistency of process and NRC approval
 - Observation of peer evaluations
 - Every three years, next in 2017
 - Implementation of process
- Additional activities, as appropriate



Industry Implementation of NEI 14-05A

Utility Implementation

- The change represents a reduction in commitment
- One Licensee must serve as pilot licensee
- Must submit QA Program change / QA program is a part of licensing document
- NRC must approve
- A second SER will be issued by NRC
- Other licensee can implement NEI 14-05A based on 2nd SER

Ameren has agreed to serve as pilot licensee

- Plans to submit license change within 2-3 weeks
- NRC has 60 days to respond after receipt of submittal

Industry Implementation of NEI 14-05A

Supplier/Vendor Implementation

- Suppliers can implement immediately after making appropriate QA program changes
 - QA Manual and/or procedures – NEI14-05A includes an acceptable QA program template
- Implementation must be in conjunction with Commercial Grade Dedication program
 - Rules for Dedication Apply

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.- **Mandatory**
- 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 the SER and NEI 14-05A are met as follows:

Industry Implementation of NEI 14-05A

The documented methodology shall consist of

- 1) A documented review of the laboratory's accreditation which includes a verification of the following:
 - a. The calibration/test lab holds accreditation by an AB which is a signatory to the ILAC MRA. The accreditation is to ISO/IEC 17025:2005, “General Requirements for the Competence of Testing and Calibration Laboratories.” There are currently 89 Accreditation Bodies (AB's) worldwide which are signatories to the ILAC MRA.

Industry Implementation of NEI 14-05A

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

- c. For procurement of testing services, the published scope of accreditation for the test laboratory shall cover the needed testing services including test methodology and tolerances/uncertainty.

Industry Implementation of NEI 14-05A

- 2) The procurement documents shall require that:
 - a. The services are provided in accordance with the lab's accredited ISO/IEC 17025:2005 program and scope of accreditation.
 - 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 must be identified in the certificate of calibration (for calibration services only).

Industry Implementation of NEI 14-05A

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

- e. 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

Industry Implementation of NEI 14-05A

- 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 the laboratory's ISO/IEC-17025:2005 program and within the laboratory's scope of accreditation;
 - b. The purchase order's requirements are met.

NUPIC Checklist

Changes to Section 3 - Commercial Grade Dedication- Added 3.5

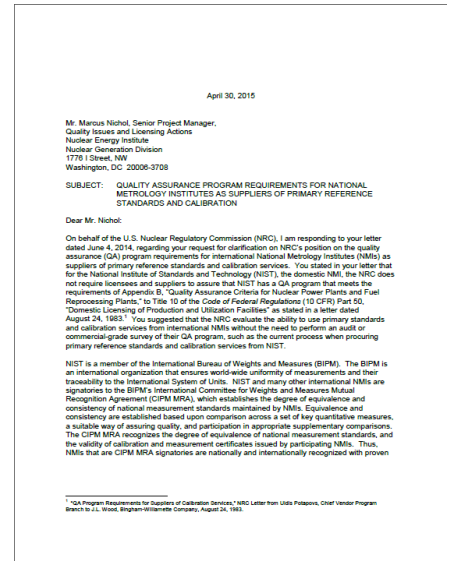
- Verification that process is properly proceduralized
- Verification that technical evaluation has been performed.
- Implementation of APS SER
- Implementation of NEI 14-05A SER
- Verification that Receiving Inspections are performed

Changes to Section 5 – Procurement

- Verification appropriate requirements are specified in PO's

National Metrology Institutes

- Each country has an NMI
- U.S.: National Institute of Standards and Technology (NIST)
- NRC position since 1970s/1980s
 - No need to audit NIST
 - NIST does not need App. B QA program
 - Silent on international NMIs
- NRC clarification in 2015 (ML15111A477)
 - NMIs that are signatories to CIPM/BIPM



QUESTIONS?