

# American Association for Laboratory Accreditation

# A2LA



# How is Traceability Assessed?

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TNI Assessment Forum  
Washington D.C.  
August 7, 2012



# Objectives

- Determine what the 2009 TNI Standard requires for Traceability
- Determine what ISO/IEC 17025:2005 requires for Traceability
- Examine the additional PI0 requirements
- Explain how these standards/requirements are assessed in the laboratory



# 2009 TNI Standard Volume 1

## ■ Reference Standards

- Shall have a program and procedure for calibration of reference standards
- Shall be calibrated by a body that can provide traceability to a national standard where available
- Shall only be used for calibration
- Shall be calibrated before and after any adjustment



# 2009 TNI Standard Volume 1

## ■ Reference Materials

- Shall, where possible, be traceable to SI units of measurement, or to certified reference material
- Internal reference materials shall be checked as far as is technically and economically practicable



# 2009 TNI Standard Volume 1

- Documentation of Standards, Reagents, and Reference Materials
  - Shall retain records of all standards, reagents, media, and reference materials
  - Expiration date must be recorded on the container if provided
  - Preparation records providing traceability to the stock must be maintained
  - All containers must have a unique identifier, and expiration date



# ISO/IEC 17025:2005 Additional Requirements

- All equipment used for test/calibrations having a significant effect on accuracy/validity of the result shall be calibrated
- The laboratory shall have an established program and procedure for the calibration of its equipment
- Calibration labs shall be operated so that the calibrations and measurements are traceable to the SI



# ILAC AB Traceability Requirements (per P10)

- External calibrations of critical equipment shall be conducted by:
  - A calibration lab accredited to ISO/IEC 17025 by a recognized AB
  - A recognized NMI
- External calibration certificates shall contain:
  - An endorsement by the recognized AB or NMI (symbol or narrative)
  - An indication of the type of entity accredited
  - Measurement uncertainty





# ILAC AB Traceability Requirements (per P10)

- Internal calibrations shall be supported by:
  - Procedure
  - Training Records
  - Traceability to an NMI
  - Measurement Uncertainty



# How is Traceability Assessed?

- Equipment, reference standards, and reference materials are noted throughout the course of the assessment while observing tests and interviewing analysts
- Calibrations records (both external and internal) are reviewed to ensure they contain the required information
- Training records are examined for personnel performing internal calibrations
- Procedure are reviewed



# How is Traceability Assessed?

- Accreditation and the assessment practice requires assessors to sample; however it is important that all technologies are assessed
- Recommend that the Accreditation Body creates an assessment form that can guide the assessor through the traceability path for each technology-checklists are not useful for this aspect
- This will aid in efficient assessment recording, clear assessment team communications and helps to ensure assessor consistency



# What is the Difference?

- Calibration certificates that simply say “NIST Traceable” are not acceptable
- External calibration certificates must be endorsed with the accepted accreditation body’s symbol or narrative
- Internal calibrations must be done with traceable reference standards/materials



# Why is Traceability Required?

- The purpose of requiring traceability is to ensure that measurements are accurate representations of the specific quantity subject to measurement, within the uncertainty of the measurement
- Gives customers confidence in the reported results



# Is Traceability Economically Feasible?

- Large labs with larger resources may choose to use external accredited calibration labs to perform all of their calibrations
- Smaller labs may meet the traceability requirements simply by having only their reference standards calibrated by an accredited calibration provider or purchasing certified reference materials and then performing internal calibrations of their equipment meeting the applicable requirements
- The financial burden is dependent on how much the lab wants to rely on external calibration providers
- The cost of external calibrations has decreased with competition in the market



# Conclusions

- The 2009 TNI standard serves as a good baseline for traceability requirements; but needs to include all of ISO/IEC 17025:2005
- ISO/IEC 17025:2005 adds additional traceability requirements that provide a higher level of confidence in the final results reported by a lab
- The P10 requirements implemented by ILAC MRA signatory accrediting bodies allow for true traceability and ultimate confidence in results

