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Metrological Traceability fundamentals



Summary of Issues

- Connection to ISO 17025 and the Big Three
- Traceability definition and elements
- Overlap with measurement uncertainty
- Calibration programs for measurement devices
- Metrology Institutes around the world NMIs / DIs
- Gray area traceability
- OEMs and CRMs
- Recommendations





Location of ANAB Offices Lab-related Group (formerly ACLASS) 500 Montgomery St., Suite 625 Alexandria, VA 22314 11617 Coldwater Road Suite 101 Ft. Wayne, IN 46845 (L-A-B legacy) Forensics-related Group (FQS + ASCLD-Lab) ASCLD/LAB, 139 J Technology Drive \rightarrow Garner, NC 27529 • Phone 919-773-2600 Management Systems Group 600 N. Plankinton Ave., Suite 300 Milwaukee, WI 53203 4



- Laboratories ISO/IEC 17025
- Inspection Bodies ISO/IEC 17020
- RMPs ISO 17034 /Guide 34 (Reference Material Producers)
- PT Providers ISO 17043
- Medical Labs ISO 15189
- Product Certifiers ISO 17065 with ANSI
- Government Programs: DoD ELAP, EPA Energy Star, CPSC Toy Safety, NRC, NIST IPV6, TNI, NLLAP, NEFAP
- TRAINING Programs

- Certification Bodies -ISO/IEC 17021
 - Accreditation for Management System Certification Bodies that certify to :
 - ISO 9001 (QMS),
 - ISO 14001 (EMS),
 - TS 16949 (US Automotive) etc.
 - ISO 13485 / 22001
- Forensic agencies 17025 and 17020



Connection to ISO 17025 and the Big 3

- Testing and calibration labs either take measurements or determine properties
- The "Big 3" is understood as :
 - Measurement uncertainty
 - Metrological traceability
 - Proficiency testing
- Overlapping elements are key to assure conformity



Traceability definition and elements

- property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty (VIM 2.41)
- "reference" can be a ref std, measurement unit, or a measurement procedure
- Elements include :



Traceability elements

- Reference standard or material (CRM / RM)
- Calibration procedure
- Chain of comparisons thru NMI to SI units or consensus standards, when possible
- Calibration environmental management
- Measurement uncertainty assured
- PT participation by cal lab



Calibration

Definition -- operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication (VIM 2.39)



Overlap with measurement uncertainty

- Traceability includes two levels of confidence
 - **First,** confidence that the chain of calibrations was done diligently, with good technique and reference standards
 - **Second**, confidence that the measurement error with your calibrated device are known
 - Lastly, calibration presumes determination or consideration of MU



Calibration programs for measurement devices

- Calibration intervals are often annual but can be variable your lab metrologist can decide
- Daily verification checks are independent of cal interval
- Critical that devices display labels with due date
- Other factors may affect cal interval
 - Dropped / damaged / removed from lab / failed verification check



Metrology Institutes around the world - NMIs / DIs

- Related to BIPM / CIPM
- Roughly 60 countries have participating members
- Internationally acceptable for traceability, BUT... not exclusively ... more automatically accepted



Gray area traceability

- Many measuring devices can only be calibrated by their OEM (manufacturer) or limited people
- Many of them are not accredited
- Some, not all, AB's may accept non-accredited calibration sources, if . . .
- Elements of metrological traceability needed
- Some tests or cal's may not be accredited
- Huge area if not SI unit measurands bio / chem



Non-SI unit Traceability Issues

- Biological and microbial extra element to check
- Chemical
- Consensus standards
- Traceability to a method



Recommendations

- Prepare a list of measuring devices
- List of key reference standards, RMs, CRMs
- Schedule for calibrations
- Schedule for verifications
- Assurance of metrological traceability elements for key equipment and standards
- Ask your AB for advice and clarifications in advance of accreditation visits

