



ACCLASS Guidance on Metrological Traceability

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Purpose

The purpose of this document is to establish guidance on metrological traceability requirements for all laboratories accredited by ACLASS. Customers are required to demonstrate traceability for their reference standards and reference materials which in most cases includes measurement uncertainty. See the ACLASS Uncertainty Guidance Document for related guidance.

Definitions

Metrological Traceability: 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 JCGM 200:2008)

ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (ILAC P-10:2002).

Measurand: Quantity intended to be measured. (VIM 2.3 JCGM 200:2008)

Uncertainty of Measurement: Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. (*Also referred to as “measurement uncertainty”*)

OEM: The original manufacturer of a reference standard device or Original Equipment Manufacturer. Often an OEM is the most reliable and competent location for repair and/or calibration of the device.

Calibration and Measurement Capability (CMC): The smallest uncertainty of measurement a laboratory can achieve within its scope of accreditation, when performing more or less routine calibrations of nearly ideal measurement standards intended to define, realize, conserve or reproduce a unit of that quantity or one or more of its values, or when performing more or less routine calibrations of nearly ideal measuring instruments designed for the measurement of that quantity.

Intrinsic Measurement Standard: Measurement standard based on an inherent and reproducible property of a phenomenon or substance.

Metrological Traceability

The term *metrological traceability* means a process whereby the indication of a measuring instrument (or a material measure) can be compared with a national standard for the measurand in question in one or more stages.

Metrological Traceability: is characterized by a number of essential elements (ILAC-G2:1994):

An unbroken chain of comparisons going back to a standard acceptable to the parties, usually a national or international standard and ending with laboratory working reference standards used in a metrology laboratory;

Measurement uncertainty for each step in the traceability chain must be calculated according to defined methods and must be stated so that an overall uncertainty for the whole chain may be calculated;

Documentation of each step in the chain must be performed according to documented and generally acknowledged procedures; the results must be equally documented (calibration certificate or test report);

Competence: The laboratories performing one or more steps in the chain must supply evidence of their technical competence (e.g., demonstrating they are accredited);

Reference to SI units: The “appropriate” standards must be primary standards (national, international, or intrinsic) for the realization of the SI units;

Recalibrations must be repeated at appropriate intervals; the length of these intervals depends on a number of variables (uncertainty required, frequency of use, type of use, stability of equipment); it is imperative the traceability of the standard is preserved. See also ILAC-G24, *Guidelines for the Determination of Calibration Intervals of Measuring Instruments*.

Laboratories accredited to ISO/IEC 17025 essentially participate in the chain of traceability to the SI units in their calibration and testing operations. They purchase and use reference standards and materials which have traceability, and the laboratory use of these items in the ISO/IEC 17025 scheme adds another step in the chain. The chain of comparisons precedes them, and the uncertainty of measurement includes the prior comparisons. It is then extended another step of the chain in the current laboratory operation.

Intrinsic standards represent a unique category in metrological traceability. They are each defined as a standard having or realizing, under its prescribed conditions of use and intended application, an assigned value, the basis of which is an inherent physical constant or an inherent and sufficiently stable physical property. They do not allow direct comparison in a chain to SI units, but rather represent a demonstration of a universally-accepted physical constant by the configuration of the device in question. These include a Josephson-junction-based voltage standard, a Quantum-Hall-effect resistance standard, and Cesium atomic standards for time and frequency, and ITS-90 International Temperature Scale standards. These are considered to have an “uncertainty of realization” which is extremely small and defined in the scientific literature. These

standards are sometimes used in high-end laboratories and contribute to traceability, though not in the SI chain directly.

A significant number of intrinsic standards such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well characterized laws of physics, fundamental constants of nature, or invariant properties of materials and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored, and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, inter-laboratory comparisons, or other suitable means that its intrinsic standard measurement results are correlated with those of national or international standards. (NIST Handbook 143, *State Weights and Measures Laboratories Program Handbook*)

Calibration Certificates / Test Reports

To demonstrate measurement traceability, calibration certificates shall, whenever applicable, indicate traceability to national/international standards of measurement and provide the result of the measurement and the associated uncertainty of measurement.

To this end, effective August 1, 2010, all ACLASS customers are required to implement either the use of the ACLASS symbol on all accredited calibration certificates and test reports or the use of the following statement (edited as appropriate):

“This/these calibration(s)/test(s) is/are accredited and meet(s) the requirements of ISO/IEC 17025 as verified by the ANSI-ASQ National Accreditation Board/ACLASS. Refer to certificate and scope of accreditation (insert accreditation number here).

See the ACLASS Guidance on Symbol Usage for more information.

Whenever applicable, and if suitable for customer requirements, a statement of compliance with an identified metrological specification may be accepted in lieu of measurement results and associated uncertainties.

Calibration certificates / test reports shall be accompanied by a recognized accreditation body symbol, or otherwise make reference to accredited status, to be assumed satisfactory for traceability purposes. Recognized bodies include bodies recognized by ILAC, APLAC, and IAAC. Additionally, recognized bodies may include those accredited by ACLASS.

Certificates/reports will contain a statement of measurement results and/or a statement of compliance with an identified metrological specification accompanied by both a sufficiently defined uncertainty statement and an appropriate statement of traceability. The traceability statement shall affirm the calibration was performed using standards traceable to an appropriate national, international, intrinsic, or mutual consent standard.

Calibration certificates which refer only to NIST report of test numbers as evidence of traceability are not considered sufficient demonstration of measurement traceability. NIST report of test numbers do not in and of themselves provide a statement of uncertainty associated with the farthest link in the chain from NIST (the last facility providing the measurement value).

ACLASS will honor and enforce the requirements of each respective MRA and/or MLA for which ACLASS is a signatory, including but not limited to:

- The use of equivalent procedures in the accreditation of laboratories
- The recognition of a laboratory and/or inspection body as equivalent to an ACLASS laboratory
- Accept endorsed calibration/test/inspection reports of MRA/MLA signatories
- Promote the acceptance of international MRA/MLA
- Investigate complaints
- Contribute to the appropriate MRA/MLA Councils
- Provide other available resources as determined by ACLASS

ACLASS will issue non-conformances against the traceability requirements. Because ACLASS classifies its non-conformances into two categories (major and minor), the following shall apply:

Issuance of a Non-Conformance for Traceability

A non-conformance shall be issued against 5.6 of the standard if evidence exists that instruments have been calibrated using an OEM not compliant with ILAC P10, *ILAC Policy on Traceability of Measurement Results*. A non-conformance shall also be issued against 5.6 of the standard if evidence exists that instruments have been calibrated using a laboratory accredited by an Accreditation Body that is not a signatory to the above mentioned co-operations or even a subcontracted laboratory from a signatory AB that has not provided an accredited certificate of calibration or is not accredited specifically for the parameter calibrated. The severity of the non-conformance is dependent upon the effect on the resultant calibration(s) done with that device. For example, a major non-conformance is typically issued if the calibration uncertainty of the particular instrument in question has a major impact on the uncertainty and/or validity of the calibration(s) with that instrument.

Examples and Scenarios

The most common reference standards used in metrology are the dimensional tools including gage blocks and dozens of other gages. Many accredited laboratories are available for the calibration of nearly all of these tools, but there may be exceptions. Regardless of the circumstances, the laboratory must verifiably demonstrate traceability per ISO 17025:2005. One exception example may be when the laboratory deals with a specialty tool OEM that is not ISO/IEC 17025 accredited. Can this OEM be utilized for the tool's calibration? The answer is that the OEM may not be used for accredited

calibrations with the tool, unless the specialty tool has some internationally recognized consensus standard to use for its calibration. Traceability may allow for consensus standards, but if there is no traceability, then there is no accredited operation.

In addition, many calibration service laboratories offer calibrations in several formats, and often the proper format is not requested or secured. To be compliant, the accreditation seeking laboratory must request ISO/IEC 17025 compliant calibrations and certificates (see also section 5.6.2.1 of ISO/IEC 17025). This must include the reference standards used, a NIST traceability reference, the measurement uncertainty for the calibration, and any out of tolerance relevant information.

As an aside, ACLASS laboratories are encouraged to be alert for lapses in correct accredited certificates from the sub-calibration of its standards. These certificates should meet the requirements of section 5.10 of ISO/IEC 17025. The laboratories are encouraged as well to get feedback to those lapsing laboratories to update their formats and information or they may have to be removed from the approved supplier lists. This may often be due to an inability to provide adequate traceability.

Use of OEMs for Traceability/Difficult to Achieve Traceability

Occasionally laboratories receive calibration certificates from OEMs of common tools and there is no other source or economical means to have a tool calibrated, but the OEM laboratory is not accredited. In this case, the OEM needs first to be encouraged by all such applicant and accredited laboratories to get its accreditation. Secondly, the laboratory needs to receive information, and submit such information to ACLASS for consideration as best as possible, that the laboratory is ISO/IEC 17025 compliant and that their certificates reflect the information required for traceability.

As a minimum, the following would be expected to be accomplished by the laboratory seeking support from OEMs for traceability for submittal to ACLASS for consideration:

1. Conduct an evaluation of the OEM/laboratory to ensure the OEM/laboratory is operating under a quality/management system that is ISO/IEC 17025 compliant. This assessment could be indirect if the laboratory seeking accreditation from ACLASS has access to a reliable evaluation of the OEM/laboratory from another ISO/IEC 17025 accredited laboratory
2. Ensure that the laboratory is using standards traceable to NIST or other NMI and that their uncertainties are supportable
3. Ensure that the processes used for calibration are validated
4. Assure that measurement uncertainties for the laboratory are appropriate
5. Ensure that relevant out of tolerance data is provided, including before and after data
6. Get evidence of participation in proficiency testing/inter-laboratory comparisons
7. Document the steps of review undertaken in determining that these facts are true
8. Submit evidence of the evaluation and all supporting documents to ACLASS for review

An OEM that is not accredited and calibrates an applicant or accredited laboratory's device(s) will not be accepted for traceability if they cannot provide evidence of the required items listed above. ACLASS will not include those calibrations on the scope of accreditation where this evidence has not been provided.

Legal Metrology Laboratories

In the case of calibration of scale and balance weights, a high percentage of laboratories are required to use their state agricultural laboratory. In instances where state and/or federal statutes mandate such, these are deemed acceptable in most circumstances, although many of them are not accredited to ISO/IEC 17025.¹ It is hoped that all such laboratories will be accredited in the near future for consistency's sake. Some of these state laboratories do not provide uncertainties with their weight calibrations. In this case, laboratories have no realistic alternative but to utilize their weight tolerance values instead of mass uncertainties in their uncertainty budgets. The state laboratories should be consulted to provide uncertainties on a case-by-case basis if these are not automatically provided.² Calibration of some fraction of the weights at an accredited location should be done as verification of traceability when state laboratories provide no uncertainty or verification of accreditation.

Reference Materials and Reference Cultures

Chemical, physical, and microbial reference materials represent a completely different arena within traceability. Chemicals and strains of microorganisms require assurance of both purity and identity. Traceability for chemical reference materials is adequately covered in Appendix A of ISO Guide 34:2000 (E). This covers gases and gas mixtures, metal alloys, pure compounds, trace elements, organics, molecular biologics, and others. ACLASS subscribes to the descriptions in this appendix. Primary sources of these chemicals include NIST and US Pharmacopeia. Microbes should normally be obtained from the American Type Culture Collection (ATCC) or other internationally recognized source.

ACLASS considers the use of reference materials and calibrated artifacts as an important tool for demonstrating the validity and traceability of a method or the component parts of a method.

Reference materials play an important role in underpinning the accuracy and validity of measurements made within testing and calibration laboratories. Purchasers of reference materials require confidence in their accuracy, traceability, and homogeneity to be able to determine fitness for purpose. This document will assist laboratories in the selection of appropriate reference materials and provide guidance on determining the competence of reference material suppliers.

¹ Primarily in these instances, state laws require use of state laboratories.

² Measurement results acceptable under the rules and regulations adopted or promulgated by a state are acceptable to ACLASS and typically the measurements results are provided by state weights and measure divisions typically found within the state's department of agriculture or similar department.

ACLASS acknowledges that:

- a) The concept of traceability of measurement in fields such as chemical and biological sciences is still under international debate and progress towards unified understanding and use of this concept is not yet complete.*
- b) The role of certified reference materials in providing traceability of measurement results has not yet been fully established internationally.*

Laboratories are required to investigate the availability and suitability of reference materials and calibrated artifacts for their accredited procedures. The competence of organizations conducting the production or calibration of reference materials/artifacts is key to determining the suitability of the materials or artifacts. ISO/IEC 17025 requires laboratories to evaluate suppliers; this includes producers of reference materials and suppliers of calibration services/items. It is important that the laboratory determines the suitability of the producers of these items and not only the distributor who handles them.

Note 1: ISO/IEC Guides 31:2000 and 34:2000 and ILAC G12:2000 contain recommendations and guidance on the requirements for the competence of reference material producers. These documents should be used as a basis for such an evaluation.

Note 2: Although no single source of information on the availability of reference materials currently exists, laboratories are recommended to contact reference material producers and distributors to discuss availability and suitability. In addition, laboratories may find it useful to refer to the COMAR database for availability of reference materials. COMAR is a non-commercial network of national and international organizations, which is funded by BAM. The website address is www.comar.bam.de.

If no appropriate reference materials or calibrated artifacts are available, the laboratory shall demonstrate that the alternatives used have sufficient traceability, stability, homogeneity, and accuracy such that the method and subsequent results can be deemed fit for purpose.

There is overlap between ISO/IEC 17025 calibration accreditation and ISO Guide 34 reference material producer accreditation, in that organizations accredited to these standards can both provide materials that can be used as a reference and provide traceability for analytical methods. Laboratories should consider the following points when selecting the service/product they require.

Where the laboratory also requires that the artifact is homogenous and stable or if the artifact has the potential for heterogeneity and/or instability, they should purchase an artifact from a reference material producer that can demonstrate that these requirements have been met. Alternatively, a competent laboratory could be used to determine homogeneity and stability.

Examples of materials that fall into this category are solution of metals used to calibrate an ICP Soil with certified dioxin content used for the validation of a dioxin method, Reference cultures for identify and characteristics of microorganisms.

References

- ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*
- NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, 1994
- ISO / IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*
- ISO Guide 34:2000, *General Requirements for the competence of reference material producers*
- ISO/IEC Guide 99:2007, *International Vocabulary of Metrology -- Basic and general concepts and associated terms (VIM) Third Ed. 2007.*
- ILAC-G24: 2007, *Guidelines for the Determination of Calibration Intervals of Measuring Instruments*
- ILAC-P10:2002, *ILAC Policy on Traceability of Measurement Results*