EGAC Policy on Traceability for Measurements and Calibration
PB04G

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Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
6.1/May 2013	Quality Manager	3/5	To encourages for legal metrology labs to safeguard proper tractability
6.2/May 2016	Quality Manager	4/7 & 7/7	Updating the clauses according new standards & update new issue of ILAC procedure

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1. SCOPE

This document defines the policies for the calibration and traceability of measuring equipment and results for all laboratories. This includes: calibration laboratories, testing laboratories, medical laboratories, laboratories included in inspection bodies, and laboratories included in certification bodies.

2. POLICY

2.1. EGAC concept of traceability of measurements results

The criteria on traceability which laboratories have to meet are laid down in clause 5.6 of ISO/IEC 17025 Latest version– *General requirements for the competence of testing and calibration laboratories*, clause 5.3.1.4 of ISO 15189 Latest version – *Medical laboratories - Requirements for quality and competence* and clause 6.2.7 & 6.2.8 of ISO 17020 Latest version – *Conformity assessment - Requirements for the operation of various types of bodies performing inspection.* EGAC will apply the principles of ILAC P10:01, *ILAC Policy on Traceability of Measurement Results* (which can be viewed at www.ilac.org) to the assessment and accreditation of laboratories.

The formal definition of traceability is given in the *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM-2012) as: "2.41 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".

Traceability (as given in both ILAC G2 and VIM) is characterized by:

- **An unbroken chain** of comparisons going back to stated references acceptable to the parties, usually a national or international standard;
- **Uncertainty of measurement**; the uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated or estimated;
- **Documentation;** each step in the chain must be performed according to documented and generally acknowledged procedures; the results must be recorded.
- **Competence;** the laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence (e.g. by demonstrating that they are accredited);
- **Reference to SI units;** the chain of comparisons must, where possible, end at primary standards for the realization of the SI units;
- **Calibration intervals;** calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of the equipment).

2.2. EGAC policy on traceability of measurements results

Accredited testing and calibration laboratories shall be able to demonstrate that measurement results obtained under their scopes of accreditation are traceable to the International System of Units (SI units). Where such traceability is not technically possible or reasonable, the laboratory and the client and other interested parties may agree to using Certified Reference Materials provided by a competent supplier or using specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Accredited calibration laboratories, for critical equipment and calibrations relevant to their scopes of accreditation, ***shall in all cases***, where possible, derive their traceability from direct reference to accredited laboratories. ***If and only if accredited laboratories are not available in a specific testing scope***, then a reference to an intrinsic standard or to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee on Weights and Measures (CIPM) or directly from an appropriate National Metrology Institute. ***For Calibration Laboratories***, in cases when an accredited laboratory is not available locally, not feasible to find internationally, and the scope is not covered by the National Metrology Institute (NIS), then this case shall have to be discussed with EGAC's relevant Accreditation Manager on a case by case basis. In this case, with EGAC relevant Accreditation Manager's consent, traceability maybe secured by a calibration laboratory that can demonstrate competence, measurement capability, traceability to SI units, and appropriate measurement uncertainty.

Note 1: *"Critical" equipment used by testing and calibration laboratories is considered by EGAC to be those items of equipment necessary to perform a test or calibration from the scope of accreditation and which have a significant effect on the uncertainty of measurement of test or calibration results.*

Note 2: *Calibrations performed by verifying authorities appointed under Egypt's legal metrology frameworks are also accepted. EGAC encourages Egyptian legal metrology laboratories to seek accreditation to ensure competence and safeguard proper traceability of their measurement and calibration results and to make their competence transparent to third parties.*

Note 3: *EGAC considers an "appropriate" national metrology institute to be one that participates regularly and successfully in relevant international interlaboratory comparisons performed by BIPM (see, e.g., the* CIPM MRA*) and/or by the Egyptian metrology body* (NIS).

Note 4: *Accredited calibration laboratories are those accredited to the requirements of ISO/IEC 17025either by EGAC or by another accreditation body that is a signatory to the ILAC Mutual Recognition Arrangement (MRA). Calibration certificates from accredited laboratories should display the accreditation mark of the relevant accreditation body and all calibration certificates should provide a statement of uncertainty (and/or compliance if appropriate).*

Note 5: *Laboratories should maintain current copies of their accredited calibration service providers' scopes of accreditation.*

Where an intrinsic standard or system is used as a standard, the following requirements apply:

- Direct intrinsic standard or system-to-intrinsic standard or system comparison with NIS, other NMI, or an accredited laboratory shall be conducted at appropriate intervals to ensure the correct realization of the measurand;
- Documented calibration history of the device used to measure differences between intrinsic standard or system and unknown values shall be maintained;
- Documented calibration history of the intrinsic standard or system components (e.g., the time base of the reference frequency counter in a Josephson voltage array system) shall be maintained;
- Documented evidence of periodic checks on system precision and stability (e.g., leakage currents, ground loops, thermal EMF's, step integrity, trapped magnetic flux, noise, and microwave power impinging on a Josephson voltage array) shall be maintained.

Where the concept of traceability is relevant and technically possible, accredited testing and calibration laboratories shall ensure the traceability of their in-house calibration and/or accredited test/calibration results to an external calibration provider that is accredited for suitably small uncertainties. If accredited laboratories are not available, these accredited tests shall be traceable to ***-in the following sequence according to availability-*** a National Metrology Institute, National Reference Laboratory, a Certified Reference Material, Mutual Consent Standard, or Agreed Method that can demonstrate its competence.

Laboratories holding only management systems certification will be deemed to have not demonstrated the necessary technical competence.

Accredited testing and calibration laboratories may have equipment calibrated by a calibration service provider that is not accredited by EGAC or by a signatory to the ILAC MRA subject to the following requirements[1]:

- The laboratory shall audit the traceability of the calibrations to NIS or some other national metrology institution, and must document results of this audit to the satisfaction of EGAC.
- The laboratory shall maintain records that non-accredited calibration service providers have been audited. These records must include all findings of nonconformance with standards and the service provider's resolution of the nonconformities.
- Calibration certificates and/or reports issued by non-accredited calibration service providers shall meet the requirements of ISO/IEC 17025, including appropriate statements of uncertainty.

Laboratories shall document the following:

- Information regarding assessment of the quality system used by the calibration service provider. This information shall include who assessed the calibration service provider and the results of the assessment. It is preferable that the laboratory have on file a copy of the assessment report from whoever assessed the service provider.
- Information on the calibration procedures used by the service provider.
- A list of the test and measuring equipment used by the calibration service provider. The calibration of this equipment must be traceable to NIS, to some other national metrology institution, or to a calibration service provider accredited to ISO Standard 17025:2005 by an organization
- Copies of its calibration service provider’s certificates of calibration.
- Information on environmental conditions at the facility of the service provider.
- The methods by which the service provider determines uncertainties of measurement.
- Information on the uncertainties obtained at all steps in the calibration process.

Accredited testing and calibration laboratories may calibrate their own equipment provided that:

- Appropriate measuring equipment, reference materials and/or reference standards are available.
- Staff is properly trained in the calibration procedure, training records are maintained, evidence of proficiency is available and laboratory personnel are competent to estimate uncertainty of calibration results.
- The laboratory's calibration procedures are documented and calibration records are maintained.
- Internally-developed calibration methods (if any) are properly validated and validation records are maintained.

[1] This also applies to calibration providers that are accredited, but not for the specific calibrations required by the laboratory.

3. REFERENCES

- ILAC G2, “Traceability of measurements”.
- ILAC P10 “ILAC Policy on Traceability of Measurement Results”.
- International vocabulary of metrology – Basic and general concepts and associated terms – VIM.
- Guide to the Expression of Uncertainty in Measurement (GUM) - BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML.
- ISO/IEC 17025– General requirements for the competence of testing and calibration laboratories.
- CITAC Policy on traceability, Co-Operation on International Traceability in Analytical Chemistry
- CIPM MRA, International Committee on Weights and Measures.
- ISO 15189- Medical laboratories - Particular requirements for quality and competence.
- ISO 17020- Conformity assessment - Requirements for the operation of various types of bodies performing inspection