EGAC Policy on Traceability for Measurements and Calibration
R2G

Prepared by:	EGAC Quality General Manager Ashraf Saif
Reviewed and Authorized by:	EGAC Accreditation Director Mohamed Osman

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1. Scope

This policy specifies the forms of objective evidence, by which the proof of metrological traceability in context of accreditation process is provided by testing laboratories, calibration laboratories, medical laboratories, inspection bodies, forensic service providers and where applicable proficiency testing providers.

2. Policy

EGAC concept of traceability of measurements results

The criteria on traceability which laboratories have to meet are laid down in:

- ISO/IEC 17025:2017 – *General requirements for the competence of testing and calibration laboratories;*
- ISO 15189:2012 – *Medical laboratories - Requirements for quality and competence* and;
- ISO/IEC 17020:2012 – *Conformity assessment - Requirements for the operation of various types of bodies performing inspection;*
- ISO/IEC 17043:2010 - *Conformity assessment — General requirements for proficiency testing.*

EGAC will apply the principles of ILAC P10:01/2013, ILAC Policy on Traceability of Measurement Results (which can be viewed at www.ilac.org) to the assessment and accreditation of laboratories.

3. Terms and Definitions

3.1 Traceability

The formal definition of traceability is given in the International vocabulary of metrology (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:

3.2 An unbroken chain

The chain of comparisons going back to stated references acceptable to the parties, usually a national or international standard.

3.3 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.

3.4 Documentation

Each step in the chain must be performed according to documented and generally acknowledged procedures; the results must be recorded.

3.5 Reference to SI units

The chain of comparisons must, where possible, end at primary standards for the realization of the SI units.

3.6 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).

3.7 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).

4. 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).

The following certificates / reports are recognized as proof of the metrological traceability for the accreditation of testing laboratories, calibration laboratories, medical laboratories, inspection bodies, forensic service providers and, where applicable proficiency testing providers.

4.1 Reports by NIS within the CIPM MRA.

4.2 Reports of foreign national metrology institutes or designated institutes with a corresponding entry in the CMC lists of BIPM , and not as a limitation LNE ,INRIM,...

4.3 Calibration certificates of Egyptian accredited calibration laboratories (with accreditation symbol) in the area covered by the accreditation (EGAC calibration certificates).

4.4 Calibration certificates of foreign calibration laboratories (with accreditation symbol) covered by the accreditation with the accreditation body to be a signatory to MLA/MRA/BLA agreements of EA or ILAC for calibration.

4.5 Reports of (CRMs) certified reference materials:

- Reports of (CRMs) with assigned quantity values for which there is a corresponding entry in the CMC lists of BIPM.
- Reports of (CRMs) produced by producers of reference materials accredited according ISO 17034:2016 (with accreditation symbol).
- Reports of certified and non-certified reference materials with assigned quantity values produced by non-accredited reference material producers if it is demonstrated, that they are suitable for the intended use (ISO/IEC 17025:2017 or ISO 15189:2012.

4.6 Reports without accreditation symbol

All of the following reports shall meet the requirements of ISO/IEC 17025:2017, in particular they shall contain a statement about the measurement uncertainty and metrological traceability. The recognition of these reports as proof of metrological traceability is only possible, if the competence of the issuing body for each report is assessed by EGAC. The result of this assessment is justified and documented in the assessment report.

Reports without accreditation symbol issued by accredited testing or calibration laboratories shall be as well treated as calibration certificates issued by non-accredited bodies.

4.6.1 Reports for internal calibrations:

This type of metrological traceability is in general possible for all CABs, For assessments of the competence of the body for the special calibration in accordance with ISO/IEC

17025:2017, assessors and technical experts of EGAC for testing laboratories, calibration laboratories, medical laboratories, inspection bodies, forensic service providers and, where applicable proficiency testing providers in their respective scope are used. Technical experts shall only be used when accompanied by an appointed assessor of the accreditation activities (testing and calibration laboratories, medical laboratories, inspection bodies, forensic providers & PTP laboratories.

4.6.2 Reports without accreditation symbol, issued by non-accredited bodies or by accredited testing or calibration laboratories:

This type of metrological traceability is in general possible for all CABs mentioned in the scope of this publication. For assessments of the competence of the bodies for the special calibration in accordance with ISO/IEC 17025:2017 assessors and technical experts of EGAC for testing and calibration laboratories, medical laboratories, inspection bodies, forensic providers and PT providers in their respective scope are used. Technical experts shall only be used when accompanied by an appointed assessor of the accreditation activities (testing and calibration laboratories, medical laboratories, inspection bodies, forensic providers & PTP laboratories).

Reports without accreditation symbol, issued by accredited calibration laboratories covered by their accreditation scope are as well not subject to consecutive assessment as part of an accreditation process. Therefore, they shall not be treated as an appropriate evidence of metrological traceability.

4.7 Where the metrological traceability is technically not possible, the approach for metrological traceability to appropriate standards stated in ISO/IEC 17025:2017 shall be applied.

CABs falling under the scope of this document which have demonstrated metrological traceability through the use of calibration services offered have made use of services that have been subject to relevant peer review or accreditation.

The CABs falling under the scope of this document must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available. EGAC assesses this evidence and the body's ability to evaluate it using the criteria outlined in clause 5.

5. Internal calibration

To demonstrate the technical competence of CAB that perform internal calibrations or issue reports without accreditation symbol, the assessment may include, but is not limited to, the following:

1. Documentation of the validation of self-developed or modified standardized calibration methods (ISO/IEC 17025:2017) or verification using standardized calibration methods (e. g. ISO standards, calibration guidelines of AFRAMET).
2. Methods for the estimation of measurement uncertainty including the uncertainty budgets (ISO/IEC 17025:2017).
3. Necessary equipment for special calibration and its suitability to achieve the required accuracy. Program for calibration of equipment and documentation/evidence of metrological traceability (ISO/IEC 17025:2017).
4. Documentation/evidence of assuring the quality of calibration results (ISO/IEC 17025: 2017), for example, inclusion of proficiency tests or comparison with one or more accredited calibration laboratories).

5. Documentation/evidence of the competence of staff by e.g. training certificates for the special calibrations (ISO/IEC 17025:2017).
6. Documentation/evidence of the suitability of accommodation and environmental conditions (ISO/IEC 17025:2017). Where it is necessary for the special calibration method the environmental conditions shall traceably be recorded.
7. Inclusion of special calibration in internal audits (ISO/IEC 17025:2017).
8. On-site visit of the issuing body.

Note:

Accredited testing and calibration laboratories shall be able to demonstrate that measurement results obtained under their accreditation scopes and calibration certificates are traceable to the International System of Units (SI units), EGAC prefers the requirements of its laboratories to use SI units during their measurement and calibration whenever possible .EGAC accept that Lab's use non SI units in their scopes and calibration certificates with a clear justification.

A conversion factor should be used before providing their related uncertainty, scopes and calibration certificates, These Labs should realize Validation and verifications for non SI unit along the whole range.

6. 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 .
- ISO/IEC 17025:2017– General requirements for the competence of testing and calibration laboratories.
- ISO 15189:2012- Medical laboratories - Particular requirements for quality and competence.
- ISO 17020:2012- Conformity assessment - Requirements for the operation of various types of bodies performing inspection