حكومة دبي
GOVERNMENT OF DUBAI

مركز الإمارات العالمي للاعتماد
Emirates International Accreditation Centre

مركز الإمارات العالمي للاعتماد

Emirates International Accreditation Centre

سياسة مركز الامارات العالمي للاعتماد فيما يتعلق بتتبع القياس

EIAC Requirements on Metrological Traceability of Measurement Results

EIAC-RQ-GEN-005

Signatories	
Approved:	Director, Laboratories Accreditation Department Director, Inspection Bodies Accreditation Department

Revision history			
Issue no.	**Rev. No.**	**Details**	**Date**
1	0	Updated the document to: a) Modification in Purpose and Scope to Include explicit coverage of Inspection Bodies, Medical Laboratories, and Proficiency Testing Providers to comply with ILAC P10. b) Modification in the Terms and Definition to comply with ILAC P10. c) Change the document number from EIAC-RQ-LB-012 to EIAC-RQ-GEN-005. d) Incorporate the new identity of the Dubai Government.	27-08-2024

Contents

1 Purpose and Scope

1.1 The purpose of this policy document is to describe the EIAC policy with regard to the metrological traceability requirements in testing and calibration accredited under ISO/ IEC 17025, including medical laboratories accredited under ISO 15189, proficiency testing providers accredited under ISO/IEC 17043, and inspection activities accredited under ISO/IEC 17020. This policy may also be applied to other conformity assessment activities where measurement is involved (e.g., biobanks and reference materials producers). The policy aims also to ensure that CABs comply with requirements regarding traceability of measurement as prescribed in the related accreditation criteria and ILAC P10 procedure.

1.2 This policy applies to all applicants and accredited CABs

1.3 This policy applies for all equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling.

1.4 For calibrations performed by an Accredited Organization in order to establish metrological traceability for its own activities, and which are not a part of the organization's scope of accreditation, the EIAC policy in section 5 is applicable. These internal calibrations are also known as "in-house" calibrations.

1.5 This document supersedes document EIAC-RQ-LB-012. The date of implementation is 3 months from the date of publication.

2 Terms and Definitions

The formal definitions of the following expressions are given in the "International Vocabulary of Basic and General Terms in Metrology":

2.1 Calibration

is defined as the "set of operations which establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure, or a reference material, and the corresponding values realized by standards". In general, "calibration" means determining and documenting the deviation of the indication of a measuring instrument (or the stated value of a material measure) from the conventional "true" value of the measurand.

2.2 Metrological Traceability (VIM 3 clause 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.

Note 1: For this definition a 'reference' can be a "definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard".

2.3 Metrological traceability chain (VIM 3 clause 2.42)

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference.

2.4 Metrological traceability to a measurement unit (VIM 3 clause 2.43)

Metrological traceability where the reference is the definition of a measurement unit through its practical realization.

Note: The expression "traceability to the SI" means 'metrological traceability to a measurement unit of the International System of Units'.

2.5 NMI (National Metrology Institute)

The Institute/laboratory develops and maintains the national primary measurement standards then disseminate the national measurement system through the establishment of national measurement standards.

An NMI shall participate in the key comparison organized by BIPM or Regional metrology organization wherever possible and maintain a report showing accepted results when its reference measurement standard is a primary standard that realizes the International System of Units (SI).

2.6 BIPM (Bureau International des Poids et Mesures)

BIPM is the intergovernmental organization through which Member States act together on matters related to measurement science and measurement standards.

2.7 CIPM MRA (International Committee for Weight and Measures Mutual Recognition Arrangement)

The CIPM MRA – is an arrangement between National Metrology Institutes (NMI) which provides the technical framework to assure the mutual recognition of national measurement standards and for recognition of the validity of calibration and measurement certificates issued by National Metrology Institutes.

2.8 Measurement Standard [VIM3 5.6]

Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location.

2.9 Working Measurement Standard [VIM3 5.7]

Measurement standard that is used routinely to calibrate or verify measuring instruments or measurement systems.

2.10 RM (Reference Material) [VIM3 5.13]

Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

2.11 CRM (Certified reference material) [VIM3 5.14]

Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

2.12 RMP (Reference Material Producer)

Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces.

2.13 JCTLM (Joint Committee for Traceability in Laboratory Medicine)

JCTLM formed by the BIPM, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and ILAC, provides a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

2.14 KCDB (Key Comparison Database)

The KCDB is a publicly available, free web resource related to the CIPM MRA. It contains information on participants of the CIPM MRA, results of key and supplementary comparisons and peer reviewed Calibration and Measurement Capabilities (CMCs).
(https://www.bipm.org/kcdb).

2.15 Critical equipment

“Critical equipment used by testing and calibration laboratories is considered by ILAC 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.”

2.16 Recognized Calibration Provider

laboratory that is ISO/IEC 17025 accredited for the relevant service by an Accreditation Body which is Signatory to the ILAC Mutual Recognition Arrangements (MRA) or through ILAC MRA Recognized Regional Cooperation Bodies, or NMI whose service is covered by CIPM MRA

2.17 Non-Recognized Calibration Provider

All providers other than those identified above.

3 Sources of Traceability

EIAC requires that all calibrations of measuring and test equipment, reference standards, and reference materials be traceable through one of the following ways:

3.1 A recognized National Metrology Institute (NMI)

including designated institutes whose service is suitable for the intended need and is covered by the CIPM MRA for those services. Recognition of the NMI is based on the Institute or designated institute being a signatory to the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service see https://www.bipm.org/kcdb/cmc/quick-search.

3.2 An Accredited calibration laboratory

whose service is suitable for the intended use (i.e., the scope of accreditation specifically covers the appropriate calibration) and which is accredited for those services by an Accreditation Body that is included in the ILAC Arrangement or by Regional Arrangements recognized by ILAC. Scope of accreditation for EIAC accredited labs is available on www.eiac.gov.ae.

There may be situations where it is not possible to obtain calibrations for the required quantities from any of the sources described above. In such cases, the following sources of traceability may be acceptable providing additional assurance is obtained as described in 3.5.

3.3 A national measurements institute

or a designated institute, whose service is suitable for the intended need but is not covered by the CIPM MRA.

3.4 A calibration laboratory

whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC

3.5 EIAC has the following policy to ensure that those services provided in 3.3 and 3.4 meet the relevant criteria for metrological traceability in ISO//IEC 17025:

- The choice of the services mentioned in 3.3 and 3.4 is unlikely to be made on purely economic grounds and is more likely to be a last resort if other routes are unavailable.

- Appropriate evidence for the technical competence of the laboratory and claimed metrological traceability will be assessed by EIAC assessors which may include but not limited to the following: -

  a) Records of calibration method validation

  b) Procedures for estimation of uncertainty

  c) Documentation for traceability of measurements

  d) Documentation for assuring the validity of calibration results and the associated outcome.

  e) Documentation for competence of staff

  f) Documentation for accommodation and environmental conditions

  g) Records for equipment which can influence laboratory activities

  h) Audits of the calibration laboratory.

  i) Any other evidence required by EIAC according to the case.

4 Traceability for reference materials

EIAC policy for traceability for reference materials is as described in ILAC-P10 is that the certified values assigned to CRMs are considered to have established valid metrological traceability when:

a) The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP is covered by the ILAC Arrangement or by Region Arrangements recognized by ILAC. under its scope of accreditation to ISO 17034, are considered to have established valid traceability.

b) The certified values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.

c) CRMs may not be available from accredited Reference Materials Producers (RMPs), where CRMs are produced by non-accredited RMPs, Accredited Organizations shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

d) When metrological traceability to the SI is not technically possible, it is the responsibility of the Accredited Organization to choose a way to satisfy metrological traceability requirements by using certified values of certified reference materials provided by a competent producer, or document the results of a suitable comparison to reference measurement procedures, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use.

5 In-House Calibrations

5.1 The laboratory carrying out in-house calibration activities shall maintain documented procedures for the in-house calibrations and the in-house calibrations shall be evidenced by a calibration report/ certificate, or sticker, or other suitable method, and calibration records shall be retained for an appropriate, prescribed time.

5.2 The in-house calibration laboratory shall maintain training records for personnel performing calibrations and these records shall demonstrate the technical competence of the personnel performing the calibrations.

5.3 The in-house laboratory shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from accredited calibration labs or a national metrology institute.

5.4 The in-house laboratory shall have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be taken into account when statements of compliance with specifications are made.

5.5 Reference standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable.

5.6 Policy and procedures for establishing and changing calibration intervals shall be based on the historical behavior of the reference standard, Inherent stability, required accuracy and quality assurance requirements.

5.7 Organizations carrying out in-house calibrations in support of their accredited activities are required to provide details of these calibrations to EIAC. These details will normally include information regarding the methodology involved, the traceability arrangements and the uncertainty budgets and EIAC will normally request such information for initial assessments, reassessments and extensions to scope. Furthermore, is important that EIAC is notified of any changes to these details as soon as they occur. EIAC will use this information to ensure that the appropriate expertise is included in the assessment team to assess these activities. Wherever practical the assessment of in-house calibrations will be covered as part of the traceability and calibration aspects within normal assessment/surveillance activities. Where significant additional assessment time or additional assessors are required, there will be an additional cost associated with this activity.

Specialist calibration assessors will be used if the in-house calibration is outside the area of expertise of the assessment team already involved in the assessment of the accredited activities. The assessment procedures used will include document review and on-site witnessing as appropriate. On-site witnessing of in-house calibration activities can be expected at least at initial assessment and at reassessment visits.

The ability to perform in-house calibrations will not be included in the published schedule of accreditation. EIAC will, however, retain records of the in-house calibrations assessed.

An organization may be required to participate in a measurement audit programme for the in-house calibration activities if it is determined that:

a) The extent of internal calibrations is such that a significant proportion of the accredited activities is strongly dependent on them.

b) an assessment has identified concerns about the performance of, or deficiencies in, the conduct of in-house calibrations.

c) the organization has identified nonconforming work in its accredited activities (e.g. poor performance in a proficiency test) and it is reasonable to suspect that the in-house calibration may have contributed to the poor performance.

6 Additional Requirements:

6.1 In case of testing and medical labs, If a calibration is not a dominant factor in the testing result, the laboratory shall have quantitative evidence to demonstrate that the associated contribution of a calibration contributes little (insignificantly) to the measurement result and the measurement uncertainty of the test and therefore traceability does not need to be demonstrated, but If the calibration of instruments used in testing contributes significantly to the overall uncertainty, the same policy for traceability applies (as detailed above)

6.2 The traceability statement shall include information about the closest source of traceability and the NMI providing the traceability to SI unit.

6.3 Where traceability to SI units is not technically possible, traceability can be to certified reference materials or consensus standards agreed by EIAC or by labs following EIAC policies, taking into consideration that Values associated with RMs may not be metrologically traceable. Values associated with CRMs (by definition) are metrologically traceable.

6.4 It is emphasized that calibration certificates issued by equipment manufacturers or agents are not acceptable evidence of external traceability, unless these are clearly identified as having been issued by recognized Calibration Provider given in section 2.13.

6.5 For equipment and standards requiring calibration, the laboratory calibration program shall be documented and specify the frequency of re-calibration. The laboratory shall have documented justification for the selected re-calibration. The intervals between calibrations will depend on various factors like measurement uncertainty required, fresh calibration with performance suitability review, equipment's history of use with calibration and maintenance, intermediate checks, manufacture recommendations and environmental conditions. In case of CMCs of the calibration lab is affected, the lab shall inform EIAC. Further information of calibration intervals are included in EIAC accreditation requirements and ILAC G24 "Guideline for the determination of calibration intervals of measuring instruments".

7 Normative References

7.1 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms VIM, 3rd edition, JCGM 200:2012 (JCGM 200:2008 with minor corrections) available from the BIPM homepage www.bipm.org.

7.2 ISO/IEC 17000: Conformity assessment - Vocabulary and general principles.

7.3 ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories.

7.4 ISO 15189 Medical laboratories — Requirements for quality and competence

7.5 ISO 17034 General requirements for the competence of reference material producers

7.6 ILAC P10 ILAC Policy on Metrological Traceability of Measurement Results

7.7 ISO/IEC Guide 99:2007 (Corrected version 2010) International vocabulary of metrology - Basic and general concepts and associated terms.

7.8 ILAC-G24:2022 Guidelines for the determination of calibration intervals of measuring instruments.

7.9 UKAS Policy on Metrological Traceability TPS 41. (2022), Edition 6.