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**Supplementary Requirements
for Traceability of Measurements**

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1 Purpose and Scope

This document specifies the PAB requirements for metrological traceability where testing and/or calibration are involved.

2 Terms and Definition

2.1 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 clause 2.41 states that 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."

In ISO/IEC 17025:2005 and ISO 15189:2007 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "traceability" is used throughout this document.

2.2 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

2.3 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

Note1: The expression "traceability to the SI" means metrological traceability to a measurement unit of the International System of Units.

2.4 NMI

National Metrology Institutes (NMI) and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both National Metrology Institutes as well as Designated Institutes.

2.5 JCTLM

The CIPM, IFCC and ILAC Joint Committee for Traceability in Laboratory Medicine

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3 General Requirements

- 3.1 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 shall be calibrated before being put into service.
- 3.2 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI).
- 3.3 For laboratories with reference standards, the laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability (refer to PNS ISO/IEC 17025:2005 section 5.6.2.1). Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

Note: In order to maintain traceability in calibration programmes, refer to ILAC G24:2007, "Guidelines for the determination of calibration intervals of measuring instruments".

- 3.4 When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.

Equipment and reference standards must be calibrated by (one or more) of the following:

- 3.4.1** An NMI (National Metrology Institute) whose service is suitable for the intended need and is covered by the CIPM MRA. See Appendix C (<http://kcdb.bipm.org/AppendixC/default.asp>) of the BIPM KCDB for the list of services including range and uncertainty.

Note: Services covered by the CIPM MRA can be viewed in Appendix C of BIPM KCDB which includes the range and uncertainty for each listed services.

Some NMIs may also indicate that their services is covered by the CIPM MRA by including the CIPM MRA logo on their calibration certificates, however the fixing of the logo is not mandatory and the BIPM KCDB remains the authoritative source of verification.

NMIs from Member States participating in the Metre Convention may take traceability directly from measurements made at the BIPM. The KCDB provides an automatic link to the relevant BIPM calibration services (including the range and uncertainty). Individual calibration certificates issued by the BIPM are also listed.

- 3.4.2 An accredited calibration laboratory whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate calibration) and the

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Accreditation Body is covered by the ILAC Arrangement or by the Regional Arrangements recognized by ILAC.

Note: Some calibration laboratories indicate that their service is covered by the ILAC Arrangement by including the ILAC Laboratory Combined MRA mark on the calibration certificate. Alternatively, the accreditation symbol of the accreditation body that is a signatory to the ILAC Arrangement and/or a recognised regional MLA may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

3.4.3 An NMI whose service is suitable for the intended need but not covered by the CIPM MRA. In this case, PAB shall ensure that the NMI indicates the traceability to international standards of measurement (SI Unit) and should provide the measurement result and associated uncertainty of measurement.

3.4.4 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. In this case, PAB shall ensure that appropriate evidence for claimed traceability and measurement uncertainty is available.

Appropriate evidence for the technical competence of the laboratory and claimed metrological traceability is likely to include but not restricted to the following:

- 3.4.4.1 Records of calibration method validation
- 3.4.4.2 Procedures for estimation of uncertainty
- 3.4.4.3 Documentation for traceability of measurements
- 3.4.4.4 Documentation for assuring the quality of calibration results
- 3.4.4.5 Documentation for competence of staff
- 3.4.4.6 Documentation for accommodation and environmental conditions
- 3.4.4.7 Audits of the calibration laboratory

Note: Option 3.4.3 and 3.4.4 is unlikely to be made on purely economic grounds, and is more likely to be a last resort if other options are unavailable.

3.5 In case calibrations cannot be strictly made in SI Unit. Calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

3.5.1 Use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material.

3.5.2 Use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

3.5.3 Participation in a suitable programme of inter-laboratory comparisons.

Note: It is the responsibility of the laboratory to choose a way, document and to provide the appropriate evidence. This also applies for testing and medical laboratories.

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3.6 For testing laboratories (including medical laboratories):

3.6.1 If a calibration of instrument used in testing contributes significantly to the overall uncertainty, policy of traceability detailed under section 3.4.1 1 to 3.4.4 shall apply.

3.6.2 If a calibration is not a dominant factor in the testing result, the laboratory shall have a 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.

3.7 For Reference Materials (RMs) and Certified reference materials (CRMs):

3.7.1 Reference materials shall possible be traceable to SI Units of measurement, or to certified reference materials.

Note:

Values associated with RMs may not be metrologically traceable. Values associated with CRMs (by definition) are metrologically traceable.

At present, the ILAC Arrangement does not cover accreditation of reference material producers (RMPs). At the regional level, APLAC operates an MRA for RMPs and a number of countries operate systems for the accreditation of RMPs, and the number of accredited RMPs is therefore increasing.

3.7.2 The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO Guide 34:2009, are considered to have established valid traceability.

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

3.7.4 The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the laboratory shall demonstrate that each RM and CRM is suitable for its intended use as required by ISO/IEC 17025 or ISO/IEC 15189.

4 Statement of Traceability

4.1 Wherever applicable, and when suitable for customer requirements, a statement of compliance with an identified metrological specification can be accepted instead of measurement results and associated uncertainties.

4.2 Only calibration certificates or reports endorsed by a recognized accreditation body's logo is considered to satisfy traceability requirements.

4.3 Calibration certificates or reports must contain a traceability statement. This statement will affirm that the calibration reported was conducted using standards whose values are traceable to an appropriate national, international, intrinsic, or mutual consent standard. For example, if the traceability chain for a given laboratory originates at an

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acceptable National Metrology Laboratory to PAB, then the statement will affirm that “This instrument was calibrated using reference standard traceable to SI units as maintained by NMI” (if directly calibrated by NMI) or “This instrument was calibrated using reference standard traceable to SI units as maintained by NMI through accredited laboratory” (if calibrated by an accredited calibration laboratory).

- 4.4 To establish an audit trail for traceability, a proper calibration result should include:
- assigned or measured value
 - stated uncertainty of measurement
 - identification of the standards used in the calibration
 - specification of any environmental conditions of the calibration where correction factors should be applied, if the standard or equipment were to be used under different environmental condition.

- 4.5 Calibration certificates and reports, which do not contain equivalent statements of traceability are insufficient to demonstrate measurement traceability.

5 Internal Calibration are also known as “In-House Calibration”

- 5.1 It is not always easy to define the precise circumstances under which a given calibration should be considered to be an in-house calibration. However at least two cases can be distinguished:

- 5.1.1 If the calibration service is performed within the same physical location as the customer, and if the calibrations are performed in a permanent calibration laboratory (i.e., customer equipment to be calibrated is transported to the calibration laboratory), then the calibration should be considered to be an in-house calibration and must be subjected for competence verification as specified in section 5.4 to 5.6.

- 5.1.2 If the calibration service is performed at a location other than a permanent calibration laboratory (i.e., if reference standards are being transported to the customer equipment to be calibrated), then such calibration service shall be subjected to accreditation.

- 5.3 The nature and scope of the metrological control of in-house calibration is at the discretion of the parent organization. They must be adapted to the particular applications so that the results obtained with the measuring and test equipment are sufficiently accurate and reliable.

- 5.4 All in-house calibrations must be supported by the following set of elements. These must be verified by a qualified Technical Assessor or experts in the field of calibration.

- 5.4.1 The in-house calibration system shall ensure traceability of measurement by having its reference standards calibrated at an accredited calibration laboratory within its scope of accreditation or a national metrology institute.

- 5.4.2 The in-house laboratory must maintain appropriate documented procedures for the in-house calibrations and the in-house calibrations must be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records must be retained for an appropriate prescribed time;

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5.4.3 The in-house laboratory must maintain the following records to demonstrate the technical competence of the laboratory and personnel performing the calibration:

1. Relevant training and evaluation of training effectiveness;
2. Result of proficiency testing or measurement audits (with proper endorsement from PAB); and
3. Compliance to ISO/IEC 17025 (current version) which includes but not limited to the following
 - a. Audits of the calibration provider
 - b. Documentation for competence of staff
 - c. Documentation for accommodation and environmental conditions
 - d. Records of calibration method validation
 - e. Procedure for estimation of uncertainty
 - f. Documentation for traceability of measurement
 - g. Documentation for assuring the quality of calibration result

5.4.4 In practical terms, the in-house calibration would need to have evidence of an assessment of the calibration service provider similar to that which would be conducted by an accreditation body which is a signatory to the ILAC MRA.

5.4.5 Reference standards must be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals must be based on the historical behaviour of the reference standard.

5.5 In-house calibrations that support accredited testing and form part of the assessment of a testing facility are assessed using the above criteria.

5.6 Where possible, the assessment of in-house calibrations and equipment verifications will be covered as part of the equipment and metrological traceability aspects within the normal assessment schedule. Where, significant additional assessment time or additional Technical Assessors/Experts are required, there will be an additional cost associated with the activity. Calibration Technical Assessors/Experts will only be used when either the calibration is outside the area of expertise of the Technical Assessors who would normally conduct the assessment or it will be more time or costs effective. In some cases, additional post-assessment follow-up may be necessary.

6 Acceptable Accreditation Bodies of Calibration and Testing Laboratories

6.1 Accredited test and calibration results, reported by laboratories that are accredited by any of these bodies which are signatories to the Asia-Pacific Laboratory Accreditation Cooperation (APLAC), the European cooperation for Accreditation (EA) and other regional accreditation bodies which are signatories to ILAC MRA, and reported in a test or calibration report endorsed by the accrediting body's logo, or which otherwise refers to its accredited status, are recognized by PAB as satisfying the requirements pertaining to measurement traceability.

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7 Reference

- 7.1 ILAC-P10:01/2013 ILAC Policy on the Traceability of Measurement Results
- 7.2 National Association of Testing Authorities Policy Circular 11 – October 2015
- 7.3 National Association of Testing Authorities Procedure for Accreditation

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ISSUE AND AMENDMENT RECORD

Title	Issue	Revision	Date	Amendments
Supplementary Requirements for Traceability of Measurements	01	00	January 2015	Initial Issue
Supplementary Requirements for Traceability of Measurements	01	01	01 May 2016	<ul style="list-style-type: none"> • Deleted statement “acceptable to PAb in section 5.1. • Rearranged numberings in section 5. • Added the following requirements for in-house calibration <ul style="list-style-type: none"> - Must be verified by qualified technical assessors/experts - Compliance to ISO/IEC 17025 - Result of Proficiency Testing and measurement audits (with proper endorsement from PAB) • Deleted requirement regarding procurement of calibration services (clause is for in-house calibration, not appropriate).