INTERNATIONAL ACCREDITATION SERVICE®

IAS POLICY ON METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS FOR MEDICAL LABORATORIES

1.0 SCOPE:

1.1 This document defines the International Accreditation Service (IAS) policy on requirements for metrological traceability of measurement results.

1.2 This policy applies to medical laboratories.

1.3 This policy is also applicable for accredited or applicant medical laboratories performing calibration of its own equipment or reference standards in order to establish metrological traceability for its own activities, which are not a part of the organization's scope of accreditation.

1.4 This policy incorporates the requirements of ILAC P10 *ILAC Policy on Metrological Traceability of Measurement Results* published by the International Laboratory Accreditation Cooperation (ILAC).

2.0 NORMATIVE AND REFERENCES DOCUMENTS: Publications listed below refer to current editions (unless otherwise stated)

2.1 *ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories*

2.2 *ISO 15189, Medical laboratories - Requirements for quality and competence*

2.3 *ISO 17034, General requirements for the competence of reference material producers*

2.4 *ISO/IEC 17043, Conformity assessment — General requirements for the competence of proficiency testing providers.*

2.5 *ILAC-P10, ILAC Policy on Metrological Traceability of Measurement Results*

2.6 *JCGM 200, International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), 3rd edition*

2.7 *ANSI/NCSL Z540.3, Requirements for the Calibration of Measuring and Test Equipment*

2.8 *ANSI/NCSL Z540, Calibration Laboratories and Measuring and Test Equipment—General Requirements*

3.0 DEFINITIONS:

The terms and definitions provided in the standards and documents referenced in Section 2.0 shall apply to this policy.

4.0 REQUIREMENTS:

4.1 Metrological traceability of measurement results:

4.1.1 When metrological traceability is required, the measurement equipment used during the delivery of conformity assessment services shall be calibrated by:

a) A National Metrology Institute (NMI) whose service is suitable for the intended use and is covered by the International Committee for Weight and Measures Mutual Recognition Arrangement (CIPM MRA). Services covered by the CIPM MRA can be viewed in the Bureau International des Poids et Measures Key Comparison Database (BIPM KCDB) which includes CMCs (Calibration Measurement Capabilities) for each listed service.

Or

b) An accredited calibration laboratory whose service is suitable for the intended use (i.e., the scope of accreditation specifically covers the appropriate calibration) and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

4.1.2 IAS accredited medical laboratories shall use an appropriate NMI or calibration providers accredited to ISO/IEC 17025 by a signatory body to the ILAC MRA or one of its recognized Regions. IAS accredited laboratories shall ensure that their calibration providers maintain appropriate accreditation and be able to provide objective evidence to that effect. The simplest method of accomplishing this is to maintain a copy of the provider's accreditation certificate and scope of accreditation for the period during which the provider issued calibration certificates to the IAS accredited medical laboratories.

4.1.3 On rare occasions, medical laboratories may need to have equipment calibrated by a calibration provider that is not accredited by an ILAC MRA signatory, or not accredited for the specific calibration required, such as a manufacturer of an item where the technology or application is proprietary, or where accredited calibrations for certain equipment are not offered.

In such cases, if options 4.1.1 a) and 4.1.1 b) are not feasible, the medical laboratories may consider the following calibration services as per ILAC P10, provided that conformity with ISO/IEC 17025 and measurement traceability can be demonstrated.

a) A NMI whose service is suitable for the intended use but not covered by the CIPM MRA or

b) A laboratory whose calibration service is suitable for the intended use but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC

4.1.4 These options shall be applicable only when 4.1.1. a) and 4.1.1 b) are NOT possible for a particular calibration. In these cases, the medical laboratories shall provide the evidence for claimed metrological traceability and ensure measurement uncertainty is available.

4.1.5 The accredited medical laboratories shall verify the metrological traceability of the calibrations and shall document verifications to the satisfaction of IAS.

4.1.6 The accredited medical laboratories shall maintain records that the nonaccredited calibration provider has been assessed to confirm its competency against the requirements of ISO/IEC 17025. The personnel who perform the assessment shall be trained in the requirements of ISO/IEC 17025 and be competent for the technical portion that is evaluated. Records shall be maintained of this evaluation.

4.1.7 The evidence of conformity with ISO/IEC 17025 includes but not be limited to the following (ILAC P10 – Appendix A): (numbers refer to clauses in ISO/IEC17025:2017):

a) Records of calibration method validation (7.2.2.4).

b) Procedures for evaluation of measurement uncertainty (7.6).

c) Documentation and records for metrological traceability of measurement results (6.5).

d) Documentation and records for ensuring the validity of results (7.7).

e) Documentation and records for competence of personnel (6.2).

f) Records for equipment which can influence can influence quality of laboratory examination results (6.4).

g) Documentation and records for facilities and environmental conditions (6.3).

h) Audits of the calibration laboratory (6.6 and 8.8).

4.1.9 In addition, if it is not possible or appropriate to obtain or achieve metrological traceability to the SI, IAS accredited medical laboratories shall demonstrate comparison to a widely used standard which is clearly specified and mutually agreeable to all parties concerned and accepted as providing measurements results for their intended use. For example, there are several widely used commercial control materials available for blood glucose testing, but these materials may not all produce equivalent measurement results across different analytical systems. Therefore, it is important to specify which

standard is to be used and to obtain an agreement among all the parties involved that the choice of standards is acceptable.

4.2 Metrological Traceability provided through Certified Reference Materials (CRMs):

4.2.1 The certified values assigned to CRMs are considered to have established valid metrological traceability when:

a) CRMs are produced by NMIs using a service that is included in the BIPM KCDB.

Or

b) CRMs that are produced by an accredited RMP under its scope of accreditation and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

Or

c) The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

4.2.2 In case of CRMs are not available from accredited Reference material producers, or CRMs that are produced by non-accredited RMPs, medical laboratories shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

4.3 Requirements for in-house calibration

4.3.1 Medical laboratories may calibrate their own equipment, such as working standards or support equipment, even if this capability is not listed in their scope of accreditation and shall fulfill below requirements.

a) Appropriate, metrologically traceable reference materials or instruments are available.

b) The calibration includes an evaluation of measurement uncertainty, in accordance with ISO/IEC Standard 17025.

c) Staff is properly trained in the calibration procedure, and the training is documented.

d) The laboratory's calibration procedures are documented and calibration records, including measurement uncertainty, are maintained.

e) The laboratory's internally developed calibration procedures are verified and validated, and records of this are maintained.

f) The laboratory is able to demonstrate, to the satisfaction of IAS,

competency in the proper use of traceable reference materials and instruments when in-house calibrations are conducted. (The demonstration shall include ability of laboratory personnel to determine measurement uncertainty).

4.3.2 IAS accepts any means of evidence to demonstrate the establishment of metrological traceability of measurements. For this purpose, calibration records may include physical records, electronic records maintained in calibration management software, electronic records maintained on internal or external servers, or on-line records administered by an external calibration provider, as appropriate.

4.3.3 When organizations performing intermediate verification within the validity period of calibration to confirm the calibration status by using CRMs or reference standards, such reference standards and CRMs also should comply with the requirements section 4.2.

4.4 Other general requirements

4.4.1 Expression of measurement results in SI Units may require conversion from other units of measure, such as pound or inch. In these cases, the medical laboratories shall use a conversion factor from a recognized reference source, such as NIST documents (Special Publication 330 and 811).

4.4.2 When reporting metrological traceability information on calibration certificates, PT reports, reference material documents and labels. Medical laboratories shall comply with the requirements of applicable accreditation standards, e.g. ISO/IEC 17025, ISO/IEC 17043 and ISO 17034 in addition to the requirements outlined in this policy. When surplus test materials are available from proficiency testing (PT) providers, medical laboratories should check and confirm whether the PT provider can provide additional stability information to demonstrate the ongoing stability of the property value and matrix of the test material. If this cannot be provided by PT Provider, these test materials should not be considered as an alternative way to ensure the validity of results.

4.4.3 When medical laboratories unable to meet above requirements and provided supported information, for examinations where certified reference materials are not available, conformity to ISO 15189 is demonstrated through participation in suitable EQA programs, structured peer review systems, documented competence management, and evidence of diagnostic concordance monitoring. During onsite assessments, medical laboratories shall demonstrate sufficient evidence to confirm nonavailability of traceable materials with relevant records (web search, communication with manufacturers, suppliers etc.).

4.4.4 Medical laboratories are required to define retention time for records related to metrological traceability information.

5. OTHER REFERNCES

1. ISO 17511, In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

2. *Joint BIPM, OIML, ILAC and ISO declaration on metrological traceability* (http://www.bipm.org/utils/common/pdf/BIPM-OIML-ILAC-ISO_joint_declaration_2011.pdf)