INTERNATIONAL ACCREDITATION SERVICE®

IAS POLICY ON ESTABLISHING METROLOGICAL TRACEABILITY OF MEASURMENT FOR ACCREDITATION OF PROFICIENCY TESTING PROVIDERS AND REFERENCE MATERIAL PRODUCERS

1.0 SCOPE:

1.1 This document defines the International Accreditation Service (IAS) guidelines for metrological traceability of measurement results used in the process for provision of proficiency testing programs and/or reference material production by Proficiency Testing Providers (PTP)/or Reference Material Producers (RMP).

1.2 This guidelines incorporates the requirements published by the International Laboratory Accreditation Cooperation (ILAC) (refer to Section 2).

1.3 This guidelines requires all IAS accredited/applicant CABs to establish accreditation in accordance with ISO/IEC 17043 and ISO 17034 respectively.

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/IEC 17043- Conformity assessment — General requirements for the competence of proficiency testing providers.

2.4 ISO 17034: *General requirements for the competence of reference material producers*

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

2.6 *IAS/CL/014: IAS Policy on Calibration, Traceability and Measurement Uncertainty for calibration laboratories.*

2.7 *IAS/TL/025: IAS Policy on Calibration, Traceability and Measurement Uncertainty for testing laboratories.*

3.0 DEFINITIONS:

Refer to section 2 for details on terminologies.

4.0 REQUIREMENTS:

4.1 To establish metrological traceability, accredited/applicant PTP/RMP shall perform testing/calibration activities in accordance with IAS/CL/014: IAS Policy on Calibration, Traceability and Measurement Uncertainty for calibration laboratories or IAS/TL/025: IAS Policy on Calibration, Traceability and Measurement Uncertainty for testing laboratories,as applicable.

4.2 PT schemes in the area of calibration shall have assigned values with metrological traceability. PT schemes in areas other than calibration are also require to ensure metrological traceability and the associated uncertainty of the assigned value are determined by taking into account the purpose of the PT scheme.

4.3 In the event of outsourcing of permitted activities by the PTP/RMP to accredited laboratories or use of internal accredited laboratories, it is responsibility of PTP/RMP to ascertain the requirements of metrological traceability. However, if the PTP/RMP uses non accredited facilities, PTP/RMP shall conduct a detailed assessment of the nonaccredited facilities' compliance to metrological traceability as required in ISO/IEC 17043, ISO 17034 and IAS policies.

- The IAS accreditation process requires Reference Material Producers (RMPs) to have established valid metrological traceability assigned through certified values of the Certified Reference Materials (CRMs) that are produced. Such validated metrological traceability can be achieved as stated below: CRMs produced by National Measurement Institute (NMIs) included in the BIPM KCDB.

  Or

- CRMs produced by aRMP accredited by an accreditation body who is a signatory to the the ILAC Arrangement or Regional Arrangements recognized by ILAC.
  Or
- The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

4.4 Recognizing that the accreditation of RMPs is still developing and CRMs may not be available for all types of materials from accredited RMPs, in such instances CRMs produced by non-accredited RMPs shall demonstrate that CRMs have been provided by a RMP that meets the requirements of ISO 17034 and suitable for its intended use.

4.5 When metrological traceability to the SI is not technically possible, it is the responsibility of the Applicant /Accredited Organization to:

a) use certified values of certified reference materials provided by a competent producer.

or

a) 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. Evidence of this comparison shall be assessed by the Accreditation Body.

4.6 When metrological traceability to solely SI units is not appropriate or applicable to the application, a clearly defined measurand should be selected. Establishing metrological traceability therefore includes both the proof of identity of the property measured and the comparison of the results to an appropriate stated reference. The comparison is established by ensuring the measurement procedures are properly validated and/or verified, that measuring equipment is appropriately calibrated and that conditions of measurement (such as environmental conditions) are under sufficient control to provide a reliable result.

4.7 When using surplus test materials from PTPs, It should be checked whether the PTP 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, then these test materials should not be considered as an alternative way to ensure the validity of results.

5.0 SUMMARY OF REQUIREMENTS AS PER ISO/IEC 17043 AND ISO 17034

The processes of proficiency testing providers and reference material producers require the execution of testing and calibration activities to assign values to PT items and certified values for reference materials, as well as to assess the homogeneity and stability of PT items and RM materials. Additionally, ISO/IEC 17043 and ISO 17034 require the reporting of metrological traceability information on PT reports, reference material documents, labels, and any surplus PT items. The above policy on metrological traceability provides guidance for applicants and accredited PTPs, RMPs, as well as the accreditation body to ensure the application of metrological traceability requirements are met for accredited PTPs and RMPs.