IAS POLICY ON CALIBRATION, TRACEABILITY AND MEASUREMENT UNCERTAINTY FOR TESTING LABORATORIES

1. SCOPE

This document defines the IAS policies for testing laboratories regarding calibration of test equipment, metrological traceability and estimation of measurement uncertainty of test results.

2. REFERENCES

ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*

JCGM 100:2008: GUM 1995 with minor corrections: Evaluation of measurement data — Guide to the expression of uncertainty in measurement or ISO/IEC Guide 98-3:2008 Uncertainty of measurement—Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)

IAS/TL-CL/013, IAS Calibration/Testing Definitions

IAS/CL/014 IAS Policy Guide on Calibration, Traceability, and Measurement Uncertainty for Calibration Laboratories

ILAC-P10: ILAC Policy on Traceability of Measurement Results

ILAC P14: ILAC Policy for Uncertainty in Calibration

JCGM 200:2008: International vocabulary of metrology — Basic and general concepts and associated terms (VIM)

3. DEFINITIONS

APAC: Asia Pacific Accreditation Cooperation
https://www.apac-accreditation.org/

Appropriate NMI: An appropriate NMI is one that participates regularly and successfully in relevant international interlaboratory comparisons performed by the BIPM.

BIPM: International Bureau of Weights and Measures (BIPM). BIPM is the organization whose task is to ensure world-wide uniformity of measurements and their traceability to the International System of Measurements (SI).
http://www1.bipm.org/en/home/

CGPM: General Conference of Weights and Measures (CGPM)

CIPM: International Committee on Weights and Measures (CIPM)
http://www.bipm.org/en/committees/cipm/

CMC: In the context of the CIPM MRA and ILAC Arrangement, and in relation to the CIPM-ILAC Common Statement, the following shared definition is agreed upon: a *CMC* is a calibration and measurement capability available to customers under normal conditions:
    a) as published in the BIPM key comparison database (KCDB) of the CIPM MRA; or
    b) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement.

Conversion tables: Tables that provide multiplication factors to convert measurements from one unit of measure to a different unit of measure. Use of conversion tables published in NIST SP 811 is recommended.

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GIDEP: Government-Industry Data Exchange Program, a source for U.S. Military and various industry calibration procedures.
http://www.gidep.org

ILAC: The International Laboratory Accreditation Cooperation.
http://www.ilac.org

INTERNATIONAL SYSTEM OF UNITS (SI): System of units, based on the International System of Quantities, their names and symbols, including a series of prefixes and their names and symbols, together with rules for their use, adopted by the General Conference of Weights and Measures (CGPM).

METROLOGICAL TRACEABILITY: 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.

METROLOGICAL TRACEABILITY CHAIN: Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference.

MEASUREMENT UNCERTAINTY: Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

UNCERTAINTY BUDGET: Statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination.

4. REQUIREMENTS

4.1 Equipment

Equipment used by IAS accredited testing laboratories whose accuracy or measurement uncertainty can affect the validity of the reported results must meet the requirements of ISO/IEC

17025. Such instruments or equipment must be appropriately marked or labeled and must be calibrated so as to be metrologically traceable.

4.2 Metrological Traceability

4.2.1   Metrological traceability of test results requires that equipment having an influence on the test results is metrologically traceable through one of the following methods:

a) Calibrations performed by an appropriate NMI.

b) Calibrations performed by a calibration laboratory under its scope of accreditation, issued by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), or one of its recognized Regions. Exceptions can only be made if the laboratory meets the requirements of Clause 4.4.3 of this document.

4.2.2 When metrological traceability needs to be established through Certified Reference Materials (CRMs), the CRMs need to be produced by

a) an appropriate NMI,

b) a Reference Material Provider (RMP) accredited by an ILAC MRA signatory accreditation body. If the CRM is not available from the NMI or an accredited RMP, the accredited laboratory must provide objective evidence that the CRM has been produced by a competent RMP and is suitable for the intended use.

4.2.3   If it is not possible or appropriate to obtain or achieve calibrations traceable to the SI, IAS accredited laboratories may demonstrate comparison to a widely used standard which is clearly specified and mutually agreeable to all parties concerned. For example, there are several widely used commercial standards available for hardness, but these standards may not all give equivalent measurement results. Therefore, it is important to specify which standard is to be used and to obtain agreement among all the parties involved that the choice of standards is acceptable.

4.3 Evaluation of Measurement Uncertainty Associated with Test Results

4.3.1   In accordance with ISO/IEC 17025:2017 Cl. 7.6.3, a laboratory performing testing must evaluate measurement uncertainty.

4.3.2 It is recognized that a particular test method may preclude rigorous evaluation of measurement uncertainty. In such cases, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

4.3.3 Measurement uncertainty does not need to be evaluated for a particular test if

a) Note 1 of Clause 7.6 of ISO/IEC 17025:2017 is applicable, i.e., where a well-recognized test method specifies the limits of the major sources of measurement uncertainty and the laboratory follows the test method and the reporting instructions;

b) Note 2 of Clause 7.6. is applicable, i.e., the measurement uncertainty of the result obtained by following a well-recognized method has been established and is included in the test method.

4.3.4 IAS requires a testing laboratory to develop an uncertainty budget example for each category of test methods on the Scope of Accreditation, unless Note 1 or Note 2 of Clause 7.6.3 apply. While IAS may only check one uncertainty analysis during the onsite visit, the laboratory must have documented examples of evaluation of measurement uncertainty for each category of tests on the scope of accreditation.

4.3.5 These uncertainty budgets must be periodically reviewed and updated as necessary.

4.3.6 The laboratory is required to perform an uncertainty analysis and report uncertainty to its customers under any of the following conditions:

a) The customer requests the uncertainty

b) There is a regulatory or similar requirement

c) A conformity statement is required and a decision rule must be formulated and agreed upon by the laboratory and its customer.

4.4 Calibration Providers

4.4.1 Testing laboratories must ensure the competency of their calibration providers. Competency is most easily demonstrated by use of calibration providers accredited to ISO/IEC 17025:2017 by an accreditation body that is a signatory to the ILAC MRA.

4.4.2 Testing laboratories performing internal calibrations of their own equipment must ensure that:

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.)

4.4.3. On rare occasions, IAS accredited testing laboratories may need to have equipment calibrated by an external calibration provider that is not accredited by an ILAC MRA signatory, or not accredited for the specific support 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, the laboratory may use the provider, provided *all* of the following apply:

a) The IAS accredited laboratory must audit the metrological traceability of the calibrations, and must document this audit to the satisfaction of IAS.

b) The laboratory must maintain records that the nonaccredited calibration provider has been assessed during a second or third party audit against the requirements of ISO/IEC 17025. . The personnel who perform the assessment must be trained in the requirements of ISO/IEC 17025 and be competent for the technical portion that is evaluated.

c) Laboratories must obtain information from their calibration providers and *document* the following:

(1) The laboratory must review the calibration procedures used by the calibration provider.
(2) The laboratory must retain a list of the specific test and measuring equipment used by the calibration provider to calibrate the laboratory's equipment. The calibration of this equipment must be metrologically traceable.
(3) The laboratory must document the environmental conditions at the facility of the calibration provider.
(4) The laboratory must have records of having reviewed the methods by which the calibration provider determines uncertainties of measurement.
(5) The laboratory must have information on the relative uncertainties present at all steps in the calibration process.

4.4.4 It is possible that a laboratory may use a calibration provider that is accredited, but not for the specific calibrations required for the laboratory. In those instances, the laboratory must evaluate and verify the provider's ability to perform the calibrations, by the methods outlined above. Records of this evaluation must be maintained.

4.4.5 It is the responsibility of the testing laboratory to ensure that calibration certificates or reports, whether obtained from external or internal calibration providers, meet the requirements
→ of ISO/IEC 17025. Calibration certificates <u>must include</u> appropriate statements of uncertainty.