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IAS POLICY GUIDE 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

IAS Calibration Definitions, IAS/CL/013

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: Bureau International des Poids et Mesures (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.
http://www.nist.gov

EA: The European Cooperation for Accreditation.
http://www.european-accreditation.org

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.

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 must meet the requirements of ISO/IEC 17025:2017 Clauses 6.4 and 6.5. Such instruments or equipment must be appropriately marked

or labeled and must be calibrated so as to be traceable to the SI through the National Institute of Standards and Technology (NIST) or other national metrology institution, as described in Clause 6.5 of the standard.

4.2 Metrological Traceability

4.2.1 Metrological traceability of test results requires 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 accredited 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 Cl. 4.3.2 or 4.3.3 of this document.

c) Direct reference to a primary standard or to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the (CGPM) and the (CIPM).

4.2.2 If it is not possible or appropriate to achieve traceable calibrations, IAS accredited testing laboratories may demonstrate comparison to a widely used standard which is clearly specified and mutually agreeable to all parties concerned, particularly in regard to measurements where NIST does not maintain a U.S. national standard. 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 Calibration Providers

4.3.1 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.

4.3.2 Testing laboratories performing internal calibrations of their own equipment must meet the requirements of the IAS Policy Guide on Calibration, Traceability, and Measurement Uncertainty for Calibration Laboratories, IAS/CL/014. They must ensure that:

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

b) The calibration includes calculations of measurement uncertainty, or best estimation 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 written and calibration records, including 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.)

4.3.3. 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 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 traceability of the calibrations to the International System of Units (SI) through the National Institute of Standards and Technology (NIST), an appropriate NMI or a standard reference material, and must document this audit to the satisfaction of IAS.

b) The laboratory must maintain records that the nonaccredited calibration provider has been assessed, or must assess the nonaccredited calibration provider themselves, and maintain records of the assessment. These records must include all findings of nonconformance with standards *and* the calibration provider's resolution of the nonconformities. The IAS Assessment Checklist for ISO/IEC Standard 17025, which may be used for the assessment, is available from IAS on request. The personnel who perform the assessment must be trained in the requirements of ISO/IEC Standard 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 have information regarding assessment of the management system used by the calibration provider. This information shall include who assessed the calibration provider and the results of the assessment if the assessment was conducted by an entity other than the IAS accredited laboratory. The laboratory must have on file a copy of the assessment report from whoever assessed the calibration provider. The laboratory must maintain on file documentation of the qualifications of the person(s) that perform the assessment of the nonaccredited calibration provider.

    (2) The laboratory must obtain the calibration procedures used by the calibration provider.

    (3) 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 traceable to the SI through standards maintained by NIST, another appropriate NMI, or a calibration provider accredited to ISO/IEC Standard 17025 by a signatory to ILAC or one of its Regions.

(4) The laboratory must document the environmental conditions at the facility of the calibration provider.

(5) The laboratory must have records of the methods by which the calibration provider determines uncertainties of measurement.

(6) The laboratory must have information on the relative uncertainties present at all steps in the calibration process.

4.3.4 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.

4.3.5 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 17025:2017 Clause 7.8. Calibration certificates must include appropriate statements of uncertainty.

4.4 Evaluation of Measurement Uncertainty Associated with Test Results

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

4.4.2 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.

4.4.3 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 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 test result obtained by following a well-recognized method has been established and is included in the test method.

4.4.4 IAS requires a testing laboratory to develop uncertainty budgets for all test methods on the Scope of Accreditation, unless Note 1 or Note 2 of Clause 7.6.3 apply. These uncertainty budgets must be periodically reviewed and updated as necessary. While IAS may only check one uncertainty analysis during the onsite visit, the laboratory must have documented estimates of measurement uncertainty for all tests.

4.4.5 The laboratory is not required to report uncertainty analysis to its customers unless:

a) The customer requests the uncertainty

b) There is a regulatory or similar requirement

c) A conformity statement is made

d) It is relevant to the validity or application of the test results

4.4.6 It is recognized that some test methods will have an uncertainty sufficiently large that it will create questions and doubts regarding the results of the test method. An example of this is fire testing. In these instances, the laboratory must document a justification.▪