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

1. SCOPE

This document defines the IAS policies for calibration laboratories (internal or external), metrological traceability, and estimation of measurement uncertainty.

The terms “calibration laboratory” and “calibration provider” as used in this document refers to both internal and external calibration providers.

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2. REFERENCES

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

ANSI/NCSL Z540.3-2006 (R2013), *Requirements for the Calibration of Measuring and Test Equipment*

ANSI/NCSL Z540-1-1994 (R2002), *Calibration Laboratories and Measuring and Test Equipment—General Requirements*

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

ILAC-P10 ILAC Policy on Traceability of Measurement Results

ILAC-P14 ILAC Policy for Uncertainty in Calibration

JCGM 2002008 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 an NMI whose service is suitable for the intended need and is covered by the CIPM MRA. For the service to be considered covered, it must be listed in the BIPM Key Comparison Database (KCDB).

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 Units (SI).
http://www1.bipm.org/en/home/

BIPM KCDB: BIPM Key Comparison Database

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 (MU): Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand**,** based on the information used.

NIST: National Institute of Standards and Technology, the NMI for the U.S.
http://www.nist.gov

NMI: National Measurement Institute or National Metrology Institute

Uncertainty Budget: Statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination.

4. REQUIREMENTS

Calibration laboratories seeking to acquire accreditation from IAS and IAS accredited laboratories must comply with requirements of ISO/IEC Standard 17025, the IAS Accreditation Criteria for Calibration Laboratories AC204, applicable ILAC Policies and IAS Policies.

4.1 Certificates of Calibration

4.1.1 Calibration certificates or reports issued by IAS accredited calibration laboratories and laboratories seeking IAS accreditation must meet the requirements of ISO/IEC Standard 17025.

4.1.2 Calibration certificates must include appropriate statements of uncertainty. Measurement uncertainty (MU) should be stated at the 95% confidence level, unless there are compelling reasons to represent the uncertainty at a higher confidence level. Both the confidence level and the coverage factor *k* to achieve it must be stated

4.1.3 Calibration certificates shall not state measurement uncertainties that are lower than those claimed as part of the laboratory's accredited Calibration Measurement Capability (CMC) on the scope of accreditation.

4.1.4 Use of the IAS symbol on certificates of calibration issued under the laboratory's accreditation is strongly encouraged. If any portion of the calibration results on the certificate is not covered by the laboratory's accredited scope, this must be clearly indicated.

4.1.5 If a calibration laboratory uses a competent external calibration provider or an appropriate National Metrology Institute (NMI) for some calibrations and/or support, the laboratory must retain or have access to copies of its calibration service provider's certificates/reports of calibration and proof of competence to maintain traceability of its measurements. A laboratory accredited by an accreditation body who is a signatory to the ILAC Mutual Recognition Agreement (MRA) is considered competent.

4.1.6 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.

4.1.7 Calibration certificate numbers are used to audit traceability. This requires that each certificate be uniquely identifiable and applicable to a specific calibration of a specific instrument or material. When a calibration is performed by an appropriate NMI, the specific report, uniquely identified by number and applicable to a specific calibration of a specific instrument or material, is used.

NOTE: Test report numbers issued by NIST are intended to be used solely for administrative purposes and should not be used nor required as the sole proof of traceability (see https://www.nist.gov/traceability/supplementary-materials-related-nist-policy-metrological-traceability#references)

4.2 Calibration Procedures

4.2.1 Calibration procedures may be obtained from external sources such as the manufacturer, national/international standards, published calibration guidelines, the U.S. military, or they may be internally developed. The laboratory must verify that it has the resources and technical capability to perform the calibration procedure. Laboratory-developed calibration procedures must be validated to ensure that the calibration provides the correct results. Verification and validation records must be maintained.

4.2.2 Calibration procedures obtained from some external sources may be considered validated. An example would be a military calibration procedure, or those following national/international standards.

4.3 Equipment

4.3.1 Calibration laboratories seeking accreditation with IAS and IAS-accredited calibration laboratories must have access to calibration equipment that meets the requirements of ISO/IEC 17025. These pieces of equipment must be appropriately marked or labeled, and must be calibrated so as to be metrologically traceable to SI units where possible (refer to the section on traceability).

4.3.2 Environmental monitoring equipment is included as equipment whose function has an effect on the calibration operations of the laboratory and must be calibrated.

4.4 Metrological Traceability

4.4.1 Metrological traceability may be accomplished by:

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 4.6.3.

4.4.2 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.

4.4.3. 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.

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

4.5 Evaluation of Measurement Uncertainty

4.5.1 Evaluation of measurement uncertainty (MU) is a crucial portion of ensuring traceability. MU calculations must be performed in accordance with the *Guide to the Expression of Uncertainty in Measurement* (GUM).

4.5.2 Uncertainties must be supported by an uncertainty budget taking into account all significant contributors to the uncertainty of a particular measurement result. Expanded uncertainties are to be reported at the 95 percent or higher level of confidence. The coverage factor (k) necessary to achieve the required level of confidence is determined using degrees of freedom and the T-Tables.

4.5.3 The laboratory must use appropriate methods to develop their uncertainty budgets. The method used to develop the uncertainty budget must be defined and documented. All readings, observations and derived data must be maintained with appropriate units of measurement.

4.5.4 Developing an uncertainty budget generally requires repeatable testing and statistical analysis of the results. Laboratories should analyze the results in accordance with the GUM**.** In cases where statistical studies cannot be performed for some reason, an estimation of uncertainties is still required. See the GUM for specific guidance on developing uncertainty budgets in such cases.

4.6 Calibration Providers

Calibration laboratories must ensure that calibration providers meet the requirements noted in this section. Documentation must be maintained to provide evidence that the calibration providers meet the applicable requirements.

4.6.1 IAS accredited laboratories must 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 must 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 laboratory.

4.6.2 The highest level of standards used by an IAS accredited calibration laboratory, whether to calibrate customers' equipment, the laboratory's own internal support equipment, or used to create working standards, must be calibrated by an accredited calibration provider or an appropriate NMI.

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4.6.3 On rare occasions, IAS accredited calibration 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, the laboratory may use the non-accredited calibration provider provided *all* of the following apply:

a) The 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 and valid at the time of measurement.

(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.

4.6.4. 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 method~~s~~ outlined above. Records must be maintained of this evaluation.

4.6.5 Laboratories may calibrate their own equipment such as working standards or support equipment, even if this capability is not listed on their scope of accreditation, provided 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).

4.7 ANSI/NCSL Z540.3-2006 (R2013) and ANSI/NCSL Z540-1-1994 (R2002)

4.7.1 The American National Standard for calibration, ANSI/NCSL Z540-1-1994 (R2002), known as Z540-1, was formally retired in July 2007, although the standard continues to be used by some. The standard was replaced by ANSI/NCSL Z540.3-2006 (R2013), known as Z540.3. There are significant differences between the two documents, one being the Z540.3 Section 5.3 requirement to ensure that the probability of a "false accept" conformance statement is less than 2 percent, and another one being the replacement of test accuracy ratio (TAR) with test uncertainty ratio (TUR).

4.7.2 It is understood that some laboratories may need to be assessed to the requirements of ANSI/NCSL Z540.3-2006 (R2013), either solely for Section 5.3, or for the entire Standard, in addition to the ISO/IEC 17025 standard. This will require additional assessment time and the laboratory must provide additional documentation as required by the Z540.3 standard.