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

Scope

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

Calibration certificates and/or reports held by IAS accredited testing laboratories must meet the requirements of ISO/IEC Standard 17025:2005, *General requirements for the competence of the standard of testing and calibration laboratories* Clause 5.10.2 and 5.10.4, and additional sub-Clauses as appropriate. Calibration certificates must include appropriate statements of uncertainty.

IAS accredited testing laboratories must create and maintain a list of the test equipment, measurement equipment, and physical-standards that may have an effect on their test results. These instruments or equipment must be appropriately marked or labeled, and must be calibrated so as to be traceable to SI through the National Institute of Standards and Technology (NIST) or some other national metrology institution.

Testing laboratories conducting internal calibration must meet the requirements of the IAS Policy Guide on Calibration, Traceability, and Measurement Uncertainty for Calibration Laboratories.

REFERENCES

ISO/IEC Standard 17025:2005, *General requirements for the competence of testing and calibration laboratories*

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

ANSI/NCSL Z540.2-1997 (R2012), *U.S. Guide to the Expression of Uncertainty in Measurement*

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

JCGM 100:2008: GUM 1995 with minor corrections: Evaluation of measurement data — Guide to the expression of uncertainty in measurement

IAS Calibration Definitions

ILAC-P10: 2013 ILAC Policy on Traceability of Measurement Results

ILAC P14: 2013 ILAC Policy for Uncertainty in Calibration

JCGM 200:2008: International vocabulary of metrology — Basic and general concepts and associated terms (VIM)
NIST Policy on Traceability, Section II.B.4

DEFINITIONS:

APLAC: Asia Pacific Laboratory Accreditation Cooperation
http://www.aplac.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: Calibration Measurement Capability: Smallest uncertainty of measurement a laboratory can achieve within its scope of accreditation, when performing more-or-less routine calibrations of nearly ideal measurement standards intended to define, realize, conserve or reproduce a unit of that quantity or one or more of its values, or when performing more-or-less routine calibrations of nearly ideal measurement instruments designed for the measurement of that quantity.

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.

REQUIREMENTS:

Traceability may be achieved through one of the following methods:

1. Laboratories may submit equipment for calibration directly to NIST or some other national metrology institution or through a calibration laboratory accredited by an accreditation body who is a signatory to the ILAC MRA. Alternatively, laboratories may obtain certified reference materials from NIST (called Standard Reference Materials) or from another national metrology institution. There must be appropriate documentation to justify use of national institutions other than NIST. If a laboratory elects to use an NMI that is not a member of the CIPM MRA that laboratory must have a program and procedure for the calibration of its reference standards that can provide traceability as described in clause 5.6.2.1 of ISO/IEC 17025. IAS will require such laboratories to provide evidence to demonstrate comparison to a widely used standard or procedure consensually agreed by all parties concerned (refer to section 5 below) including providing evidence on the method validation (where required), establishment of measurement uncertainty estimation, traceability documentation, information on participation in measurement audits, staff competency, EUT calibration conditions and internal audit records.

2. Laboratories may calibrate their own equipment, provided:

   - Appropriate, traceable reference materials or instruments are employed.
   - Staff is properly trained in the calibration process and procedure.
   - The laboratory's calibration procedures are documented and calibration records are maintained.
   - 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 evaluate measurement uncertainty.

3. IAS accredited laboratories may use calibration service providers accredited as operating under ISO/IEC Standard 17025:2005 by an accreditation body that operates under ISO/IEC 17011:2004 *(General requirements for accreditation bodies accrediting conformity assessment bodies)* and is a signatory to ILAC or one of its recognized Regions. This means that IAS accredited testing laboratories must ensure that their calibration service providers maintain appropriate accreditation as described above, and must be able to produce copies of certificates of accreditation of their calibration providers.

4. The laboratory may have equipment calibrated by a calibration service provider that is not accredited by an agency operating under ISO/IEC 17011:2004 provided all of the following apply:

   a. The laboratory must audit the traceability of the calibrations to NIST or some other national metrology institution, and must document results of this audit to the satisfaction of IAS. Citation of a NIST test number by the calibration service provider is not acceptable evidence of traceability. However, there may be occasions when the NIST test number is the information provided. In these instances the laboratory must obtain the evidence that the NIST test number applies to the calibration of the specific item on the specific date in order to be considered valid.

   b. The laboratory shall maintain records that non-accredited calibration service providers have been audited. These records must include all findings of nonconformance with standards, and the service provider's resolution of the nonconformities.

   c. Laboratories must obtain information from their non-accredited calibration service providers and document the following:

      (i) Testing laboratories must have information regarding assessment of the quality system used by the calibration service provider. This information shall include who assessed the calibration service provider and the results of the assessment. *Please note that the assessment of the calibration service provider must be conducted by a person or certified metrologist having the required technical expertise in the field of calibration performed by the calibration service provider.* It is preferable that the laboratory have on file a copy of the assessment report from whoever assessed the service provider. The calibration service provider shall also keep copies of the certificates of the assessor’s credentials, so as to authenticate the assessment process.

      (ii) Testing laboratories must have appropriate information on the calibration procedures used by the service provider.

(iii) Testing laboratories must hold a list of the test and measuring equipment used by the calibration service provider. The calibration of this equipment must be traceable to SI through NIST, to some other national metrology institution, or a calibration service provider accredited under ISO/IEC Standard 17025:2005 by a signatory to ILAC or a recognized Region. The laboratory must keep copies of its calibration service provider's certificates of calibration of the test and measuring equipment used to calibrate the laboratory's equipment.

(iv) Testing laboratories must have information on environmental conditions at the facility of the service provider.

(v) Testing laboratories must have records of the methods by which the service provider determines uncertainties of measurement.

(vi) Testing laboratories must have information on the relative uncertainties present at all steps in the calibration process.

(vii) Testing laboratories must have information on the training and technical competence of key personnel of the calibration service provider.

(viii) A calibration laboratory may claim compliance to either ANSI/NCSL Z540.1-1994 (R2002) or to ANSI/NCSL Z540.3-2006 (R2013). Currently both are self-declared compliance; however a laboratory accredited to ISO/IEC 17025:2005 is considered compliant with ANSI/NCSL Z540.1-1994 (R2002) Part 1, and accredited calibration laboratories may request further assessment to the requirements of ANSI/NCSL Z540.3-2006 (R2013) for either Section 5.3 alone, or for the entire Standard.

5. If it is not possible or appropriate to achieve traceable calibration, IAS accredited testing laboratories may demonstrate comparison to a widely used standard which is clearly specified and mutually agreeable to all parties concerned, particularly as regards 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.

ESTIMATION OF MEASUREMENT UNCERTAINTY

Estimation of measurement uncertainty is an essential part of any calibration exercise. Where it is possible to estimate uncertainty, the estimations must be performed in accordance with the Guide to the Expression of Uncertainty in Measurement (also known as GUM). This document can be obtained as an ISO document, or as ANSI/NCSL Z540.2-1997 (R2012), *U.S. Guide to the Expression of Uncertainty in Measurement*.
When estimating uncertainties, all factors which affect the testing process and results should be considered.

This is typically calculated using a coverage factor of k = 1.96 for the 95% level of confidence. However, it is general practice to use k=2 for 95% confidence level, which is acceptable. Testing laboratories are to determine their uncertainties to the 95% confidence level to assure consistency. Any other level of coverage below 95% confidence is not desirable, but if it must be used, then it must be supported by documented justification.

Calibration certificates and reports must provide statements of the measurement results and the associated uncertainty. Such statements must include the coverage factor and confidence level.

The laboratory must use appropriate methods to develop its uncertainty budget. The method used to develop the uncertainty budget must be defined and documented. All readings, observations and derived data must be maintained.

Developing an uncertainty budget generally requires repeated testing, and statistical analysis of the results. Sometimes, statistical studies cannot be performed, for various reasons. In cases where statistical studies cannot be performed, an estimation of uncertainties is still required. See the Guide to the Expression of Uncertainty in Measurement for specific guidance on statistical analysis of results, or developing uncertainty budgets in such cases.

While the laboratories should make every effort to evaluate uncertainty of the testing process, there may be instances where uncertainty estimations are too rigorous or just not possible to do. In such cases, it is permissible not to do the estimation. However, it is necessary that all the measuring instruments employed in the testing process are calibrated, by recognized agencies (see point no.1 under requirements), with traceability to national/international standards.

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INTERPRETATION BY IAS:

For specific language of the Standard, refer to ISO/IEC 17025:2005 Clauses 5.4.6.2, 5.4.6.3, and 5.10.3.1.c

The laboratory must have a documented procedure for the calculation of uncertainty for test methods. It is recognized that some test methods may have sufficient information regarding uncertainty of the method to preclude calculation of uncertainty for those methods. However many test methods do not include sufficient information and for those methods that laboratory must be capable of calculating uncertainty of the method.

IAS requires a testing laboratory to develop and demonstrate an uncertainty analysis for at least one test method, unless the Scope of Accreditation includes exclusively test methods that include sufficient estimates of uncertainty. This estimate of uncertainty must be maintained and available during the assessment by IAS, and updated annually as contributing factors may have a change in quantity. While IAS may only check one uncertainty analysis during the on-site visit, the laboratory must have procedures in place to calculate uncertainty for all accredited test methods that allow for reasonable uncertainty estimation.

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

- The customer requests the uncertainty

- There is a regulatory or similar requirement

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

The laboratory must have at least one person trained in uncertainty analysis; if not, theymay outsource the uncertainty such as to the laboratory's calibration provider.

GUIDELINES FOR DOCUMENTATION TO BE KEPT ON CALIBRATION SERVICE PROVIDERS

The following is an outline of the documentation that testing laboratories must maintain on their calibration service providers, if the laboratories have chosen option no. 4 on page 2 of this Policy Guide:

- **Documentation on the Calibration Service Provider**

    - Name of service provider.
    - Address.
    - Phone, fax or e-mail.
    - Director or responsible person.
    - Competence of key personnel and of personnel carrying out the calibration

- **Documentation on the Quality System**

    - Is the service provider accredited to ISO/IEC Standard 17025:2005 and therefore considered compliant with ANSI/NCSL Z540.1-1994 (R2002) Part 1; or additionally assessed to ANSI/NCSL Z540.3-2006 (R2013), and have provided the assessment information?
    - Name of the body accrediting the service provider.
    - If not accredited, has the service provider been assessed by a third party?
    - If yes, by what organization, and to which standard/specification?

- **Documentation on Calibration Methods and Uncertainties**

    - What are the reference standards used by the service provider to calibrate your laboratory's equipment?
    - Which documented calibration procedure was used, and is there clear evidence that this procedure was used, when your laboratory's equipment was calibrated?
    - What is the uncertainty of the standards used to calibrate your laboratory's equipment?
    - What is the total uncertainty of the calibration and what method was used to compute the total uncertainty of the calibration?

- **Documentation on the Service Provider's Physical Environment**

- Is the environment at the service provider's facility properly controlled as to temperature, barometric pressure, humidity, and other relevant conditions?

- **Calibration Reports**

  - Do the service provider's reports or certificates comply with the requirements of ISO/IEC Standard 17025:2005 Clause 5.10 (including sub-clauses)?

- **Audit Reports**

  - When laboratories conduct assessments of their calibration service providers, the assessment report must be signed by the person conducting the audit, who shall be approved by the laboratory that is using the audit to demonstrate compliance with IAS policy. *The assessment must be conducted by a person or certified metrologist having the required technical expertise in the appropriate field of calibration.*