International Accreditation Service, Inc.
3060 Saturn Street, Suite 100
Brea, CA 92821 USA
t: 562.364.8201
t: 866.427.4422
f: 562.699.8031
www.iasonline.org

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

1. SCOPE

This document defines the IAS policies for calibration laboratories (internal or external), calibration 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.

This document also applies to management of calibration programs within testing labs.

2. REFERENCES

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

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

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)

3. DEFINITIONS

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: 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 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.
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.

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. REQUIREMENT

Calibration laboratories seeking to acquire accreditation from IAS and IAS accredited laboratories must comply with requirements of ISO/IEC Standard 17025:2017, the IAS Accreditation Criteria for Calibration Laboratories AC204, applicable ILAC Policies and IAS Policies in order to be accredited by IAS.

4.1 Certificates of Calibration

Calibration certificates or reports issued by IAS accredited calibration laboratories and laboratories seeking IAS accreditation must meet the requirements of ISO/IEC Standard 17025:2017.

Calibration certificates must include appropriate statements of uncertainty. Uncertainty must be stated at the 95% confidence level. Confidence levels above 95% are also allowed, but must be specifically stated.

All calibration certificates issued under the laboratory's accreditation must include the IAS logo and the uncertainty of the calibration.

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 keep copies of its calibration service provider's certificates/reports of calibration and proof of competence to maintain traceability of its measurements.

Calibration records may include physical records, electronic records maintained in calibration management software, or on-line records administered by an external calibration provider, as appropriate.

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: NIST Test Numbers, sometimes known as "NIST numbers" are not valid for ensuring or demonstrating traceability. The report or certificate numbers provide the *documentation* of the path of traceability. It is noted that some calibrations from NIST do not include specific report numbers. In these instances there must be sufficient information to link that specific NIST number to that specific calibration. An example of the information can include the date of calibration and specific description of the item calibrated by NIST under that NIST number.

4.2 Calibration Procedures

Calibration procedures may be obtained from external sources such as the manufacturer, national/international standards, 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.

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.

Evidence of the verification and validation must be maintained for as long as the procedure is considered valid for use. Associated uncertainties must be documented as part of the evidence.

A procedure documented internally may also be a distillation of a validated method or procedure into a working document. This is common where such validated methods or procedures are extensive and only a portion is necessary to effect the calibration. In these cases there must be a clear reference back to the method or procedure that is the source of the laboratory procedure in order for the working procedure to also be considered validated.

4.3 Equipment

Calibration laboratories seeking accreditation with IAS and IAS-accredited calibration laboratories must have access to equipment that meets the requirements of Section 6.4 of ISO/IEC 17025:2017. These pieces of equipment must be appropriately marked or labeled,

and must be calibrated so as to be traceable to SI units where possible (refer to the section on traceability).

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 Calibration Providers

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

4.4.1 IAS accredited laboratories are to use calibration providers accredited as operating under ISO/IEC Standard 17025 by a signatory body to ILAC or one of its recognized Regions. IAS-accredited laboratories must ensure that their calibration providers maintain appropriate accreditation and also must be able to document the accreditation. The simplest method of accomplishing this is to maintain a current copy of the provider's accreditation certificate, and a current copy of the provider's scope of accreditation. The highest level of standards used by the laboratory, whether to calibrate customer's 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.

It is noted that the laboratory may have measurement standards that are considered to be primary standards (e.g., Bell Prover) and therefore do not require calibration by the NMI. In such instances verification by additional alternate means should be employed. An example is the use of the disciplines of length and mass to verify the appropriate operation and condition of the Bell Prover. The laboratory must have a procedure or standard for the verifications and employ calibrated equipment in the verifications. Uncertainty studies must be updated whenever a change in the measurement system is made.

4.4.2 On rare occasions, IAS accredited calibration laboratories may need to have equipment calibrated by a 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 accredited laboratory must audit the traceability of the calibrations to 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 non-accredited calibration provider has been assessed, or must assess the non-accredited 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 non-accredited 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 Standards maintained by NIST, to an appropriate NMI, or to a calibration provider accredited under 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.

4.4.3. 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 must be maintained of this evaluation.

4.4.4. Laboratories may calibrate their own equipment such as working standards or support equipment, provided:

- Appropriate, *traceable* reference materials or instruments are available.
- The calibration includes calculations of measurement uncertainty, or best estimation of measurement uncertainty, in accordance with ISO/IEC Standard 17025.
- Staff is properly trained in the calibration procedure, and the training is documented.
- The laboratory's calibration procedures are written and calibration records, including uncertainty, are kept.
- The laboratory's internally developed calibration procedures are verified and validated, and records of this 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 determine measurement uncertainty).

4.4.5. Laboratories may submit equipment for calibration to an NMI that is not a member of the CIPM MRA as long as the laboratory has developed a program and procedure for the calibration of its reference standards that can provide traceability as described in Section 6.5 of ISO/IEC 17025:2017.

4.5 Traceability

4.5.1 Test equipment having an influence on results must be appropriately marked or labeled, and must be calibrated so as to be traceable to SI units where possible. Traceability may be accomplished by:

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 Clause 4.4.2.

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).

4.5.2. If it is not possible or appropriate to achieve traceable calibration, IAS accredited 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.

4.5.3. 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) or the *Metrology Handbook*.

4.6. Estimation of Measurement Uncertainty

Estimation of measurement uncertainty is a crucial portion of ensuring traceability. Where it is possible to calculate uncertainty, the calculations must be performed in accordance with the *Guide to the Expression of Uncertainty in Measurement* (GUM). This document can be obtained as an ISO document, or as NCSL Z540.2-1997 (R2012).

Uncertainties must be supported by an uncertainty budget and represented as expanded uncertainties. Uncertainties are to be reported at the 95 percent or higher level of confidence. Any lower level of coverage must be supported by documented justification. The coverage factor (k) is determined using degrees of freedom and the T-Tables. Uncertainty is typically calculated at k=1.96 for 95% confidence. However, k=2 is typically used in reporting. The use of k=2 is acceptable for reporting uncertainty.

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 their 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 repeatable testing and statistical analysis of the results. Laboratories should analyze the results in accordance with the GUM**.**

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 GUM for specific guidance on developing uncertainty budgets in such cases.

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

The American National Standard for calibration, NCSL Z540.1-1994 (R2002), known as Z540-1, has been formally retired effective in July 2007, although the standard continues to be used. The standard was replaced by NCSL Z540.3-2006 (R2013), known as Z540.3. There are significant differences between the two documents. The two most obvious differences are the alignment of Z540.3 to be consistent with the requirements of ISO/IEC 17025 in Section 5.3, and requirements regarding what is termed the “Measurement System.”

It is understood that some laboratories may have a need to be verified as compliant to the requirements of ANSI/NCSL Z540.3-2006 (R2013), either solely for Section 5.3, or for the entire Standard. This will require additional assessment time and the laboratory must provide additional documentation as required by the Standard.