



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

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Calibration certificates and/or reports held by IAS accredited testing laboratories must meet the requirements of ANS/ISO/IEC Standard 17025:2005, *General requirements for the competence of testing and calibration laboratories* augmented by ANSI/NCSL Z540.1-1994 (R2002), *Calibration Laboratories and Measuring and Test Equipment - General Requirements*. 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 equipment that may have an effect on test results. These pieces of equipment must be appropriately marked or labeled, and must be calibrated so as to be traceable to the National Institute of Standards and Technology (NIST) or some other national metrology institution.

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. 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.
2. Laboratories may calibrate their own equipment, provided:
 - Appropriate, traceable reference materials or instruments are available.
 - Staff is properly trained in the calibration procedure.
 - The laboratory's calibration procedures are written and calibration records are kept.
 - 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.
3. IAS accredited laboratories may use calibration service providers accredited as operating under ANS/ISO/IEC Standard 17025:2005 by an accreditation organization that operates under ISO/IEC 17011:2004 (*General requirements for accreditation bodies accrediting conformity assessment bodies*). This means that IAS accredited testing laboratories must ensure that their calibration service providers maintain the appropriate accreditation as described above, and must be able to document the accreditation.
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.)

- b. The laboratory shall maintain records that nonaccredited 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 calibration service providers and document the following:
 - (1) The laboratory 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.
 - (2) The laboratory must have appropriate information on the calibration procedures used by the service provider.
 - (3) The laboratory 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 NIST, to some other national metrology institution, or to a calibration service provider accredited under ANS/ISO/IEC Standard 17025:2005 by an organization operating under ISO/IEC 17011:2004. The laboratory must keep copies of its calibration service provider's certificates of calibration.
 - (4) The laboratory must have information on environmental conditions at the facility of the service provider.
 - (5) The laboratory must have records of the methods by which the service provider determines uncertainties of measurement.
 - (6) The laboratory must have information on the relative uncertainties present at all steps in the calibration process.
 - (7) The laboratory must have information on the training and technical competence of key personnel of the calibration service provider.
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 crucial to 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 (also known as GUM). This document can be obtained as an ISO document, or as ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*.

Uncertainties must be supported by an uncertainty budget and represented as expanded uncertainties. Uncertainties for calibration laboratories are to be reported using a coverage factor of $k = 2$ to approximate the 95% level of confidence. However, testing laboratories are to determine their uncertainties to the 95% confidence level to assure consistency, and realize that the k value (coverage factor) will fluctuate, as determined in the T-tables. Any other level of coverage 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 repeatable testing, and statistical analysis of the results. Sometimes, statistical studies can not be performed, for various reasons. In cases where statistical studies can not 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.

Clauses of ANS/ISO/IEC Standard 17025:2005 on Measurement Uncertainty Applicable to Testing Laboratories

Section 5.4.6.2

Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

Note 1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as the requirements of the test method, the requirements of the client, and the existence of narrow limits on which decisions on conformance to a specification are based.

Note 2: In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

Section 5.4.6.3

When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

Note 1: Sources of uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

Note 2: The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating measurement uncertainty.

Note 3: For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement.

Section 5.10.3.1 c

Test reports shall, where necessary for the interpretation of the test results, include the following:

c) Where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instructions so requires, or when the uncertainty affects compliance to a specification limit.

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.

- **Documentation on the Quality System**
 - Is the service provider accredited to ANS/ISO/IEC Standard 17025:2005 or to ANSI/NCSL Z540.1-1994 (R2002)?
 - 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 ANS/ISO/IEC Standard 17025:2005 ?

- **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.*