



# **Specific Accreditation Criteria**

## **ISO/IEC 17025 Application Document Calibration - Appendix**

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## Purpose

In addition to the *ISO/IEC 17025 Standard Application Document (SAD)*, this document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 for calibration activities for both applicant and accredited facilities.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package for Calibration (refer to *NATA Procedures for Accreditation*).

The clause numbers in this document follow those of ISO/IEC 17025:2017, however as not all clauses require interpretation, the numbering may not be consecutive.

## 5 Structural requirements

### 5.4

#### In-situ calibrations and mobile laboratories

Facilities can be accredited for carrying out calibration(s) at the customer's premises and/or offer mobile calibration activities. Where such calibrations are accredited, they will be indicated in the facility's scope of accreditation and the applicable ranges and least measurement uncertainties (MUs) will be identified. Furthermore, if the calculated uncertainties and/or limits of ranges are different to work carried out at the laboratory's premises, separate Calibration and Measurement Capability (CMC) shall also be defined.

When accredited to perform calibrations at the customer's premises, the facility bears the responsibility for ensuring that conditions at each location are suitable for ensuring the validity of the work to be carried out there.

Where necessary precautions shall be adopted and documented. Issues to consider may include, but are not limited to:

- the handling and transport of reference equipment to prevent vibration, shock and temperature excursions;
- reduced calibration intervals on reference equipment and regular cross-checking to prove that it is not being adversely affected;
- an increase in drift due to transportation of the reference equipment;
- separation of the activity from other activities that could adversely affect the integrity of the work;
- ensuring that the environment is suitable and meets all of the requirements specified in the calibration procedure, including that the temperature is monitored and recorded during both stabilisation and calibration work conducted in-situ;
- ensuring that reference equipment has reached thermal equilibrium, this includes mobile laboratories;
- other factors outside of the control of the facility staff (e.g. the electromagnetic environment, stability of the available power supply) when setting up and conducting calibrations.

Where control of the test environment is assured through use of a purpose-built mobile laboratory and the CMC for the on-site calibration is dependent on the control of this test environment, the mobile laboratory becomes part of the critical test

equipment and will form part of the assessment process in the same manner as other key reference equipment.

## **6 Resource requirements**

### **6.2 Personnel**

#### **6.2.6**

##### Personnel authorised to perform specific laboratory activities

Authorisation of personnel for the development, modification, verification and validation of methods shall be in alignment with the Calibration and Measurement Capability (CMC) indicated in the scope of accreditation. These personnel must have demonstrated technical competence to work to the level (measurement range and measurement uncertainty) provided in the CMC, through their demonstrated application of acknowledge and/or via suitable measurement comparisons with equivalent or higher-level calibration facilities.

Personnel authorised for the analysis, authorisation and reporting of results must have a sound knowledge of:

- the NATA Accreditation Criteria (NAC);
- the principles of the calibrations, measurements and/or tests they perform or supervise;
- the standards or specifications for which accreditation is sought or held;
- measurement ranges and the estimation of measurement uncertainty associated with the test or calibration results for which the facility is accredited or seeking accreditation.

### **6.3 Facilities and environmental conditions**

**6.3.2** The facility shall specify the limits on the environmental conditions to be achieved in the laboratory, at customer premises and/or in mobile facilities. The conditions shall be appropriate to the level of accuracy required for the calibration, or as specified in a relevant measurement specification.

### **6.4 Equipment**

**6.4.6** Reference standards and equipment shall be calibrated over the range for which accreditation is held and to an appropriate level of accuracy. Nominally accreditation cannot be given for extremes of the measurement range based on extrapolation beyond the maximum and minimum calibration points.

**Note:** Interpolation is permitted, provided a suitable contribution for doing so has been included within the facility's uncertainty estimation.

### **6.5 Metrological traceability**

Accreditation of National Metrological Institutes and Designated Institutes that are members or applicant members of the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA) will consider the processes and guidance provided in the publication '*Joint ILAC – CIPM Communication regarding the Accreditation of Calibration and Measurement Services of National Metrology Institutes*'.

## **7 Process requirements**

### **7.1 Review of requests, tenders and contracts**

**7.1.1** The following shall be considered at the time that a request is received for reporting compliance of results against a specification in a published standard:

- if the customer has indicated that calibration is to be performed for multiple markets and regulatory frameworks, that their requirements are clearly understood, including whether the calibrations are to be conducted and reported to multiple standards;
- the version of the standards to which the calibrations or tests are to be conducted is explicit.

Where appropriate, the facility shall confirm with customers whether the equipment undergoing calibration is to be adjusted and if so, measurements taken both before and after adjustment, if available, are to be reported.

The calibration facility's least measurement uncertainty as stated in its scope of accreditation must be appropriate for the level of accuracy the device under test may achieve or to the customer's needs. When a facility's CMC is known to be larger than what is necessary to ensure optimal performance from the item being calibrated, for example, one quarter of manufacturer's specification or one quarter of the customer's criteria, then evidence that the customer has accepted and approved this calibration must be retained.

### **7.2 Selection, verification and validation of methods**

#### **7.2.1 Selection and verification of methods**

**7.2.1.1** Recommended reference literature and standard methods that are acceptable may be found in the associated Annexes to this document, which cover measurement activities for several different metrology disciplines.

### **7.4 Handling of test or calibration items**

**7.4.1** Where the equipment to be calibrated may need to be dismantled, the facility must provide appropriate means of identifying and storing the various components. Similarly, when equipment is provided with accessories, these must be appropriately identified and stored.

**7.4.2** As many instruments are identified by a manufacturer's model type or number as well as a unique serial number, additional labelling of equipment being calibrated may not be necessary provided the instrument's identification and the customer's details are recorded immediately upon receipt.

### **7.5 Technical records**

**7.5.1** Calibration certificates on reference equipment shall be retained for periods longer than the next calibration in order to determine the equipment's stability. Evidence of drift forms part of the inputs considered in the measurement uncertainty estimation.

## 7.6 Evaluation of measurement uncertainty

### 7.6.2

#### Scope of accreditation

The scope of accreditation is expressed in terms of a Calibration and Measurement Capability (CMC), which includes the facility's estimate of its best capability (measurement uncertainty) that can be achieved across each measurement range. Any associated measurand parameters that are required to fully define ranges will also be stated (e.g. frequency for AC voltage or temperature for relative humidity).

#### Expressing the Calibration and Measurement Capability (CMC)

The least uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a coverage probability of approximately 95%. The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand (e.g. percentage of the reading or percentage of full scale). Usually, the inclusion of the relevant unit provides the necessary explanation. Because of the ambiguity of definitions, the use of the terms "PPM" and "PPB" are not acceptable. The uncertainty in the CMC shall be stated to no more than two significant figures.

Where the measurand covers a value, or a range of values, one or more of the following methods for expression of the measurement uncertainty shall be applied:

- a single value that is valid throughout the measurement range;
- a range of measurement uncertainty in which case linear interpolation is appropriate in order to find the uncertainty at intermediate values;
- an explicit function of the measurand and/or a parameter;
- a matrix where the values of the uncertainty depend on the values of the measurands and additional parameters.

Open intervals (e.g. " $U < x$ ", or "less than  $2 \mu\Omega/\Omega$ ") are incorrect in the expressions of CMCs and an expression cannot imply zero uncertainty of measurement at any point within the range.

For activities where the facility reports results in both magnitude and phase (e.g. acoustics, vibration and high frequency electrical metrology), the CMC is to include a range and uncertainty for both the magnitude and phase components when applicable.

#### Contributions to measurement uncertainty

Uncertainty calculations must include components for contributions from the customer's device under test including the resolution of the device, repeatability and observed drift.

Facilities shall provide evidence that they can provide calibrations to customers with measurement uncertainties equal to those covered by the CMC. In the formulation of a CMC for an activity, the facility shall take notice of the performance of the "best existing device" which is available for a specific calibration category. At a minimum, all of the uncertainty contributions that are applicable to the "best existing device" are to be included in the CMC calculation.

A reasonable amount of contribution to uncertainty from repeatability shall be included and contributions due to reproducibility are to be included in the CMC uncertainty component, when available. Conversely there should be no significant contribution to the CMC uncertainty component attributable to physical effects that can be ascribed to imperfections of even the “best existing device” under calibration or measurement.

**Note:** The term “best existing device” is understood as a device to be calibrated that is commercially or otherwise available for customers, even if it has a special performance (stability) or has a long history of calibration.

It is recognised that for some calibrations a “best existing device” does not exist such as is the case with high level time measurement. In these cases, the scope of accreditation will clearly identify that the contributions to the uncertainty from the device are not included and each of these CMCs as stated in a scope are to be approved by the Accreditation Advisory Committee.

Contributions to the uncertainty shall include both those which are relevant short-term during calibration and those that can reasonably be attributed to the customer's device. Where applicable, the uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except the uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device.

Reported uncertainties tend to be larger than the uncertainty covered by the CMC as stated in the scope. Random contributions that cannot be known by the facility, such as transport uncertainties, should normally be excluded in the uncertainty estimate. If, however, a facility anticipates that such contributions will have significant impact on the uncertainties attributed by the facility, the customer shall be notified.

#### Provision of reference values to customers

Where a facility provides services such as reference value provision, the uncertainty covered by the CMC generally shall include factors related to the measurement procedure as it will be carried out on a sample (i.e. typical matrix effects, interferences, etc. are to be considered). The uncertainty covered by the CMC will not generally include contributions arising from the instability or inhomogeneity of the material. The CMC shall be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

**Note:** The uncertainty covered by the CMC for the reference value measurement is not identical with the uncertainty associated with a reference material provided by a reference materials producer. The expanded uncertainty of a certified reference material will in general be higher than the uncertainty covered by the CMC of the reference measurement on the reference material.

#### Methods for estimating measurement uncertainty

Appropriate methods for estimating measurement uncertainty are described in the following:

- ISO/IEC Guide 98-3 *Uncertainty of measurement Part 3: Guide to the expression of uncertainty in measurement* (GUM: 1995);
- test or calibration specifications which follow the methods defined in the GUM.

## Review and update of measurement uncertainty estimates

Facilities are required to maintain detailed records for their CMC estimates and to review these periodically for currency.

Following recalibration of reference equipment, the facility must review and update as necessary its uncertainty calculations. Review must also take place when other changes occur which may significantly affect the magnitude of relevant uncertainty components. Review of estimates would cover both the uncertainty of the latest calibration results reported for the reference equipment and a review of the stability of the equipment by comparing the latest results with at least two previous results, where available. In the absence of an established calibration history, an uncertainty contribution for drift from reference equipment may be obtained from sources such as manufacturer's specification.

## **7.7 Ensuring the validity of results**

### **7.7.2**

Records of proficiency testing (PT) activities that support the CMCs are to be made available prior to the initial assessment, scheduled reassessments or requests for extensions to a facility's scope of accreditation.

**Note:** Measurement comparisons / audits (interlaboratory comparisons) can be considered where formal PT programs are not available.

**Note:** Key purposes for interlaboratory comparisons, which can be addressed by PT, includes establishment of the effectiveness of measurement or test methods, comparability of results and validation of measurement uncertainty claims. Facilities should consider this when changing methods and reviewing changes to their CMCs.

The facility must develop a participation plan for proficiency testing. The documented plan must include or be accompanied by a risk assessment of the level and frequency of the PT to be performed by the laboratory. Further information regarding frequencies is described below. The plan must cover each measurement group and be designed to validate measurement uncertainty claims.

The plan shall be regularly reviewed and updated, as necessary, in response to changes in staffing, methodology, instrumentation, etc.

### Participation in PT

Facilities are required to participate in PT in at least one measurement group once per year. Each year, PT must be performed in a different measurement group until all accredited activities are covered within a reasonable timeframe based on risk. However where a facility's scope covers only one or two measurement groups, participation is required once every 2 years. Where a facility's capability covers a range of 6 orders of magnitude or more, additional PT activity across the range may be required.

For facilities with an extensive scope of accreditation, a higher frequency of PT may be necessary.

Participation will be based on measurement type or a group of similar measurements as per the table below. All measurements related to electrical low-frequency

calibration, voltage, current and resistance are combined into one measurement group. However, mass calibration and voltage standards are considered to belong to two different measurement groups. This grouping of measurements has been modeled on measurement disciplines.

- Acoustic equipment
- Force calibration
- Gas analysis
- Humidity calibration
- Ionising radiation
- Irradiance instrument calibration
- Length metrology
- LIDAR/RADAR calibration
- Low frequency calibration (Electrical)
- Mass, density and balances
- Metering - electrical
- Metering - gas
- Metering - liquid
- Optical systems
- Photometry
- Pressure calibration
- Pyrometer calibration
- RF and microwave calibration
- Spectrophotometry
- Speed measuring devices
- Survey equipment calibration
- Temperature calibration
- Time and frequency calibration
- Torque calibration
- Ultrasonic calibration
- Vibration equipment calibration
- Volume and flow

On occasions, facilities are offered the opportunity to participate in PT programs (round robins) organised by the Asia Pacific Accreditation Cooperation (APAC). It is expected facilities participate in these programs when available.

The facility shall ensure that as part of its PT plan, the best Calibration and Measurement Capability (CMC), as reported in its scope of accreditation, is evaluated periodically over time and prior to a request for a new capability. This can be done by:

- participating in commercial PT programs;
- arranging individual measurement audits with other accredited facilities of an equal or better capability;
- participating in the identified round robins when they become available;
- utilising a PT artefact which has sufficient resolution and stability to test a facility's capability.

In some circumstances in which formal PT is not available or it is difficult to arrange an appropriate measurement comparison, other records in support of the claimed CMC may be considered based on risk and existing measurement techniques.

Where supporting records of a measurement comparison with another facility to the best claimed CMC is not available, the CMC as stated in the scope of accreditation may need to be revised to a lesser capability. It must be ensured that the measurement traceability claims of the other facility are able to be confirmed as per the NATA *General Accreditation Criteria: Metrological Traceability Policy*.

In addition to PT or interlaboratory comparisons, when a facility initiates and conducts its own inter- or intra-laboratory comparison, it must be able to demonstrate that each of the personnel involved are not aware of the reference values.

### Selecting PT programs and reporting of results

PT may take the form of a program involving a number of participants where the results are inter-compared or, particularly in the calibration and measurement areas, a measurement audit on an artefact where an individual facility's results are compared with those of a higher-level reference facility (a facility with a lower uncertainty of measurement). The facility's best capability as described in its scope of accreditation (CMC) or proposed scope is to be tested. To enable this, a facility should report its best uncertainty in PT documents.

For measurement audits, results will be evaluated by  $E_n$  ratios. This ratio is used to evaluate each individual result from a facility.  $E_n$  stands for 'Error normalised' and the ratio is defined as:

$$E_n = \frac{LAB - REF}{\sqrt{U_{LAB}^2 + U_{REF}^2}}$$

Where:

LAB is the participating facility's result

REF is the reference facility's result

$U_{LAB}$  is the participating facility's evaluated uncertainty (may be less than the accredited CMC)  $U_{REF}$  is the reference facility's reported uncertainty combined with a component for artefact stability where appropriate.

As a minimum for the result to be acceptable absolute values of  $E_n$  less than or equal to unity should be obtained, that is:

$|E_n| \leq 1$  = satisfactory

$|E_n| > 1$  = unsatisfactory

Generally, the desired outcome is for the value to be as close to zero as possible, with values approaching unity requiring further investigation.

**Note:** For  $E_n$  ratios to be statistically useful as a PT activity it is necessary that  $U_{REF} \leq U_{LAB}$ .

## 7.8 Reporting the results

### 7.8.4 Specific requirements for calibration certificates

#### 7.8.4.1

Unless otherwise required by a calibration specification, uncertainties shall be reported as an expanded uncertainty at a 95% coverage probability. The coverage probability and coverage factor 'k' shall be reported.

The estimated uncertainty shall be reported using a maximum of two significant figures.

SI units and unit symbols shall be used unless the device being calibrated reads in other units or where contractual arrangements demand otherwise.

The numerical value of the measurement result should, in the final statement, be rounded to the least significant figure in the value of the expanded uncertainty to avoid reporting of over-precise measurement results. Observation of long term drift may require the added precision.

For the process of rounding the reported uncertainty of measurement, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided for example, in Section 7 of ISO/IEC Guide 98-3 *Uncertainty of measurement Part 3: Guide to the expression of uncertainty in measurement* (GUM: 1995).

When a percentage is applied to calibration certificates in order to clarify expression of uncertainty, it should be expressed as a percentage (%) of full scale, % of reading, or % of property.

For transducer calibration (pressure, force, acceleration, etc.), when reporting results in terms of electrical quantities, the uncertainty evaluation shall include contributions attributed to the reference electrical meter and any reported curve fitting algorithm. To assist the end user, the reported uncertainty may be stated in both the accredited measurand, e.g. pressure, dimension and the electrical value.

When comparing a measured value, such as a reading displayed on an instrument, with a reference value, the percentage error can be calculated by dividing the difference between the measured and reference values by either the reference value or the measured value. Normally the reference value would be used as the divisor, but either way it should be clear to the reader of the report how the percentage error has been calculated.

**Note:** Care should also be taken not to introduce additional error by rounding the values before calculating the percentage error.

Pre-calculated (typical) uncertainties may only be reported where there is adequate and documented justification. If uncertainties are derived using a pre-characterised standard deviation for the facility's measurement system, then an appropriate acceptance limit shall be set for the spread of results.

The statement in calibration certificates, identifying how the measurement(s) are metrologically traceable, is to include the "stated reference" to which traceability is claimed. For example in addition to SI units, the stated reference, may include a primary test method, certified reference material, published standard, etc.

An example traceability statement may be reported as:

*“Measurement results for temperature are traceable to SI and reference ITS-90 for interpolations. Reference equipment has been calibrated by the National Measurement Institute or NATA accredited laboratories”*

The facility may also identify the reference equipment used to support the traceability statement.

When a calibration facility is requested to perform equipment checks (in between periodic calibrations) these may be reported provided they are fit for purpose, and the issued report makes reference to the previous calibration report for which the check result supports.

An accredited facility is not permitted to issue a calibration certificate, on activities covered by its scope of accreditation, stating a measurement uncertainty which is less than that stated in its CMCs. Certificates used for internal quality assurance activities only (e.g. interlaboratory comparisons, etc) are exempt from this requirement.

## **7.8.6 Reporting statements of conformity**

**7.8.6.2** Where a customer requests a statement of conformity with a specification, the measured value and measurement uncertainty may be omitted on the calibration certificate if it is not intended to be used in support of the further dissemination of metrological traceability (e.g. to calibrate another device).

In addition to ISO/IEC Guide 98-4, further information regarding the role of measurement uncertainty in conformity assessment decisions may be found in OIML (Organisation Internationale de Métrologie Légale / International Organization of Legal Metrology) G 19 *The role of measurement uncertainty in conformity assessment decisions in legal metrology*.

## References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

### Standards

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 98-3 *Uncertainty of measurement - Part 3: Guide to the expression of uncertainty of measurement* (GUM:1995)

### NATA Publications

NATA Accreditation Criteria (NAC) package for Calibration

*General Accreditation Criteria*      *Metrological Traceability Policy*

### Other Publications

OIML G 19 *The role of measurement uncertainty in conformity assessment decisions in legal metrology*

## Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Whole document	Minor editorial revisions.
7.1.1	Clarified that the two points included under this clause number shall be considered upon request receipt.
7.5.1	Clarified that records shall be retained and that evidence of drift forms part of the inputs considered in the measurement uncertainty estimation.
7.6.2	<p><u>Expressing the Calibration and Measurement Capability (CMC)</u></p> <p>Requirement relating to expression of measurement uncertainty for a measurand covering a value or range of values has been edited to align with the September 2020 revision of ILAC P14.</p> <p><u>Contributions to measurement uncertainty</u></p> <p>Clarified that the facility shall notify customers in cases where it is anticipated that random contributions will have a significant impact on the attributed uncertainty.</p> <p><u>Provision of reference values to customers</u></p> <p>Clarified the following:</p> <ul style="list-style-type: none"> <li>• Factors relating to the measurement procedure shall be included in the uncertainty covered by the CMC.</li> <li>• The CMC shall be based on an analysis of the inherent performance of the method.</li> </ul>
7.8.4.1	For the paragraph regarding rounding of numerical values, added that observation of long-term drift may require added precision.