# Specific Accreditation Criteria

## ISO/IEC 17025 Application Document

## Calibration - Appendix

July 2018

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# ISO/IEC 17025 Application Document, Calibration - Appendix

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 since not all clauses require interpretation, the numbering may not be consecutive.

## 5 Structural requirements

### 5.4

<u>In-situ calibrations and mobile laboratories</u>

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

When accredited for conducting in-situ calibrations, 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 test method, 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 themselves;
- 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

<u>Personnel authorised to perform specific laboratory activities</u>

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

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

- the NATA Accreditation Criteria (NAC);
- the facility's management system;
- 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 the uncertainties of measurement associated with the test or calibration results for which the facility is accredited or seeking accreditation.

## 6.3 Facilities and environmental conditions

The facility shall specify the limits on the environmental conditions to be achieved in the laboratory, in-situ and 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.

# 7 Process requirements

## 7.1 Review of requests, tenders and contracts

**7.1.1** When reporting compliance to a published standard, the review phase should address the following:

- if the customer has indicated that calibration or testing is to be performed for multiple markets and regulatory frameworks, that their requirements are clearly understood, including whether the calibrations or tests 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 uncertainty of measurement 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 best calibration uncertainty (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

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 under test 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 should be kept for periods longer than the next calibration in order to determine the equipment's stability. Any evidence of drift should be a component considered in the uncertainty estimation.

## 7.6 Evaluation of measurement uncertainty

**7.6.2** The scope of accreditation is expressed in terms of a Calibration and Measurement Capability (CMC), which includes the facility's estimate of its least uncertainty of measurement for 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. Facilities are required to maintain detailed records for their least uncertainty estimates and to review these periodically for currency.

Particular care should be taken when the measurand covers a range of values. One or more of the following methods are generally employed for the expression of the facility's best achievable uncertainty:

- a single value, that is valid throughout the measurement range;
- a range. In this case a calibration facility should have proper assumption for the interpolation to find the uncertainty at intermediate values, e.g. the uncertainty increases linearly with range;
- an explicit function of the measurand or a parameter;
- a matrix of measurement points.

Open intervals (e.g. "U < x") are not allowed in the specification of uncertainties and an expression cannot imply zero uncertainty of measurement.

The least uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a specific coverage probability of 95%. The unit of the uncertainty will always be the same as that of the measurand or in a term relative to the measurand e.g. percentage of the reading or full scale. Usually the inclusion of the relevant unit provides the necessary explanation. The uncertainty in the CMC shall be stated to no more than two significant figures.

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.

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.

**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.

Where facilities provide services such as reference value provision, the uncertainty covered by the CMC should generally 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 should 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.

An accredited facility is not permitted to issue a report, on activities covered by its scope of accreditation, stating an uncertainty of measurement which is less than that stated in its CMCs.

**Note:** The facility's ability to achieve its stated CMC, giving consideration to the extremes of measurement range and smallest uncertainty, is evaluated by the assessment team during the NATA assessment and by review of proficiency testing results.

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

Appropriate methods of uncertainty of measurement analysis 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);
- certain test or calibration specifications which specify the method for the estimation of uncertainty.

Facilities shall have a system for reviewing and, where necessary, updating their uncertainty calculations following recalibration of reference equipment or other changes that would significantly affect the magnitude of relevant uncertainty components. This review 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

<u>Proficiency testing (PT)</u>

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

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

The facility shall ensure that its best Calibration and Measurement Capability (CMC), as reported in its scope of accreditation, is being tested. This can be done by:

- participating in the identified round robins when they become available;

- arranging individual measurement audits with other accredited facilities of an equal or better capability;
- participating in commercial PT programs;
- utilizing a PT artifact which has sufficient resolution and stability to test a facility's capability.

In some circumstances in which it is difficult to arrange an appropriate measurement comparison, other records in support of the claimed CMC will be considered, including:

- comparisons conducted with non-accredited facilities;
- validation of the facility's measurement methodology;
- suitability of reference equipment;
- evaluation of measurement uncertainty calculations;
- on going intra-laboratory checks.

Where supporting records of a measurement comparison with another accredited 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.

Frequency of participation will be based on measurement type or a group of similar measurements as per the table below. For example, calibration of thermometers and thermocouples will be considered one measurement group. Similarly, 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 and the assessment effort for each accreditation.

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. However where a facility's scope covers only one or two measurement groups, participation is required once every 2 years. Where a facilities capability covers a range of 6 order 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.

The following table provides a listing of the common measurement groups for which ongoing PT is required.

| | | | |
|---|---|---|---|
| Acoustic Equipment | Mass, density and Balances | Low Frequency calibration (Electrical) | Thermocouple calibration |
| Force calibration | Metering - electrical | Pressure calibration | Thermometer - calibration |
| Humidity calibration | Metering - gas | Pyrometer calibration | Time and Frequency calibration |
| Ionising Radiation | Metering - liquid | RF and microwave calibration | Torque calibration |
| Irradiance instrument | Optical systems | Spectrophotometry | Vibration equipment calibration |

| | | | |
|---|---|---|---|
| calibration | | | |
| Length metrology | Photometry | Speed measuring devices | Volume and Flow |
| Ultrasonic calibration | LIDAR/RADAR calibration | Survey equipment calibration | Gas analysis |

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.

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

$U_{\mathrm{LAB}}$ is the participating facility's best uncertainty

$U_{\mathrm{REF}}$ 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

Units and unit symbols shall be in the form specified in AS 1000 unless the device being calibrated reads in other units or where contractual arrangements demand otherwise.

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 that the checks support.

**7.8.4.1** Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions 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 that uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device.

Therefore, 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 statement. If, however, a facility anticipates that such contributions will have significant impact on the uncertainties attributed by the facility, the customer should be notified.

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.

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.

The numerical value of the measurement result shall in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result to avoid the reporting of over-precise measurement results beyond that presented by the estimated uncertainty of measurement.

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 (ISO GUM).

To aid in clarity of expression of uncertainty in calibration certificates when percentage is applied, it should be expressed as % of full scale or % of reading or % of property.

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

> *"Measurement results for temperature are traceable to SI and 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.

### 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 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 decision may be found in OIML G 19.

# 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*

### NATA Publications

NATA Accreditation Criteria (NAC) package for Calibration

### Other Publications

AS 1000 *The International System of Units (SI) and its application*

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

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 | Clauses have been aligned with ISO/IEC 17025:2017.<br>Criteria and recommendations included in the previous issue have been removed where these are now covered in ISO/IEC 17025:2017.<br>The document includes editorial changes with no new interpretative criteria included for clauses 4 to 7<br>Additional clarity has been provided for a number of points as detailed below. |
| 5.4 | Additional guidance covering purpose built mobile laboratories included. |
| 7.8.4 | Additional guidance when reporting equipment checks to monitor drift, supplementary to a previous calibration. |
| 7.8.4.1 | Additional guidance on the traceability statement to include in calibration certificates. |
| 7.8.6.2 | Addition of OIML G 19 as an information guide. |