Specific Accreditation Criteria
Calibration ISO/IEC 17025 Appendix

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Calibration ISO/IEC 17025 Application Document

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 in the activity type of Calibration for both applicant and accredited facilities.

Applicant and accredited facilities must also comply with ISO/IEC 17025, the NATA ISO/IEC 17025 Standard Application Document (SAD), General NATA Documents and General Accreditation Criteria documents and applicable Sector Annexes (refer to *NATA Procedures for Accreditation).*

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

The terms facility and laboratory are interchangeable in this document.

4 Management requirements

4.1 Organisation

4.1.3 In-situ calibration

Facilities can be accredited for carrying out in-situ, at the customer's site and/or mobile calibration of equipment. 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;
- 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;

- 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.

4.4 Review of requests, tenders and contracts

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

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

Where appropriate, the facility shall confirm with their customer 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 laboratory's least uncertainty of measurement as stated on the 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.

4.13 Control of records

4.13.2.1 Information on the sources of uncertainty

Calibration certificates on reference equipment shall be kept for longer periods than just their validity in order to determine the equipment's stability. Any evidence of drift will be a component to be considered in the uncertainty estimation.

5 Technical requirements

5.2 Personnel

Facilities must document a policy or procedure for the approval of appropriate staff authorised to perform critical tasks, which includes the issuing of reports and/or assuming technical control of a facility's calibration and measurement capability. Approval is to be based on academic qualifications, practical experience and demonstration of technical competence.

Records of staff authorisation by management and the information on which it has been made must be maintained.

5.2.5

Persons who have overall technical control of the calibrations

For calibration activities, the facility shall have one or more key personnel who assume overall technical control of each set of calibrations as recorded in the Calibration and Measurement Capability (CMC) in the Scope of Accreditation. These staff 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 laboratories (see clause 5.9 of this document).

The facility's management must formally authorise these personnel to assume this responsibility, linking the authorisation to the CMC/s listed in the Scope of Accreditation. These personnel may or may not be the same individuals as those authorised to release results and/or issue reports. When a new individual is authorised to assume this responsibility, a series of proficiency tests or measurement audits (to the best CMCs) that supports the technical competency of the application of knowledge is required. Where such are not available, then other means of demonstrating competency must be established which will be reviewed by NATA at assessment. This is particularly critical where the facility's CMC in the Scope of Accreditation is listed at a level better than which has been supported or demonstrated through suitable proficiency testing or measurement audits.

Where a facility's approval process for authorising staff to perform critical tasks, (including the release of results or assuming overall technical control of the calibrations) is found to not satisfy the requirements for accreditation, the facility will be required to review all results issued since the time it was determined not to comply and, if necessary, withdraw and/or issue replacement reports. The accreditation status of the facility may also be reviewed.

Persons issuing results

NATA will no longer formally recognise facility staff as approved signatories (however named) in the activity type of Calibration unless a requirement exists under a regulatory framework such as for Legal Metrology or is covered in a Deed of Agreement, Memorandum of Understanding or other binding agreement with a third party. NATA will continue to provide signatory approval for Legal Metrology Authorities. For these Authorities, the facility must nominate individuals who are authorised to release calibration results and NATA will formally acknowledge these individuals as Approved Signatories in the report on assessment.

Any individuals issuing results assumes responsibility for the technical validity and accuracy of all the information that they approve to be released, irrespective of whether the results are contained in a report. Accordingly, they must have and demonstrate a sound knowledge of:

- the principles of the calibrations, measurements and/or tests they perform or supervise;
- the standards or specifications for which accreditation is sought or held;
- the facility's management system;

- ISO/IEC 17025, NATA Rules, this document and other pertinent NATA Accreditation Criteria;
- 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.

Facility staff who release results shall hold a position within the organisation which provides authority over the calibration and/or testing activities and, where necessary, results are to be rejected when they consider them to be inadequate.

5.3 Accommodation and environmental conditions

The facility shall specify 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.

5.4 Test and calibration methods and method validation

5.4.1 General

In the activity type of Calibration, the accreditation covers calibration activities only and the Scope of Accreditation encompasses all calibrations associated with the items listed in the scope.

5.4.2 Selection of methods

Recommended reference literature and standard methods that are acceptable may be found in the appendices of this document, which cover measurement activities for several different metrology disciplines.

5.4.6 Estimation of uncertainty of measurement

The Scope of Accreditation is to be expressed in terms of a Calibration and Measurement Capability (CMC), which includes the facility's estimate of their least uncertainty of measurement for each measurement range. Any associated measurand parameters that are required to fully define ranges must 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 them periodically for currency.

There shall be no ambiguity on the expression of the CMC on the scopes of accreditation and, consequently, on the least uncertainty of measurement that can be expected to be achieved by a facility during a calibration or a measurement. 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 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 full scale. Usually the inclusion of the relevant unit gives the necessary explanation. The uncertainty in the CMC shall be stated to no more than two significant figures.

Laboratories 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, a laboratory shall take notice of the performance of the “best existing device” which is available for a specific category of calibrations. 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 shall clearly identify that the contributions to the uncertainty from the device are not included and each of these CMCs as stated in a scope is 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 laboratories 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. shall 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 an endorsed report stating an uncertainty of measurement which is less than that stated in their CMCs. The facility’s ability to achieve their stated CMC giving consideration to the extremes

of measurement range and smallest uncertainty is evaluated by the assessment team during on-site assessments 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.

5.4.7 Control of data

Whenever possible, a second staff member should check all calculations and data transfers. Worksheets must have a place dedicated, or other means available for the identifying the individual checking the results.

Problems may arise when computer files such as spreadsheets, word processor worksheets and/or report files are reused by overwriting previous results. Accordingly, only blank templates should be used.

Where measurements are highly automated and/or routine, or where information is processed electronically, the emphasis may be moved to checking for errors created by the system (e.g. by audit checks) and to automatic highlighting of results falling outside the expected range.

Validation of spreadsheets must be carried out initially and after significant changes. It must include examination of cell formulae as well as comparison against data sets that have been manually checked. Validation records must be kept.

5.6 Measurement traceability

5.6.2 Specific requirements

In-house calibrations

A facility performing calibrations of its own equipment will also be subject to technical assessment of these in-house calibrations. The assessment team will determine if the in-house calibrations are fit for the purpose for which they are being used and that a reasonable estimate of the associated measurement uncertainty has been made. Where possible, the review of in-house calibrations

will be covered as part of the traceability and calibration aspects during reassessments. Where significant additional assessment time or additional assessors are required, there will be an additional and ongoing cost associated with this activity. Additional specialist assessors will only be used when either the calibration is outside the area of expertise of the Technical Assessors who would normally conduct the assessment or it will be more time or cost effective.

Note: Refer to NATA's *Equipment Assurance, In-house Calibration and Equipment Verification* for additional information.

5.6.2.1 Calibration

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.

5.8 Handling of test and calibration items

5.8.1 Where the equipment to be calibrated or tested 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.

Where type testing or product development testing is performed, facilities must take steps to ensure the issues covered by Clause 5.8.1 of ISO/IEC 17025, including 'visual' security of the equipment under test, are adequately addressed.

5.8.2 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.

5.9 Assuring the quality of test and calibration results

NATA requires calibration activities to be supported by appropriate proficiency testing (PT), or measurement audits on an ongoing basis and that PT performance records are submitted to support requests for variations to scopes of accreditation (and signatory approvals where applicable).

On occasions, facilities are offered the opportunity to participate in proficiency testing programs (round robins) organised by members of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and facilities will be expected to participate in these programs when available.

PT participation

The onus is on each facility to ensure participation in suitable quality assurance activities with regard to their Scope of Accreditation and to ensure that their best Calibration and Measurement Capability (CMC) as reported in their 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; or
- performing PT available through commercial PT scheme providers.

Records of proficiency testing activities that support the CMCs are to be made available prior to requests for variations to scope, initial assessment or prior to scheduled reassessments.

Compliance with this criterion will be assessed during NATA assessments with continuation of accreditation being subject to the adequacy/suitability of the activity.

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

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

However the facility must be aware that when supporting records of a measurement comparison with an 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 during the accreditation decision process.

All staff authorised as having overall technical control of the calibrations as listed in the scope (see clause 5.2 above) are expected to have participated in an inter or intra-laboratory measurement comparison.

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.

Accredited facilities are required to participate in proficiency testing 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.

For facilities with an extensive Scope of Accreditation, a higher frequency of PT may be necessary. This will be determined at assessments.

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 calibration	Optical systems	Spectrophotometry	Vibration equipment 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. The appropriateness of the facility's quality assurance activity will be assessed during assessment.

Proficiency testing may take the form of a program involving a number of participants where the results are intercompared 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 the Scope of Accreditation (CMC) is to be tested.

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 laboratory's result

REF is the Reference Laboratory's result

U_{LAB} is the participating laboratory's reported uncertainty

U_{REF} is the Reference Laboratory's reported uncertainty combined with a component for artefact stability where appropriate.

For the result to be acceptable absolute values of E_n less than or equal to unity should be obtained, i.e.:

$|E_n| \leq 1$ = satisfactory

$|E_n| > 1$ = unsatisfactory

Generally, the desired outcome is for the value to be as close to zero as possible.

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

5.10 Reporting the results

5.10.2 Test reports and 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.

5.10.3 and 5.10.4

Sampling

When a batch or consignment is sampled in accordance with a method included in the Scope of Accreditation, test results for samples may be extended to the batches or consignments from which they are drawn.

Reporting the uncertainty of measurement

Calibration reports must include both numerical measurement result and the associated uncertainty of measurement even when compliance with a specification is stated.

By exception, and where it has been established during contract review that only a statement of compliance with a specification is required, then the measured value and measurement uncertainty may be omitted on the calibration certificate, given the following also applies:

- the calibration certificate is not intended to be used in support of the further dissemination of metrological traceability (for example, to calibrate another device);
- as specified in Clause 5.10.4.2 of ISO/IEC 17025, the facility shall determine the uncertainty and take that uncertainty into account when issuing the statement of compliance; and
- the facility shall retain documentary evidence of the measured quantity value and the uncertainty of measurement, as specified in Clauses 5.10.4.2 and 4.13 of ISO/IEC 17025, and shall provide such evidence upon request.

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 according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.

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).

The uncertainty should be in the same units as the results. However, there may be cases where it is more practical for the uncertainty to be reported as a percentage that applies to all results. To aid in clarity of expression where percentage is applied it should be expressed as % of full scale or % of reading or % of property.

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.

NATA Publications

NATA Rules

ISO/IEC 17025 Standard Application Document (SAD) for the accreditation of testing and calibration laboratories

General Accreditation Criteria, *Metrological Traceability*

General Accreditation Criteria*, Equipment Assurance, In-house Calibration and Equipment Verification*

Standards and other references

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*

Amendment Table

The following amendments were made to the *Calibration ISO/IEC 17025 Application Document*.

Please refer to this sheet in conjunction with the *NATA Procedures for Accreditation* and the associated ISO/IEC 17025 Application Document and Annexes to ensure that you are familiar with these amendments.

AMENDMENT TABLE	
Section or Clause	**Amendment**
New document	This document represents a direct adoption of the former Calibration ISO/IEC 17025 Application Document. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.