General Accreditation Criteria

ISO/IEC 17025 Standard Application Document

January 2018

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ISO/IEC 17025 Standard Application Document for accreditation of testing and calibration facilities

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 in all activity types of testing and calibration for both applicant and accredited facilities.

Applicant and accredited facilities must also comply with ISO/IEC 17025, 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 but since not all clauses require interpretation the numbering may not be consecutive.

4 Management requirements

4.1 Organisation

4.1.4 An example of this clause is where facility staff have production and marketing-related responsibilities.

4.2 Management system

4.2.1 Quality documentation must include or reference the scope of accreditation and the policy on the use of the NATA endorsement.

4.5 Subcontracting of tests and calibrations

Facilities should seek approval from the subcontractor to report excerpts from the subcontractor's report or certificate and ensure under no circumstances excerpts are misleading.

4.5.1 A competent subcontractor is for example, but not limited to, an accredited NATA facility or a facility accredited by a signatory to a Mutual Recognition Arrangement.

4.5.4 The accreditation status of subcontractors should be regularly reviewed to ensure currency.

Note: Information on accreditation status and scope of accreditation may be found at NATA's website or by contacting one of NATA's offices.

4.13 Control of records

4.13.1 General

All records must include the identity of the person making the record.

It is recognised that a number of staff may be involved in test processes or other laboratory procedures. It is the facility's responsibility to identify the critical steps(s) in the procedure and ensure that the identities of the staff concerned are recorded.

4.13.1.2 Unless otherwise prescribed by legislation or contractual obligation, retention times shall not be less than 4 years or, in the case of equipment records, the maximum recalibration interval of equipment (whichever is the longer period).

4.13.2 Technical records

4.13.2.1

a) The records system must include a copy of each report or certificate that contains work covered by the scope of accreditation, or must allow one to be reproduced, including details such as the endorsement (if applicable) and identification of the person who authorised the report.

b) In general, the records system must include the following:

- i) the sample identification;
- ii) the test or calibration document identification;
- iii) date of test or calibration;
- iv) the identity of the method;
- v) the identity of the equipment;
- vi) original observations and calculations;
- vii) the identity of the person performing the test or calibration;
- viii) an indication that calculations and manual data transfers have been checked;
- ix) any other information specified in the method, other contractual documents or relevant statutory regulations.

c) Rounding of results shall only be performed at the final stage of reporting, unless otherwise required by the method. Rounding should be made to the level of precision specified in the reporting requirements of the method.

d) As far as practicable, all records must be indelible and data or observations recorded in such a manner that prevents amendment or loss of the original.

4.13.2.3 Alterations to data must also include the date the change was made.

4.14 Internal audits

The internal audit schedule must cover, ideally within a twelve-month period, both the management and technical requirements of ISO/IEC 17025.

Note: Refer to the international document *APLAC TC 002 Internal Audits for Laboratories and Inspection Bodies* for additional information.

4.15 Management reviews

The effectiveness of the management system shall be reviewed by management at least once per year.

Note: Refer to the international document *APLAC TC 003 Management Review for Laboratories and Inspection Bodies* for additional information.

5 Technical requirements

5.2 Personnel

5.2.5 Personnel records maintained by the facility must be available for review during the assessment. This would include evidence of qualifications, recognition by professional or regulatory bodies (e.g. licencing and registration), and any other authorisations as defined in the relevant activity type ISO/IEC 17025 Appendix.

NATA will list individuals, however named (previously approved signatories), where there is 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. The facility must nominate individuals who are authorised to release results and NATA will formally acknowledge these individuals in the report on assessment.

5.4 Test and calibration methods and method validation

5.4.1 A standard method is defined as a method written by a body that has authority to write standards. Standard methods must be followed without variation for it to be referenced as a standard method on the scope of accreditation. The date of publication is not included on the scope of accreditation, where standard methods are used; the current version must be used unless a legal or regulatory requirement requires the use of a superseded or withdrawn version (in which case the year of issue will be denoted on the scope of accreditation).

Facilities accredited to standard methods must maintain records of all interpretive decisions which they may make as a response to ambiguities in the methods or specifications contained in standards.

Note: Facilities should make all reasonable efforts to ensure that interpretations made are consistent with those of other facilities and regulatory authorities. The appropriate Standards Australia committee should be advised of any interpretive issues. Other facilities accredited for the same test should also be consulted. Attendance at relevant fora where such interpretations are discussed is strongly encouraged.

In some circumstances NATA may impose additional requirements on standard methods. This action is only taken where testing in accordance with the stated requirements of a standard is likely to cause an inappropriate interpretation of the results appearing in a report and thereby bring NATA into disrepute. Such a requirement would only remain in place until the standard was appropriately amended.

Where a standard does not adequately define the methods or contains ambiguities which would make it impossible to consistently apply the requirements, NATA may refuse accreditation.

5.4.2 Selection of methods

Where a test can be performed by more than one method, there must be documented criteria for method selection. Where relevant, the degree of correlation between the methods must be established and documented.

5.4.3 Laboratory developed methods

Accreditation for draft standards is not available. Facilities may however be accredited for such methods if they are documented and validated as in-house test methods.

5.4.6 Estimation of uncertainty of measurement

The requirements for stating calibration and measurement capability (CMC) in a facility's scope of accreditation can be found in the *Calibration ISO/IEC 17025 Appendix*, clause 5.4.6.

5.6 Measurement traceability

For calibration activities or reported results intended to be used in support of the further dissemination of metrological traceability, the criteria provided in the *Calibration ISO/IEC 17025 Appendix* and NATA's *Metrological Traceability* must also be applied.

5.6.1 General

The results of all tests, measurements and calibrations that have a significant effect on the reported result and associated uncertainty of measurement must be traceable, where possible, to national or international standards. The criteria provided in NATA's *Metrological Traceability* must be applied.

5.6.2 Specific requirements

5.6.2 In-house calibrations

A facility performing its own calibrations will also be subject to technical assessment of these 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. Fees will be charged where significant additional assessment effort is required (i.e. time or additional assessors). Specialist calibration assessors will only be used when either the calibration is outside the area of expertise of the technical assessor(s) who would normally conduct the assessment, or if it would be more time or cost effective.

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

5.6.2.2 Testing

Reference standards and equipment shall be calibrated over the range and to the appropriate level of accuracy specified in relevant methods.

Accreditation cannot be given for extremes of the test or measurement range based on extrapolation beyond the minimum and maximum calibration points.

A facility performing its own calibrations may also be subject to proficiency testing and technical assessment for these activities to ensure that all the relevant requirements of ISO/IEC 17025 are met (e.g. adequately documented procedures, procedures to estimate the uncertainty of measurement and complete records of calibration data).

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

5.6.3 Reference standards and reference materials

5.6.3.2 Reference materials

Facilities must demonstrate suitable traceability of assigned values of reference materials, where possible. The criteria provided in NATA's *Metrological Traceability* must be applied.

5.7 Sampling

Sampling may be conducted by the facility, by another section in the organisation or by a separate organisation. Routine sampling falls within the scope of ISO/IEC 17025, so that where ISO/IEC 17025 uses the word 'laboratory' it is also referring to bodies conducting sampling. The phrase 'testing and/or calibration' includes sampling activities. Bodies responsible for sampling are encouraged to seek accreditation with NATA for this activity. Depending upon the structure of the organisation, the assessment of sampling activities may be included as an element of the facility's assessment, or may demand a different assessment team. In conducting an assessment of an organisation's sampling activities, all the management and technical requirements of ISO/IEC 17025, as relevant to sampling, will be assessed.

In some cases appropriate sampling activities demand the development of job-specific sampling plans and/or the use of professional judgement. Sampling may also be performed as part of a wider inspection activity. Accreditation for these activities is possible under NATA's Inspection Accreditation Program. Interested bodies are encouraged to contact NATA to discuss accreditation of these sampling activities.

Where a sampling body samples materials that are to be tested by another facility, the sampling body should include in its report the information of ISO/IEC 17025, Clause 5.10.3.2.

The following conditions must be met to gain accreditation for sampling.

- Documented sampling procedures must be maintained. These may be national or international standards. If in-house methods are used, their validity for the intended purpose must be demonstrated.
- The sampling procedure must be cited on the test report whenever the facility wishes to extend the test results from a sample to an entire batch.

5.9 Assuring the quality of test and calibration results

The on-going competence of facility staff to perform infrequent tests which are covered by the facility's scope of accreditation must be demonstrated and records must be maintained.

5.9.1 Proficiency testing (PT)

Each applicant or accredited facility is required to participate in appropriate PT activities.

Note: Measurement audits are considered a form of PT activity.

Facilities are encouraged to participate in as broad a range of PT activities as practicable, but at least once every two years (different frequencies may be stated in the various activity type/program policies) for each major area of test, measurement or related activity covered by the scope of accreditation, where such programs are available.

Where formal PT programs are not available for any activities or do not provide sufficient coverage, facilities must investigate other means of assuring the quality and performance of the activities for which they seek or hold accreditation.

Note: See NATA's *Proficiency Testing* for further information.

5.10 Reporting the results

5.10.2 Test reports and calibration certificates

Reports on results from tests covered by the scope of accreditation must include the name in which accreditation is held and the accreditation number.

In instances where results of tests or calibrations not covered by the scope of accreditation are included in reports covering accredited activities, the notation 'NATA accreditation does not cover the performance of this service' shall be applied.

Preliminary reports (however named) may be issued when components of a test or suite of tests have not yet been completed. However, those results which are reported must be checked and authorised and the status of the report evident (i.e. preliminary).

Where an accredited facility issues a preliminary report prior to the final report, the final report shall contain a reference to the preliminary report.

No report, whether preliminary or final, shall include results not authorised for release.

5.10.2 (j) Reports issued on activities covered by the scope of accreditation must be authorised by personnel approved by the facility.

Note: Verifying Authorities

NATA accredited facilities that have been appointed as Verifying Authorities by the National Measurement Institute (NMI) must comply with reporting, calibration and test method requirements of NMI where relevant and hold Regulation 13 certificates for their reference equipment. Such facilities should contact NMI to ensure that they are aware of current requirements for Verifying Authorities.

5.10.3 Test reports

5.10.3.1 (b) Statements of compliance

Compliance statements shall reference those sections or clauses of the specification to which the compliance statement relates.

When statements of compliance are made, the uncertainty of measurement shall be taken into account.

A compliance statement may be made if:

- the measurement results fall within the specification limits by an amount at least equivalent to the uncertainty of measurement; or
- the measurement results fall within the specification limits and the uncertainty of measurement is within the maximum permissible uncertainty prescribed in the specification; or
- the test specification defines the compliance decision rule to be used and the measurement results meet the specified criteria; or
- the customer and facility have agreed to a compliance decision rule. When this applies, it should be detailed in the report and reference to the compliance statement made.

Testing facilities may not make compliance statements in the situations described in the fourth point above, if the testing is for the purposes of regulatory compliance.

Calibration labels

Calibrations labels that include the NATA emblem shall also include an identification of the facility and must be traceable to the appropriate report.

5.10.6 Testing and calibration results obtained from sub-contractors

A test document on results on activities covered by the scope of accreditation may include results of tests performed by a subcontractor provided that it is not the sole result(s) included on the document and includes the following information:

- identification of the subcontracted facility;
- report/document identification;

- results and any other relevant information as issued by the subcontracted facility.

5.10.7 Electronic transmission and remote issue of results

Test reports may be electronically issued (including from a site other than the accredited facility) provided that the reports have been appropriately authorised for release. The adequacy of such arrangements will be reviewed at assessment.

The facility must be able to demonstrate appropriate controls over the electronic generation, access, storage and back-up of results and reports and program controls such as password protection. If the report is to be accessed from a web site by the customer there must be appropriate controls in place to ensure the report can only be accessed and downloaded in a protected format.

Any information normally included in a hardcopy report must be included on the electronically transmitted version and appear in any hardcopy printed by the recipient. Flexible pagination to accommodate formatting changes when printed by the recipient may also be required.

It must be ensured that any handwritten comments included on issued reports are also included in the copy of the reports retained by the facility.

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 9000	Quality Management
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories

NATA Publications

NATA Rules

General Accreditation Criteria	*Proficiency Testing*
General Accreditation Criteria	*Metrological Traceability*
General Accreditation Criteria	*Equipment Assurance, In-house Calibration and Equipment Verification*
Specific Accreditation Criteria	*Calibration ISO/IEC 17025 Appendix*

Other Publications

APLAC TC 002	Internal Audits for Laboratories and Inspection Bodies
APLAC TC 003	Management Review for Laboratories and Inspection Bodies

Amendment Table

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

Section or Clause	Amendment
Entire document	This document replaces the former ISO/IEC 17025 Standard Application Document for accreditation of testing and calibration facilities. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure and replace field with activity type.