




Specific Accreditation Criteria

Manufactured Goods ISO/IEC 17025 Annex

Electrotechnology testing - General

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Electrotechnology testing - General

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 for Electrotechnology testing.

Applicant and accredited facilities must also comply with ISO/IEC 17025 and the NATA ISO/IEC 17025 Standard Application Document (SAD).

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

4.1.3 On-site testing

Facilities can be accredited for carrying out on-site and/or mobile testing. Specific capability, ranges and least uncertainties applicable to on-site work and mobile facilities will be included in the facility's Scope of Accreditation.

The facility bears the responsibility for ensuring that conditions at the customer's premises are suitable for the work to be carried out.

Special precautions shall be adopted and documented with regard 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 that it meets the requirement of the test specification. Temperature shall be monitored and recorded during work;
- ensuring that reference equipment has reached thermal equilibrium.

As well as factors such as temperature and humidity, additional care needs to be exercised that other factors outside of the control of the facility staff (e.g. the electromagnetic environment, stability of the available power supply) are considered when setting up and conducting tests.

4.4 Review of requests, tenders and contracts

Facilities issuing compliance results to a published conformity assessment standard such as product testing standards, must ensure the name or identification of the published standard is evident in the Scope of Accreditation. The use of 'and similar standards' in scopes of accreditation is not permitted.

When testing to a 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.

4.13 Control of records

4.13.2 Technical records

- a) Information on the sources of uncertainty:

Calibration certificates on reference equipment need to be kept for longer periods than just their validity in order to be able to determine the equipment stability. This will be a component to be considered in the uncertainty estimation.

- b) Testing facilities should retain sufficient information to allow the equipment under test to be uniquely identified and show the configuration of the sample tested. In a dispute situation, this additional information is essential to the facility.

5 Technical requirements

5.2 Personnel

Facilities must document a policy or procedure for the approval of appropriate staff authorised to perform critical tasks including the issuing of test reports. Approval is to be based on academic qualifications, practical experience and demonstration of technical competence.

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

5.2.5 Persons issuing test reports

Individuals who issue test results assume responsibility for the technical validity and accuracy of all information contained in test reports. 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;
- sound understanding of quality control data;
- awareness of the status of equipment checks and calibrations;

- understanding of the requirements for test item acceptance handling;
- ISO/IEC 17025, NATA Rules, this document and pertinent NATA Accreditation Criteria;
- measurement ranges and the estimation of the uncertainties of measurement associated with the test results for which the facility is accredited or seeking accreditation.

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

Consultants to the facility may issue test reports provided they have the knowledge necessary to allow them to have authority over the testing and/or calibration activities. Consultants must also hold a written contract or agreement with the facility in which their role and authority is clearly defined and that they agree to hold confidential information relating to customers of the facility. The agreement should further indicate that the facility is responsible for work performed by the consultant including acceptance of the indemnity responsibilities detailed in NATA Rules.

Where a facility's approval process for assigning staff to critical tasks including the release test results is found to not satisfy the requirements for accreditation, the facility will be required to review all reports 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.

5.3 Accommodation and environmental conditions

The facility shall specify limits on the environmental conditions to be achieved in the laboratory, on-site and in mobile facilities. The conditions shall be appropriate to the level of accuracy required for the testing, or as specified in a relevant test specification.

The environmental conditions shall be monitored at appropriate intervals and testing activities suspended when the environmental conditions fall outside the specified limits.

5.4 Test and calibration methods and method validation

5.4.1 General

Where a facility is requesting a minor variation to the Scope of Accreditation and this variation relates to changes or additions of published standards, the application for variation must be supported by a gap analysis between relevant standards that are already in the scope and the new standard.

5.4.2 Selection of methods

Facilities accredited for tests to published test methods must have a system in place to ensure that such documents are the current version.

Recommended reference literature and test methods that are acceptable may be found in the technical discipline appendices.

5.4.6 Estimation of uncertainty of measurement

Testing facilities are required to identify all significant components contributing to the overall uncertainty of measurement and assign reasonable estimates to them based on numerical/historical evidence and experience. Where the application allows for a relatively large measurement uncertainty, the uncertainty components may be combined in a more simplified way (e.g. arithmetic addition or square root of the sum of the squares), rather than using a full ISO GUM analysis. Pre-calculated uncertainties may be used, provided the facility can demonstrate that each uncertainty component for a particular test fell within the value assigned for that component in the pre-calculated uncertainty. In that case, it would be reasonable to assign an overestimate to some of the uncertainty components to cover the range of values for that component that would typically be encountered in practice.

In applications requiring small uncertainties, e.g. where small tolerances are specified or results generally fall very close to specification limits, a more rigorous uncertainty analysis, more consistent with the ISO GUM, is required.

Information regarding measurement uncertainty may be included within a facility's Scope of Accreditation where there is a known regulatory need for such information or where the accredited facility has made specific request for inclusion of such information on the basis of a client or end-user requirement.

Where the 'least uncertainties of measurement' is stated in the Scope of Accreditation, it represents the lowest uncertainties that a facility is permitted to report under the Scope of Accreditation. It is estimated from a combination of:

- the uncertainty associated with the facility's measurement or testing system (including any environmental influences), and;
- the uncertainty associated with a specified quality of instrument or item under test.

The facility's ability to achieve their nominated 'least uncertainties of measurement' is evaluated during on-site assessments and by review of proficiency testing results.

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 previous results.

5.4.7 Control of data

Facilities shall ensure that appropriate checks of calculations and data transfers have been carried out before results are issued. Whenever possible, a second officer should check all calculations and data transfers.

Problems may arise when computer files such as spreadsheets, word processor worksheets and/or report files are reused by overwriting previous results. 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 changes to software. It must include careful examination of cell formulae as well as comparison against data sets that have been manually checked. Signed and dated validation records must be kept.

5.6 Measurement traceability

5.6.2 Specific requirements

In-house calibrations

A facility performing its own calibrations will also be subject to technical assessment of these calibrations. Where significant additional assessment time or additional assessors are required, there will be an additional and ongoing cost associated with this activity. Specialist calibration 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 testing and/or measurements are taken and to an appropriate level of accuracy. Accreditation cannot be given for extremes of the measurement range based on extrapolation beyond the maximum and minimum calibration points.

5.8 Handling of test and calibration items

5.8.1 Where the equipment to be 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 this clause, 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 identification and customer are recorded immediately upon receipt.

5.9 Assuring the quality of test and calibration results

Facilities must be able to demonstrate how it complies with the requirements of this clause and regularly seek participation in proficiency testing round robins when they become available.

Proficiency testing may take the form of a program involving a number of participants where the results are compared or testing on an artefact where an individual facility's results are compared with those of another accredited facility.

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 test standard reads in other units or where contractual arrangements demand otherwise.

NATA endorsed reports must not state compliance of a product to an approval scheme as such a statement would represent a product certification activity, which is outside of the scope of ISO/IEC 17025.

5.10.3.2 Statements of Compliance

Where testing is performed in the context of electrical compliance testing, the following protocol is to be adopted in order to align with regulatory norms within this area:

- If a result of a test falls within the range of the specified limit, then a 'Pass' is to be reported. However, if the result when combined with its associated measurement uncertainty would fall outside the specified limit, the result and its uncertainty of measurement must also be reported.
- If the result falls outside the range of the specified limit, then a 'Fail' is to be reported. However, if the result when combined with its associated measurement uncertainty would fall inside the specified limit, the result and its uncertainty of measurement must also be reported.

Any associated statements of compliance must include the basis on which these are made (for example, in accordance with regulatory rulings).

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

General NATA Documents	NATA Rules
NATA General Accreditation Criteria	Proficiency Testing
NATA General Accreditation Criteria Calibration and Equipment Verification	Equipment Assurance, In-house

Standards and other references

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

Assessment of Uncertainties of Measurement for calibration and testing laboratories, R R Cook, NATA

Guidance documents covering the implementation of specific accreditation requirements are also available from the ILAC (www.ilac.org) and APLAC (www.aplac.org) websites.

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

ISO Guide to the Expression of Uncertainty in Measurement

National Measurement Regulations 1999

Amendment Table

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

AMENDMENT TABLE	
Section	Amendment
New Document	This document represents a direct adoption of the former PAT Application Document (excluding Appendices), as circulated for Public Comment in December 2016. The technical content is unchanged. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.