



Specific Accreditation Criteria

ISO/IEC 17025 Application Document Manufactured Goods - Annex

Electrotechnology testing - General

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Purpose

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

Facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package for Manufactured Goods (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.

5 Structural requirements

5.4 In addition to testing carried in a laboratory, facilities can be accredited to carry out on-site and/or mobile testing.

Specific capability, ranges and least uncertainties applicable to such testing will be included in the facility's scope of accreditation.

5.6 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.

6 Resource requirements

6.2 Personnel

6.2.3

Personnel 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;
- measurement ranges and the estimation of the uncertainties of measurement associated with the test results for which the facility is accredited or seeking accreditation;
- the NATA Accreditation Criteria.

6.3 Facilities and environmental conditions

6.3.2 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.

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

6.3.5 The facility must ensure 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 such 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.

6.4 Equipment

6.4.6 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.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.7.1 When testing is to be conducted 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 of the standards to which the tests are to be conducted is explicit.

7.2 Selection, verification and validation of methods

Where a facility requests a variation to the scope of accreditation and this variation relates to changes or additions of published standards, the request must be supported by a gap analysis between relevant standards that are already covered by the scope of accreditation and the new standard.

7.4 Handling of test or calibration items

7.4.2 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.

As many instruments are identified by a manufacturer's model type or number along with a unique serial number, additional labelling of equipment under test may not be necessary provided the identification and customer are recorded immediately upon receipt.

7.5 Technical records

7.5.1 Calibration certificates on reference equipment must be kept for periods longer than the next calibration in order to determine the equipment's stability. Any evidence of drift must be a component considered in the uncertainty estimation.

7.6 Evaluation of measurement uncertainty

7.6.1 Testing facilities are required to identify all significant components contributing to the overall measurement uncertainty 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.

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 JCGM 100 (commonly referred to as the 'GUM'), would be necessary.

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 facility has made specific request for inclusion of such information on the basis of a customer 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. 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 its 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 must 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.

7.8 Reporting of results

7.8.1 General

7.8.1.2 Reports issued by a facility for testing activities covered by its scope of accreditation shall not state compliance of a product to an approval scheme. Such a statement represents a product certification activity (i.e., ISO/IEC 17065) which is outside the scope of ISO/IEC 17025.

7.8.6 Reporting statements of conformity

7.8.6.2 Where testing is performed in the context of electrical compliance testing, in the absence of requirements to the contrary, the following protocol shall 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.

7.11 Control of data and information management

7.11.2 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 include careful examination of cell formulae, as well as comparison against data sets that have been manually checked.

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	<i>General requirements for the competence of testing and calibration laboratories</i>
ISO/IEC 17065	<i>Conformity assessment—Requirements for bodies certifying products, processes and services</i>
JCGM 100	<i>Evaluation of measurement data — Guide to the expression of uncertainty in measurement ('GUM')</i>

NATA publications

NATA Accreditation Criteria (NAC) package for Manufactured Goods.

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 amendments.