General Accreditation Criteria

ISO/IEC 17025 Standard Application Document

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ISO/IEC 17025 Standard Application Document (SAD)

Purpose

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025:2017 covering all testing, calibration and standalone sampling activities for both applicant and accredited facilities.

Facilities must also comply with other relevant General Accreditation Criteria and the relevant Specific Accreditation Criteria, including ISO/IEC 17025 Application Documents (ADs) and their associated Appendices and Annexes covering the specific activities for which accreditation is held or being sought. The *NATA Procedures for Accreditation* identifies the documents covering the criteria for accreditation.

In addition to the above, all International Federation of Horseracing Authorities (IFHA) Reference Laboratories and International Equestrian Federation (FEI) Approved Laboratories must comply with the requirements in ILAC G7 *Accreditation Requirements and Operating Criteria for Horseracing Laboratories*.

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

5 Structural requirements

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

6 Resource requirements

6.2 Personnel

6.2.5 Personnel records include evidence of qualifications, recognition by professional or regulatory bodies (e.g. licencing and registration) and any other authorisations as defined in the relevant field ISO/IEC 17025 Application Document Appendices and/or Annexes applicable to the activities covered by the scope of accreditation. Such records must be available for review during NATA assessments.

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.

NATA will list individuals, however named (previously approved signatories), where there is a regulatory framework 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.

6.4 Equipment

6.4.7 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.

Note: Refer to the NATA document, *General Accreditation Criteria - Equipment assurance, in-house calibration and equipment verification.*

In-house calibration

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 may 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 a non-standardised calibration method is adopted, or if it would be more time or cost effective.

A facility performing its own calibrations may also be subject to proficiency testing or measurement audits where non-standard calibration methods are used.

Note: Refer to the NATA document, *General Accreditation Criteria - Equipment assurance, in-house calibration and equipment verification,* for additional information.

6.5 Metrological traceability

The NATA document, *General Accreditation Criteria - Metrological traceability,* details the criteria for demonstrating metrological traceability.

6.6 Externally provided products and services

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

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

The accreditation status of external providers 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.

7 Process Requirements

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 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.

7.2.1.3 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 included in 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, hence consultation with such facilities should occur. The appropriate Standards Australia committee should also be advised of any interpretive issues. Attendance at relevant fora where such interpretations are discussed is strongly encouraged.

In some circumstances NATA may impose additional criteria 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 criteria would only remain in place until the standard is 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.

7.2.1.4 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.

Note: The date of publication is not included in the scope of accreditation.

7.2.2 Validation of methods

7.2.2.1 Accreditation for draft standards is not available. Facilities may, however, be accredited if the methods covered by the draft are documented and validated as in-house test methods.

7.3 Sampling

Sampling may be conducted by the facility, by another section in the organisation or by a separate organisation. 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 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.

7.3.1 The sampling method used may be a national or international standard.

If in-house methods are used, their validity for the intended purpose must be demonstrated.

7.5 Technical records

7.5.1 It is recognised that a number of staff may be involved in laboratory activities. 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.

Records must include information specified in the method, other contractual documents or relevant statutory regulations.

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.

7.6 Evaluation of measurement uncertainty

7.6.2 NATA includes the calibration and measurement capability (CMC) in the scope of accreditation of calibration facilities. Refer to the *Specific Accreditation Criteria: Calibration ISO/IEC 17025 Appendix.*

7.7 Assuring the validity of results

7.7.2 As detailed in NATA's document, *General Accreditation Criteria - Proficiency testing*, facilities must participate in proficiency testing (PT) at least once every two years (different frequencies may be stated in the various *Specific Accreditation Criteria: ISO/IEC 17025 Application Document Appendices and Annexes*) for each major area of test, measurement or related activity covered by the scope of accreditation, where such programs are available.

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.

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.

7.8 Reporting of results

7.8.1 General

7.8.1.2 Refer to *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation.*

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.

In instances where results of laboratory activities 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', or similar wording, 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.

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 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.

Note: Legal Authorities

NATA accredited facilities that have been appointed as Legal Authorities by the National Measurement Institute (NMI) are reminded of their obligation to 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.

7.8.2 Reports (test, calibration or sampling) - common requirements

7.8.2.1 A report on results on activities covered by the scope of accreditation may include results of laboratory activities performed by an external provider so long as the externally provided results are not the sole ones reported. Such reports must include any relevant information as issued by the external provider for the interpretation of the results. A copy of the external provider's report must be retained by the facility.

7.8.4 Calibration certificates - specific requirements

7.8.4.1 Refer to *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation* for requirements relating to calibration labels.

7.8.6 Reporting statements of conformity

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

A statement of conformity 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.

Facilities shall not make a statement of conformity in the situation described in the last point above, if the statement is for the purpose of regulatory compliance.

8 Management system requirements

8.1.1 General

Unless otherwise prescribed by legislation or contractual obligation, retention times for records 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).

The internal audit schedule must cover all the requirements of ISO/IEC 17025 ideally within a twelve-month period.

The effectiveness of the management system shall be reviewed by management at least once per year. It is recognised that facilities have different organisational structures. Accordingly, various items covered by management review may be considered at different times and at different organisational meetings.

8.1.3 Option B

Certified ISO 9001 management system

A facility seeking accreditation to ISO/IEC 17025 may exercise Option B i.e. establish an ISO 9001 management system. In such a case, the system may not be assessed in full by NATA subject to:

- the management system being certified by a certification body accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA). The certification body must be accredited to certify management system schemes to ISO 9001. NATA may request the facility to provide evidence of the certification body's scope of accreditation; and
- copies of the most recent certification audit reports being made available to NATA for review, including confirmation from the certification body of the close out of any non-conformities raised; and
- the management system allows the fulfillment of the requirements of clauses 4 to 7 of ISO/IEC 17025 for the activities covered by the facility's NATA scope of accreditation.

The required extent of assessment will depend on the evidence provided.

Where nonconformities are identified, these will be reported against clause 8.1.3.

The facility shall notify NATA within 14 days when a change occurs in its ISO 9001 certification status.

Non-certified ISO 9001 management system

NATA will assess the management system in full against the requirements of Option A when the facility has adopted an ISO 9001 system which has not be independently certified by a certification body recognized under the IAF MLA.

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

General Accreditation Criteria	Equipment assurance, in-house calibration and equipment verification
General Accreditation Criteria	Proficiency testing
General Accreditation Criteria	Use of the NATA emblem, NATA endorsement and references to accreditation.
Specific Accreditation Criteria	Calibration ISO/IEC 17025 Appendix

NATA Rules

Other Publications

ILAC G7	Accreditation Requirements and Operating Criteria for Horseracing Laboratories

Amendment Table

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

Section or Clause	Amendment
Purpose	Additional information provided that all International Federation of Horseracing Authorities (IFHA) Reference Laboratories and International Equestrian Federation (FEI) Approved Laboratories, must comply with the requirements in ILAC G7 *Accreditation Requirements and Operating Criteria for Horseracing Laboratories*.