General Accreditation Criteria Proficiency Testing Providers

ISO/IEC 17043 Standard Application Document

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Purpose

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17043 *Conformity assessment — General requirements for the competence of proficiency testing providers* for both applicant and accredited facilities.

Facilities must comply with all relevant documents in the ISO/IEC 17043 NATA General Accreditation Criteria (NAC), for the activities for which accreditation is held or being sought (refer to NATA Procedures for Accreditation). The clause numbers in this document follow those of ISO/IEC 17043, 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

6.1   General

6.1.2, 6.1.3   Facilities must ensure they comply with the applicable General Accreditation Criteria documents are listed as General Accreditation Criteria for Proficiency Testing Providers on the NATA website.

For tests, measurements, calibrations and use of reference materials that support the validity of proficiency testing schemes, the relevant requirements of ISO/IEC 17025 and ISO 17034 apply. Consideration is to be given to the requirements for metrological traceability, validity of measurement procedures and equipment.

Facilities using 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. Draft standards are to be managed as non-standard.

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.

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. Where possible, the review of in-house calibrations will be covered as part of the measuring equipment 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. 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 when it will be more time or cost effective.

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

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

6.2   Personnel

6.2.5   Personnel records maintained by the facility must be available for review during the assessment. These would include evidence of qualifications and of recognition by professional or regulatory bodies (for example licensing and registration where relevant).

6.4   Externally provided products and services

6.4.2   Externally provided services includes activities that support the provision of the Proficiency Testing (PT) schemes such as material preparation, determination of homogeneity, stability testing, characterisation of property values, handling and storage, and distribution. These activities may be conducted by either the Proficiency Testing Provider (PTP) or an external provider or a combination of both.

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 categories for Scope of Accreditation may be found at NATA's website or by contacting one of NATA's offices.

Where an external provider is not accredited for its testing, characterisation and determination of assigned values, the following should be considered during review of the external provider:

a) property value, testing or characterisation (homogeneity, stability, etc.) required;

b) method(s) used;

c) required measurement uncertainty or accuracy of the determination or testing;

d) metrological traceability;

e) reporting requirements; and

f) attention by the external provider to performing the work with the required technical requirements.

The PTP's assessment of the externally provider as to compliance with ISO/IEC 17043 will form part of the PTP's NATA assessment.

7 Process requirements

7.2 Design and planning of a PT scheme

7.2.1 General

Facilities accredited to standard methods for the preparation of the samples 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 the testing (participant) facilities and regulatory authorities.

In some circumstances NATA may impose additional requirements on standard methods. This action is only taken where the stated requirements of a standard are likely to cause an inappropriate interpretation of the results. Such a requirement would only remain in place until the standard was appropriately amended.

7.4 Evaluation and reporting of PT scheme results

7.4.3 PT Reports

In instances where results that are 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 shall be applied.

Note: Refer to NATA's Use of the NATA Emblem, NATA Endorsement and References to Accreditation regarding the use of the endorsement.

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

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

7.5 Control of the PT scheme process

7.5.1 Technical records

7.5.1.1 The records system must include a copy of each report that relates to 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.

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.

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

7.5.2 Control of data and information management

7.5.2.2 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 data transfer is 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.

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

8 Management system requirements

8.1   General requirements and options

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 17043 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.

8.1.2   Fulfilment of management system requirements

Certified ISO 9001 management system

A facility seeking accreditation to ISO/IEC 17043 may establish a management system in accordance with ISO 9001. In such a case, the system may not be assessed in full by NATA subject to all of the following:

- 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 supports and demonstrates the consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9 of ISO/IEC 17043 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 with the management system, these will be reported against the relevant clause (i.e. 8.2 to 8.9).

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 clauses 8.2 to 8.9 when the facility has adopted an ISO 9001 system which has not been independently certified by a certification body recognised 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 Guide 99   *International vocabulary of basic and general terms in metrology (VIM)*

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

ISO/IEC 17043   *Conformity assessment — General requirements for the competence of proficiency testing providers*

ISO 17034   *General requirements for the competence of reference material producers*

ISO Guide 98-3   *Uncertainty of measurement- Part 3: Guide to the expression of uncertainty in measurement (GUM)*

ISO 13528   *Statistical Methods for Use in Proficiency Testing by Interlaboratory Comparisons*

NATA publications

NATA Rules

General Accreditation Criteria   *Metrological Traceability*

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

General Accreditation Criteria   *Use of the NATA emblem, NATA endorsement and references to accreditation*

Specific Accreditation Guidance   *Scope of Accreditation - activity and service descriptors for Proficiency Testing Providers*

Other references

IUPAC   International Union of Pure and Applied Chemistry for chemical testing laboratories

Guidance documents covering the implementation of specific accreditation requirements are also available from the ILAC (www.ilac.org) and APAC (www. apac-accreditation.org/) websites.

Amendment Table

The following amendments were made to the ISO/IEC 17043 Standard Application Document for Proficiency Testing Providers.

AMENDMENT TABLE	
Section or Clause	**Amendment**
Whole document	This document replaces the former Proficiency Testing Scheme Providers ISO/IEC 17043 Standard Application Document. Criteria and recommendations included in the previous General Accreditation Criteria: ISO/IEC 17043 Standard Application Document have been removed where these are now covered in ISO/IEC 17043:2023. The term 'subcontractor' has been replaced by 'external provider'. Note that the name of the general name of the program has been changed from "Proficiency Testing Scheme Providers" to "Proficiency Testing Providers".