General Accreditation Criteria
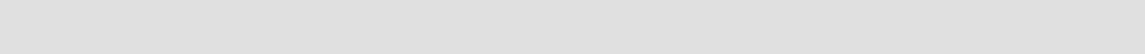
Proficiency Testing Scheme Providers

ISO/IEC 17043 Standard Application Document

January 2018

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ISO/IEC 17043 Standard Application Document for accreditation of Proficiency Testing Scheme Providers

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17043 for both applicant and accredited facilities.

Facilities must also comply with other Accreditation Criteria. The *NATA Procedures for Accreditation* identifies the documents covering the criteria for accreditation.

The clause numbers in this document follow those of ISO/IEC 17043, *Conformity assessment — General requirements for proficiency testing*, however as not all clauses require interpretation the numbering may not be consecutive.

Technical requirements

4.2   Personnel

4.2.4 k)   Individuals who issue proficiency testing scheme results and documentation assume responsibility for the technical validity and accuracy of all information contained in the reports. They must have and demonstrate a sound knowledge of:

- the standards or specifications for which accreditation is sought or held;
- the facility's management system;
- the principles of production, production planning and material handling, data analysis, the evaluation of scheme results and the factors that contribute to the quality of the material produced;
- sound understanding of quality control data;
- awareness of the status of equipment checks, periodic verification and calibrations for equipment under the scheme provider's control;
- understanding of the requirements for the scheme and the testing industry the scheme supports; and
- ISO Standards, NATA Rules, this document and pertinent NATA Policy and Technical Circulars.

Facility staff who release results shall hold a position within the organisation that provides authority over the accredited activities and, where necessary, over results to be rejected when they consider them to be inadequate.

4.2.5   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).

4.4   Design of proficiency testing schemes

4.4.2   Preparation of proficiency testing items

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.

4.4.5 Assigned values

When determining if the assigned values for the measurands or characteristics in a particular scheme are fit for its purpose, the criteria provided in NATA's *Metrological Traceability* must also be applied.

<u>Equipment calibration and intermediary checks</u>

A facility performing its own calibrations of test equipment 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 traceability and calibration aspects during assessment. Where significant additional assessment time or additional assessors are required, there will be an additional and on going 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.

Equipment shall be calibrated over the range of use and to an appropriate level of accuracy.

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

4.7 Data analysis and evaluation of proficiency testing scheme results

4.7.1 Data analysis and records

4.7.1.1 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.

4.7.1.2 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.

4.8 Reports

4.8.2 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.

5 Management requirements

5.2 Management system

5.2.1 Quality documentation must include or reference the Scope of Accreditation and the policy on the use of the NATA endorsement. The Scope of Accreditation will be stated in terms of description of the types schemes provided.

Note: Refer to NATA's guidance document for stating scopes of accreditation for *Proficiency Testing Scheme Providers.*

5.5 Subcontracting services

This clause applies in those cases where a facility is required to subcontract part of its normal service, for example owing to temporary incapacity or excess workload, or where a facility subcontracts owing to the need for further expertise, and the results of the subcontracted service(s) are incorporated into the facility's reports. It is noted that material preparation, determination of homogeneity, stability testing, characterisation of property values, handling and storage, and distribution, may be conducted by either the PTSP or a subcontractor. Where these activities are conducted by a subcontractor the PTSP shall ensure and determine that the subcontractor is technically competent and complies with the requirements of ISO/IEC 17043.

5.5.1 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. The accreditation must cover the subcontracted service where possible.

5.5.5 The accreditation status of subcontractors 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 a subcontractor is not accredited for its testing, determination, provision of a property value or characterisation measurements, the following should be considered during review of the subcontractor:

a)   property value, testing or determination (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 subcontractor to performing the work with the required technical requirements.

The PTSP's assessment of the subcontractor as to compliance with ISO/IEC 17043 will form part of the PTSP's NATA assessment.

5.13   Control of records

5.13.1   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 the activities for the provision of proficiency testing schemes. It is the facility's responsibility to identify the critical steps in the procedure and ensure that the identities of the staff concerned are recorded.

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

5.13.2   Technical records

5.13.2.1   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.

In addition, the records system must include the following:

a)   the scheme(s) identification;

b)   date of the scheme(s);

c)   the identity of the methods used to produce the samples (if applicable);

d)   the identity of the equipment;

e)   original observations and calculations;

f)   the identity of the persons performing any testing or measurements;

g)   an indication that calculations and manual data transfers have been checked; and

h)   any other information specified in the method, other contractual documents or relevant statutory regulations.

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.

5.13.2.3   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.

5.14   Internal audits

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

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

5.15   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.

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 3)*
ISO/IEC 17025	*General requirements for the competence of testing and calibration laboratories*
ISO/IEC 17043	*Conformity assessment - General requirements for proficiency testing*
AS2243	*Safety in laboratories*
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 Scheme Providers*

Other references

ILAC P13	*Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers*
APLAC TC 002	*Internal Audits for Laboratories and Inspection Bodies*
APLAC TC 003	*Management Review for Laboratories and Inspection Bodies*
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 APLAC (www.aplac.org) websites.

Amendment Table

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

AMENDMENT TABLE	
Section or Clause	**Amendment**
Entire document	This document replaces the former Proficiency Testing Scheme Providers ISO/IEC 17043 Standard Application Document. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.