Specific Accreditation Criteria

Materials ISO/IEC 17025 Annex

Characterisation of Industrial Materials - General

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Characterisation of Industrial Materials - General

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 for both applicant and accredited facilities involved in testing for the characteristion of industrial materials.

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

4.6 Purchasing services and supplies

4.6.2 Consumable materials must be appropriately stored. Shelf lives of perishable materials must be set, documented and applied.

The following details of standard solutions must be recorded and retained along with other analytical data:

- all raw data relating to preparation (weights, volumes, etc.);
- results of standardisation, if applicable (including standard curves);
- date of preparation and preferably an expiry date; and
- the identity of the preparer.

Each batch of purchased standard solution must be similarly verified before use (and records retained). Each container must be labelled with the date of opening.

5 Technical requirements

5.2 Personnel

Facilities carrying out a range of complex tests are normally expected to be under the control of an officer who is qualified to gain ‘Member’ category of an appropriate professional body such as the Royal Australian Chemical Institute.

Any testing away from the base facility (such as in field or mobile testing facilities) must be under adequate technical control.

Staff authorised to release test results

1. Facilities must document a policy and procedure for the approval of staff to release test results for work covered by the Scope of Accreditation.
2. Staff releasing results must be approved on the basis of their demonstrated ability to evaluate the validity of test results. This may be demonstrated by a combination of academic qualifications and practical experience for the testing.
    - Academic qualifications may include:
        – a degree in a subject relevant to the testing concerned and a minimum of two years practical experience;

  - a diploma or certificate IV in a subject relevant to the testing concerned and a minimum of five years practical experience;
  - no tertiary qualifications and a minimum of 10 years practical experience.
- Practical experience must include:
  - sound knowledge of the principles of the core competencies related to the testing for which approval has been authorised;
  - sound understanding of quality control data including:
    - results of method controls run in conjunction with testing
    - results of quality control checks on consumables
  - awareness of the status of equipment checks and calibrations;
  - understanding of the requirements for sample acceptance applied to samples under test;
  - understanding of the principles and application of measurement uncertainty; and
  - understanding of the NATA requirements for the content and issue of test reports including the use of the NATA endorsement.

Where a facility's approval process for assigning staff to release test results (for work covered by the Scope of Accreditation) 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.

Records

Records of the staff approved to release test results and the information on which this approval was made must be maintained.

5.3 Accommodation and environmental conditions

5.3.1 A facility undertaking analyses at trace concentrations may need to take special precautions to prevent sample contamination. It may also be necessary to monitor the testing environment to demonstrate that contamination does not occur. Where dedicated clean rooms are required, they must also be monitored for contamination.

When testing in the field, testing sites must be chosen to minimise the effects of environmental conditions and contamination. All relevant environmental conditions must be recorded and the records retained with other test data.

5.4 Test and calibration methods and method validation

5.4.2 Selection of test methods

Published test methods must be verified by the facility to demonstrate it can achieve the expected results. Records of the verification must be retained. Refer to NATA's *Validation and Verification of Quantitative and Qualitative Test Methods* for guidance on method verification. For published test methods that do not include precision data, the facility must determine its own precision data

based on test data. All methods must include criteria for rejecting suspect results.

Facilities performing analyses according to standard test methods such as those mentioned above, must strictly follow the test procedures described in the methods. Only those deviations approved within the method are allowed. The facility must comply with all quality assurance and within-batch quality control measures stipulated in the method.

Facilities intending to apply a method based on a standard method should discuss the modifications to the standard method with customers, and obtain their agreement to the modifications, prior to testing. Modifications to standard methods must be validated.

5.4.3 Laboratory-developed methods

Methods must be documented, and details of validation studies recorded in a manner to ensure consistent application of the method within its scope and defined performance parameters. Document control must be exercised to restrict unofficial copying and to ensure that only the current versions of authorised methods are used for analysis.

AS 2929: Test methods – Guide to the format, style and content provides guidance on the documentation of test methods. *ISO 78-2-Chemistry-Layouts for standards-Part 2: Methods of chemical analysis* also provides useful guidance. *AS 2706 –Numerical values-rounding and interpretation of limiting values* provides guidance on the presentation of numerical values.

Documentation of laboratory-developed methods must include criteria for rejection of suspect results.

NATA will consider requests for accreditation for a test kit method provided that the facility has records of its own verification and/or validation of the method for all applicable matrices.

5.4.5 Validation of methods

5.4.5.2 Methods may be validated by comparison with other established methods using reference materials, preferably certified reference materials. In developing and validating test methods, the following parameters require consideration:

a) selectivity;

b) linearity of response;

c) sensitivity;

d) accuracy (trueness and precision);

e) limit of detection and limit of quantitation;

f) range;

g) ruggedness;

h) measurement uncertainty of results; and

i) traceability of results.

The facility must have documented procedures for method validation. The procedures need to include details of the statistical analysis to be applied when

deriving precision data. Records of the application of these procedures must be retained and will be reviewed at each assessment.

Note: Reference to NATA's *Validation and Verification of Quantitative and Qualitative Test Methods* is recommended in formulating procedures for validation.

5.4.6 Estimation of uncertainty of measurement

NATA will not grant extensions to a facility's Scope of Accreditation until the facility has estimated the measurement uncertainty (MU) of the test results to be reported under the proposed extension to their scope.

In estimating MU, a facility needs only to account for those factors under its direct control. For example, if a facility is not responsible for the original sampling, then it does not have to estimate the uncertainty associated with this process.

NATA's *Estimating and Reporting Measurement Uncertainty of Chemical Test Results* provides information and references regarding the estimation of MU.

Laboratories are also referred to the Eurachem/CITAC Guide - Quantifying Uncertainty in Analytical Measurement. This is available on the internet at http://www.eurachem.ul.pt/or www.measurementuncertainty.org. NATA's *Validation and Verification of Quantitative and Qualitative Test Methods*, and references therein, provide further guidance. Further information is available on the NATA website.

5.4.6.2 Estimation of uncertainty of measurement only applies, at present, to quantitative tests. This includes those tests where a numerical value is reported as a qualitative result e.g. detected or not detected. As indicated in 5.4.6, in estimating the measurement uncertainty, the facility needs to consider those components under its control. It should however be clear what components have been included in the uncertainty estimation.

Where results of tests are not numerically derived i.e. qualitative, estimates of uncertainty are not required. This should not however preclude the facility from developing an understanding of the components that contribute significantly to the variability of results of such tests.

5.7 Sampling

When the facility has partial or no control over sampling the following issues must be addressed:

a) Test documents must include details of the supplier of the sample and other relevant historical information such as condition on receipt and reported date of sampling. If a sample has a characteristic that casts doubt on its validity, but it is not possible to reject the sample, a clear statement of the perceived deficiencies must be made on the report.

b) When non-facility staff such as customers, suppliers or factory personnel take samples, they should be provided with written sampling instructions. It may be necessary for the facility to supply appropriate clean and labelled sampling containers and/or training in sampling techniques. Sample containers provided need to be checked to ensure they are not a source of sample contamination.

c) If the test method specifies the use of a particular sampling method, and the facility has no evidence as to whether the sampler followed this method, this fact must be acknowledged on reports.

5.8 Handling of test and calibration items

5.8.1 Sample containers must be leak-proof and impervious to contamination during transport. Any temperature or other environmental tolerances specified in the method must be satisfied during transport and storage. It may be necessary to test containers before use to ensure freedom from contamination.

5.8.2 Identification labels must be secure and legible. Labelling on caps or lids alone is not acceptable because of the risk of wrongly replacing lids during testing like batches.

5.9 Assuring the quality of test and calibration results

The program for monitoring the reliability of test results must include criteria for rejecting suspect results. Factors that influence the design of the program include the availability of reference materials, the nature and range of the tests, and the number of testing staff.

The on-going competence of facility staff to perform infrequent tests, e.g. less than once per year, which are covered by the facility's Scope of Accreditation must be demonstrated and records must be maintained. A documented procedure must be available describing how the facility assures the results generated by infrequently performed tests. If, for example, suitable reference materials are analysed with each infrequent batch of samples for this purpose, acceptance criteria must be established for the results of such tests and the criteria must be met prior to reporting results for samples.

5.9.1 Proficiency testing

The primary function of Proficiency Testing (PT) is to supplement the internal quality control procedures of facilities by providing an additional external audit of their testing capability. Participation in PT gives laboratories confidence in their results (including estimation of measurement uncertainty) as they can compare their results with other facilities.

The results from participation in PT programs are also used to complement NATA's assessment activities. Facilities can use the results from their participation in relevant PT programs to demonstrate competence in performing the tests for which they hold or seek NATA accreditation.

It is mandatory that each applicant or accredited facility participate in appropriate proficiency testing activities.

NATA's *Proficiency Testing* specifies the frequency for proficiency testing as 'at least once every two years for each major area of test or measurement, where such programs are available'.

Within the current accreditation framework, NATA has responsibility to facilitate the provision of relevant PT programs to accredited and applicant facilities.

Availability can be checked through contact details from the NATA *Proficiency Testing Directory* available on the NATA website.

It is the responsibility of a facility to check the availability of appropriate PT programs and to select the programs in which to participate.

Facilities shall consider the accreditation status of PT providers and are advised to choose accredited providers wherever possible.

In the areas of testing where formal proficiency testing programs are not available or not providing sufficient coverage of a facility's activities, facilities should demonstrate compliance with the requirements of ISO/IEC 17025:2005 (Section 5.9.1) by other means. For example, a facility may participate in less formal inter-laboratory comparisons, regularly use certified reference materials, conduct in-house replicate tests or compare results using different methods.

NATA will review each facility's approach to ISO/IEC 17025, Section 5.9.1 including their selection of PT programs, at reassessment and surveillance visits.

It should be noted that there may be cases in which participation in certain PT programs is mandated by regulators.

Programs offered by industry or professional groups may be suitable. If there are no commercial proficiency testing programs available laboratories may be able to organise their own inter-laboratory or intra-laboratory proficiency programs. Inter-laboratory programs should ideally be conducted using a standard procedure such as *AS 2850 Chemical analysis - Interlaboratory test programs - For determining precision of analytical method(s) - Guide to the planning and conduct.*

A facility's PT performance and any corrective action that needs to follow the investigation of performance are reviewed at surveillance and reassessment visits. This requires that facilities make their records of PT performance and corrective action (where applicable) available to NATA.

It is NATA's policy that all information received by NATA regarding a facility's PT participation is treated in a confidential manner.

5.10 Reporting the results

5.10.3 Test reports

5.10.3.1 Reporting totals

When required to report a 'total' result, for example 'total polynuclear aromatic hydrocarbons', 'total microcystins' or 'total phenols', a facility must ensure that:

- a scientifically valid method is used to calculate the total result;
- the 'total' is clearly defined in the test method;
- the way the total is calculated, in particular the value attributed to compounds included in the total that are measured at less than their limit of quantitation, is clearly described in the test method;

- the test report clearly defines ‘total’ in the context of the reported result. This information may be provided by reference to a Standard method; and
- the customer fully understands all aspects of the test result.

5.10.3.1(e) When reporting the results for organic analytes, for which no reference material is available and the result is reported on the basis of a GC-MS database match, the following apply:

a) for identity, the report must cite the database used, the library ranking (in-house, commercial (specify)), and the percentage match. The match must be done on the basis of full scan mode only.

b) Quantitation must not be reported on the basis of a database match.

5.10.5 Opinions and interpretations

Facilities can include expressions of opinion and interpretation of test data on test reports for testing covered by the Scope of Accreditation where the opinion or interpretation is based on the data reported and is technically valid. Such opinion must be demonstrated to be professionally valid and be traceable to authoritative references*. Any opinions or interpretations offered by the organisation will be reviewed as part of the assessment of the related testing.

Organisations engaged in testing performed on human specimens may not include any opinions or interpretations on test reports for the purposes of diagnosis, treatment or monitoring of a patient. Where opinions or interpretations are to be reported, accreditation against ISO 15189 in the activity type of Human Pathology is to be sought.

Note: * Authoritative references include guidelines and standards set by government bodies such as the NEPC and NHRMC.

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

AS 2706	Numerical values-rounding and interpretation of limiting values.
AS 2850	Chemical analysis - Interlaboratory test programs - For determining precision of analytical method(s) - Guide to the planning and conduct
AS 2929:	Test methods – Guide to the format, style and content provides guidance on the documentation of test methods.
ISO 78-2	Chemistry-Layouts for standards-Part 2: Methods of chemical analysis also provides useful guidance
ISO/IEC 17043	Conformity assessment - General requirements for proficiency testing

NATA publications

General Accreditation Guidance: *Validation and verification of quantitative and qualitative test methods*

General Accreditation Guidance: *Estimating and Reporting Measurement Uncertainty of Chemical Test Results*

Other references

EURACHEM/CITAC *Quantifying Uncertainty in Analytical Measurement* (2nd Edition).

Amendment Table

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

Section or Clause	Amendment
New Document	This document is based on the former Chemical Testing ISO/IEC 17025 Application Document. The technical content is unchanged although non-relevant sections have been removed. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.