Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Materials - 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 characterisation of industrial materials.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package for Materials (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

5.2 For facilities where chemistry is a major underpinning discipline, 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.

6 Resource requirements

6.2 Personnel

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

Where a facility's approval process for assigning staff to release test results 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.

6.2.6 Facilities must have available a procedure for the approval of staff to release test results for work covered by the scope of accreditation.

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 include:

- a degree in a subject relevant to the testing concerned and a minimum of 2 years practical experience;
- a diploma or certificate IV in a subject relevant to the testing concerned and a minimum of 5 years practical experience;
- no tertiary qualifications and a minimum of 10 years practical experience.

Note: Staff operating under an alternative framework, such as the Level 1 - 5 supervisory framework that is common in geotechnical and civil construction facilities, may be acceptable for related activities such as bitumen and/or cement testing facilities.

Practical experience includes:

- sound knowledge of the principles of the core competencies related to the testing for which approval has been authorised which must include participation in proficiency testing and or internal staff assurance programs;
- 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;
- understanding of the NATA requirements for the content and issue of test reports including the use of the NATA endorsement.

6.3 Facilities and environmental conditions

6.3.1 A facility undertaking analyses at trace concentrations may need to take special precautions to prevent sample contamination.

When testing in the field, testing sites must be chosen to minimise the effects of environmental conditions and contamination.

6.3.3 For analyses of trace concentrations, it may 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.

For testing in the field, all relevant environmental conditions must be recorded and retained with other test data.

6.4 Equipment

6.4.3 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.

7 Process requirements

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of test methods

7.2.1.5 Refer to NATA's *General Accreditation Guidance: 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.

7.2.1.7 Facilities performing analyses according to standard test methods, must strictly follow the test procedures described in the methods. Only those deviations approved within the method are allowed.

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.

7.2.2 Validation of methods

7.2.2.1 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.

The facility's procedure for methods validation needs to include details of the statistical analysis to be applied when deriving precision data.

Methods may be validated by comparative validation with other established methods. In developing and validating test methods, the following parameters require consideration:

- selectivity;
- linearity of response;
- sensitivity;
- accuracy (trueness and precision);
- limit of detection and limit of quantitation;
- range;
- ruggedness;
- measurement uncertainty of results; and
- traceability of results.

Reference to NATA's *General Accreditation Guidance: Guidelines for the validation and verification of quantitative and qualitative test methods* is recommended in formulating procedures for validation.

<u>Laboratory-developed methods</u>

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.

7.3 Sampling

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

- 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.
- 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.
- 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.

7.4 Handling of test or calibration items

7.4.1 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.

7.4.2 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.

7.6 Evaluation of measurement uncertainty

In estimating measurement uncertainty (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 *General Accreditation Guidance: Estimating and Reporting Measurement Uncertainty of Chemical Test Results* provides information and references regarding the estimation of MU.

Facilities are also referred to the Eurachem/CITAC *Guide - Quantifying Uncertainty in Analytical Measurement* (http://www.eurachem.ul.pt/ or www.measurementuncertainty.org).

7.6.3 Estimation of MU 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). It should be clear what components have been included in the MU 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.

7.7 Ensuring the validity of 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), 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.

7.7.2 The primary function of Proficiency Testing (PT) is to supplement the internal quality control procedures.

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

NATA's *General Accreditation Criteria: 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'.

It is the responsibility of a facility to check the availability of appropriate PT programs and to select the programs in which to participate. Availability of relevant PT programs can be checked on the NATA website.

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

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, facilities may be able to organise their own inter-laboratory or intra-laboratory proficiency programs. Interlaboratory 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*.

7.8 Reporting of results

7.8.1 General

7.8.1.2 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.

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:

- 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;
- quantitation must not be reported on the basis of a database match.

7.8.7 Reporting opinions and interpretations

7.8.7.1 Where opinions and interpretations are included in reports, they must be technically and professionally valid and traceable to authoritative references

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

Facilities may include comments and/or interpretation of results in a separate document that is clearly linked to the corresponding report (e.g. by report number).

Facilities engaged in testing performed on human specimens shall 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 is to be sought.

Note: Testing on human specimens may be subject to the Therapeutic Goods Administration (TGA) In-Vitro Diagnostic (IVD) medical device Framework and assessment against the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices*.

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
ISO 78-2	Chemistry-Layouts for standards-Part 2: Methods of chemical analysis
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.

NATA publications

NATA Accreditation Criteria (NAC) package for Materials

General Accreditation Criteria	Proficiency Testing
General Accreditation Guidance	Estimating and Reporting Measurement Uncertainty of Chemical Test Results
General Accreditation Guidance	Validation and verification of quantitative and qualitative test methods

Other references

EURACHEM/CITAC *Quantifying Uncertainty in Analytical Measurement*

Amendment Table

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

Section or Clause	Amendment
Whole document	Clauses have been aligned with ISO/IEC 17025:2017. Any criteria included in the previous issue that are now covered by ISO/IEC 17025:2017 have been removed. No new interpretative criteria or recommendations have been included other than editorial changes.