Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Life Sciences - Appendix

Applicable to the following activities:

- **Agribusiness;**
- **Environment;**
- **Food & Beverage;**
- **Healthcare, Pharmaceutical & Media Products;**
- **Human Testing for Workplace and/or Community Screening**

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ISO/IEC 17025 Application Document, Life Science - Appendix

In addition to the *ISO/IEC 17025 Standard Application Document* (SAD), this document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 in Life Sciences for both applicant and accredited facilities.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package applicable to the activities covered, or proposed to be covered, by their scope of accreditation (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 Facilities must be under the control of an appropriately qualified and experienced staff member. Facilities carrying out a range of complex chemical 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.

6 Resource requirements

6.2 Personnel

6.2.3 Evidence of the qualifications and experience used in the approval of staff to hold positions of responsibility will be requested as part of the assessment process.

Where staff are expected to work in areas, or at times other than those in which they would normally work, (e.g. when relieving other staff or working on a weekend) a program of regular refresher training must be established and records retained. Staff who work only 'out-of-hours' must have regular contact with routine staff and in particular supervisory staff. As a guide, one day per month spent in the facility during normal working hours would be appropriate. The time allocated should, however, be sufficient for the staff member to update all skills required for the out-of-hours service. Records of the above must be available to the assessment team and be sufficiently detailed to demonstrate compliance.

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

Staff with colour vision impairment may have difficulty performing some tests. Colour vision is, therefore, one of the issues that facility management must consider, when determining the suitability of staff to perform specific tests.

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 document a policy and 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.

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 Requirements for laboratory accommodation are determined by the nature of the work undertaken and must not compromise the integrity of samples or the results generated.

6.3.2 Specific requirements for facilities carrying out molecular testing including analysis of genetically modified organisms (GMO) are detailed in the *Specific Accreditation Criteria: ISO/IEC Application Document, Life Sciences Annex, Accreditation of facilities testing for genetically modified organisms (GMO).*

6.3.4 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.

6.3.5 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.

6.4 Equipment

6.4.4

Microbiological Media

Refer to *General Accreditation Criteria: Quality Control of Prepared Media and Media Preparation* for requirements related to media preparation and quality control.

Virology

The Australian Society for Microbiology recommends that commercial suppliers of viral culture media be NATA accredited. Facilities should therefore purchase culture media from NATA accredited suppliers.

Kits

QC must be performed on microbiological identification kits (e.g. API) using relevant test organisms from a recognised type culture. QC must be performed on commencing the use of a batch of kits with a new production lot number, using one or more of the strains of organism recommended by the manufacturer (preferably in rotation).

Consumables

Items must be stored in accordance with the manufacturer's recommendations and should be discarded on the expiry date. Consumables used beyond the manufacturer's expiry date must be validated routinely prior to each use. The onus is on the facility to prove that reagents used beyond the manufacturers recommended date do not adversely affect the outcome of the test.

6.4.8 Shelf lives of perishable materials must be set, documented and applied.

6.4.13 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.

Records must be kept of the date of receipt and/or date of initial use of consumables including diagnostic reagents.

Details of the preparation of all types of standard solutions and reagents must be recorded. These records must include:

- ingredients, including manufacturer and manufacturer's batch number (where applicable) and quantities used;
- date of preparation
- identity of preparer
- date of expiry; and
- safety precautions and/or handling instructions, where relevant.

Further, reagent containers must be labelled appropriately.

6.5 Measurement traceability

Note: *ISO Guide 31 Reference materials – Contents of certificates, labels and accompanying documentation* and *ISO Guide 33 Reference materials – Good practice in using reference materials* provide further guidance on the selection and use of reference materials.

Microbiological culture collection management

Refer to *General Accreditation Criteria: Maintenance of Microbiological Reference Culture Collections (MRCC)* for requirements covering the selection, maintenance and use of microbiological cultures.

7 Process Requirements

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 A facility seeking accreditation for a more open scope of accreditation (where groups of analytes, for example, 'organochlorine pesticides' are specified rather than individual analytes) must have fully documented procedures covering such elements as method selection, method development, method validation or verification, acquisition of appropriate reference standards or reference materials and staff training. Records of the application of these procedures will be reviewed as part of each assessment.

All methods must include criteria for rejecting suspect results.

7.2.1.5 Published and standard test methods must be verified before being introduced to demonstrate expected results can be achieved. Records of the verification must be retained. For published test methods that do not include precision data, the facility must determine its own precision data based on test data.

7.2.1.7 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.

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 published and standard methods must be substantiated by technical justifications and verification or validation data as applicable. Refer to *General Accreditation Guidance: Validation and verification of quantitative and qualitative test methods*.

7.2.2 Validation of methods

7.2.2.1 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.

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.

Note: Reference to *Guidelines for the validation and verification of quantitative and qualitative test methods* is recommended in formulating procedures for validation.

7.3 Sampling

7.3.1 Where sample collection is outside the control of the facility, the collectors should be informed of the facility's collection requirements. For example:

- containers/tubes required for each test;
- sampling procedure to follow;
- amount of sample required;
- labelling requirements;
- sample storage requirements (e.g. room temperature vs refrigeration);
- sample transport requirements;
- requirements with respect to request forms;
- provision of other relevant information.

Sample containers must be leak-proof and impervious to contamination. It may be necessary to test containers before use to ensure freedom from contamination.

7.4 Handling of test and calibration items

7.4.1 Facility procedures for sample receipt/reception/acceptance must be documented and include details of the supplier of the sample and other relevant historical information such as condition on receipt and reported date of sampling.

The date, and if relevant, the time of receipt of samples at the facility, must be recorded.

7.4.2 Samples and associated records (worksheets, slides etc.) must be uniquely identified during all stages of testing, for example, by using a traceable numbering system.

Identification labels must be secure and legible. Samples must be identified on the body of the container and the lid. Labelling only on caps and lids is not acceptable because of the risk of wrongly replacing lids.

7.6 Evaluation of measurement uncertainty

7.6.3 Measurement uncertainty (MU) associated with the measurand must be determined:

- for tests where a quantitative determination is reported, including the most probable number technique;

- for tests where a numerical value is reported as a qualitative result (e.g. ELISA assays with a 'cut off' value);
- where the numerical result is reported as detected or not detected.

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.

In cases where a quantitative test consistently returns results at the limit of detection (e.g. <1/10mLs) the result is to be treated as a qualitative result and MU is therefore not required to be reported.

7.7 Assuring the validity of results

7.7.1 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.

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.

Internal quality control

The facility must comply with all quality assurance and within-batch quality control measures stipulated in the method.

The program for monitoring the reliability of results shall be based on the implementation and documentation of a comprehensive internal quality control program. Element of the program includes:

- use of control material (positive and negative as appropriate);
- media quality control (see clause 6.4.4);
- instrument calibration and maintenance;
- staff training and competency performance evaluation;
- checking of calculations and results.

Where bacteria are tested, positive controls must be run for each method in parallel with each batch of samples. The availability of manufacturers' kit controls does not preclude the use of positive controls. The level of the inoculum of positive controls must be sufficient to adequately replicate low level contamination and the limit of detection of the tests.

Each sample batch tested must include positive control samples (e.g. target organisms or analyte).

Criteria for rejecting suspect results must be based on predetermined criteria defined in the internal quality control program.

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

General Accreditation Criteria: Proficiency Testing document 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'. Where specific criteria for participation applies this will be documented in the relevant ISO/IEC 17025 Application Document, Life Science Annex to this Appendix.

Enrolment in a proficiency testing program may include multiple deliveries of samples for testing through the year, and each delivery may consist of several samples. A 'round' of proficiency testing is a single delivery, regardless of the number of samples included.

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

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.

7.7.3 Quality control data (both internal and external) shall be documented in such a way that it is readily accessible for troubleshooting and following up on possible errors and trends.

A facility's proficiency testing performance and any corrective action taken in response to unsatisfactory performance are reviewed during NATA assessments. Accordingly, facilities are to make such records available.

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 Guide 31	Reference materials – Contents of certificates, labels and accompanying documentation
ISO Guide 33	Reference materials – Good practice in using reference materials

NATA Publications

Applicable NATA Accreditation Criteria (NAC) package(s) (Agribusiness; Environment; Food & Beverage; Healthcare, Pharmaceutical & Media Products; Human Testing for Workplace and/or Community Screening)

General Accreditation Criteria	Proficiency Testing
General Accreditation Criteria	Quality Control of Prepared Media and Media Preparation for requirements
General Accreditation Criteria	Maintenance of Microbiological Reference Culture Collections (MRCC)
General Accreditation Guidance	Validation and verification of quantitative and qualitative test methods
Specific Accreditation Criteria	ISO/IEC Application Document, Life Sciences Annex, Accreditation of facilities testing for genetically modified organisms (GMO).

Other Publications

National Pathology Accreditation Advisory Council (NPAAC), Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices

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.