Specific Accreditation Criteria

Life Sciences ISO/IEC 17025 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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Life Sciences ISO/IEC 17025 Appendix

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 also comply with ISO/IEC 17025, the NATA ISO/IEC 17025 Standard Application Document (SAD), General NATA Documents and NATA General Accreditation Criteria documents and applicable Sector annexes (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.

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.

Microbiological Media

Refer to *Media Preparation and Quality Control* for requirements related to media preparation and quality control

5 Technical requirements

5.2 Personnel

5.2.1 Staff competence and technical control

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.

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.

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 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 include:
        - 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

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 (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.

5.3 Accommodation and environmental conditions

5.3.1 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.

Specific requirements for facilities carrying out molecular testing including analysis of genetically modified organisms (GMO) are detailed in the Life Sciences Annex *Accreditation of facilities testing for genetically modified organisms (GMO).*

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

5.4.1 General

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.

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

5.4.2 Selection of test methods

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. 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.

5.4.5 Validation of methods

5.4.5.2 Validation of methods

In house or laboratory developed methods must be validated before being put into use.

Modifications to published and standard methods must be substantiated by technical justifications and verification or validation data as applicable. Refer to *Guidelines for the validation and verification of quantitative and qualitative test methods*.

Methods may be validated by comparative validation with other established methods. 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 *Guidelines for the validation and verification of quantitative and qualitative test methods* is recommended in formulating procedures for validation.

5.4.6.2 Estimation of measurement uncertainty (MU)

All laboratories undertaking quantitative determinations, including the most probable number technique and those 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, are required to establish the MU associated with measurand.

MU is defined as:

"A parameter associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand".

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.

5.6 Measurement traceability

Refer to *Metrological Traceability* for criteria related to calibration of equipment and for reference materials.

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.

Personal Radiation Monitoring Devices

The specific requirements for all ionising radiation measurements in Australia are described in the Calibration Annex *Ionising radiation measurements*.

Microbiological culture collection management

Refer to *Maintenance of Microbiological Reference Culture Collections* for criteria covering the selection, maintenance and use of microbiological cultures.

5.7 Sampling

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

a) containers/tubes required for each test;
b) sampling procedure followed
c) amount of sample required;
d) labelling requirements;
e) sample storage requirements (e.g. room temperature vs refrigeration);
f) sample transport requirements;
g) requirements with respect to request forms;
h) 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.

5.8 Handling of test and calibration items

5.8.1 Sample reception

Facility procedures for sample receipt/reception/acceptance 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.

These requirements must be documented.

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

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

5.8.2 Sample identification

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.

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.

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

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

NATA's *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 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 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.

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.

Performance in proficiency testing

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.

Internal quality control

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

- Use of positive controls.
- media quality control (see clause 4.6);
- instrument calibration, maintenance and use;
- 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 sufficiently to adequately replicate low level contamination and the limit of detection of the tests.

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

5.9.2 Use of Quality Control data

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.

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.

Alternatively facilities may include comments and/or interpretation of results in a separate document that is clearly linked; (i.e. by report number) to the report on which the opinion is based.

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 Human Pathology activity 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

APHA: *Standard methods for examination of water and waste water.* APHA-AWWA-WPCF (American Public Health Association, American Water Works Association, Water Pollution Control Federation), Washington DC, USA.

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*.

AS/NZS: 4659(Parts 1-3) – *Guide to determining the equivalence of food microbiology test methods.*

ISO 78-2: Chemistry-Layouts for standards-Part 2: Methods of chemical analysis also provides useful guidance

ISO 11133: *Microbiology of food and animal feeding stuffs -- Guidelines on preparation and production of culture medium*

ISO/IEC 17043: *Conformity assessment - General requirements for proficiency testing*

ISO 19036ISO: Technical Specification – *Microbiology of food and animal feed stuffs – Guide on estimation of measurement uncertainty for quantitative determinations.*

NATA Publications

General Accreditation Criteria *Proficiency Testing*

General Accreditation Criteria *Maintenance of Microbiological Reference Culture Collections (MRCC)*

General Accreditation Criteria *Media Preparation and Quality Control*

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

ISO Guide 31: *Reference materials – Contents of certificates, labels and accompanying documentation*

ISO Guide 33 *Reference materials – Good practice in using reference materials*

ASM *Guidelines for Assuring Quality of Food and Water Microbiological Culture Media*

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

Amendment Table

AMENDMENT TABLE	
Section or Clause	**Amendment**
5.2.1 Staff authorised to release test results page 5 of 13.	Correction to text “must” to “may” to indicate that the combinations of qualifications and experience are indicative only and that other combinations may be sufficient.