



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;**
- **Human Pathology.**
(qualified as detailed in this documents)

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Purpose

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.

*In exceptional circumstances, facilities performing Human Pathology are accredited to ISO/IEC 17025. These exceptional circumstances are:

- 1) facilities performing routine pathology testing in the context of the support of clinical trials where no diagnostic results for patients are made available;
- 2) non-medical testing facilities (e.g. facilities routinely testing animal products) that are performing specialised diagnostic testing. These facilities are considered by NATA on a case-by-case basis and are aligned with the Therapeutic Goods Administration (TGA) In Vitro Diagnostic (IVD) Regulations. Facilities performing this testing, using In house IVDs, are subject to assessment against National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the development and use of in-house in vitro diagnostic medical devices (IVDs)*.

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, however, as 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. Membership of professional societies should be maintained where possible to keep abreast of contemporary industry knowledge and developments (e.g. Australian Institute of Food Science and Technology, Australian Institute of Occupational Hygienists, Australian Society for Microbiology, Royal Australian Chemical Institute, etc.).

Any testing performed 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

6.2.3 Where staff are expected to work in locations, or at times other than those at 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. A mechanism must be in place to ensure that staff who work outside of normal working hours are kept up to date with changes and decisions that occur during the normal working day (e.g. via email or virtual platform chat function).

The time allocated must, however, be sufficient for the staff member to update all the 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.

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.

6.2.6 Staff authorising results must be approved on the basis of their demonstrated ability to evaluate the validity of the test results they are authorising.

6.3 Facilities and environmental conditions

6.3.2 Specific requirements for facilities carrying out molecular testing, including analysis of genetically modified materials, are detailed in the *Specific Accreditation Criteria: ISO/IEC 17025 Application Document, Life Sciences - Annex, Facilities using nucleic acid detection techniques (including testing for genetically modified materials)*.

6.3.5 When testing in the field, testing locations must be chosen with a view to minimise the effects of environmental conditions and the risk of contamination.

6.4 Equipment

Microbiological culture collection management

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

6.4.4

Consumables

Items must be stored in accordance with 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 manufacturer's recommended expiry or use-by date do not adversely affect the outcome of the test.

Kits

Quality Control (QC) must be performed on microbiological identification kits (e.g. API), using relevant test organisms from a recognised type culture collection. QC must be performed upon 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). Where required, the organisms used should express both positive and negative reactions.

Microbiological Media

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

Virology

When viruses are culturable, and culture is requested or needed, 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.

6.4.8 The shelf lives of consumables must be established and documented where these may affect the validity of results.

6.4.13 Details of standard solutions and reagents, both prepared in-house and purchased, must be recorded. These records must include:

- the identity of the solution or reagent;
- all raw data pertaining to the preparation of the solution or reagent, including ingredients and quantities used (weights, volumes, etc.);
- date of preparation;
- identity of preparer;
- date of expiry;
- manufacturer and manufacturer's batch number (where applicable);
- results of standardisation, including standard curves (where applicable); and
- safety precautions and/or handling instructions, where relevant.

Further, reagents must be labelled appropriately.

Each batch of a purchased standard solution (that are not Certified Reference Materials) and/or reagent must be verified before use and records retained.

Records must be kept of the date of receipt and date of initial use of all consumables that are used, including diagnostic reagents.

7 Process Requirements

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1

Open scope of accreditation

NATA may grant an "open" scope of accreditation for a defined group of analytes. Group descriptors will be included under the 'Determinant' column on scopes of accreditation, for example:

- the group descriptor "Organochlorine pesticides" is listed under the "Determinant" column, rather than specific individual analytes, such as "Dichlorvos," "Dieldrin," "Endosulfan," etc.; and

Note: An open scope of accreditation is not available for the following:

- Microbiological and pathogen testing including bacteria, fungi, yeasts and mould;
- Gluten and allergens;
- Fixed chemical parameters (i.e., analytes which are already fully defined such as pH, conductivity, turbidity, etc.);
- Sensory and organoleptic testing;
- Toxicological markers and defined toxins;
- Indexes and calculated parameters;

- Tests conducted under a formal agreement, or regulatory deed (e.g., the Department of Agriculture, Fisheries and Forestry (DAFF) meat export program);
- Tests with a known and limited set of analytes such as dioxins (i.e., open scope is intended for situations with ongoing analyte evolution - not for well-defined characterised, finite panels where all relevant analytes can and should be listed at the outset).

An open scope of accreditation permits a facility to claim accreditation for new analytes that fall within the collective group descriptor, without the need for seeking an extension to their scope of accreditation for the new analyte.

Accreditation of an open scope of accreditation places more responsibility on the facility to demonstrate that valid, fit-for-purpose methods are performed competently. This, however, does not mean that a facility can undertake any test requested by a customer and claim accreditation. The bounds within which the scope of accreditation is open must be clearly defined and supported by established procedures.

Documented procedures must include, as a minimum:

- how the facility applies existing techniques covered by its scope of accreditation to a collective group of analytes;
- what matrices and analytes may be covered, including the maintenance of a current listing of these;
- how methods are selected and modified, as necessary;
- the verification and/or validation processes necessary for any modifications required to existing methods to test for additional analytes; and
- define the appropriate reference standards or reference materials to be used.

In addition to the above, records of analytes added between assessment activities must be maintained by the facility.

Review of the procedures and supporting records will be performed as part of each assessment. The facility will also be expected to demonstrate its competence to analyse samples covered by the group descriptor(s). This will particularly include new analytes added since the last assessment activity.

Facilities may apply for an open scope of accreditation only if they:

- have completed at least one full assessment cycle;
- maintain a sound assessment history; and
- fulfilled the requirements for documented procedures.

In addition to the above, multi-site facilities may apply for an open scope of accreditation at other sites if::

- centralised governance and oversight of technical procedures are in place; and
- validation processes are consistent and demonstrably applied.

Where concerns are raised with a facility's competence to implement and maintain an open scope of accreditation, reports issued that cover results under the open scope of accreditation may be required to be withdrawn and affected customers advised. Further, the eligibility of the facility to hold an open scope of accreditation may be reviewed.

An open scope of accreditation is not available when a new technique is adopted that is not already covered by the “Service” applicable to the open scope of accreditation (e.g. the introduction of ICP-MS for calcium when accreditation is held for AAS).

7.2.1.5 Published test methods that do not include precision data (i.e. working range, detection limit, reproducibility and measurement uncertainty) must be supplemented by the facility, based on its own test data.

7.2.2 Validation of methods

7.2.2.1 Procedures for method validation must include details of the statistical analyses to be applied for determining precision data.

In developing and validating test methods, as a minimum, the following parameters must be considered:

- selectivity and specificity (ability to detect the target analyte in the presence of others));
- sensitivity (minimum quantity that can be reliably detected);
- linearity (of response over a given range);
- range;
- accuracy, including:
 - trueness
 - precision (repeatability/reproducibility)
- limit of detection (LOD) and limit of quantification (LOQ);
- ruggedness;
- measurement uncertainty; and
- traceability of results.

When MALDI-TOF is used for the identification of target microorganisms, colonies used must be demonstrated to be pure, and care must be taken to ensure that a validated database is used which is appropriate to the range of microorganisms expected. The use of MALDI-TOF must include appropriate techniques such as Gram stain which provide invaluable information in relation to the microorganism under investigation.

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 be followed;
- amount of sample required;
- labelling requirements;
- recording the date and time and location of sampling;
- sample storage requirements (e.g. room temperature vs refrigeration);
- sample transport requirements;
- holding time requirements between sample collection and delivery of the sample to the facility
- requirements with respect to request forms;
- preservation requirements; and

- 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.

Where samples of air are collected using a pump (or similar) for the purposes of generating a volume measurement, the placement of pumps must in accordance with the documented sampling plan for a specific job and be in accordance with the facility's procedure(s).

7.4 Handling of test and calibration items

7.4.2 Sample containers must be securely and legibly labelled on the body of the container. Labelling only caps / lids is not acceptable because of the risk of wrongly replacing these.

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 most probable number (MPN) techniques;
- 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 measurement 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 for such tests.

7.7 Assuring the validity of results

7.7.1 Internal quality control procedures shall include:

- use of control material (positive and negative controls, as appropriate):
 - where the target organisms are tested, positive controls must be run for each method in parallel with each batch of samples;
 - the level of the inoculum of positive controls must be appropriate to adequately replicate low level contamination and the limit of detection of the test method.

Note: The availability of manufacturers' kit controls does not replace the requirement to use positive control cultures.

- media quality control (see clause 6.4.4);
- instrument calibration and maintenance;
- implementation of criteria for rejecting questionable results;
- implementation of predetermined control criteria for infrequently performed tests (e.g. use of suitable reference materials with each batch of samples).

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', the facility must ensure that:

- a scientifically valid method is used to calculate the total result;
- the derivation, or calculation, of 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 test report enables a customer to fully understand 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 database match (e.g., for GC-MS, LC-MS, etc.), the following apply:

- the match must be done on the basis of the use of full scan mode only, and the report must cite the database used, the library ranking (in-house, commercial (specify)), and the percentage match;
- where applicable, the use of tandem mass spectral data to support identification of the analyte; and
- quantitation must not be reported on the basis of a database match.

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 Reports, including preliminary reports, which contain concentration results derived from volume measurement must include the name of the analyst and the person who undertook the volume measurement.

A facility which does not hold accreditation for volume measurement must not make any claim implying that accreditation is held for such an activity. For further information, refer to the General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references.

7.8.3 Specific requirements for test reports

7.8.3.1

Reporting thresholds

Results must be reported in accordance with the requirements of the method used, including the correct application of terms such as limit of detection (LOD), limit of quantification (LOQ), or other defined thresholds (e.g. reporting limit, practical quantitation limit).

Where a test consistently returns results at or below the LOD, the result may be considered qualitative and measurement uncertainty (MU) is not required.

Reporting of results below the LOQ (e.g. "< LOQ" or "< x µg/L") is acceptable where this is:

- specified or permitted by the method;
- required by a customer or regulator; or
- defined and validated in an in-house method.

In microbiological testing, where an LOQ may not be defined, it is acceptable to report quantitative results above the method LOD but below statistical minimum counts (e.g. <15 CFU), provided this is consistent with the method and clearly interpreted.

LOD or similar thresholds must not be included in reports unless they are defined by the method or otherwise scientifically justified. Where included, the basis and meaning of the term must be clear to the report user.

MU must be reported for all quantitative results at or above the LOQ, in accordance with the method and NATA accreditation criteria.

Reporting MU

Where measurement uncertainty is reported, it must be expressed in a way that is meaningful and appropriate to the result.

Facilities must ensure that:

- The magnitude of the MU is consistent with the reported result and does not lead to misinterpretation;
- The format of the MU (absolute or relative) is appropriate to the type and scale of the result; and
- The reported MU value reflects any variability related to concentration or level (e.g. by using a function, table, or stated range if applicable).

In cases where different levels of MU apply across the reportable range, the facility must define how MU is selected and applied, and ensure this is reflected clearly in the report.

7.8.5 Reporting sampling - specific requirements

Volume measurement of air

Where a facility is not responsible for the collection of air samples, and/or receives samples from a non-accredited customer where a volume measurement is required, results must be reported as a raw count. The calculation of a concentration cannot be assured because the volume of air collected, and the process of collection, is not covered by the scope of accreditation. This applies to volume measurements made for asbestos testing, mould testing, respirable crystalline silica testing, dust testing and any other testing where air is sampled.

Where a facility is accredited only for volume measurement, the following information must be reported by the entity responsible for the sampling to the facility undertaking the analytical work:

- start and finish times for the pump(s) used to collect the sample(s);
- initial and final flow rates of the pump(s) used to collect the sample(s);
- volume of air sampled;
- measurement uncertainty for the volume of air collected.

Results can only be reported as fibres per millilitre under the following circumstances:

- where the facility is accredited for asbestos fibre concentration and have collected and analysed the samples;
- where the facility is accredited for asbestos fibre concentration and receive the samples from another accredited facility that has collected the samples (these data can be endorsed with a note that the samples were collected by facility XXX);
- where a facility is accredited for asbestos fibre concentration and receives samples from an external party that the facility has supervised. Records of the training and supervision of the external party must be retained.

Where a facility is accredited for asbestos fibre concentration and receives samples collected by an external party with no relationship to the accredited facility, results can only be reported as 'x' fibres per 'y' fields and no reference made to concentration.

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 the 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 TGA 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 (IVDs)*.

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

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 Policy
General Accreditation Criteria	Media Preparation and Quality Control
General Accreditation Criteria	Maintenance of Microbiological Reference Culture Collections (MRCC)
Specific Accreditation Criteria	ISO/IEC 17025 Application Document, Life Sciences - Annex, Facilities using nucleic acid detection techniques (including for genetically modified materials)

Other Publications

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

Amendment Table

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

Section or Clause	Amendment
Whole document	Minor editorial changes.
6.4.4	<u>Kits</u> Added requirement that organisms used for QC should express both positive and negative reactions.
6.4.13	Included the requirement that the identity of the solution or reagent must be recorded.
7.2.1.1	<u>Open scope of accreditation</u> <ul style="list-style-type: none"> Expanded requirements for facilities holding an open scope of accreditation, including the need to maintain and make available records of new analytes added between assessments. Clarified scope limitations, responsibilities for method validation, and eligibility criteria. Strengthened guidance around assessment of competency and possible withdrawal of reports in cases of non-compliance.
7.2.2.1	<ul style="list-style-type: none"> Clarified the parameters to consider when developing and validating test methods. Included specific validation requirements for the use of MALDI-TOF in microorganism identification.
7.3.1	<ul style="list-style-type: none"> Added holding time as an additional consideration to the list under this clause. Added requirement to ensure that sampling of air is done according a sampling plan.
7.4.2	Clarified labelling requirements for sample containers.
7.8.1.2	Expanded the section allowing database matches to include LC-MS.
7.8.2.1	<ul style="list-style-type: none"> Added requirement that reports must include the name of the analyst and person responsible for volume measurement. Clarified restrictions for facilities not accredited for volume measurement.

7.8.3.1	<p><u>Reporting thresholds</u></p> <ul style="list-style-type: none"> Expanded reporting requirements to clarify the use and interpretation of reporting thresholds such as LOD and LOQ. Added criteria for when results below LOQ may be reported and specified that MU must be reported for quantitative results at or above the LOQ. <p><u>Reporting MU</u></p> <ul style="list-style-type: none"> Included criteria for appropriate expression and selection of MU values in reports.
7.8.5	<ul style="list-style-type: none"> Added new section to define specific reporting requirements for facilities involved in air sampling and analysis. Clarified conditions under which results can be reported as fibre concentrations versus raw counts. Included requirements for data to be provided by the sampling party when only analysis is performed.