General Accreditation Criteria

Research and Development

Accreditation Appendix

January 2018

Table of Contents

Section 1: Principles for accreditation in research

The following principles apply across all research streams in the R&D Program. To demonstrate compliance against these principles, an R&D facility is required to adopt a specific code or standard. The code or standard adopted is dependent on the R&D activities performed, for example, ISO/IEC 17025 for testing activities.

Principle 1: Staff

Staff shall be appropriately qualified and trained, and free from pressures that might adversely affect the quality of work.

The organisational structure and related resources and systems shall be such to promote robust and reliable technical performance.

Principle 2: Accommodation and Environment

The accommodation and environment shall allow for the proper conduct of activities.

Principle 3: Processes and Methods

The processes and methods used shall be supported by appropriate control measures.

Principle 4: Equipment

All equipment (including software) shall be maintained to ensure proper functioning.

Principle 5: Records

Systems must be in place for the appropriate capture of information and the security and control of records, data and documents.

Principle 6: Outcomes

The outcomes and conclusions shall be supported by the data generated and be traceable.

Principle 7: Management System

A management system shall be established and implemented to ensure that outcomes are based on good research practices and risk minimisation.

Section 2: Interpretation of codes and standards

This section provides interpretation of the relevant codes or standards applied in the R&D Program to demonstrate compliance with the R&D Principles.

Currently, the only standards that have been used are ISO/IEC 17025 and ISO 15189.

NATA will consider other codes and standards which comply with the principles for accreditation as they become available or following a request from a R&D facility seeking NATA accreditation.

Application Document for research laboratory testing

The clause numbers in this section follow those of ISO/IEC 17025, as this standard has been applied predominantly by research facilities. As not all clauses require interpretation the numbering may not be consecutive.

The CITAC Guide CG2 *Quality Assurance for Research and Development and Non-Routine Analysis (1998)* has been used to guide the following interpretations.

4 Management requirements

4.1 Organisation

The degree of complexity of documentation and the extent to which staff members can hold several functions will depend upon the size of the organisation. Where staff members hold several functions, consideration must be given to defining how impartiality is assured (where there is potential for it to be compromised).

Regardless of the size of the facility, it is important to clearly define the range of responsibilities that each person might hold.

This also applies to student researchers that might be performing work covered by the facility's Scope of Accreditation.

4.2 Management System

Organisations are free to choose their own format and style of collating and presenting policy, procedure and information in documents.

For research staff operating away from the main research facility, it must be ensured that they are kept up-to-date with changes. In particular, it must be ensured that research occurs as intended under the facility's management system.

4.3 Document Control

Documents may take many different forms in the research environment. Examples include but are not limited to:

- laboratory proformas;
- worksheets;
- work instructions;
- methods;
- external standards, codes or guidance documents; and
- notebooks.

4.4 Review of requests, tenders and contracts

In the research setting, this clause includes the review of project planning.

Project plans must be documented and include the objectives, timelines, responsibilities and commitments of all parties involved in the project.

Project plans must be reviewed periodically to determine their ongoing suitability or need for change. All deviations from the original plan must be fully recorded and authorised by the person in charge of the research work. All significant changes to the project plan must be agreed and communicated to the relevant parties.

Project plans must be sufficiently detailed to allow the reconstruction of the project when coupled with all relevant procedures, methods, records and reports.

4.5 Subcontracting of tests and calibrations

Temporary incapacity of equipment resulting in testing being performed on equipment outside the control of the research group and by an operator outside the research group is considered to be subcontracted work.

Subcontracting may cover activities including, but not limited to, referral of testing and statistical analysis.

4.5.4 The accreditation status of subcontractors must be regularly reviewed to ensure currency.

4.6 Purchasing services and supplies

Reagents and materials that are critical to the quality of the research work must be demonstrated to be fit for purpose prior to use.

Procedures for the supply, transportation, receipt, and storage of key reagents and materials must be documented with records of monitoring kept.

4.7 Service to the customer

In the research setting there are a number of different types of customers:

- other departments within the same organisation that lack the specialist skills the work demands;
- external customers who commission specific tasks;
- regulatory bodies which commission the work to help enforce law, regulatory or licensing requirements; and
- funding bodies that commission large work programs within which specific tasks lie.

In the research setting this often ties back to clause 4.4 Review of requests, tenders and contracts.

4.8 Complaints

As a minimum, the complaints procedure must capture complaints from clients, sponsors, funding bodies, participants in research projects and ethics committees where relevant to the research being conducted.

4.9 Control of nonconforming testing and/or calibration work

It is acknowledged that nonconforming testing may be more difficult to identify in a research setting than in a routine testing environment.

It is essential that complete records be kept of the observations and action taken in response to nonconformities. These records are important for evaluating the full significance of discrete or serial nonconformities.

4.11 Corrective action

Where feedback from technical operations or the research management system reveal discrepancies or departures from procedures, timely corrective action must be taken with records kept.

4.12 Preventive action

Preventive action is a proactive process to identify improvement opportunities, rather than a reaction to the identification of problems or complaints.

Consideration should also be given to providing staff with a formal mechanism for contributing suggestions for improvement.

4.13 Control of records

See also section 5.4 for more details on protection of data.

Records must be retained in accordance with the facility's own retention period or to meet contractual or legislative obligations.

There should be a system for recalling and archiving records appropriate to the nature of the record.

4.13.1.3 Records must be retained under secure conditions that minimise deterioration and must be retrievable should reconstruction of any section of the research work be required.

4.13.2.1 In the research setting technical records may include, but are not limited to:

- notebooks;
- worksheets;
- check sheets;
- quality monitoring;
- analyser printouts;
- calibration and equipment check records;
- observations made in the field; and
- sample details.

All results must be recorded including test and control data and statistical tests where relevant to the research being performed.

Records must be sufficiently detailed to enable trackability (traceability) and reconstruction of research activities. They may also be required for regulatory, licensing and legislative purposes.

The person performing each critical stage of testing must be identifiable in the test records.

The date and time of testing, or making an observation, must be recorded when this information is critical for the correct interpretation of results.

Where notebooks are used to capture results it must be ensured that these are retained by the facility.

Data transcriptions and calculations must be checked with a record kept of who made the check and when it was made.

4.13.2.3 Any amendment to data must be made in a way that does not obscure the original entry. Records must indicate who made the change, when it was made and the reason for the change.

5 Technical requirements

5.2 Personnel

All staff, including student researchers, must be trained and deemed competent to perform given tasks. Records reflecting the level of competence achieved in a given task must be kept.

Records for staff, including students who perform work covered by the facility's scope of accreditation, must be kept and reviewed periodically for currency.

As a minimum, records must include:

- qualifications;
- relevant research experience;
- training received in-house; and
- a summary of professional development activities.

The training program must be regularly assessed and adjusted to ensure it continues to be relevant for the area of research being pursued.

5.3 Accommodation and environmental conditions

Management must be aware of the different projects in progress at any given time and the corresponding risks of one project affecting another both from a resource and contamination perspective.

5.4 Test and calibration methods and method validation

5.4.1 General

Where generic practices exist in the research facility, these must be documented and included in the document control system. If generic practices are being refined or adjusted, records of the technical justification for these changes must be kept.

Where an entirely new activity is undertaken, detailed recordkeeping is essential to ensure that the activity can be fully tracked and recreated or further developed if necessary.

5.4.2 Selection of methods

Where a test can be performed by more than one method, there must be documented criteria for method selection. Where relevant, the degree of correlation between the methods must be established and recorded. The method used must be reflected in the research records.

5.4.5 Validation of methods

Where methods already exist, it is expected that validation of these tests would have been completed with validation data reviewed and retained.

Validation is assessed to the extent possible given the stage that the research testing or analysis is at.

5.4.6 Estimation of uncertainty of measurement

Estimation of uncertainty of measurement only applies to quantitative tests.

Estimation of the uncertainty of measurement must be explored to the extent possible and with the degree of rigor appropriate to the given area or stage of research.

5.4.7 Control of data

Where electronic systems including spreadsheets, are used to capture, relay and in some cases perform calculations, it must be established that data moves through each stage of the system securely, as intended and without corruption. Records of performance of such system checks must be kept.

5.5 Equipment

5.5.1 All equipment used for the purpose of research must be demonstrated to be fit for purpose for the period of use in each given research project. This includes equipment that is outside the control of the research group.

5.5.2 Equipment must be subject to initial commissioning and be serviced, maintained, checked and calibrated at defined frequencies with records kept. Where equipment is not in continuous use in a research project, it must be established that it is operating satisfactorily prior to each period of use.

5.5.7 If checks demonstrate that the equipment is not operating as intended, the implication this has to previous research activities must be considered and results withdrawn and/or the work repeated as necessary.

5.7 Sampling

In many research environments samples are tested as received and this clause, therefore, may not be relevant.

In other cases sampling activities may be integral to the research being performed. This demands the development of job-specific sampling plans and/or the use of professional judgement. The sampling strategy should try to anticipate potential problems and if possible make allowances. Where relevant, consideration must be given to sample homogeneity, separation and enrichment. Records must indicate the reasoning behind particular choices.

5.8 Handling of test and calibration items

5.8.1 If the facility is responsible for sample collection, collection and sample transport instructions must be documented. If the facility is not responsible for sample collection, it must have access to collection and transport data, if required.

Sample retention times, retention conditions and safe sample disposal must be established and documented.

5.8.2 Samples must be uniquely identified and labeled at all times.

5.8.3 Any ambiguity in sample labeling or samples that are not optimal must be investigated and resolved with records kept.

5.8.4 Particular caution must be taken in handling and subsequent storage of research samples where there is little knowledge of the sample content.

Where security of samples is required, the conditions must be monitored and recorded.

5.9 Assuring the quality of test and calibration results

Internal measures

Control procedures must be applied to all research work.

Clearly defined procedures for acceptance or rejection of results must be available.

Records must be kept of all control testing including successes and failures.

Where appropriate, control results may need to be statistically analysed and subsequent records kept.

External measures

The facility must make use of external measures of performance that contribute to the validity of the research data.

Where relevant and available, the facility must participate in proficiency testing programs in its area of research. Program results must be reviewed and action taken and recorded if the results indicate performance issues.

5.10 Reporting the results

Research reports can take many different formats and in some cases will include interpretation of the research data. There is no set format for reports however; they must be accurate, clear, unambiguous and objective.

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 ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
AS ISO 15189	Medical laboratories - Requirements for quality and competence

Other references

EURACHEM/CITAC Guide CG2 - Quality Assurance for Research and development and Non-routine Analysis

Guidance documents covering the implementation of specific accreditation requirements are also available from the ILAC (www.ilac.org) and APLAC (www.aplac.org) websites.

Amendment Table

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

Section	Amendment
Entire document	This document replaces the former Research and Development Accreditation Application Document. The document has been renamed to reflect the new accreditation criteria documentation structure.