General Accreditation Criteria

Application Document

Research and Development - Appendix

July 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.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package for Research and Development (refer to NATA Procedures for Accreditation).

ISO/IEC 17025 Application Document for research laboratory testing

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 General requirements

4.1 Impartiality

The extent to which staff members can hold several functions will depend upon the risk to impartiality. Where staff members hold several functions, consideration must be given to defining how impartiality is ensured (where there is potential for it to be compromised).

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

5 Structural requirements

5.4 Research staff operating away from the main research facility must be kept up-to-date with changes, to ensure that research activities occur as intended.

5.5 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.

6 Resource requirements

6.2 Personnel

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

6.2.5 Records for staff must be reviewed periodically for currency.

In addition to the requirements of clause, records must also include:

- relevant research experience;
- professional development activities.

6.6 Externally provided products and services

6.6.2 Products that are critical to the quality of the research work must be demonstrated to be fit for purpose prior to use. This includes human or animal biological material obtained from Biobanks and animals that are used in research activities.

Procedures for the supply, transportation, receipt and storage/housing of these products must be documented with records of monitoring kept.

7 Process requirements

7.1 Review of requests, tenders and contracts

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

- 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;
- funding bodies that commission large work programs within which specific tasks lie.

7.7.1 For research activities, 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 and the required reporting formats.

Where applicable, project plans must include milestones and requirements for the reporting of these milestones.

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

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.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 Where generic practices exist in the research facility, these must be documented.

7.2.1.7 If generic practices are being refined or adjusted, records of the technical justification for these changes must be kept.

7.2.2 Validation of methods

7.2.2.1 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.

7.3 Sampling

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

7.3.1 Where sampling activities are integral to the research being performed, the development of job-specific sampling plans and/or the use of professional judgement are required.

The sampling strategy should try to anticipate potential problems and take these into account when developing the sample plan.

Where relevant, consideration must be given to sample homogeneity, separation and enrichment. Records must indicate the reasoning behind particular choices.

7.5 Technical records

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

The facility must ensure capacity for recalling and archiving records appropriate to the nature of the record.

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;
- 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 traceability and reconstruction of research activities. They may also be required for regulatory, licensing and legislative purposes.

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

7.6 Evaluation of measurement uncertainty

7.6.3 Estimation of measurement uncertainty only applies to quantitative tests.

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

7.7 Ensuring the validity of results

7.7.1 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.

7.7.2 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 (PT) programs relevant to the research activities performed. Program results must be reviewed and action taken and recorded if the results indicate performance issues.

7.8 Reporting the results

7.8.1 General

7.8.1.2 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.

7.9 Complaints

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

7.10 Nonconforming work

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

7.10.2 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.

7.11 Control of data and information management

7.11.3 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.

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

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 15189	Medical laboratories - Requirements for quality and competence

NATA publications

NATA Accreditation Criteria (NAC) package for Research and Development

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.