Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Applicable to all Activities - Annex

Testing in support of research and development

Issued: June 2022

Effective: June 2022

Table of Contents

Purpose

In addition to the *ISO/IEC 17025 Standard Application Document* (SAD), this document provides interpretative criteria and recommendations for testing and/or related activities conducted in support of research and development (R&D) for both applicant and accredited facilities applicable to any activity covered by the scope of accreditation.

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).*

Where a facility wishes to include Good Clinical Laboratory Practice (GCLP) as a capability on their scope of accreditation, the facility must comply with the requirements of the World Health Organization (WHO) Good Clinical Laboratory Practice (GCLP) principles. The WHO document is intended to provide a framework for the analysis of samples from clinical trials on the facilities, systems and procedures that should be present to assure the reliability, quality and integrity of the work and results generated by their contribution to a clinical trial.

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.

Testing in support of Research and Development

Covers testing and/or related activities in support of research and development work, using established or novel techniques. Testing and/or related activities does not cover routine analysis.

Analytical development work includes the following and would be described as such in the facility's NATA scope of accreditation:

- analysis in support of research;
- analysis in support of clinical trials and/or pre-clinical studies;
- analysis in support of the development and/or optimisation of new assays, devices or techniques,
- activities in support of research.

Note: Any testing on human samples 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* (IVDs). It is the facility's responsibility to confirm this with the TGA.

In the case where analytical development work is adopted as routine testing, it would be redescribed in the scope of accreditation as per the relevant "Service" descriptors detailed in the *Specific Accreditation Guidance, Service descriptor* documents.

5 Structural requirements

5.5 Supervisory staff shall be responsible for:

- the development of analytical design plans based on the nature of requests received;
- the development and/or modification of assays, devices or techniques used to meet the intended use of the results;

- the validity of the results, which includes the design of quality control programs;
- the identification of deviations, their significance and resolution.

6 Resource requirements

6.2 Personnel

6.2.3 Personnel must:

- have access to literature resources and demonstrate knowledge of current developments in the techniques used and their application for analytical development work;
- have the necessary scientific expertise and experience to understand the uses and limitations of analytical techniques.

6.2.5 The personnel records must identify the technical breath of their expertise and demonstrate how they maintain currency in knowledge (e.g. advancements in the relevant field).

7 Process Requirements

7.1 Review of requests, tenders and contracts

7.1.1 The objective of the testing required must be clearly defined and agreed upon and may include milestones to be achieved.

7.1.6 Any change to the objective(s) for the testing must be incorporated into the analytical plan and a record of the agreement between the facility and customer maintained.

7.2 Selection, verification and validation of methods

7.2.2 Validation of methods

The facility must have a documented procedure for the development and validation of analytical development work. It is acknowledged that the procedure may be generic in nature, in order to be amenable to individual customer requests.

The procedure may consist of a decision tree, flow chart, diagram or other format identifying each step that needs to be undertaken or considered. In addition to a description of the steps involved in the analyses, as a minimum the documentation must include, where appropriate:

- description of the sample/item to be tested;
- sample preparation;
- parameters or quantities to be considered;
- description of the analytical process(es);
- a discussion of precautions, possible sources of error or limitations;
- quality control measures or other applicable measures to ensure the validity of results;
- criteria for the rejection of suspect results;
- data/observations to be recorded;
- literature references.

7.2.2.4 Records of validation must be available to reflect the work undertaken.

7.4 Handling of test or calibration items

7.4.1 Where possible, as much of the original sample(s) must be retained for reanalysis (if required) and arrangements for the retention, disposal or return of the sample(s) must be clearly defined and agreed upon with the customer.

7.4.2 Where the identity of the sample(s) is 'blinded' to ensure the objectivity of the testing, a code that enables unambiguous traceability to the source of the sample(s) must be provided by the customer.

7.5 Technical records

7.5.2 Any alteration to data must also include the reason for the change.

7.6 Evaluation of measurement uncertainty

7.6.3 Measurement Uncertainty (MU) associated with the measurand must be estimated to the extent possible and with the degree of rigour appropriate to the given area or stage of development.

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.

7.7 Ensuring the validity of results

7.7.1 It is acknowledged that suitable samples for "traditional" quality control purposes may not be available for tests under development. In such cases, the facility must identify other appropriate means for monitoring the reliability of results.

The main emphasis of quality control for testing under development should be directed towards ensuring instrumentation is calibrated and/or checked, using reference materials (where available) and replicate analysis.

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

7.7.2 It is unlikely that formal proficiency testing programs will be available for analytical development work. However, this should not preclude the facility from giving due consideration to any available external measures, including collaboration with other facilities, to monitor performance of its activities.

7.8 Reporting the results

7.8.1 General

7.8.1.2 Reporting requirements must be clearly defined and agreed upon with the customer.

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

NATA Accreditation Criteria (NAC) package applicable to the activities covered, or proposed to be covered, by the facility's scope of accreditation

NATA Procedures for Accreditation

Specific Accreditation Guidance relevant *Service descriptor* document

Other Publications

World Health Organization (WHO) *Good Clinical Laboratory Practice (GCLP)*

Amendment Table

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

Section or Clause	Amendment
7.5	Inclusion of heading.
Whole document	Added Security Classification Label