# Specific Accreditation Criteria

## ISO/IEC 17025 Application Document

## Life Sciences - Annex

## Investigative testing using chemical techniques

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# Table of Contents

# Purpose

In addition to the *ISO/IEC 17025 Standard Application Document* (SAD) and the accompanying *Life Sciences - Appendix*, this document provides interpretative criteria and recommendations for investigative testing using chemical techniques for both applicant and accredited facilities.

Investigative testing covers “non-routine” work (e.g. testing of unknowns, product de-formulation, the analysis of a failed part or product, etc.). It involves the use of established techniques; however, the application of these techniques is not pre-assigned.

The assessment of investigative testing focusses on:

- the management of the facility;
- the qualifications, experience and training of personnel involved in investigative testing;
- the systems in place for the validation or verification of new or modified test methods;
- the procedures, together with the equipment used, for performing investigative testing;
- the records and outcomes supporting the testing.

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.

# 6 Resource requirements

## 6.2 Personnel

**6.2.3** Personnel must be competent to understand and evaluate the nature of requests for investigations and develop an appropriate testing plan.

**6.2.5** The personnel records maintained shall identify the technical scope of their areas of responsibilities.

**6.2.6** Authorisation of personnel must include those able to supervise investigative testing. Specifically, supervisory personnel shall:

- have the necessary scientific expertise and experience to understand the:
  - uses and limitations of the instrumental techniques, including the various types of equipment, detectors, etc.;
  - methods and procedures used and their selection;
  - interpretation of results.
- have access to current literature and maintain an up-to-date knowledge of recent developments in the techniques and how they are applied to relevant matrices;
- demonstrate experience in method validation for the techniques involved;
- be responsible for the testing, including testing performed by other personnel working under their direction.

# 7 Process Requirements

## 7.1 Review of requests, tenders and contracts

**7.1.1** For investigative testing, the analyses required will be dependent on the customer's needs. Discussion at the request stage will often be more in depth than is the case for routine testing. It may be that the customer will be dependent on the facility's technical expertise to determine a suitable investigate testing plan.

The objective of the investigation required shall be agreed upon and clearly defined, which may include milestones to achieve.

**7.1.6** Any change to the objective of the investigation must be incorporated into the testing plan and a record of agreement between facility and customer maintained.

## 7.2 Selection, verification and validation of methods

### 7.2.1 Selection and verification of methods

**7.2.1.2** It is acknowledged that the procedure for investigative testing may be generic in nature, in order to be amenable to individual customer requests.

The procedure may consist of a decision tree, flow chart or other diagram identifying each step that may need to be undertaken or considered to determine (e.g. the identity of an unknown sample, product de-formulation, the analysis of a failed part or product, etc. including reference to the associated testing procedures). In addition to a description of the steps involved in the analyses, documentation must include, where appropriate:

- description of the sample / item to be tested;
- parameters or quantities to be considered;
- descriptions of sample preparation, controls, standards, calibration procedures and methods of analyses;
- a discussion of precautions, possible sources of error or limitations;
- quality control measures applicable or other measures to ensure the validity of results;
- criteria for the rejection of suspect results;
- data / observations to be recorded;
- literature references.

### 7.2.2 Validation of methods

**7.2.2.1** Facilities must be able to retrospectively demonstrate that the processes adopted have been validated or verified prior to the results being issued.

Records maintained must demonstrate the validity of results for a new determinant or a newly encountered matrix.

## 7.4 Handling of test or calibration items

**7.4.1** Where possible, as much of the original sample must be retained for reanalysis (if required).

## 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** Where quantitative results are generated, measurement uncertainty must take into account the product(s) and technique used.

## 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 investigative testing. In such cases, the facility shall identify, where possible, other suitable means for monitoring the reliability of results.

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

# 8 Management system requirements

## 8.1 Options

### 8.1.1 General

The facility’s investigative testing procedures, together with selected investigations, shall be included in the internal audit schedule.

# 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

# Amendment Table

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

| Section or Clause | Amendment |
|---|---|
| 6.2.3 | Clarification of competency requirements for personnel. |
| 6.2.6 | Revision of requirements for supervisory personnel. |
| 6.4 | Deletion of requirements pertaining to equipment. |
| 7.1.1 | Clarification of requirements for review of requests, tenders and contracts. |
| 7.6.3 | Inclusion of requirements pertaining to measurement uncertainty. |
| 7.8.1.2 | Deletion of requirements pertaining to reporting of results. |
| Whole document | Editorially updated including deletion of requirements already specified in the NATA Standard Application Document (SAD) and/or the Life Sciences Appendix. |