Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Life Sciences - Annex

Investigative testing using chemical techniques

July 2018

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Investigative testing using chemical techniques

This document provides additional interpretative criteria and recommendations for the application of ISO/IEC 17025 for both applicant and accredited facilities conducting investigative testing using chemical techniques.

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 but since not all clauses require interpretation the numbering may not be consecutive.

Introduction

The addition of investigative testing under the scope of accreditation recognises a facility's ability to perform various "investigations" using its technical capabilities.

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.

Assessment process

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.

6 Resource requirements

6.2 Personnel

6.2.3 Management is responsible for ensuring staff have the resources to maintain the necessary professional skills by providing the opportunity for continuing education (either in-house training or through external courses, seminars, etc.) and by enabling access to appropriate reference texts and journals.

6.2.5 The facility shall maintain records of staff who have been deemed competent to supervise and/or perform investigative testing including the technical scope of their areas of responsibilities.

6.2.6 The facility management shall appoint personnel with the responsibility to supervise investigative testing work. Such personnel shall have the necessary scientific expertise and experience to understand the uses and limitations of the instruments, methods and procedures used.

Specifically, such supervisory personnel shall:

- be responsible for the testing being performed, either directly by them, or by other staff working under their direction;
- exercise a high level of judgement about how to approach analyses, about the selection of best methods and about interpretation of results;
- demonstrate experience in the instrumental technique(s) or in the non-instrumental classical analytical techniques (as appropriate) required to carry out the investigative testing;
- be familiar with all aspects of the instrumental or non-instrumental techniques (as appropriate) including various types of equipment, detectors, etc.;
- 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 (preferably in accordance with the facility's own procedures for validation).

Supervisory personnel may also need to have experience in literature searching and other information gathering techniques in order to resolve issues.

7 Process Requirements

7.1 Review of requests, tenders and contracts

7.1.1 Before accepting a request for investigative testing the facility must consider whether the proposed work is within its technical capabilities taking into account the instrumentation necessary and the expertise of staff available.

For investigative testing, determination of the analyses required is dependent on the customer's needs. This will often require more in depth discussions with the customer than is the case for routine testing. The objective of the investigation required shall be agreed upon and clearly defined.

Note: The customer may only have a vague idea of what analyses are required and accordingly will rely on the facility's technical expertise to determine a suitable investigative testing plan.

7.1.6 The objective of the investigation, as defined at the time the facility accepts the work, may change during the course of the investigation. Any change to the objective of the investigation must be incorporated into the testing plan.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.2 A procedure describing the approach to be taken for conducting investigative testing must be documented. It is acknowledged that such a procedure may be generic

in nature which is amenable to individual customer requests. The procedure may consist of a decision tree, flow chart or other diagrams stipulating each step that may need to be undertaken/considered to determine, for example, the identity of the 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 of methods and procedures must include, where appropriate:

- description of the sample/item to be tested;
- parameters or quantities to be considered;
- descriptions of sample preparation methods, controls, standards, calibration procedures and methods of analyses;
- a discussion of precautions, possible sources of error or limitations of the procedure;
- 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 demonstrate retrospectively that the methods used have been through the internal development and validation or verification protocol prior to the results being issued. Accordingly, a facility must have fully documented procedures for assuring the validity of results reported for the first time a test is performed for a new determinant or on a newly encountered matrix.

7.4 Handling of test or calibration items

7.4.1 When destructive tests are necessary, the facility must retain, where possible, the original sample for reanalysis (if required).

7.5 Technical records

7.5.2 Alterations to data must also include the reason for the change.

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 checked/calibrated and working properly, monitoring values from reference materials (where available) and replicate analysis.

7.8 Reporting of results

7.8.1 General

7.8.1.2 The results and conclusions of an investigation shall be relevant to the objective originally agreed with the customer.

8 Management system requirements

8.1 Options

8.1.1 General

Regardless of whether Option A or B is adopted, the critical phases of 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
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.