Specific Accreditation Criteria
Life Sciences ISO/IEC 17025 Annex

Investigative Testing using chemical techniques

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This document provides additional interpretative criteria and recommendations for the application of ISO/IEC 17025 in the Life Sciences sector for both applicant and accredited facilities conducting Investigative Testing using chemical techniques.

Applicant and accredited facilities must also comply with ISO/IEC 17025, the NATA ISO/IEC 17025 Standard Application Document (SAD) and the Life Sciences ISO/IEC 17025 Appendix. 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 recognises a facility's ability to perform "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 is directed, in particular, towards:

- 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.

In addition to the Life Sciences ISO/IEC 17025 Appendix and all relevant clauses of ISO/IEC 17025:2005, facilities will need to comply with the criteria outlined below.

Criteria

The clause numbers follow those of ISO/IEC 17025 but since not all clause numbers require interpretation the numbering system may not be consecutive.

4 Management Requirements

4.4 Review of requests, tenders and contracts

4.4.1 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.

4.4.5 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.

4.13 Control of records

4.13.2.3 Any significant alterations to data must also include the reason for the change.

4.14 Internal audits

Critical phases of the facility's investigative testing procedures, together with selected investigations, shall be included in the facility's internal audit schedule.

5 Technical Requirements

5.2 Personnel

5.2.1 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.

5.2.2 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.

5.2.5 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.

5.4 Test and calibration methods and method validation

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.

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.

5.4.6 An estimation of the uncertainty of measurement shall be applied to all quantitative investigative chemistry work undertaken. However, a rigorous evaluation of the measurement uncertainty may not be possible at all times in which case more emphasis is placed on professional judgement to obtain a reasonable estimate.

5.8 Handling of test and calibration items

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

5.9 Assuring the quality of test and calibration results

Quality Control

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.

5.10 Reporting the results

Test documents reporting the results of investigative chemistry work may include opinions and interpretations.

Where opinions and interpretations have been formed from testing not covered by the scope of accreditation of the facility (or a subcontracted facility) then this must be clearly identified in the report to the customer.

The conclusion of an investigation shall be relevant to the objective originally agreed with the customer.

References

NATA Publications

Life Sciences ISO IEC 17025 Appendix

Amendment Table

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

Section or Clause	Amendment
New document	This document represents a direct adoption of the former Chemical Testing Annex M. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.