



IMPLEMENTATION OF ISO/IEC 17025

The general requirements for the competence of testing and calibration laboratories are now described by in ISO/IEC 17025: 1999 General requirements for the competence of testing and calibration laboratories. These requirements are designed to apply to all types of testing and calibration and therefore will often need to be interpreted with respect to the type of calibration or testing concerned, and the techniques involved.

WHAT IS THE NEW STANDARD ALL ABOUT

There are five parts in the new Standard. Only the Introduction, Scope and parts 4 Management requirements and 5 Technical requirements will be discussed here. Commentary is only provided for clauses where this is considered necessary to assist accredited laboratories with the implementation of the new Standard, therefore numbering is not continuous. The clauses, or part thereof, in bold font represent new requirements or additional emphasis with the introduction of ISO/IEC 17025.

ISO/IEC 17025 makes frequent reference to the need for “policies and procedures” in relation to certain clauses and sub-clauses. It may be possible for only one document, that is a policy or a procedure, to meet the requirements of the Standard.

Introduction and Scope

ISO/IEC 17025 incorporates the management system requirements of the ISO 9000 series. Laboratories accredited against ISO/IEC 17025 may therefore state that they operate in accordance with either ISO 9001: 1994 or ISO 9002: 1994.

Clause 1.6 of the Scope explains that laboratories may claim operation to ISO 9001: 1994 if they design/develop new methods and/or develop test programs that combine standard and non-standard test and calibration methods.

Management requirements

4.1 Organization - Sub-clause 4.1.3 requires that the scope of the management system cover activities in the laboratory’s permanent facilities, **sites away from its permanent facilities, and temporary or mobile facilities.**

Sub-clause 4.1.4 requires that when the laboratory is part of a larger organization and provides a testing service to that organization, the laboratory must define the responsibilities of key personnel **to identify conflicts of interest and defined action to be taken by staff.** This requirement is reiterated in sub-clause 4.5 with the need for laboratories to have **policies and procedures to avoid involvement in activities that compromise the confidence in its competence, impartiality, judgement or operational integrity**

4.2 Quality system -This clause gives specific direction on what must be in a quality policy statement. Laboratories should therefore review their existing policy statements to ensure all specified areas are covered; the quality policy statement must be issued under the authority of the chief executive and include:

1. Laboratory management’s commitment to good professional practice and quality of its service
2. Statement of the laboratory’s standard of service
3. Objectives of the quality system
4. Requirement for all personnel to be familiar with & implement the quality documentation
5. Laboratory management’s commitment to compliance with ISO/IEC 17025

4.3 Document control

This is one section in which ISO 9000 requirements previously missing from ISO/IEC Guide 25 have been incorporated into the new Standard. The Standard therefore provides very specific direction on how document control is to be demonstrated:

Documents are reviewed and approved by authorized personnel prior to issue, and are included on a master list which identifies the revision status and distribution

All necessary quality documentation is available where required, reviewed and revised to maintain suitability

Documents are removed where obsolete and suitably marked if retained for their legal or knowledge preservation purposes

Quality system documents must be uniquely identified and include:

- a. Date of issue and/or revision identification**
- b. Total number of pages or a mark to signify the end of the document**
- c. Issuing authority**

4.4 Review of RFP, RFQ and contracts

There are some major additions here to bring the Standard into line with ISO 9000: 1994. This activity now has a higher profile and is more prescriptive:

- 1. Policies and procedures related to review of RFP, RFQ and contracts are established, maintained and include:
 - a. Defining, documenting and understanding client requirements before commencing work**
 - b. Laboratory's capabilities and resources**
 - c. Appropriate method selection****
- 2. Maintain records of reviews, including any significant discussions and/or changes throughout the contract**
- 3. Policies and procedures related to review of subcontracted work are established, maintained**
- 4. Client is informed of any deviation from the contract**
- 5. Ensure records are maintained of subcontractors used and their competency**

4.5 Subcontracting of tests and calibrations -A competent subcontractor is defined as an appropriately accredited laboratory or a laboratory accredited by a mutually recognized partner. All results reported by the subcontractor shall be covered by an appropriate endorsed report:

- 1. Some contract review process is repeated if a contract has to be amended after work has commenced and that all affected staff are advised of the amendment**
- 2. Ensure that subcontractors are competent**
- 3. Ensure that client is advised in writing and approval gained where appropriate**
- 4. Unless client or regulatory authority specifies subcontractor, laboratory is responsible for the subcontractors' work**

4.6 Purchasing services and supplies -The Standard is prescriptive with regard to requirements for policy/procedure and records. Laboratories must maintain a list and records of the **evaluations** of all approved suppliers.

Sub-clause 4.6.3 refers to a "Purchasing Document". Laboratories should **ensure purchasing documents for items affecting quality of work are reviewed and approved for technical content prior to release.**

4.7 Services to the client -This is a new requirement, but the Standard does not specify that a policy or procedure must be in place: Afford clients cooperation to clarify requests and monitor laboratory's performance whilst ensuring confidentiality to other clients. To demonstrate that this clause has been given consideration, some statement about the laboratory's policy on this matter should be incorporated.

4.9 Control of nonconforming testing and/or calibration work

There are some major new areas under this clause and reflect the compliance with the ISO 9000:1994 series. There are specific requirements for dealing with non-conforming testing/calibrations/results and reference to the need for immediate corrective action in such cases:

1. **Ensure policy and procedures are implemented when work or results do not conform to own procedures or client requirements and include:**
 1. **Defined responsibilities, authorities and actions**
 2. **Evaluation of the significance of the nonconforming work**
 3. **Corrective actions and decisions re acceptability of nonconforming work to be taken immediately**
 4. **Notification of client and work recall, if necessary**
 5. **Defined responsibility for authorising the resumption of work**
2. **Corrective action procedures (4.10) must be implemented when evaluation indicates recurrence could occur or there is doubt regarding compliance of laboratory's operations with their own policies & procedures**

4.10 Corrective action -This clause is new but the idea is not and should therefore already be part of a laboratory's quality system. There are specific procedures defined for cause analysis, selection and implementation of corrective action, subsequent monitoring and follow-up audits:

Establish policy and procedures, and designated appropriate authorities for implementing corrective actions that include:

1. **Cause analysis to determine root cause(s) (4.10.2)**
2. **Selection, implementation and documentation of corrective actions (4.10.3):**
 - **Appropriate to the magnitude and risk of the problem**
 - **Documentation and implementation of changes**
3. **Monitor results to ensure effectiveness of corrective actions (4.10.4)**
4. **Areas affected must be audited (4.13) if nonconformance indicated laboratory not complying with own quality system**

4.11 Preventive action -This clause is a new requirement:

Ensure needed improvements and potential sources of nonconformances are identified and action plans developed, implemented and monitored, using controls to ensure they are effective

4.12 Control of records -This clause is specific in regard to the requirements for retention of both technical and quality records; establish and maintain procedures covering aspects listed below for control of **quality** and technical records:

1. Identification
2. Collection
3. Indexing
4. Accessing
5. Filing
6. Storage
7. Maintenance
8. Disposal
9. Protect, back-up and prevent unauthorised access to or amendment of records stored electronically (4.12.1.4)

4.14 Management reviews -The Standard provides specific guidance on what is to be covered under management review:

Ensure laboratory's management conducts a review yearly of the quality system and testing/calibration activities, based on a predetermined schedule and procedure to ensure continuing suitability and effectiveness and to introduce changes or improvements. Ensure review includes:

1. Suitability of policies and procedures

2. Reports from managerial and supervisory personnel
3. Outcome of recent audits
4. Corrective and preventative actions
5. Assessments by external bodies
6. Results of interlaboratory comparisons or proficiency tests
7. Changes in the volume and type of work
8. Client feedback
9. Complaints
10. Quality control activities
11. Staff training
12. Resources
13. Suppliers & subcontractors
14. Housekeeping & safety

5.2 Personnel –

Sub-clause 5.2.2 requires that **policy and procedures must be implemented for identifying training needs and providing training.**

Sub-clause 5.2.3 requires that the laboratory **ensure personnel are employed or contracted and ensure contracted personnel are supervised, competent and work in accordance with the quality system**

Sub-clause 5.2.5 requires that management has **authorized** specific personnel to:

1. Perform specific sampling, testing and/or calibration activities
2. Issue test reports and/or calibration certificates and that NATA signatory approval has been taken into consideration
3. Operate particular types of equipment

And that records for all technical personnel (including **contracted personnel**) are maintained for:

1. **Relevant authorization(s) including date on which authorization and/or competence is confirmed**
2. Competence
3. Educational and professional qualifications
4. Training, skills and experience

5.4 Test and calibration methods and method validation

Sub-clause 5.4.1 is prescriptive in relation to the need for the **client to accept any method deviations**. The spirit of the sub-clause should be followed, therefore the client must be kept informed of method deviations and good business practice dictates that a record of discussions with clients should be kept.

5.4.2 Selection of methods

This sub-clause continues the requirement of consultation with the client although the “needs of the client” could conflict, in some cases, with what the laboratory considers ethical practice. This sub-clause has a direct connection with sub-clause 4.4 RFP, RFQ and contracts.

The clause requires that the laboratory selects and uses tests and/or calibration methods that:

1. Meet the needs of the client
2. Appropriate for test and/or calibration
3. Client must be informed of method chosen if not specified
4. Where appropriate, are based on latest international, regional or national standard and **where necessary the standard be supplemented with additional details to ensure consistent approach**
5. **Verified for use in laboratory, if a standard method**

And that the laboratory informs the client if the method proposed by the client is inappropriate or out of date

5.4.5 Validation of methods

Although non-standard methods always required validation, most re-assessments did not involve assessment of original validation data. Under the new standard

Laboratory must validate:

1. **Non-standard methods**
2. **Laboratory designed/developed methods**
3. **Standard methods used outside their intended scope**
4. **Amplifications and modifications of standard methods**

Records for method validation must include:

1. **Results obtained**
2. **Procedure used**
3. **Statement as to whether the method is fit for intended use**

The laboratory must ensure the range and accuracy of the values obtainable from validated methods are relevant to the clients' needs.

5.4.6 Estimation of uncertainty of measurement -The Standard places greater emphasis on this area than previously.

Sub-clause 5.4.6.1 requires calibration laboratories or **testing laboratories performing their own calibrations** must have and implement procedures for estimating the uncertainty of measurement for all calibrations.

Sub-clause 5.4.6.2 requires that **testing laboratories must document and implement procedures for estimating uncertainty of measurement**. There is however recognition that "rigorous, metrologically and statistically valid calculations" of measurement uncertainty may not be possible, although a reasonable estimate must still be attempted.

The Standard also recognizes laboratories that **exactly follow** a "well-recognized test method which specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results" as having met the intent of the Standard. Currently, such cases will be deemed to have met the Standard.

5.4.7 Control of data

The need to **sufficiently document and validate software developed by the user** is a new requirement and evidence of this evaluation is required.

5.5 Equipment

The laboratory must ensure records of equipment and its software and maintained and include:

1. Identity of the equipment and its software
2. Manufacturer's name, model, and serial number or other unique identification
3. **Evidence that the equipment complies with the accuracy requirements and with specifications relevant to the tests and calibrations**
4. Current location, where appropriate
5. The manufacturer's instructions, if available, or reference to their location
6. Calibration history + next calibration date
7. The maintenance plan, where appropriate, and maintenance carried out to date
8. Any damage, malfunction, modification or repair to the equipment

The laboratory must ensure procedures for measuring equipment are documented and include:

1. Safe handling

2. Transport
3. Storage
4. Use
5. Planned maintenance
6. **Where applicable, that copies of correction factors are correctly updated**

The laboratory must ensure when equipment goes outside the direct of the laboratory, that the function and calibration status are checked before returning to service

The laboratory must ensure equipment, both hardware and software, is safeguarded from adjustments that could invalidate the test/calibration results

5.6 Measurement traceability -Laboratories must ensure the program for calibration of equipment is designed and operated so that measurements are traceable to SI units, where traceability cannot be strictly made to SUI units, traceability can be established by use of:

1. Certified reference materials
2. Specified methods and/or consensus standards that are clearly described and agreed by all parties concerned
3. Participation in suitable inter-laboratory comparisons is required where possible

Traceability to the International System of Units (SI) is possible and desirable in some areas and not in others.

5.6.3 Reference standards and reference materials

Reference standards and reference materials provide the key of traceability in laboratories, therefore laboratories should wherever possible use reference materials and reference standards in the testing process.

5.7 Sampling

This is an important new area of the Standard. Where methods or specifications do not specify sampling procedures, laboratories will be required to:

1. **Ensure procedures for sampling are available at the sampling location and include:**
 - a. **A sampling plan (based on appropriate statistical methods, wherever reasonable)**
 - b. **Factors to be controlled to ensure validity of the test/calibration results**
2. **Ensure client-requested deviations, additions or exclusions from the documented sampling procedures are recorded and communicated to the appropriate personnel**
3. Ensure laboratory has procedures for recoding sampling data and operations and that records include:
 - a. Sampling procedure used
 - b. Identification of the sampler
 - c. Environmental conditions (if relevant)
 - d. **Diagrams (or equivalent) to identify sampling location**
 - e. **Statistics that sampling procedure is based on, if appropriate**