ISO/IEC 17025

Requirements Document

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Introduction

- ISO/IEC 17025 is the international standard that sets out the general requirements for the competent, impartial, and consistent operation of laboratories. It specifies the activities that must be included in laboratory operations to promote confidence in its ability to produce valid and consistently reliable testing, calibration, and sampling results.
- ISO/IEC 17025:2017 is the current, revised standard. The standard was published with collaboration between the International Organization for Standardization (ISO) and the International Electro technical Commission (IEC).

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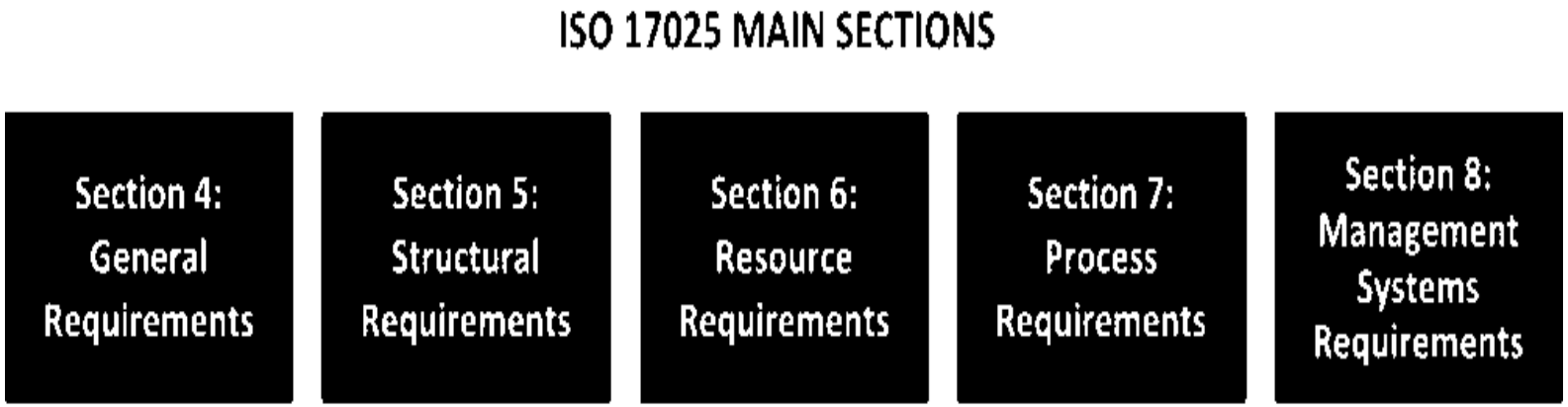
What does ISO/IEC 17025:2017 look like?

- The ISO/IEC 17025:2017 structure is divided into five main sections that contain the requirements for laboratory accreditation.



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Clause 4:

General Requirements are broken down into 2 sub-clauses

- Impartiality
- Confidentiality

4.1 Impartiality

Impartiality is a major clause in ISO/IEC 17025. This clause addresses the risks associated with creating biased results. Under no circumstance is the lab allowed to let conflict of interest impact its results, and the lab must be committed to risk-based thinking when addressing impartiality. In essence, there must not be any conflict of interest regarding the following:

- commercial interest
- financial interest
- relationship interest

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And the laboratory must identify risks to impartiality from:

- activities
- relationships
- personal relationships

The lab must identify any risks to impartiality on an ongoing basis. If a risk or impartiality is identified, the lab must take corrective action and demonstrate how it has eliminated or minimized the risk.

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4.2 Confidentiality

Clause 4.2 of ISO/IEC 17025:2017 discusses the requirements involving confidentiality. The lab is responsible for the management of all information obtained or created during laboratory activities and is held responsible by legal enforcement. The standard requires that the lab must inform its customer in advance of what information it intends to share with the public. Furthermore, it addresses actions it will take if confidential information is released into the public. In general, the laboratory and its personnel are responsible for the information obtained or created during the performance of laboratory activities, and all information is considered proprietary information and shall be regarded as confidential, with exception to what is required by law.

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Clause 5 identifies the structural requirements.

To become ISO/IEC 17025:2017 accredited, the laboratory must define and document the following about the laboratory operations:

- The organizational structure
- The management with responsibility
- The responsibility of the laboratory personnel
- The activities of the laboratory

The laboratory will need to have personnel authorized to ensure that regular communication takes place regarding:

- Implementation and improvement of the management system
- The effectiveness of the management system
- The importance of meeting customer as well as regulatory requirements

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The laboratory is required to document its procedures in order to produce consistency of its activities and to ensure that the results are valid. Typically, the laboratory's processes are documented with a quality manual, standard operating procedures and/or work instructions. The new standard has clearly identified the requirement that the lab must only claim conformity with ISO 17025:2017 standard for this range of laboratory activities. This excludes externally provided laboratory activities on an ongoing basis. Meaning, the lab is expected to be accredited and must include in its scope of accreditation only testing/calibration/sampling activities that are utilizing its own resources. This standard states that the lab can only be accredited for the laboratory activities for which it is competent.

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Clause 6
- Resource Requirements is broken down into six sub-clauses:

- 6.1 General
- 6.2 Personnel
- 6.3 Facilities and environment
- 6.4 Equipment
- 6.5 Metrological Traceable
- 6.6 Externally provided services

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6.1 General Resource Requirements

- Resource requirements encompass personnel, facilities, equipment, systems and support services. The 17025 standard requires all internal and external personnel of the laboratory to be competent and have an impartial stance. This includes personnel who are directly involved in testing/calibration/sampling activities, and also personnel who is indirectly involved, like technical personnel.

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6.2 Personnel

To be an ISO/IEC 17025 accredited lab, all personnel of the laboratory, both internal (i.e., employees) or external (i.e., contractors), must be competent and work within the structure of the laboratory's management system.

Proper documentation is required for each job function of the laboratory. This includes job descriptions and detail competence, training, supervision, and authorization of laboratory personnel.

Laboratory management shall communicate the duties, responsibilities and authorities to laboratory personnel through regular meetings or personnel performance reviews.

Management are required to communicate to personnel their duties, responsibilities and what work they are authorized to perform. In addition, the lab must have procedures and retain records for:

- determining the competency requirements
- supervision of personnel
- authorization of personnel

Management should also authorize personnel for:

- Development, modification, verification, and validation of methods
- Analysis of results
- Reports, reviews and authorization of results

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6.3 Facilities and Environmental Conditions

The laboratory needs to be suitable to perform all activities and not affect the validity of the results. As a laboratory the conditions must be:

- Controlled
- Monitored
- Recorded

The Lab must control the environment of its testing facilities to ensure that they do not compromise the results. Environmental conditions that could impact your lab include:

- Dust
- Humidity
- Electrical supply
- Temperature
- Vibration, etc.

Laboratory activity areas must be:

- Defined
- Controlled
- Separated from areas with incompatible laboratory activities to prevent contamination or interference of the activities.

If any activities are performed offsite, the laboratory needs to ensure that all of the environmental conditions defined in this standard are met.

6.4 Equipment

The laboratory shall have access to the proper equipment required for the performance of laboratory activities.

A documented calibration program will need to be established that includes:

- Records for all equipment which can influence laboratory activities, including the handling, transport, storage, use and maintenance of equipment
- Identification of calibration status, including non-calibrated and out of service equipment
- Tamper resistance program to safeguard unauthorized adjustments that would invalidate the calibration status of the equipment.

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6.5 Metrological Traceability

Laboratories must establish and maintain metrological traceability of their measurement results using a documented unbroken chain of calibrations, each contributing to measurement uncertainty and linking them to an appropriate reference. Laboratories must provide objective evidence.

The measurement results need to be traceable to the International System of Units (SI) in one of these three ways:

- Calibration provided by a competent laboratory
- Use of certified reference materials provided by a competent producer with stated metrological traceability to the SI

If the measurement cannot be traceable to the SI, the laboratory must demonstrate metrological traceability to an appropriate reference.

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6.6 Externally Provided Products and Services

ISO/IEC 17025 laboratories need to ensure that only satisfactory/competent externally provided products and services that may or do impact the laboratory's activities are used when products and services are:

- intended for incorporation into the laboratory's own activities
- are provided directly to the customer by the laboratory, as received from the external provider
- are used to support the operation of the laboratory

As defined, the laboratory must have a procedure and maintain records for:

- Defining, reviewing and approving requirements for externally provided products and services
- Defining the basis for evaluation, selection, monitoring of performance and re-evaluation of the external providers
- Ensuring that externally provided products and services meet the lab's requirements
- Actions arising from evaluations, monitoring or performance of external providers

The laboratory must also communicate requirements to external providers including:

- Acceptance criteria
- Competence, including any required qualification of personnel
- Activities that the lab, or its customer, interns to perform at the external provider's premises

Clause 7
- Process Requirements is broken down into 11sub-clauses:

- Review of requests, tenders and contracts
- Selection, verification and validation of methods
- Sampling
- Handling of Test and Calibration items
- Technical records
- Evaluation of Measurement of Uncertainty
- Ensuring Validity of results
- Reporting of results
- Complaints
- Non conforming work
- Control of data and information management

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7.1 Review of Requests, Tenders and Contracts

ISO 17025, requirement 7.1 states that the laboratory must have a procedure for the review of requests, tenders, and contracts. This procedure must ensure that:

- The requirements are defined, documented and comprehended
- The lab has the capability and resources to meet the requirements
- If external providers are used, the lab must meet requirements of clause 6.6
- The suitable methods or procedures are selected and capable of meeting the customer's requirements

The laboratory needs to have good communication with the customer. Also, the lab must ensure that the customer's needs are met, but also inform the customer if their methods are inappropriate or out of date, or if their request cannot be completed because it would compromise the integrity of the lab.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and verification of methods

The laboratory is required to use appropriate methods and procedures for activities, and when necessary, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. Methods, procedures and supporting documentation need to be kept up to date and made available.

In addition, ISO 17025:2017 mandates that the lab stays up-to-date with methods as appropriate and when the customers do not specify a method; the lab selects the best and latest valid version. The lab must communicate what method they are using with the customer.

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When choosing a method, the lab needs to verify that this method has been published internationally, regionally, or nationally, or by another reputable technical organization. Scientific journals and texts are also valid publications. The lab must verify that it can perform the methods that they select.

Another requirement of ISO 17025 Section 7.2 is that lab needs to retain records of verification and validation. Additionally, when method development is required, the development needs to be planned and assigned to competent personnel. Periodic reviews need to take place for method developments.

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7.2.2 Validation of Methods

ISO/IEC 17025 requires laboratories to validate methods that they use. This includes non-standard methods, laboratory-developed methods and standard methods. The validation of the methods needs to be as extensive as necessary to meet the needs of the given application. If changes are made to a validated method, the influence of the changes needs to be understood.

The laboratory retains the following records of validation:

- The validation of the procedure used
- Specification of the requirements
- Determination of the performance characteristics of the method
- Results obtained
- A statement on the validity of the method

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7.3 Sampling

ISO / IEC 17025:2017 requires all laboratories to have a sampling plan and method when carrying out sampling of substances, materials or products for subsequence testing or calibration. The laboratory must determine if the sampling methods address the factors to be controlled to ensure the validity of subsequent testing, and ensure that the sampling plan and method is available at the site where sampling is undertaken. Sampling needs to use appropriate statistical methods.

Sampling methods must describe:

- The selection of samples or sites
- The sampling plan
- The preparation and treatment of samples

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When the laboratory is sampling, they must retain appropriate records of samples. These records must include, when appropriate:

- References to the sampling method
- Date and time of sampling
- Data to identify and describe the sample
- Personnel performing the sample
- Environmental or transportation conditions
- Diagrams or other equivalent means to identify the sampling location
- Deviations, additions or exclusions from the sampling method and sampling plan

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7.4 Handling of Test and Calibration Items

The laboratory must have a procedure for transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items. This includes all provisions necessary to protect the integrity of the test or calibration item, and to protect the integrity of the test or calibration item, and the interest of the lab and customer. The lab must take precautions to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing and preparation for testing or calibration.

In addition the laboratory must:

- Establish handling instructions
- Have a system for the unambiguous identification of test or calibration items
- Retain identification while the lab is responsible for the item
- Ensure that items do not get confused
- Record any deviations

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- The lab should consult customers if there is any doubt about the suitability of an item for test of calibration, or if an item does not conform to the description provided. If required by the customer, the lab must include a disclaimer in the report indicating which results may be affected by the deviation. And, if applicable, the lab should record what environment items need to be stored in.

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7.5 Technical Records

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ISO 17025:2017 clause 7.5 states the requirements for technical records. As a lab, you need to ensure that technical records for all of the lab's activities contain results, a report, and information in order to facilitate, if possible, identification of components affecting the measurement results and its associated measurement uncertainty, and enable the repetition of the lab activities under conditions as close as possible to the original. When you are keeping records, you need to include the date and identify personnel responsible for lab activities. Records should include the original observations, data and calculations, and be recorded at the time they are made. If changes are made, these amendments need to be tracked to previous versions or to the original observations. Retain all the files, including the original and amendments, including the date of alteration, altered aspects and personnel responsible for any alterations.

7.6 Evaluation of Measurement Uncertainty

As an ISO/IEC 17025:2017 accredited laboratory, it is important to understand where measurement uncertainty is coming from. The laboratory needs to identify the contributions to the uncertainties. When you are evaluating uncertainty, you need to consider all contributions that are significant, even arising from sampling. If you perform calibrations, the lab needs to evaluate its own equipment for uncertainty. When performing testing you are required to evaluate measurement uncertainty. If the test method excludes rigorous evaluation of measurement uncertainty, labs should make estimates of uncertainty based upon understanding theoretical principles or from practical experience.

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7.7 Ensuring the Validity of Results

The laboratory shall have a procedure for monitoring the validity of results. As an ISO/IEC 17025:2017 accredited lab, ensuring the validity of results should be a top priority. One of the goals of validity is to be able to identify trends using statistical techniques. To meet the requirements, the laboratory must develop a procedure for monitoring the validity of their results. The main goal is to understand if the system or process may be inefficient so you can take preventive action. Proficiency testing is now more important than it was before.

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7.8 Reporting of Results
Clause 7.8 is divided into several sub-clauses:

- 7.8.1 General
- 7.8.2 Common Requirements for Reports
- 7.8.3 Specific Requirements for Test Reports
- 7.8.4 Specific Requirements for Calibration Certificates
- 7.8.5 Reporting Sampling- Specific Requirements
- 7.8.6 Reporting Statements of Conformity
- 7.8.7 Reporting Opinions and Interpretations
- 7.8.8 Amendments to Reports

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7.8.1 General.

Reporting results is very important and needs to be done by carefully following the requirements of the standard if your lab's goal is to become ISO/IEC 17025 accredited. The results need to be reviewed and authorized prior to release. When reporting the results, 7.8.1 states that they need to be provided in a clear, concise and accurate way and include any information that the lab agreed with the customer and that is necessary for interpretation of the results and all information required by the methods used.

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7.8.2 Common Requirements for Reports.

This sub-clause identifies what needs to be provided in the test reports. When an organization is creating a report, they need to pay careful attention to identify who was responsible for testing and calibration, and carefully record dates.

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7.8.3 Specific Requirements for Test Reports (see Standard)
7.8.4 Specific Requirements for Calibration Certificates (see Standard)
7.8.5 Reporting Sampling- Specific Requirements.
These sub-clauses add additional requirements to 7.8.2. These are more specific requirements where necessary for the interpretation of the test results, calibration certificates and reporting sampling.

7.8.6 Reporting Statements of Conformity

When a statement of conformity is provided, the lab needs to document the decision rule employed and take into account the level of risk associated with it. The laboratory needs to give a statement of conformity that states which specifications, standards or parts are met or not, and what decision rule was applied.

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7.8.7 Reporting Opinions and Interpretations

If opinions and interpretations are expressed, the lab needs to ensure that only personnel authorized to do so release the respective statement. If this happens, the lab needs to document the basis upon which these statements are made. The lab also needs to clarify if any opinions or interpretations expressed are based upon the results obtained from tests or calibrations. If opinions or interpretations are communicated to the customer, records need to be retained, even if communication is made verbally.

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7.8.8. Amendments to Reports

If an issued report needs to be changed, amended or re-issued, the changes need to be clearly identified. The amendments need to be issued in a form of a further document, or data transfer and include the statement “Amendment to Report, serial number (or other identification method)”. Labs need to ensure that amendments meet the requirements. If a complete new report needs to be issued, you must refer to the original that it replaces (e.g this Test Report replaces XXX test Report).

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7.9 Complaints

If your lab wants to be ISO 17025:2017 accredited, managing customer complaints is important and you must have a documented process to receive, evaluate and make decisions on how to handle complaints. The process needs to be readily available to any interested party. If the issued complaint is relevant to activities performed by the laboratory, the laboratory needs to confirm it is responsible for the complaint, and the lab needs to be responsible for all decisions made around handling this complaint.

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7.10 Nonconformance

Clause 7.10 emphasizes that labs must have a procedure that must be implemented when activities or results do not conform to its own procedures or the agreed requirements made by the customer. The laboratory must retain records of nonconforming work, and if the lab believes nonconformities may take place again, the lab needs to take corrective action.

For nonconformances, the procedure needs to include:

- Who is responsible and authorized for the management of nonconforming work
- Establish actions based upon the risk level
- An evaluation of the significance of the nonconforming work including an impact analysis
- The decision to be taken for the nonconformity
- Assurance that the customer is notified
- Who is responsible for authorizing the resumption of work

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7.11 Control of Data and Information Management

Control of data and information is a critical component for laboratories in order for them to perform activities. Labs need to verify that they have the necessary access to data and information needed to perform all of its activities. The lab needs to ensure that the information management system used for collection, processing, recording, reporting, storing and/or retrieving data is validated for functionality. This includes the proper function of interfaces within the laboratory information management system (LIMS). If there are changes made to software configuration or modifications to commercial software, they need to be authorized and validated before being used.

When a laboratory information management system is managed and maintained off-site or through external providers, the lab needs to ensure that the provider of the system complies with all applicable requirements of the standard. The laboratory must ensure that the instructions, manuals, and reference data relevant to the management system are made available. Furthermore, calculations and data transfers need to be checked in an appropriate and systematic manner

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CLAUSE 8
Clause 8 Options

ISO 17025 states that the laboratory must establish, document, implement and maintain a management system that is capable of supporting and demonstrating commitment to the requirements. In addition to the requirements of Clauses 4-7, laboratories must implement a management system in accordance with Option A or B

Option A

Option A has many clauses that need to be followed. Overall, at the bare minimum, the management system needs to address the following:

- Management System Documentation
- Control of Management System Documents
- Control of Records
- Actions to address risks and opportunities
- Improvement
- Corrective Actions
- Internal Audits
- Management Reviews

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Option B

Option B states that your laboratory is in compliance if:

The laboratory has established and maintained a management system in accordance with the requirements of ISO 9001:2015

The lab is capable of supporting and demonstrating the consistent fulfilment of the requirements from clause 4-7 of ISO 17025:2017

You have fulfilled management system documentation and management review requirements (clauses 8.2 and 8.9 of ISO17025:2017).

In short, if your laboratory is certified to ISO 9001:2015, you may choose Option B. This allows for more flexibility as you implement 17025:2017.

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