CLAUSE-BY-CLAUSE EXPLANATION OF ISO/IEC 17025

1-Executive Summary

A large number of organizations rely on laboratories to perform sampling, calibration, and testing activities, where business decisions are based on information and results. Accreditation to ISO 17025promotes confidence in the impartiality and consistency of laboratory operations as well as the ability of a laboratory to provide valid results.

Introduction

A Laboratory Management System based on ISO 17025 assists laboratories in the control of quality, administrative, and technical activities.ISO17025:2017incorporatestheprinciplesofISO9001, so a risk-based process approach must take to identify, select, and address risks and opportunities to ensure that business and quality objectives are met. The value of this is that the requirements of ISO 17025 are more performance-based. While this affords the laboratory more flexibility in implementation and reduces the amount of mandatory documentation, it is crucial that laboratories understand the purpose of each requirement and use that to develop a risk-based approach to managing laboratory activities. This white paper clearly assists with that process. You will find the explanation of each clause in plain English, where the section titles have the samenumbersastheISO 17025:2017clauses.

2-terms and definitions

Having a clear understanding of definitions and terms is crucial to understanding the intent of specific clauses in the standard. ISO 17025:2017 includes some terms and definitions.

- **Conformity -**fulfillment requirement
- **Context (of an organization) -** a combination of internal and external issues that can have an effect on an organization’s approach to developing and achieving its objectives
- **Documentedinformation-**information required to be controlled and maintained by an organization, and the medium on which it is contained
- **Effective-**successful in producing a desired or intended result
- **Improvement-**activity to enhance performance

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- **Interested party -** person or organization that can affect, affected by, or perceive itself to affect by a decision or activity
- **Management system -** set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives
- **Mission-**organization's purpose for existing as expressed by top management
- **PDCA(plan-do-check-act)-**a tool that can be used to manage processes and systems to drive improvement
- **Procedure-**specified way to carry out an activity or a process (procedures can be documented or not)
- **Process-**set of interrelated or interacting activities that use inputs to deliver an intended result
- **Process Approach -** management of a system to achieve objectives through defining the organization processes that make up the complete system, and managing their interacting activities to reduce risk and drive improvement
- **Quality control-**part of quality management focused on fulfilling quality requirements
- **Requirement-**need or expectation that is stated, generally implied, or obligatory
- **Risk-**the"effect of uncertainty on objectives and an effect is a positive or negative deviation from what is expected
- **Risk-based thinking/approach -** quality management approach that involves considering, at all times, the possible effect of uncertainty on activities, a sit relates to interrelated inputs and outputs of processes affecting an objective or expected result of an activity
- **System-**set of interrelated or interacting elements
- **Vision -**aspiration of what

an organization would like to become as expressed by top management

3-GeneralRequirements

3.1 Impartiality

This clause brings new requirements compared to the 2005 version. Impartiality is the pretense of objectivity. The purpose of this clause is to safeguard against conflicts of interest, prejudice, favoritism, one-sidedness, favor, or bias that could result in a harmful or damaging influence on the laboratory activities. It does refer to only safeguarding the validity of test or calibration results. The objective is to ensure that personnel is free from both internal and external pressures that may compromise upholding policies and meeting laboratory objectives.

There is a specific reference to the role of laboratory management. Management must be committed to identifying and safeguarding impartiality on a continual basis. There is a need for ongoing quality awareness through policies, various communication channels, meetings, and engagement during monitoring and assessment activities such as risk assessments, internal audits, corrective actions, and review of the management system.

Risks to impartiality must consider and documented as part of meeting clause 8.5, Actions to address risks and opportunities. When risks to the laboratory's impartiality are identified, there must be a responsible and authorized person immediately taking steps to minimize that risk.

3.2 Confidentiality

The purpose of the confidentiality clause is to cover legally binding duties to both internal and external parties. Bear in mind thatISO17025:2017as an international standard outlines general requirements for accreditation. Any applicable national and international legislation must also be met. This clause ties in strongly with the need to know the laboratory's and the customer's context,i.e., what legislation applies.
Information acquired from any source (unless already public), or generated during laboratory activities, must be kept confidential by personnel as well as members of management, external bodies, contractors, or other parties unless obliged by law to reveal. The requirement is not to just sign a non-disclosure agreement, but to take necessary measures to protect confidential information, in any format (including electronic storage and transmissions). The direct link with clause 7.11 Control of data and information management is clear.
Arrangements must be in place to notify a customer in writing if a laboratory wishes to place customer information in the public domain or if confidential information needs to release due to a legal requirement.

4.0 Structural Requirements

Although this section is one of the shortest, the standard covers specific organizational requirements, crucial as the foundation to achieve the purpose of the ISO17025managementsystem. This is due to the legal nature of test or calibration reports. Laboratories need impartial reporting lines and assigned responsibilities(with the appropriate authority)to achieve the objectives of the laboratory.
The standard requires the following in this section:

1. A legal entity located at a permanent address
2. a defined scope of laboratory activities that conform to ISO 17025:2017; no claim to conformity for activities that are provided by external suppliers on a continuing basis
3. Activities must be structured in a manner to ensure that the requirements of regulatory authorities, ISO 17025, organizations that provide recognition (for example, the accreditation body), and customers are met
4. responsibility for activities in a permanent laboratory facility, at other sites, mobile facilities, and at the customer's facility

5. A defined management and organizational structure, including any parent organization
6. Specified authority, responsibility, and personnel relationships to state for any personnel involved in performing, managing, or verifying any work that could affect laboratory activities. This must include top management with overall responsibility for the laboratory, technical, and any support services(for example, procurement)
7. authorized personnel with necessary resources for their duties, responsibility to ensure the effectiveness of laboratory activities, monitor the performance to identify deviations and take action to achieve improvement

Laboratory management, specifically,must ensure that:
A quality culture is developed with communication on the importance of an effective management system and meeting all necessary requirements, including that of customers when changes are planned and implemented, the management system integrity is maintained; this links directly to the activity Actions to address risks and opportunities, 17025 clause 8.5)

6.0 Resource Requirements

In this section, the standard specifies the requirements for laboratory personnel, suitable facilities, equipment, systems, and support services.

6.1 General

ISO 17025 introduces the requirements for resources here, specifying that a laboratory must have appropriate systems, facilities, personnel, equipment, and support services available.

6.2 Personnel

this clause crosslinks strongly with requirements in clause 4.1 Impartiality and clause 5 Structural requirements. The standard requires mandatory procedures and records for personnel management, crucial to meet the requirement for competence, impartiality, and consistent operation of laboratories. This is due to the large influence personnel have on the outcome of most laboratory activities.

The standard requires management to have procedures and records for

- personnel competence requirements and evaluation
- personnel selection, training, supervision, and authorization
- communication of duties, responsibilities, and authorities to personnel
- Ongoing monitoring of personnel competence.

ISO 17025 specifically requires that for each function influencing the results of laboratory activities, the competence requirements are documented. This includes all skills and experience, education, training, qualifications, and technical knowledge.

The standard requires the following of personnel:

- commitment to and ongoing safeguarding of impartiality and confidentiality
- competence to work according to ISO 17025
- to clearly know their responsibilities and authorities
- the ability to evaluate the significance of deviations

6.3 Facilities and environmental conditions

Due to the influence that facilities and environmental conditions have on consistent operation and result validity, the standard requires laboratories to:

- ensure that facilities and environmental conditions are suitable
- document the necessary facility and environmental conditions for laboratory activities
- control, record, and monitor any applicable environmental conditions as specified in methods, procedures, and specifications
- to ensure that the requirements are met when performing activities at other facilities outside its continual control

There is a clear need to perform a risk assessment for each test or calibration method and associated activities in the laboratory's scope of work. Then the laboratory can determine what facilities and environmental conditions are suitable and what controls (measures) are required to provide consistent conditions.

6.4 Equipment

The standard brings a clear definition of equipment in the 2017 version. It includes any item used to establish and maintain the performance of any laboratory activities that could influence results. Examples are software, reference data or materials, measurement standards, consumables and reagents, instruments, and apparatus.

The standard clearly links the requirements of this clause, through the definition, to clause 6.5 Metrological traceability.

The standard requires laboratories to:

- have access to suitable equipment

- have an equipment procedure to ensure fitness for use; the way equipment is handled and transported to the laboratory, the appropriate use and storage, as well as the maintenance plan should be included
- ensure that requirements are met when using equipment outside its permanent control
- verify the performance of equipment before being used or returned after maintenance
- ensure that measuring equipment is fit for use in terms of measurement accuracy and/or uncertainty to assure the validity of results
- establish a calibration program and procedure for intermediate checks for all measuring equipment that could affect the validity of the reported results due to measurement accuracy or uncertainty, or if used to establish metrological traceability
- update and implement reference values and correction factors included in calibration and reference material data
- identify all equipment that requires calibration or verification via a code, label, or other suitable means to indicate the calibration status or valid calibration period
- prevent unplanned adjustments to equipment
- prevent the use of any equipment that is not performing to specification, is defective, or has been overloaded or incorrectly handled

Laboratories are required to retain records for equipment that could impact the validity of activities, including:

- the identity (e.g., type, serial number), name of the manufacturer, current location
- the maintenance plan, and details of maintenance or any damage, malfunction, modification, or repair of the equipment
- evidence of calibration and/or verification (acceptance criteria, dates, results, adjustments, calibration interval, or due date)
- reference materials documentation (acceptance criteria, results, relevant dates/period of validity)

6.5 Metrological traceability

In this clause, laboratories are required to document the calibrations for all equipment that contribute to the overall measurement uncertainty of test or calibration results, by establishing a linked, unbroken calibration chain. This is to ensure that measurement results can be accepted internationally through ISO 17025 accreditation. This traceability to the International System of Units (SI) is a core requirement for laboratories to demonstrate competency and the ability to provide consistently valid results.

The requirement is that:

- each calibration is linked to an appropriate reference
- the measurement uncertainty of each calibration is available

Laboratories can achieve metrological traceability in a number of ways:

- using a competent laboratory to provide the calibration service

- obtaining certified reference materials (with stated traceability to the SI) from a competent producer
- by comparison with a national or international standard, thereby obtaining a direct realization of SI units

The standard provides options for cases in which it is not technically possible to obtain metrological traceability to the SI units. In these cases, laboratories can use an appropriate reference, such as:

- certified reference materials (with certified values) from a competent producer
- consensus standards, methods, or procedures, by suitable comparison of results; this is acceptable when they are well described or defined and provide measurement results that are fit for the intended use

6.6 Externally provided products and services

This clause brings restructured requirements by combining subcontracting and purchasing requirements. It applies to all provided products and services from an external provider that could impact laboratory activities if they are:

- incorporated into an activity, i.e., as an input or control
- used to support the general operation of the laboratory
- provided directly, as received from an external provider, to a customer.

Due to the impact that a product or service could have on the consistency and validity of results and other objectives, the standard requires:

- clear communication of requirements by the laboratory to external providers regarding the nature and purpose of products and services to be provided, along with acceptance criteria and the competence of personnel providing the service
- procedures and retained records that define the criteria and describe the process for selection, evaluation, and monitoring; as well as the process to verify the suitability/conformity of the product or service before use and action is taken (arising from initial evaluations, monitoring, and follow-up evaluations of external providers)

Note that, again, a risk-based approach is appropriate. This requirement interlinks directly with the activity Actions to address risks and opportunities, clause 8.5.

7.0 Process Requirements

This section specifies requirements for the operational processes of laboratories, incorporating both management and technical requirements. As with the other clauses, the approach is to:

- establish processes and procedures to ensure requirements are met for each process requirement clause, as well as interrelated clauses in other sections (e.g.,risk, improvement, nonconforming work)
- document the laboratory's requirements were mandatory for ISO 17025 or necessary for the laboratory to ensure effective implementation
- communicate clearly to personnel and other interested parties (e.g., customers)
- retain appropriate records
- monitor activities, and evaluate and act on deviations

7.1 Review of requests, tenders, and contracts

The requirements of this clause apply to all requests, tenders, and contracts where a procedure is required, and records retained, in order to:

- adequately understand, define, and document the customer's requirements
- select appropriate methods that are fit for purpose to meet the customer's requirements
- ensure the laboratory has suitable resources and capability
- communicate changes to all affected personnel
- ensure communication and cooperation with customers

Communication and cooperation are shown by:

- clarifying requests
- informing the customer if they request a method that is not appropriate or is outdated
- advising and obtaining the customer's approval if an external provider is to be used to perform any laboratory activities
- informing the customer regarding any deviations from the contract or standard procedures or expected performance of the method
- reviewing contracts if amended following the start of work
- monitoring performance of performed work
- allowing customers reasonable access to witness specific activities related to their contract
- assisting with items the customer may need to perform verifications

The standard introduces a specific requirement regarding statements of conformity, applicable when a customer requires a declaration of result as a pass or fail, in or out of tolerance. A decision rule must be selected and agreed upon with the customer unless the decision rule is built-in or defined in the standard or specification. This involves a decision on how measurement uncertainty will be considered as affecting conformity to a specification limit. The standard details this further in the Reporting requirements in clauses 7.8.3 and 7.8.6.

The impact of the proposed decision rule must be assessed before agreeing to it. Laboratories must consider the risk of applied statistical assumptions and the impact of false reject versus

false accept outcomes because of the decision rule applied. The nature of the measurement and the use of the result are factors to consider during the risk assessment.

7.2 Selection, verification, and validation of methods

The selection, verification, and validation of methods is crucial for the technical validity of results issued to a customer. The standard requires laboratories to:

- select suitable methods if the customer does not specify
- ensure that a method is the latest version, if appropriate
- plan development of methods, if required
- assign method activities to personnel who are qualified and who have the required resources to perform the tasks
- use appropriate methods and procedures for validation, the evaluation of the measurement uncertainty, and statistical techniques for analysis of data
- verify that a method can be performed properly before introducing it
- validate any method developed or modified by the laboratory, non-standard methods, and standard methods where the scope is changed. The extent is dependent upon what parameters are required to provide performance results that confirm the suitability of the method for the intended use
- determine the influence of any changes to a valid method
- retain records of validations – namely the procedure used, specification of requirements, performance characteristics, results obtained, and a method validity statement that details its fitness for intended use

Meeting the requirement for the selection, verification, and validation of methods calls for a clear risk-based thinking and process approach where requirements and risks are known. Applying the PDCA (plan-do-check-act) method will ensure the correct selection of methods and the appropriate extent of verification or validation and that suitable controls are identified to ensure valid results.

7.3 Sampling

This requirement applies when a laboratory performs sampling of items that will be tested or calibrated. The standard requires the laboratory to have a plan for sampling, to select suitable sampling methodology, and record all necessary information for traceability of the sample to its result. This is to endure that testing or calibration results are valid.

Taking a risk-based approach, all necessary controls should be identified and put in place to ensure the validity of the testing or calibration result. An objective, where

relevant and practical, is to sample in a standard manner so that the subsequent measurement result represents the source.

7.4 Handling of test or calibration items

This requirement of the standard applies to items for testing or calibration, following any sampling activity. The standard requires laboratories to:

- establish a procedure for the handling of test or calibration items, which includes transport to and receipt at the laboratory. Conditions must be included for the protection and storage during use, retention thereafter, and/or return or disposal once testing or calibration is completed
- protect the integrity of test or calibration items
- follow handling instructions, when provided
- record any deviations from specified conditions on the receipt of the test or calibration item
- uniquely identify all test or calibration items and retain the identification while being used or retained in the laboratory
- identify, maintain, monitor, and record storage or conditioning requirements when items must be stored or conditioned

7.5 Technical records

The specific requirements for technical records (irrespective of format) are included here. Clause 8.4 Control of records, the general requirements for all records, also applies to technical records.

By definition, a record is a document or part of a document containing a structured set of self-contained but related data, selected and presented for a specific purpose. Note the crosslink to clause 7.11 Control of data and information management. The standard requires that all laboratory technical records contain:

- the date and identity of personnel responsible for each activity
- report of results
- suitable information to assist with determining aspects that affect measurement uncertainty and to allow for repetition of activities under conditions replicating the original (as far as possible)
- clear records and traceability of any amendments from original observations or versions, including the person responsible for the amendments, the date, and what changes were made

7.6 Evaluation of measurement uncertainty

Measurement uncertainty is a statistical representation, understood as the margin of doubt regarding the results of any measurement. The standard addresses the importance of measurement uncertainty as a factor to decide whether a method is suitable, resulting in test or calibration measurements that are adequate for the intended use.
The standard requires that all testing and calibration laboratories establish how large the margin of doubt is for a method, at a specified confidence level (e.g., 95% confidence). This represents the statistical certainty that the true result lies within the stated margin.

ISO 17025 distinguishes between the requirements for testing and calibration laboratories. Measurement uncertainty must be evaluated on all calibrations performed by calibration laboratories for clients, as well as in-house laboratory equipment. Note, too, that calibration laboratories must meet the more detailed requirements of the accreditation bodies, based on International Laboratory Accreditation Cooperation (ILAC) policies.

All testing laboratories must evaluate or, at least, estimate measurement uncertainty by identifying contributions to measurement uncertainty and considering all significant contributions including those arising from sampling and using appropriate methods of analysis.

Where detailed measurement uncertainty evaluation is not possible due to the nature of the test method, the measurement uncertainty may be estimated based on principles of the techniques or practical experience of the performance of the method

7.7 Ensuring the validity of results

The standard requires laboratories to ensure that the results are valid through a process of internal and external quality controls. The purpose of internal control is to provide assurance that the current test procedure (a run or batch of samples) achieves the validated method performance. Laboratories are required to have a procedure outlining:

- the various internal tests, checks, correlations, and comparisons that are included, as appropriate
- the planned monitoring schedule

The standard also requires laboratories to monitor method performance externally, by comparing results and performance to other laboratories. The purpose of this external assurance is to identify any possible bias. For each method in the accredited scope of work, either enrollment and proficiency testing program participation is required, or participation in other inter-laboratory comparisons.

For both internal and external quality control approaches, laboratories are required to:

- record data in a manner such that trends are detectable
- apply suitable statistical techniques to review the results (when practical)
- analyze data from the monitoring to identify necessary controls to improve the performance of

activities

- take appropriate action if trends are detected or results are outside of pre-defined limits/criteria
- prevent reporting of erroneous results

7.8 Reporting of results

It is understandable that this clause is the longest in the ISO 17025 standard, as calibration and testing reports are legal documents, being the final output of a contracted test measurement or calibration for a client. Laboratories must determine which requirements are applicable to service -general requirements (7.8.1), common requirements (7.8.2), specific requirements for test reports(7.8.3), specific requirements for calibration certificates (7.8.4), requirements for reporting sampling (7.8.5), reporting statements of conformity (7.8.6), reporting opinions and interpretations (7.8.7), and requirements for amendments (7.8.8). All laboratories are required to:

- review and authorize results before release
- provide results in a report (unless a simplified form is agreed to), where results and other information are unambiguous, objective, and accurate
- meet the content requirements of the appropriates clauses (7.8.1 to 7.8.8)
- indicate which data were supplied by a customer
- place a disclaimer on the report if customer-supplied information could affect the result validity
- specify that results apply to the specific sample received (“as received”) when the laboratory was not responsible for sampling
- include any decision rule on any issued conformity statement, along with specific content listed in the standard in clause 7.8.6.2 clearly mark any expressed interpretations and/or opinions reported that are associated with the tested or calibrated item results
- clearly mark any expressed interpretations and/or opinions reported that are associated with the tested or calibrated item results
- clearly identify any re-issued, changed, or amended reports and identify any changed information; if a totally new report is issued, include a reference to the original report

Laboratories issuing test reports must also include all the information/data needed for test result interpretation. This includes any specific test conditions (e.g., environmental) and measurement uncertainty (where applicable). Laboratories issuing calibration reports must meet the content requirements specified in clause 7.8.4

7.9 Complaints

The standard requires laboratories to:

- have a complaint handling process that is documented with an available description if requested by any involved party (i.e., must be able to issue externally)
- take responsibility for the receipt of a complaint, verifying the validity, evaluation of information, and decisions to address complaints
- acknowledge to the complainant, wherever possible, the complaint receipt, as well as supply progress reports, the outcome, and notice of the closure of the complaint handling
- assign an independent person, who was not involved directly in the activity subject to complain, to review, approve, or communicate the outcome to the complainant

The handling of complaints is directly interrelated with clause 8.5 Actions to address risks and opportunities and addressing nonconforming work - clauses 7.10 Nonconforming work and 8.7 Corrective actions.

7.10 Nonconforming work

The requirement for nonconforming work is that laboratories must implement a procedure when any part of its results or activities does not comply with either ISO17025, its own laboratory procedures, or customer requirements. The standard clearly links the requirements for addressing nonconforming work to clauses 8.5 Actions to address risks and opportunities and 8.7 Corrective actions. A mandatory procedure and retained records are required, detailing:

- assigned authority and responsibilities, including for the resumption of work
- the evaluation process and implication (significance) of the nonconformance
- decisions made on the halting or acceptability of work
- the impact assessment to analyze any risk to the validity of previous results
- how actions are based on identified risk levels
- notification of customers, if necessary, if work is recalled
- the need to implement corrective actions if there is uncertainty regarding compliance with laboratory policies and procedures, or if the evaluation indicates the possibility of reoccurrence of nonconforming work

7.11 Control of data and information management

As an introduction to this clause, which is new in the 2017 version of the standard, let's look at the definitions of information and data. Data is considered to be facts about an object/entity/item, i.e., anything perceivable or conceivable.

Examples of objects are systems, processes, organizations, services or products, or persons. Information is defined as meaningful data that is processed, organized, and connected (correlated) in a formal manner in order to produce meaning.

As data and information are primary inputs and outputs for all ISO 17025 activities, there is a need for clear management of these valuable resources. In this new clause, the standard applies requirements to both computerized and non-computerized system data and information. Laboratories must:

- have the necessary access to information and data, including instructions and manuals, to support the laboratory activities
- validate Laboratory Information Management Systems (LIMS), including interfaces for functionality
- authorize, document, and validate changes before implementation
- operate the LIMS according to laboratory specifications to safeguard the integrity of data and information
- protect the system from unauthorized access
- provide safeguards against tampering or loss
- check data transfers and calculations in an appropriate and systematic manner
- ensure that any operator or external service provider of any off-site LIMS activities complies with appropriate ISO 17025 requirements

Note the interrelated requirements for management system documents are specified in clause 8.2 Management system documentation and clause 8.3 Control of management system documents. Management system records are specified in clauses 8.4 Control of records and 7.5 Technical records.

8.0 Management Requirements

The purpose of the management requirements in this section is to ensure that the overall structure of the management system is in place to support upholding the policies and objectives of the laboratory. It encompasses the control of documentation, data and information, the management system performance evaluation, and improvement processes.

8.1 Options

The standard requires laboratories to create and structure a management system that will support consistent compliance with ISO 17025 to assure the quality of laboratory results. The management system must be documented, implemented, and maintained effectively. This process is directly interrelated with Addressing risk and opportunities, clause 8.5.
If a laboratory already has a management system that meets the requirements of ISO 9001, ISO 17025:2017 considers the intent of requirements specified in clauses 8.2 to 8.9 to be met. With this option (B), the laboratory must show the capability to also meet clauses 4 to 7

requirements. Option A is applicable for laboratories that do not have a management system in compliance with ISO 9001. They are required to address all ISO 17025 clauses.

8.2 Management system documentation

A documentation process is defined as a continuous and systematic compilation and processing of recorded information for the purpose of storage, classifying, retrieval, utilization, or transmission.

In this clause, the standard specifies the overall (overarching) requirement for management system documentation. It is important for laboratories to see this requirement as a process, not a once-off or once-in-a-while activity. As per clause 8.2.4, laboratories are required to include in, reference from, or link to the management system all documentation, processes, systems, and records related to the implementation and maintenance of ISO 17025 requirements.

This requirement should be met with a process approach with dynamic linking of activities as inputs and outputs, not simply cross-references. As an example, the cause analysis and handling of corrective actions (clause 8.7) is clearly directly integrated with clause 8.5 Addressing risk and opportunities. Laboratories must (dynamically and effectively):

- Create, document, implement, and support policies and objectives that address consistent laboratory operations, competence, and impartiality
- ensure that the personnel throughout the organization acknowledge and uphold the policies and laboratory objectives
- show evidence of the continual improvement of the established system
- link, reference, or include all documentation, systems, processes, and records in the management system
- provide access to applicable parts of the management system to personnel, dependent on their responsibilities

A policy is defined as the formal expression of the intentions and direction of an organization by its top management. Laboratory policies should be consistent with any overall organizational policy. The Quality Policy is specifically aligned with the laboratory's vision and mission, providing a framework for establishing the quality objectives (quality-focused results to be achieved).
The standard specifies requirements for control of documentation, information, and records in these interrelated clauses - clause 8.3 Control of management system documentation, 8.4 Control of records, 7.5 Technical records, and 7.11 Control of data and information management

8.3 Control of management system documents

Laboratories are required to control both internal and external documents that are relevant to meeting ISO 17025 requirements by:

- unique identification
- authorizing personnel to approve documents
- approving all documents before the issue
- reflecting the latest revision number
- reviewing documents periodically
- updating documents as may be required
- identifying changes
- making documents available where and when needed (points of use)
- controlling distribution, if necessary
- controlling retention of any versions of documents that are obsolete so that unplanned use is avoided.

8.4 Control of records

The standard specifies general requirements for all records (irrespective of format) in this clause, while specific requirements are covered in clause 7.5 for Technical records. Note the crosslink to clause 7.11 Control of data and information management.

Laboratories must:

- create and maintain records that are clearly legible
- implement appropriate controls, consistent with confidentiality arrangements, to ensure that records are uniquely identifiable, readily available, stored, protected, backed-up, archived, and retrievable; and that retention and disposal times are defined
- to ensure that the retention period for records is in line with legislative and contractual obligations

8.5 Actions to address risks and opportunities

This clause brings new requirements compared to the 2005 version of the standard. The standard requires laboratories to consider, plan, evaluate, and take action to address risks and opportunities. The purpose is to ensure that a risk-based approach is managed effectively. Because the ISO 17025:2017 requirements are less prescriptive, laboratories must actively consider their context and specific risks and opportunities for improvement. Aspects to consider are the regulatory requirements of the sector and the nature of the test or calibration methods (the accredited scope of work).

Laboratories must:

- consider the risks and opportunities associated with laboratory activities
- plan what actions will be taken to address those risks and opportunities

- coordinate and carry out actions within the management system (i.e., consider interrelated activities) take actions that are proportionate to the potential impact on the validity of laboratory results
- assess the effectiveness of actions taken

Note that, although ISO 17025 does not require a formal risk management system or a documented process, for most laboratories, there could be a risk that this requirement will not be adequately met unless the approach and methods are documented (see clause 8.1). Laboratories may select any suitable methodology and may choose to implement a more detailed approach to risk management by applying other standards or guidelines.

The focus in addressing this requirement must be the scope of the ISO 17025 standard, i.e., any activities that impact (negatively or positively) the competency, impartiality, and consistent operation of the laboratory, not just the final results. A laboratory's policies and objectives must be well aligned to the scope/intent of ISO 17025 (clause 8.2). They provide the core reference against which decisions should be made. This clause is directly linked to the next, clause 8.6 Improvement.

8.6 Improvement

The requirements for this clause are directly linked to clause 8.5 Actions to address risks and opportunities. Laboratory management is required to:

- find and choose opportunities for improvement. This can be through:
  - feedback from customers and personnel (positive and negative)
  - review of operational procedures, risk and opportunity assessments, audits, and management review
  - data and trend analysis, including quality control (internal and proficiency testing), corrective actions, audits, and root cause / corrective auction trends
- analyze outcomes and use the evaluation to improve customer service, specific laboratory activities, and the overall management system

8.7 Corrective action

The standard requires laboratories to address nonconformities through a sequence of specified steps, take appropriate actions based on the effects of the nonconformity, and retain appropriate records. Handling of complaints, clause 7.9, is directly associated with this process. Furthermore, as corrective actions need to be based on the impact of the nonconformity, this process is directly interrelated with Addressing risk and opportunities, clause 8.5.
The process to address nonconformities requires laboratories to:

- acknowledge the nonconformity, deal with the consequences, and, where necessary, take action to gain control and make any corrections
- determine any need to take action. This calls for reviewing and updating risks and opportunities identified prior to the event

- carry out the selected actions
- reassess the success of any action taken

If necessary, changes should be made to the Laboratory Management System.

8.8 Internal audits

ISO 17025 requires that laboratories establish an internal audit program/schedule, perform internal audits (with defined scope and criteria) at pre-planned intervals, communicate the results of audits, implement appropriate corrective actions, and retain records.

The purpose is to obtain information to evaluate if the management system complies with ISO 17025 and the requirements of the laboratory. A risk-based approach is needed.

When maintaining the program and planning individual audits, laboratories must consider any changes affecting the laboratory, the criticality of the various laboratory activities, and the previous audit results and trends. The outcomes of audits are inputs to the Management Review, clause 8; Addressing Risk and Opportunities, clause 8.5; and Improvement, clause 8.6.

8.9 Management reviews

The standard requires that laboratories review their management system at suitable pre-planned intervals to ensure its ongoing applicability, capacity, and performance capability. The way ISO 17025 specifies the requirements for the review of the Laboratory Management System is an example of the process approach.

Reference is made to the inclusion of specific inputs for the effective review of the system (all the mandatory inputs are listed in clause 8.9.2 a to;
followed by the outputs that serve as records of all decisions made and actions taken. These are:

- the capability/performance (effectiveness) of the management system and its processes
- any need for change
- improvements
- allocation of any necessary resources

To meet the intent of an effective review, plans need to be made to monitor specific activities. Data and information need to be collected so that information and trends from each activity can be evaluated.

Note that ISO 17025 does not specify how reviews should be performed (the process), nor how often they should take place. Laboratories can decide on the mechanism/format of reviews, and how many reviews take place over a period of time, as long as the decisions can be acted on. To this end, management review is usually completed in time for budgeting for the next financial cycle.

9.0 Conclusion

ISO 17025:2017 incorporates valued ISO 9001:2015 principles and specifies general requirements for laboratories to implement an internationally recognized management system with which accreditation can be achieved. The ultimate objective must be to increase the confidence your customers and other stakeholders have in your service.

Your laboratory will benefit greatly from applying a process and risk-based approach to gain a deeper understanding of the individual requirements of ISO 17025. All the requirements serve the purpose of ISO 17025 - to help you safeguard impartiality and operate competently and consistently to provide valid results, even during times of change and disruption.

Truly understanding the “why” (why were the clauses included) and the “how” (how do I implement and integrate activities) will lead to a successful and rewarding implementation and drive ongoing improvement. Sounds good, doesn’t it?