General Accreditation Guidance

ISO/IEC 17025:2017 Gap analysis

April 2018

ISO/IEC 17025:2017 Gap analysis

Purpose and background information

This document serves as an informative guide correlating the clauses in ISO/IEC 17025:2017 to the previous 2005 version of the standard.

CASCO is the ISO committee concerned with the development of policy and publishes standards related to conformity assessment, which includes ISO/IEC 17025.

ISO/CASCO specifies the minimal mandatory content of those standards it maintains or develops. This includes the structure and mandatory requirements relating to impartiality, confidentiality, complaints / appeals and management systems.

ISO/IEC 17025:2017 has adopted the revised structure specified by ISO/CASCO. Accordingly the structure of the new standard is different to the 2005 version as noted below:

Informative preliminary	Title page Table of contents Foreword Introduction (including relationship to other standards)
Normative General	Title Scope Normative references
Normative Technical	Terms and definitions Structural requirements Resource requirements (including human resources) Process requirements (including operational functions) Management system requirements Normative annexes
Informative supplementary	Any further explanations that are not part of the normative process Informative annexes Bibliography Indexes

Even though the structure of the standard is different to the previous version, the requirements now included have been adopted in a more direct (simplified) and clearer manner. With the exception of a few requirements, most of the changes in the standard are of an editorial nature.

The main changes compared to the previous edition are as follows:

- the risk-based thinking has enabled some reduction in prescriptive requirements and their replacement by performance-based outcomes;
- there is greater flexibility in the requirements for processes, procedures, documented information and organisational responsibilities;
- a definition for “laboratory” has been added;
- the mandatory adoption of the ISO/CASCO structure and requirements relating to impartiality, confidentiality, complaints / appeals and management systems;
- the requirements in the 2005 version of the standard relating to “Purchasing services and supplies” and “Subcontracting of tests and calibrations” have been combined;
- the “decision rule” to apply when reporting a statement of conformity now is to be confirmed with the customer at the review of request stage and for the rule to be included in the report.

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
1	1		**Scope**	The text has been simplified and duplication removed. For example, the relationship with ISO 9001 is now included in the Introduction section only.
2	2		**Normative References**	Reference to ISO/IEC 17000 has been removed. ISO/IEC 17000 is, however, referenced in “Terms and definitions”. ISO/IEC Guide 99 (VIM) is also a new reference.
3	3		**Terms and definitions**	“Laboratory activities” is used throughout the document and refers to testing, calibration and sampling (where conducted as a standalone activity) associated with subsequent testing or calibration.
4			**General requirements**	
4.1			**Impartiality**	
4.1.1	4.1.4; 4.1.5b) ,d) ,e) & f)	Editorial	Laboratory to manage and structure its activities to safeguard impartiality.	
4.1.2	4.1.5b)	Editorial	Laboratory management to be committed to impartiality.	
4.1.3	4.1.5b)	Editorial	The laboratory is responsible for the impartiality of its activities with impartiality not to be compromised by commercial, financial or other pressures.	
4.1.4		New	On an ongoing basis, the laboratory must identify risks to impartiality, including those arising from its activities or relationships or the relationships of its personnel.	

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4.1.5		New	The laboratory must be able to demonstrate how it minimises or eliminates the risks it identifies.	
4.2			**Confidentiality**	
4.2.1	4.1.5c)	Major	The laboratory is responsible, through legally enforceable commitments, for the management of information obtained or created during its activities. If the laboratory intends to place information in the public domain, it must inform the customer in advance. Unless agreed between the laboratory and customer or the customer makes the information publicly available, all other information is to be regarded proprietary and confidential.	4.2.1 expands on the requirements relating to confidentiality of customer information. Laboratories are now to advice customers of the information they will make publically available. 4.2.1, 4.2.2, 4.2.3 and 4.2.4 significantly expand on the confidentiality requirements concerning customer information cover by 4.1.5c) in ISO/IEC 17025:2005..
4.2.2		New	When the laboratory is required by law or authorised by contractual arrangements to release otherwise confidential information, the customer or individual is to be notified (unless the notification is prohibited by law).	
4.2.3		New	Information about the customer, obtained from other sources, is to be regarded as confidential. The source is to remain confidential to the customer unless otherwise agreed to by the source.	
4.2.4		New	Personnel must keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.	
5			**Structural requirements**	
5.1	4.1.1	Editorial	The laboratory is to be a legal entity or a defined part of a legally entity and be legally responsible for its activities.	

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5.2	4.1.5e), f), h) & i)	Editorial	Management who have overall responsibility for the laboratory need to be identified.	Specific reference to technical management and a quality manager as covered by ISO/IEC 17025:2005 has been removed.
5.3		New	The laboratory needs to define and document the range of activities which it claims conformity to the Standard. The range of activities cannot include externally provided laboratory activities on an ongoing basis.	
5.4	4.1.2; 4.1.3	Editorial	Laboratory activities need to meet the requirements of the Standard, its customers, regulatory authorities and organisation providing recognition. It is responsible for activities at its permanent facilities, at sites away from its permanent facilities, mobile facilities or at a customer's facility.	
5.5	4.1.5e) & f); 4.2.1	Editorial	The laboratory must: a) define the organisation and management structure of the laboratory; b) specify the responsibility, authority and interrelationship of all laboratory personnel whose work affects the laboratory results; c) document its procedures to assure the consistent application of its activities and validity of results, to the extent necessary.	The requirement for documentation (point c) is less prescriptive than that of ISO/IEC 17025:2005.

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5.6	4.1.5a); 4.2.2e); 4.2.3	Editorial	Laboratory personnel to have the authority and resources needed to carry out : a) implementation, maintenance and improvement of the management system; b) identification of deviations from the management system or procedures for laboratory activities; c) actions to minimise deviations; d) reporting on the management system; e) ensuring the effectiveness of laboratory activities.	
5.7	4.1.6; 4.2.7	Editorial	Laboratory management needs to ensure: a) communication on the effectiveness of the management system and customer requirements; b) management system integrity.	
6			**Resource requirements**	
6.1			**General**	
	4.1.5a); 4.4.1c)	Editorial	The laboratory to have available the necessary resources to perform its laboratory activities.	
6.2			**Personnel**	Combination of some clauses of the Management System and Personnel clauses of ISO/IEC 17025:2005.
6.2.1	4.1.4; 4.1.5b) &d); 5.2.1; 5.2.3	Editorial	All personnel are to act impartially, be competent and adhere to the laboratory's management system.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
6.2.2	5.1.2; 5.2.1; 5.2.4; 5.2.5	Editorial	The competence requirements for each function influencing the results of laboratory activities must be documented.	Reference to specific job descriptions as in ISO/IEC 17025:2005 has been removed.
6.2.3	4.1.5a) & k); 5.2.1	Minor	It must be ensured that personnel are competent to perform the activities for which they are responsible and to evaluate the significance of deviations.	Emphasis is now on staff's ability to not only identify departures from procedures, but also to evaluate the significance of these.
6.2.4	4.2.1; 4.2.4	Minor	Duties, responsibilities and authorities shall be communicated to personnel.	
6.2.5	5.2.2; 5.2.3; 5.2.5	Major	Procedures and records need to be maintained for personnel covering: a) determination of competence requirements; b) to e) selection, training, supervision and authorisation; and f) monitoring of competence.	Changed emphasis to include records covering selection, supervision and ongoing monitoring.
6.2.6	5.2.5	Major	Personnel must be authorised to perform specific activities including: a) develop, modify, verify and validate methods; b) analysis of results, statements of conformity and opinions / interpretations; c) report, review and authorise results.	Now explicitly includes method validation / verification and analysis of results / statements of conformity.
6.3	5.3		**Facilities and environmental conditions**	
6.3.1	5.3.1; 5.4.7.2c)	Editorial	The facilities and environmental conditions need to be suitable to the activities performed and not adversely affect the validity of results.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
6.3.2	5.3.1	Editorial	The requirements for suitable facilities and environmental conditions to perform laboratory activities shall be documented.	
6.3.3	5.3.2	Editorial	The laboratory shall monitor, control and record environmental conditions in accordance with the relevant specifications, methods and procedures or when they influence the validity of results.	
6.3.4	5.3.2; 5.3.3; 5.3.4	Minor	Measures to control facilities are to be implemented, monitored and periodically reviewed and include: a) access; b) prevention of contamination; **c)** effective separation of incompatible activities.	Emphasis now also placed on periodic review.
6.3.5	4.1.3; 5.3.1	Editorial	The requirements related to facilities and environmental conditions also apply to activities performed at facilities outside the laboratory's permanent control.	Clarity provided that the requirements applicable to facilities and environmental conditions also apply to activities performed at locations outside of the laboratory's permanent control.
6.4	5.5		**Equipment**	
6.4.1	5.5.1; 5.5.2	Editorial	There must be access to equipment required for the correct performance of the laboratory activities and which can influence the results.	Minor change in emphasis from the laboratory having access to equipment rather than being furnished with equipment.
6.4.2	5.5.1	Editorial	Equipment outside the permanent control of the laboratory shall be capable of satisfying the requirements in the standard.	

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6.4.3	5.4.1; 5.4.7.2c); 5.5.3; 5.5.6	Editorial	A procedure for the proper handling, transport, storage, use and planned maintenance to ensure proper functioning of equipment and to prevent contamination must be maintained.	
6.4.4	5.4.7.2a); 5.5.2	Editorial	Before being placed in or returned to service, the laboratory shall verify that equipment complies with specified requirements.	
6.4.5	5.5.2	Minor	Equipment shall be capable of achieving the measurement accuracy or measurement uncertainty (MU) required to provide a valid result.	Clarity provided that the equipment's capability is also to consider the MU contribution to the results of the laboratory activity, even if accuracy is not in question. ISO/IEC 17025:2005 stated that equipment shall comply with specifications, which implied that the MU had to be considered.
6.4.6	5.6.1; 5.6.2.1.1; 5.6.2.2.1; 5.6.3.1	Editorial	Measuring equipment must be calibrated when the measurement accuracy or measurement uncertainty affect the validity of results or if metrological traceability of the reported result is required.	Clarity provided when calibration is required.
6.4.7	5.5.2; 5.6.1	Major	A calibration program shall be established, reviewed and adjusted as necessary, to ensure confidence in the status of calibrations.	Clarity now provided that the calibration program is to be reviewed and adjusted as necessary.
6.4.8	5.5.8	Editorial	All equipment which requires calibration or has a defined period of validity must be labelled or otherwise identified.	"Whenever practicable" has been removed from the new version of the standard.

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6.4.9	5.5.7	Editorial	Overloaded, mishandled or poorly functioning equipment shall be taken out of service, isolated and not reused until verified that it performs correctly. The effect of such defective equipment shall be investigated and the management of nonconforming work initiated.	
6.4.10	5.5.10; 5.6.3.3	Editorial	A procedure is to be followed when intermediate equipment checks are necessary.	
6.4.11	5.5.11	Minor	When calibration or reference material data includes reference values or correction factors, it must be ensured the reference values or correction factors are updated and implemented as appropriate to meet specified requirements	Equipment includes reference data, hence clarity provided that correction factors are to include such data sets.
6.4.12	5.5.12	Editorial	Practical measures must be taken to prevent unintended adjustments to equipment.	

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6.4.13	5.5.5	Minor	Records need to be retained for equipment which can influence laboratory activities, including: a) identity; b) manufacturer's name, type and serial number; c) evidence of verification; d) location; e) calibration dates, results, adjustments, acceptance criteria, next calibration due date or interval; f) reference material documentation, results, acceptance criteria, relevant dates and period of validity g) maintenance plan and maintenance performed; h) details of damage, malfunction, modifications or repair.	Equipment now includes reference materials.
6.5	5.6		**Metrological traceability**	These requirements have been made clearer, with simplified text.
6.5.1	5.6.2.1.1	Editorial	The laboratory must maintain metrological traceability of its measurement results by a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.	
6.5.2	5.6.2.1.1; 5.6.3.2	Editorial	Measurement results are to be traceable to SI units through either: a) calibration by a competent laboratory; b) certified values of certified reference materials from a competent producer with stated traceability to SI units; c) direct realisation of the SI units.	Clarity provided that traceability to SI may be achieved through the use of certified reference materials.

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6.5.3	5.6.2.1.2; 5.6.2.2.2	Editorial	When metrological traceability is not possible to SI units, traceability is to be demonstrated to an appropriate reference.	
6.6	4.5; 4.6		**Externally provided products and services**	Subcontracting and Purchasing Services and Supplies from ISO/IEC 17025:2005 have been combined. The principles of ISO 9001:2015 have been adopted. These requirements are now clearer, with simplified text.
6.6.1	4.5.1; 4.6.1	Minor	Only suitable externally provided products and services that affect laboratory activities are to be used when such products or services are: a) incorporated into the laboratory's own activities; b) provided directly to the customer by the laboratory as received from the external provider; c) used to support the operation of the laboratory.	
6.6.2	4.5.1; 4.5.4; 4.6.1; 4.6.2; 4.6.3; 4.6.4	Major	A procedure and records are required for: a) defining, reviewing and approving externally provided products and services; b) the criteria for evaluation, selection, monitoring and re-evaluation of external providers; c) ensuring, prior to use or supply to customer, externally provided products and services conform to the laboratory's established requirements or the Standard; d) actions arising from evaluations, monitoring or re-evaluations of external providers.	Emphasis now placed on the laboratory defining its requirements, selecting providers who can meet these and evaluating / monitoring the providers' performance. The previous requirement that the laboratory is responsible to the customer for subcontractor's work has been removed.

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6.6.3		New	Communication to external providers is required for: a) the products and services to be provided; b) acceptance criteria; c) competence of personnel; d) activities to be performed by the laboratory or laboratory customers at the external provider's premises.	Emphasis now placed on the laboratory communicating its needs to external providers
7			**Process requirements**	
7.1			**Review of requests, tenders and contracts**	
7.1.1	4.4.1; 4.4.3; 4.5.2; 5.4.2	Editorial	A procedure must be established for the review of requests, tenders and contracts, ensuring: a) the requirements are defined, documented and understood; b) the laboratory has the capability and resources to meet the requirements; c) the customer being informed of the activities to be performed by external providers and approval from the customer obtained; d) appropriate methods or procedures are selected which customer needs.	
7.1.2	5.4.2	Editorial	The laboratory must inform the customer when the method requested is not considered appropriate or out of date.	

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7.1.3		New	The standard or specification and the decision rule must be clearly defined when the customer requests a statement of conformity to a specification or standard for a test or calibration. The decision rule must be communicated to and agreed with the customer, unless inherent in the requested specification of standard.	Clause 5.10.3.1b) and 5.10.4.2 in ISO/IEC 17025:2005 covered statements of compliance. Hence, statements of conformity are not a new concept. However, the laboratory is now required to consider such at the request / contract review stage and to include the decision rule in the report on results. Also refer to clause 7.8.6.
7.1.4	4.4.1	Minor	Before laboratory activities commence, any differences between the request or tender and the contract must to be resolved. Deviations requested by the customer shall not impact the integrity of the laboratory or validity of results.	Emphasis now placed on deviations not to impact the integrity of the laboratory or validity of results.
7.1.5	4.4.4	No change	Customer must be informed on any deviations to the contract.	
7.1.6	4.4.5	No change	Amendments to contract following commencement of work shall require the contract review process to be repeated and amendments communicated to all affected personnel.	
7.1.7	4.7.1	Editorial	The laboratory shall cooperate with customers to clarify request and to allow the customer to monitor the laboratory's performance.	Emphasis changed from "willing to cooperate" in ISO/IEC 17025:2005 to "shall cooperate".
7.1.8	4.4.2	Editorial	Records of contract reviews and significant changes must be kept. Records include pertinent discussions relating to the customer's requirements or results generated.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.2	5.4		**Selection, verification and validation of methods**	In general, there are not many changes in the requirements. This section has been re-organised mainly to differentiate between when the laboratory has to "verify" (7.2.1) that it can properly perform methods versus when the lab has to "validate" (7.2.2) methods.
7.2.1	5.4.2		**Selection and verification of methods**	
7.2.1.1	5.4.1	Editorial	Appropriate methods and procedures must be used for laboratory activities. This includes for the evaluation of measurement uncertainty and statistical techniques for analysis of data.	Clause 5.4.1 in ISO/IEC 17025:2005 has been split into three new clauses 7.2.1.1, 7.2.1.2 and 7.2.1.7.
7.2.1.2	5.4.1	Editorial	All methods, procedures and supporting documentation shall be kept current and readily available to personnel.	Clause 5.4.1 in ISO/IEC 17025:2005 has been split into three new clauses 7.2.1.1, 7.2.1.2 and 7.2.1.7.
7.2.1.3	5.4.2	Editorial	Latest versions of methods shall be used unless it is not appropriate or possible. Methods shall be supplemented, where necessary.	Clause 5.4.2 in ISO/IEC 17025:2005 has been split into two new clauses 7.2.1.3, 7.2.1.4 and 7.2.1.5.
7.2.1.4	5.4.2	Editorial	Appropriate methods shall be selected when the customer does not specify the methods to be used.	Clause 5.4.2 in ISO/IEC 17025:2005 has been split into two new clauses 7.2.1.3, 7.2.1.4 and 7.2.1.5.
7.2.1.5	5.4.2	Editorial	The laboratory must verify it can perform the methods it uses before introducing them by demonstrating it can achieve the required performance, with records kept.	Clause 5.4.2 in ISO/IEC 17025:2005 has been split into two new clauses 7.2.1.3, 7.2.1.4 and 7.2.1.5. "Properly operate" in ISO/IEC 17025:2005 has now been clarified as "verify".

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7.2.1.6	5.4.3	Editorial	Method development shall be a planned activity and be performed by qualified personnel equipped with adequate resources. Periodic review as method development proceeds shall occur.	In ISO/IEC 17025:2005, plans were to be updated as development proceeded. Now the requirement is for periodic review to occur as development proceeds.
7.2.1.7	5.4.1	Editorial	Deviations from methods shall only occur is the deviation has been documented, technically justified, authorised and accepted by the customer.	Clause 5.4.1 in ISO/IEC 17025:2005 has been split into three new clauses 7.2.1.1, 7.2.1.2 and 7.2.1.7.
7.2.2	5.4.5		**Validation of methods**	
7.2.2.1	5.4.5.2	Editorial	Non-standard methods, laboratory-developed methods and standard methods used outside of their scope shall be validated.	
7.2.2.2	5.4.5.2 Note 3	Minor	When changes are made to validated methods, the influence of such changes must be determined and validation performed again, if appropriate.	This was included as a Note in ISO/IEC 17025:2005. Whilst it has now been made an explicit requirement of the Standard, the intent of method validation remains unchanged.
7.2.2.3	5.4.5.3	Editorial	The performance characteristics of validated methods must be consistent with specified requirements and relevant to the customers' needs.	
7.2.2.4	5.4.5.2; 5.4.5.3 Note 1	Editorial	Validation records must include the following: a) the validation procedure used; b) specification of the requirements; c) performance characteristics of the method; d) results obtained; e) a statement on the validity of the method for its intended use.	The "specification of requirements" and "performance characteristics of the method" were previously a Note in in ISO/IEC 17025:2005.

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7.3	5.7		**Sampling**	
7.3.1	5.7.1	Editorial	The laboratory must have a sampling plan and method when it carries out sampling. The method shall address the factors to be controlled. The method and plan shall be available at the sampling site. The plan shall be based on statistical methods where reasonable.	
7.3.2	5.7.1 Note 2	Minor	The sampling method must include: a) the selection of samples or sites; b) sampling plan; c) preparation and treatment of a sample(s) from a substance, material or product.	Previously a Note in ISO/IEC 17025:2005. The new Note in 7.3.2 states "When received into the laboratory, further handling can be required as specified in 7.4". This implies that "sampling" is different from "sub-sampling" which is covered in 7.4.
7.3.3	5.7.3	Minor	Relevant sampling data that forms part of the testing or calibration performed is to be recorded and include: a) reference to the sampling method; b) date and time of sampling; c) data to identify and describe the sample; d) identification of the personnel performing sampling; e) identification of the equipment used; f) environmental or transport conditions; g) diagrams or other means to identify the sampling location when appropriate; h) deviations, additions or exclusions from the method or sampling plan.	Items b), c), e) and h) are new record requirements.

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7.4	5.8		**Handling of test or calibration items**	
7.4.1	5.8.1; 5.8.4	Minor	The laboratory must have a procedure for the transportation, receipt, handling, protection, storage, retention and disposal or return of test or calibration items. This includes provisions to protect the item, the interests of the laboratory and the customer.	The requirements have been expanded to include protection of items during transport.
7.4.2	5.8.2	Editorial	A system for the unambiguous identification of test and calibration items shall be established.	
7.4.3	5.8.3	Major	Upon receipt of the item, abnormalities or deviations from specified conditions must be recorded. If there is doubt as to the suitability of the item or when the item does not conform to the description provided, the customer must be consulted before proceeding and record the results of the consultation. Following, if the item is to proceed to testing or calibration, the laboratory must include a disclaimer in the report indicating that results may be compromised.	The requirement to include a disclaimer if a sample deviates from specified conditions is new.
7.4.4	5.8.4	Editorial	When items need to be stored or conditioned, the conditions shall be maintained, monitored and recorded.	The requirement to have procedures and appropriate facilities for maintaining the integrity of the test or calibration item is covered in 6.3.

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7.5	4.13		**Technical records**	
7.5.1	4.13.2.1; 4.13.2.2	Editorial	Technical records for each laboratory activity must include: • results; • report; • sufficient information to enable repetition under conditions as close as possible to the original; • identification of factors affecting the result and MU; • date of activity; • identity of personnel responsible for each activity and for checking data and results. Original observations, data and calculations are to be recorded at the time they are made and be identifiable to the specific task.	
7.5.2	4.13.2.3	Minor	Amendments to technical records must be traceable to previous versions or to original observations. Original and amended data or files are to be kept, including date of alteration, an indication of the altered aspects and the identity of the personnel responsible.	The requirement has been enhanced compared to ISO/IEC 17025:2005.
7.6	5.4.6		**Evaluation of measurement uncertainty**	
7.6.1	5.4.6.3	Minor	The contributions to measurement uncertainty (MU) must be identified. All contributions which are of significance, including those arising from sampling, are to be taken into account using appropriate methods of analysis.	Expanded to include the contributions from sampling.

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7.6.2	5.4.6.1	Editorial	The laboratory must evaluate the MU for all calibrations it performs, including of its own equipment.	
7.6.3	5.4.6.2	Editorial	A laboratory performing testing must evaluate MU. In cases where rigorous evaluation of the MU may be precluded, due to the nature of the test method, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the methods.	
7.7	5.9		**Assuring the validity of results**	Clauses 7.7.1 and 7.7.2 separate the requirements into intralaboratory and external activities respectively.

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7.7.1	5.9.1	Minor	The laboratory shall have a procedure for monitoring the validity of results. The data is to be recorded in such a way as to allow trend analysis and where practical, statistical techniques are to be applied to review the results. Monitoring is to be a planned activity and must include, where appropriate: a) use of reference materials or quality control materials; b) use of alternative calibrated instrumentation providing traceable results; c) functional checks of measuring and testing equipment; d) use of check or working standards with control charts; e) intermediate checks on measuring equipment; f) replicate tests or calibrations; g) retesting or recalibration of retained items; h) correlation of results for different characteristics of an item; i) review of reported results; j) intralaboratory comparisons; k) testing of blind sample(s).	The standard now includes, for clarity, several additional quality control tools covered by b), c), i), j) and k). These would already be adopted by laboratories.
7.7.2	5.9.1b)	Major	The laboratory must monitor its performance by comparison with results of other laboratories, where possible and appropriate. This monitoring shall be planned and reviewed and include, but not limited to: a) participation in proficiency testing; b) participation in interlaboratory comparisons.	Even though participation in PT was not mandatory in ISO/IEC 17025:2005, it was included as a requirement in NATA's ISO/IEC 17025 Standard Application Document. Therefore, the requirement is not new for NATA accredited laboratories.

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7.7.3	5.9.2	Minor	Data from monitoring activities must be analysed, used to control and if applicable, improve the improve laboratory activities. Where the results of data analysis are outside pre-defined criteria, appropriate action is to be taken to prevent incorrect results being reported.	Additional emphasis now placed on monitoring processes to control and improve laboratory activities. This emphasis, however, is not a new concept for NATA accredited laboratories.
7.8	5.10		**Reporting of results**	
7.8.1	5.10.1		**General**	
7.8.1.1	5.10.2j)	Minor	Results must be reviewed and authorised prior to release.	Review of results has now been included and together with authorisation articulated as a separate subclause.
7.8.1.2	4.13.2.1; 5.10.1	Editorial	The results must be provided accurately, clearly, unambiguously and objectively. This is usually in the form of a report. In addition to the results, all information agreed with the customer and necessary for the interpretation of the results and required by the method must also be provided. All issued reports must be maintained as technical records.	
7.8.1.3	5.10.1	Minor	The results can be reported in simplified manner when agreed with the customer. Any information in 7.8.2 to 7.8.7 not reported to the customer must be available.	ISO/IEC 17025:2005 specifically required written agreement with the customer.
7.8.2	5.10.2		**Common requirements for reports (test, calibration or sampling)**	
7.8.2.1	5.10.2; 5.10.3.1 a); 5.10.6	Minor	Unless there is a valid reason for not doing so, each report must include at least: a) title; b) name and address of the laboratory;	ISO/IEC 17025:2005 required the name and address of customer rather than contact information. The new standard now additionally requires

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
			c) location of the performed activities; d) unique identification that all its components are recognised as a portion of a complete report and a clear identification of the end; e) name and contact information of the customer; f) method used; g) a description, unambiguous identification, and if necessary, the condition of the item; h) date of receipt or date of sampling of the item where this is critical to the validity and application of the results; i) date(s) of the performance of the laboratory activity; j) date of issue of the report; k) reference to the sampling plan and sampling method used if relevant to the validity and application of the results; l) statement to the effect that the results only relate to the item tested, calibrated or sampled; m) the results with the units of measurement, where appropriate; n) additions, deviations or exclusions from the method; o) identification of the person authorising the report; p) clear identification when the results are from external providers.	points j), n) and p). Point l) has also had “where relevant” deleted compared to the previous standard.

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.8.2.2		New	The laboratory is responsible for all the information in the report, except that provided by the customer. Data provided by the customer is to be clearly identified. Additionally, a disclaimer must be included when information is supplied by the customer which can affect the validity of the results. When the laboratory is not responsible for sampling, e.g. the sample has been supplied by the customer, it must state in the report that the results apply to the sample as received.	
7.8.3	5.10.3		**Specific requirements for test reports**	
7.8.3.1	5.10.3.1	Editorial	Where required for the interpretation of test results, reports must also include: a) information on specific test conditions, e.g. environmental conditions; b) a statement of conformity with requirements or specifications, where relevant; c) where applicable, MU in the same units as the measurand or in a term relative to the measurand; d) opinions and interpretations, where appropriate; e) information which may be required by specific methods, authorities, customers or groups of customers.	
7.8.3.2	5.10.3.2	See 7.8.5	When the laboratory is responsible for sampling, test reports are to meet the requirements in 7.8.5.	
7.8.4	5.10.4		**Specific requirements for calibration certificates**	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.8.4.1	5.10.4.1; 5.10.4.2; 5.10.4.3; 5.10.5	Editorial New c)	In addition to 7.8.2, calibration certificates must include: a) the MU presented in the same unit as the measurand or in a term relative to them; b) the conditions under which the calibrations were made that have an influence on the measurement results; c) a statement to indicate how the measurements are metrologically traceable; d) results before and after any adjustments or repair; e) where relevant, a statement of conformity with requirements or specifications; f) where appropriate, opinions and interpretations.	f) is a new point, however, ISO/IEC 17025:2005 did not preclude the inclusion of opinions and interpretations in calibration reports as covered in that standard by 5.10.5. Accordingly, 7.8.4.1 in the new standard is considered to only cover editorial changes.
7.8.4.2		New. See 7.8.5.	When the laboratory is responsible for sampling, calibration certificates must meet the requirements in 7.8.5, where necessary for the measurement results.	ISO/IEC 17025:2005, clause 5.10.3.2 only related sampling as applicable to test reports and not calibration certificates.
7.8.4.3	5.10.4.4	Editorial	Calibration certificates or labels must not include any recommendation on calibration intervals, unless agreed with the customer.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.8.5	5.10.3.2		**Reporting sampling - specific requirements**	
		Editorial New f)	When the laboratory is responsible for sampling, in addition to 7.8.2 reports must include the following where necessary for the interpretation of results: a) date of sampling; b) unique identification of the item or material sampled; c) the location of sampling, including any diagrams, sketches or photographs; d) a reference to the sampling plan and sampling method; e) details of any environmental conditions that affect the interpretation of the test results; f) information required to evaluate MU for subsequent testing or calibration.	The standard now also requires information to evaluate MU for subsequent testing or calibration to be included.
7.8.6			**Reporting statements of conformity**	
7.8.6.1		New	When a statement of conformity to a specification or standard is provided, the laboratory must document the decision rule it employs, taking into account the level of risk associated with the decision rule, and apply the decision rule.	Clause 5.10.3.1b) and 5.10.4.2 in ISO/IEC 17025:2005 covered statements of compliance. Hence, statements of conformity are not a new concept. However, the laboratory is now required to record the decision rule adopted taking into account the risk such a rule will have on reporting false positive or negative results. Refer also to clause 7.1.3.

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.8.6.2	5.10.3.1b); 5.10.4.2	Major	The laboratory must report on the statement of conformity: a) the results to which the statement of conformity applies; b) which specifications, standards or parts thereof that are met or not met; c) the decision rule applied (unless inherent in the requested specification or standard).	Reports which include statements of conformity are now also required to include the decision rule applied. Refer to 7.1.3 and 7.8.6.1.
7.8.7	5.10.5		**Reporting opinions and interpretations**	
7.8.7.1	5.2.5; 5.10.5	Editorial	When opinions and interpretations are provided, it must be ensured that only authorised personnel release the respective statement. The basis upon which the opinions or interpretations have been must be documented.	
7.8.7.2	5.10.4.2; 5.10.5	Minor	Opinions and interpretations included in reports are to be based on the results obtained from the tested or calibrated item and be clearly identified as such.	Clarity provided that opinions and interpretations are to be based on the results.
7.8.7.3	5.10.5 Note 3	Minor	When opinions and interpretations are verbally communicated to the customer, a record of the dialogue must to be kept.	ISO/IEC 17025:2005 included this requirement only as an informative Note.
7.8.8	5.10.9		**Amendments to reports**	
7.8.8.1		New	When an issued report requires changing, amendment, or reissuing, any change of information must be clearly identified. Where appropriate, the reason for the change is to be included in the report.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.8.8.2	5.10.9	Editorial	Amendments to reports shall only be made by issuing another document or data transfer. This document is to including wording to which identifies it as an amended documented. The amendments to reports must meet all the requirements of ISO/IEC 17025.	
7.8.8.3	5.10.9	Editorial	When a complete new report is issued, it must be uniquely identified and reference the original report it replaces.	
7.9	4.8		**Complaints**	The requirements have been significantly expanded. Even though this may be the case, many of the revised / new requirements would already be implemented by laboratories. All of the requirements under 7.9 are mandatory ISO/CASCO wording.
7.9.1	4.8	Editorial	The laboratory must have a documented process for receiving, evaluating and making decisions on complaints.	ISO/IEC 17025:2005 stated “resolution of complaints received”. This has now been clarified to “evaluating and making decisions”.
7.9.2		New	A description of the complaint handling process must be available to any interested party on request. Upon receiving a complaint, the laboratory must determine if it relates to the laboratory activities it is responsible for and if so, needs to deal with the complaint. The laboratory is responsible for all decisions in handling the complaint.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.9.3		New	The complaints handling process must include: a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; b) tracking and recording complaints, including actions taken to resolve them; c) ensuring that any appropriate action is taken.	
7.9.4		New	The laboratory receiving the complaint is responsible for gathering and verifying all information to validate the complaint.	
7.9.5		New	Whenever possible, the laboratory must acknowledge receipt of the complaint and provide the complainant progress reports and the outcome.	
7.9.6		New	The outcomes are to be communicated to the complainant by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.	This implies that a single person laboratory will need to engage an external resource.
7.9.7		New	Whenever possible, the laboratory is to give formal notice of the end of the complaint handling to the complainant.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.10	4.9		**Nonconforming work**	
7.10.1	4.9.1	Editorial	The laboratory must have a procedure for the addressing laboratory activities or results of these activities that do not conform with its own procedures or agreed customer requirements. The procedure must ensure that: a) the responsibilities and authorities for the management of nonconforming work are defined; b) actions are based upon the risk levels established by the laboratories; c) an evaluation is made of the significance of the nonconforming work, including an analysis of the impact on previous work; d) a decision is taken on the acceptability of the nonconforming work; e) the customer is notified and work recalled, if necessary; f) the responsibility for authorising the resumption of work is defined.	
7.10.2		New	Records must be retained of nonconforming work and actions as specified in 7.10.1 b) to f).	ISO/IEC 17025:2005 did not explicitly state that records must be retained.
7.10.3	4.9.2	Editorial	Where evaluation of nonconforming work identifies the chance for reoccurrence, or doubt is cast over the laboratory's compliance with its management system, the laboratory must implement corrective action.	
7.11	4.13		**Control of data and information management**	
7.11.1		New	The laboratory must have access to the data and information needed to perform its activities.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
7.11.2	5.4.7.2a)	Minor	The laboratory information management system(s) (LIMS) used for the collection, processing, recording, reporting, storage or retrieval of data must be validated for functionality. This includes the proper functioning of interfaces within the LIMS by the laboratory before introduction. Whenever there are changes, including modifications to commercial off-the shelf software or laboratory software configuration, they need to be authorised, documented and validated before implementation.	The standard now clarifies that changes / modifications to LIMS are to be validated. This was still implied in ISO/IEC 17025:2005.
7.11.3	4.13.1.2; 4.13.1.4; 4.13.2.1; 5.4.7.2b) & c)	Editorial	The LIMS must: a) be protected from unauthorised access; b) be safeguarded against tampering and loss; c) be operated in an environment that complies with supplier or laboratory specifications or, for non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription; d) be maintained in a manner which ensures the integrity of the data and information; e) include recording system failures and the appropriate immediate and corrective actions.	
7.11.4		New	If the LIMS is maintained off-site or by an external provider, the laboratory must ensure that the provider complies with all applicable requirements of the Standard.	
7.11.5	4.13.1.1	Minor	Instructions, manuals and reference data relevant to the LIMS must be readily available to personnel.	The standard now explicitly states this information to be available for LIMS.
7.11.6	5.4.7.1	No change	Calculations and data transfers must be checked.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
8			**Management system requirements**	
8.1			**Options**	
8.1.1			**General**	
		New	The laboratory must establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of the Standard and assuring the quality of laboratory results. In addition to meeting the requirements of clauses 4 to 7, the management system implemented must comply with Option A or B.	The laboratory may now choose either Option A or B to fulfil the management system requirements provided the option taken supports fulfilment of the General, Structural, Resource and Process requirements. In ISO/IEC 17025:2005 there was only one way to meet the management system requirements i.e. what is basically covered by Option A in the new standard. Option B in the new standard allows a laboratory to implement a system compliant with ISO 9001. The requirements of ISO 9001 that are relevant to laboratory activities have been included into Option A. Laboratories that implement Option A will operate generally in accordance with the principles of ISO 9001. Annex B (Informative) - provides some background and text.
8.1.2			**Option A**	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
		Major	The management system is to address, as a minimum; • management system documentation (8.2); • control of management system documents (8.3); • control of records (8.4); • actions to address risks and opportunities (see 8.5); • improvement (8.6) • corrective actions (8.7); • internal audits (8.8); • management reviews (8.9).	The management system now includes requirements for actions to address risks and opportunities.
8.1.3			**Option B**	
		New	A laboratory that maintains a management system, in accordance with the requirements of ISO 9001 which supports and demonstrates the consistent fulfilment of clauses 4 to 7, fulfils the intent of the management system requirements of 8.2 to 8.9.	The NATA *General Accreditation Criteria ISO/IEC 17025 Standard Application Document* (SAD) describes how NATA will assess facilities who have adopted ISO 9001 in accordance with Option B.
8.2	4.2		**Management system documentation (Option A)**	
8.2.1	4.1.5k); 4.2.1; 4.2.2	Editorial	Laboratory management must establish, document, and maintain policies and objectives for the fulfilment of the Standard. Policies and objectives need to be acknowledged and implemented at all levels of the laboratory organisation.	The standard no longer prescribes a quality policy or specifically a quality manual. Procedures, however, still need to be maintained.
8.2.2	4.1.5d)	Editorial	The policies and objectives must address the competence, impartiality and consistent operation of the laboratory.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
8.2.3	4.2.3	Editorial	The laboratory must provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness.	
8.2.4	4.2.5	Editorial	All documentation, processes, systems, records, related to the fulfilment of the requirements of the Standard must be included in, referenced from, or linked to the management system.	
8.2.5	4.2.1	Editorial	All personnel involved in laboratory activities must have access to the relevant management system documentation and related information applicable to their responsibilities	
8.3	4.3		**Control of management system documents (Option A)**	
8.3.1	4.3.1	Editorial	Documents (both internal and external) that relate to the fulfilment of the requirements in the Standard must be controlled.	
8.3.2	4.3.2.1; 4.3.2.2; 4.3.2.3; 4.3.3.1	Editorial	It must be ensured that: a) documents are approved prior to issue by authorised personnel; b) documents are periodically reviewed and updated; c) changes and the current revision status of documents are identified; d) relevant versions of documents are available and their distribution is controlled; e) documents are uniquely identified; f) unintended use of obsolete documents is prevented.	The requirements are now less prescriptive in the standard.
8.4	4.13		**Control of records (Option A)**	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
8.4.1	4.13.1.2	Editorial	Legible documents must be retained to demonstrate fulfilment of the requirements in the Standard.	
8.4.2	4.13.1.1; 4,13.1.2; 4.13.1.3	Editorial	The laboratory must implement controls for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. Records are to be retained for a period consistent with contractual obligations. Access to these records are to be consistent with confidentiality commitments, with records readily available.	
8.5			**Actions to address risks and opportunities (Option A)**	
8.5.1		New	Risks and opportunities associated with the laboratory activities must be considered in order to: • give assurance the management system achieve its intended results; • enhance opportunities to achieve the purpose and objectives of the laboratory; • prevent or reduce impacts and potential failures in the laboratory activities; • achieve improvement.	Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed. There is no requirement for a formal process or documented procedure for risk management.

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
8.5.2		New	The laboratory must plan; a) actions to address risks and opportunities; b) how to integrate and implement the actions into its management system in addition to evaluating the effectiveness of the actions.	
8.5.3		New	Actions taken to address risks and opportunities need to be proportional to the potential impact on the validity of the laboratory results.	
8.6	4.10		**Improvement (Option A)**	4.7, 4.10 and 4.12 in ISO/IEC 17025:2005 have been combined and simplified.
8.6.1	4.10; 4.12.1;	Editorial	Opportunities for improvement must be identified, selected and the necessary actions implemented.	
8.6.2	4.7.2	Editorial	Feedback must be sought from customers, analysed and used to improve the management system, laboratory activities and customer service.	
8.7	4.11		**Corrective action (Option A)**	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
8.7.1	4.9.1; 4.11.2; 4.11.3; 4.11.4	Minor	When a nonconformity occurs, the laboratory must: a) react and take appropriate actions to control and correct the nonconformity and address the consequences; b) evaluate the need for action to eliminate the cause(s) of nonconformity in order that it does not recur or occur elsewhere; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning; f) make changes to the management system, if required.	The principles of corrective action remain the same in the standard, however, the prescriptive nature of the requirements in ISO/IEC 17025:2005 have been simplified. A key change is that the impact of any nonconformity in relation to risks and opportunities must be determined.
8.7.2	4.11.3	Editorial	Corrective actions are to be appropriate to the effects of the nonconformities encountered.	
8.7.3	4.11.3; 4.13.1.1	Minor	Records are to be retained as evidence of: a) the nature of the nonconformities, cause(s) and any actions taken; b) the results of corrective action.	
8.8	4.14		**Internal audits (Option A)**	
8.8.1	4.14.1; 4.14.2	Minor	Internal audits must be conducted at planned intervals to provide information on whether the management system: a) conforms to the laboratory's own requirements for the management system (including the laboratory activities) and the requirements of the Standard; b) is effectively implemented and maintained.	ISO/IEC 17025:2005 specified that internal audits were the responsibility of the quality manager. The new standard now requires personnel to be authorised (refer to 6.2).

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
8.8.2	4.14.1; 4.14.2; 4.14.3	Editorial	The laboratory must: a) plan, establish, implement and maintain an audit programme which takes into account the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits; b) define the audit criteria and scope for each audit; c) ensure that the results of the audits are reported to relevant management; d) implement appropriate correction and corrective actions without undue delay; e) retain records as evidence of the implementation of the audit program and the audit results.	The standard now requires the results of previous audits to be taken into account and that the criteria and scope for each audit be defined.
8.9	4.15		**Management reviews (Option A)**	
8.9.1	4.15.1	Editorial	Laboratory management must review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objective related to the fulfilment of the Standard.	

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
8.9.2	4.15.1	Editorial New a), b), d), k) and m)	Inputs to the management review are to be recorded and include information related to: a) changes in relevant internal and external issues; b) fulfilment of objectives; c) suitability of policies and procedures; d) status of actions from previous management reviews; e) outcomes of recent internal audits; f) corrective actions; g) assessments by external bodies; h) changes in the volume or in the range of laboratory activities; i) customer and personal feedback; j) complaints; k) effectiveness of any implemented improvements; l) adequacy of resources; m) results of risk identification; n) outcomes of the assurance of the validity of results; o) other relevant factors, such as monitoring activities and training.	The management review requirements are essentially the same, however, the elements to review have been expanded, notably points a), b), d), k) and m).
8.9.3	4.15.2	Editorial	The outputs from the management review must record all decisions and actions related to: a) the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of the Standard; c) provision of required resources; d) any need for change.	The standard now specifies those actions needing to be recorded.

ISO/IEC 17025:2017 Clause No.	Corresponding ISO/IEC 17025:2005 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17025:2017	Comments
		New	**Annex A (informative) – Metrological traceability**	Refer to the Standard for details.
		New	**Annex B (informative) Management system**	Refer to the Standard for details.