ISO/IEC 17025:2017
Transition Notice: A new laboratory accreditation standard

The NZ mark of competence
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1. Background

IANZ currently uses the International and New Zealand Standard NZS/ISO/IEC 17025:2005 as generic accreditation criteria for all laboratories except medical testing laboratories (the latter being accredited against the ISO 15189:2012). The International Standard ISO/IEC 17025:2005 has for the last three years been undergoing a revision to align it with ISO 9001:2015. This review is now complete and as a result the International Standards Organisation (ISO) has published, in December 2017, the 2017 edition of *ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories.* The following summarises the changes and up-dates in the new edition and details the transition requirements for accredited laboratories (except medical testing laboratories) to implement the new standard.

2. New and Updated Requirements

The main changes in the 2017 edition of ISO/IEC 17025 are as follows:

- Introduction of risk based thinking which has enabled the reduction in some of the prescriptive requirements, which are replaced with performance-based requirements.
- Greater flexibility in the 2017 edition for the requirements for processes, procedures, documented information and organisational responsibilities.
- The definition of a laboratory has been included, along with other definitions related to laboratory activities which have not previously been set out in the standard.

All the new requirements are included in the attached **ISO/IEC 17025:2017 Implementation Tables**, which details the changes and gives guidance from IANZ on the expectations on laboratories in terms of implementation of these requirements.

3. Transition

The International Laboratory Accreditation Cooperation (ILAC) has confirmed a transition period of three years for the implementation of ISO/IEC 17025:2017. As a signatory to the ILAC Mutual Recognition Arrangement, IANZ and its accredited laboratories are bound by this transition period.

Therefore, all accredited laboratories (except medical testing laboratories) must demonstrate their conformity with the new standard by 1 December 2020.

IANZ has arranged with Standards New Zealand to have ISO/IEC 17025:2017 adopted as a New Zealand Standard, and has published and printed the new standard, NZS ISO/IEC 17025:2018 on behalf of IANZ. This new accreditation standard is being made available free of charge to all applicant and accredited laboratories, and details on how to access a copy of this document have been provided to the Authorised Representative of the laboratory. Note that Standards New Zealand did not publish the standard as a New Zealand Standard until 2018 hence the different date on the NZS ISO/IEC 17025 edition.

As advised in January 2018, **IANZ assessment teams will commence assessment of laboratories against the requirements of the new standard from 1 July 2018.**

Assessment against the 2017 edition applies to both applicant laboratories at their initial assessment and currently accredited laboratories at their next scheduled Routine Reassessment after 1 July 2018. Accredited laboratories will initially be given 6 months to clear any Corrective Action Requests from the assessment that relate to the implementation of the new requirements. After 1 July 2019 laboratories will be given 3 months only to clear Corrective Action Requests. Laboratories are reminded that all accredited laboratories must demonstrate conformity by the 1 December 2020 deadline.

Laboratories may choose to be assessed against the updated standard earlier than their scheduled Routine Reassessment e.g. at a Surveillance Assessment. In such cases laboratories must provide updated laboratory documentation (i.e. Quality Manual) in advance of their Surveillance Assessment to allow for a document review to be carried out prior to the on-site visit. It is recommended the laboratory to contact the Programme

Manager/Programme Specialist and discuss the request with them. A review of laboratory documentation to confirm requirements of the updated standard will not be carried out at an on-site assessment.

Once conformity has been demonstrated, IANZ will issue new Certificates of Accreditation and new Schedules to the Certificate of Accreditation detailing the new accreditation standard.

4. The New ISO/IEC 17025

Table 1 below sets out the new requirements as a summary and identifies where clauses have been relocated in the new edition of the standard as a comparison. Table 2 provides more detail on what the changes are.

Where new requirements have been included in the 2017 edition of ISO/IEC 17025, some additional comments or information has been included in Table 2, unless the expanded/new requirement is considered self-explanatory.

Where part of the clause (requirement) is new this has been highlighted in red text. Where the entire clause is new as indicated in Column 2 (Table 2) then the text has not been highlighted.

Table 1: ISO/IEC 17025:2017 Implementation - OVERVIEW

	ISO/IEC 17025:2017	ISO/IEC 17025:2005	Comments
Section 4: General requirements			
4.1	Impartiality	4.1.4, 4.1.5(b, d)	New requirements in 2017
4.2	Confidentiality	4.1.5(c)	New requirements in 2017
Section 5: Structural requirements			
5.1	Legal entity	4.1.1	Similar to the 2005 edition
5.2	Identify laboratory management	-	New requirement
5.3	Define and document the range of laboratory activities for which it complies with ISO/IEC 17025	-	New requirement
5.4	Activities carried out to meet ISO/IEC 17025 requirements, and customer and regulatory requirements	4.1.2	Similar to the 2005 edition
5.5	Laboratory to: • define organisation and management structure • specify responsibilities and authorities • document procedures to ensure consistent application	4.1.5(e) 4.1.5(f) 4.2.1	Similar to the 2005 edition
5.6	Personnel with authority and resources to fulfil the Quality Manager function	4.1.5(a, i)	Amended from the 2005 edition
5.7	Laboratory management to ensure: • effective communication • integrity of the management system	4.1.6 4.2.4, 4.2.7	Similar to the 2005 edition

	ISO/IEC 17025:2017	ISO/IEC 17025:2005	Comments
Section 6: Resource requirements			
6.1	General requirement to have appropriate resources	-	Not an additional or new requirement but stated differently
6.2	Personnel	4.1.5(k) 5.2	Some amended requirements from that in the 2005 edition
6.3	Laboratory facilities and environment	5.3	Similar to the 2005 edition
6.4	Equipment	5.5.1, 5.5.2, 5.5.4, 5.5.5, 5.5.6, 5.5.7, 5.5.8, 5.5.10, 5.5.11, 5.5.12, 5.6.1	Similar to the 2005 edition with several expansive amendments
6.5	Metrological traceability	5.6.2	Similar to the 2005 edition with further clarification in the requirements
6.6	Externally provided products and services	4.5.4 4.6.1, 4.6.2, 4.6.3, 4.6.4	New requirements to that in the 2005 edition. This section is essentially what was covered by purchasing and subcontracting.
Section 7: Process requirements			
7.1	Review of requests, tenders and contracts	4.4.1, 4.4.2, 4.4.4, 4.4.5, 4.5.2, 4.7.1	Expanded on the 2005 edition with additional requirements now included.
7.2.1	Selection and verification of methods	5.4.1, 5.4.2, 5.4.3	Similar to the 2005 edition with further clarification in the requirements.
7.2.2	Validation of methods	5.4.5.2, 5.4.2.2 Note 3, 5.4.5.3	Similar to the 2005 edition with further clarification in the requirements.
7.3	Sampling	5.7.1 Note 2, 5.7.3	Expanded on the 2005 edition with additional requirements now included.
7.4	Handling of test or calibration items	5.8.1	Slightly expanded on the 2005 edition with one new requirement.
7.5	Technical records	4.13.2	Records has now been split into two sections; there are no new requirements in this section.
7.6	Evaluation of measurement uncertainty	5.4.6.1, 5.4.6.2, 5.4.6.3	A new note has been included; there are no new requirements.
7.7	Ensuring the validity of results	5.9	Expanded on the 2005 edition with additional requirements now included.

	ISO/IEC 17025:2017	ISO/IEC 17025:2005	Comments
7.8	Reporting the results	5.10	Expanded on the 2005 edition with additional requirements now included.
7.9	Complaints	4.8	Expanded and new requirements.
7.10	Nonconforming work	4.9	No change from the 2005 edition.
7.11	Control of data and information management	5.4.7.1, 5.4.7.2	Expanded on the 2005 edition with additional requirements now included.
Section 8: Management system requirements			
8.1	Options	4.2.1 and new	Introduces the option A (generally as per the 2005 edition and option B (new) which is an ISO 9001 system.
8.2	Management system documentation	4.2.1, 4.2.2, 4.2.5, 4.10	No changes from the 2005 edition.
8.3	Control of management system documents	4.3	Simplified from the 2005 edition requirements.
8.4	Control of records	4.13.1	No changes from the 2005 edition.
8.5	Actions to address risks and opportunities	-	New requirements
8.6	Improvement	4.7.2, 4.10	Amended from the 2005 edition but nothing new of significance.
8.7	Corrective actions	4.11	Expanded from the 2005 edition
8.8	Internal audits	4.14	Additional clarification as to the scope of the audit.
8.9	Management review	4.15	Expanded from the 2005 edition

Table 2: ISO/IEC 17025:2017 Implementation

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
Section 4: General requirements			
4.1 Impartiality			
4.1.1 4.1.2 4.1.3 4.1.4 4.1.5	New	**4.1.4** The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality. **4.1.5** If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.	Requirements to address impartiality were covered previously in clauses 4.1.4 and 4.1.5(b, d) of the 2005 edition. The requirements which have been introduced in clauses 4.1.4 and 4.1.5 of the 2017 edition call up the requirement for laboratories to identify risks to impartiality and to demonstrate how it eliminates or minimizes the risk.
4.2 Confidentiality			
4.2.1	Expanded	**4.2.1** The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.	Some of what is now clause 4.2.1 was previously covered under 4.1.5(c). Much of the remainder is new in theory however it is expected it will make little difference in practice.
4.2.2	New	**4.2.2** When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided	The laboratory will need to consider how this will be managed should the need arise. In particular, laboratories that routinely make information available to third parties will need to ensure they have processes that meet this requirement.

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
4.2.3	New	**4.2.3** Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.	No additional comments.
4.2.4	Expanded	**4.2.4** Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities.	The standard is now clear as to which personnel are required to maintain as confidential any information related to the laboratory's activities.
Section 5: Structural requirements			
5.2	New	**5.2** The laboratory shall identify management that has overall responsibility for the laboratory.	The laboratory is now required to identify those responsible for laboratory management; the 2005 edition required only that the laboratory have managerial and technical personnel.
5.3	Expanded	**5.3** The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.	The scope of activities as previously required in the 2005 edition has now been clarified to limit it to those for which the laboratory claims conformity with ISO/IEC 17025.
5.6	Amended	**5.6** The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: a) implementation, maintenance and improvement of the management system; b) identification of deviations from the management system or from the procedures for performing laboratory activities; c) initiation of actions to prevent or minimize such deviations; d) reporting to laboratory management on the performance of the management system and any need for improvement; e) ensuring the effectiveness of laboratory activities.	The standard no longer refers to a Quality Manager; it now defines the function of what the Quality Manager is generally responsible for.

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
Section 6: Resource requirements			
6.2 Personnel			
6.2.2	Expanded	**6.2.2** The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.	The laboratory needs to establish and document competency requirements for the staff positions that influence results i.e. competency requirements for a technician.
6.2.3	New	**6.2.3** The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.	No additional comments.
6.2.4	Amended	**6.2.4** The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.	The standard no longer specifically refers to job descriptions. This is an example of a less prescriptive requirement. The laboratory still needs to establish a process to inform staff of the duties etc.; however, this is no longer required in the form of a job description.
6.3 Facilities and environmental conditions			
6.3.2	New	**6.3.2** The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.	Laboratories now need to not only maintain records to show that requisite environmental conditions have been met, but need to document what those conditions are in the first instance.
6.3.5	New	**6.3.5** When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.	No additional comments.
6.4 Equipment			
6.4.1	Expanded	**6.4.1** The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) which is required for the correct performance of laboratory activities and which can influence the results.	The standard now includes examples of what could be considered equipment and therefore needs to be managed accordingly.

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
6.4.5	Expanded	**6.4.5** The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.	The clause has been expanded from that in the 2005 edition to state measurement uncertainty is to be considered in the selection of appropriate equipment.
6.4.6	Amended	**6.4.6** Measuring equipment shall be calibrated when: • the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or • calibration of the equipment is required to establish the metrological traceability of the reported results.	Amended to provide clarity as to when equipment requires calibration. The requirement to calibrate has not changed.
6.4.11	Expanded	**6.4.11** When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.	Expanded to include reference material which can also provide metrological traceability and therefore the same amendments need to be applied, where relevant.
6.4.13	Expanded	**6.4.13** Records shall be maintained for equipment which can influence the laboratory activities. The records shall include at least the following: a) the identity of equipment, including software and firmware version (where available);	Expanded to include software and firmware, to be managed as per other equipment.
6.5 Metrological traceability			
6.5.3	Amended	**6.5.3** When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g. a) certified values of certified reference materials provided by a competent producer; b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.	Re-worded to provide clarity around the mechanisms available where metrological traceability to the SI is not possible.

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
6.6 Externally provided products and services			
6.6.1	New	**6.6.1** The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services: a) are intended for incorporation into the laboratory's own activities; b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; c) are used to support the operation of the laboratory.	New wording and requirements. This section covers both purchased products and services (subcontracting). The new wording is also intended to provide clarity as to which services purchased by the laboratory need to be covered under these requirements e.g. those used to support the operation of the laboratory.
6.6.2	Expanded	**6.6.2** The laboratory shall have a procedure and retain records for: c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer; d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.	Point c) requires the laboratory to review information such as reports associated with subcontracted testing prior to passing this on to the customer, which should have been undertaken in the past but is now set out as a requirement. As for point c), point d) should have been carried out as part of the review of suppliers and subcontractors, and is now clearly included as a requirement.
6.6.3	Amended	**6.6.3** The laboratory shall communicate its requirements to external providers for: a) the products and services to be provided; b) the acceptance criteria; c) competence, including any required qualification of personnel; d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.	The wording is new, the concept is not. The requirement to specify what is required when purchasing items and services was in the 2005 edition.
Section 7: Process requirements			
7.1 Review of requests, tenders and contracts			
7.1.3	New	**7.1.3** When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and	The requirement for defining the decision rule where the laboratory is required by the customer to make a statement of conformity based on the test / measurement results is now included in the

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		the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.	statement. Where a laboratory is not reporting statements of conformity, this will not be required.
7.1.4	New	**7.1.4** Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.	This requirement has been included to assist laboratories in deciding if work should be accepted when the factors contributing to the validity of the result may be such that the result integrity is impacted i.e. inappropriate sample, inadequate sampling site, and customers request that testing is carried out regardless.
7.2 Selection, verification and validation of methods			
7.2.1.5	Expanded	**7.2.1.5** The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.	The standard is now very clear with regards to the retention of verification records. It is expected that this is in the form of a verification report and retained in such a way it is readily retrievable.
7.2.2.2	New	**7.2.2.2** When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.	This requirement was previously Note 3 in clause 5.4.5.3 of the 2005 edition.
7.2.2.4	Expanded	**7.2.2.4** The laboratory shall retain the following records of validation: a) the validation procedure used; b) specification of the requirements; c) determination of the performance characteristics of the methods; d) results obtained; e) a statement on the validity of the method, detailing its fitness for the intended use.	The standard now includes a list of what needs to be covered when undertaking method validation, i.e. validation of a new or modified method, and includes two additional requirements not previously included in the 2005 edition (clause 5.4.5.2).
7.3 Sampling			
7.3.2	New	**7.3.2** The sampling method shall describe:	This requirement was included in the 2005 edition as a Note so, while not completely new, it is now mandatory for those

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
		a) the selection of samples or sites; b) the sampling plan; c) preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.	laboratories seeking accreditation for their sampling activities.
7.3.3	Expanded	**7.3.3** The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant: b) date and time of sampling; c) data to identify and describe the sample (e.g. number, amount, name); e) identification of the equipment used; h) deviations, additions to or exclusions from the sampling method and sampling plan.	The list of records to support sampling activities has been expanded, with only the new records listed here.
7.4 Handling of test of calibration items			
7.4.3	Expanded	**7.4.3** Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.	While the requirement to include deviations from specified conditions is not totally new, it was previously under Clause 5.10.2 for reporting in that sample condition was to be included on the report, it has been expanded to include the laboratory is required to report a disclaimer with regards to the results which may be impacted by the sample/item condition.
7.6 Evaluation of measurement uncertainty			
7.6.3 Note 2	New	**NOTE 2** For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical	Notes are not mandatory; however, they should be regarded as informative and applied where relevant or appropriate. This note was not included in the 2005 edition of the standard.

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
		influencing factors are under control.	
7.7	**Ensuring the validity of results**		
7.7.1	Expanded	**7.7.1** The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to: b) use of alternative instrumentation that has been calibrated to provide traceable results; c) functional check(s) of measuring and testing equipment; d) use of check or working standards with control charts, where applicable; e) intermediate checks on measuring equipment; i) review of reported results;	The list of activities to ensure the validity of results has been expanded, with only the new records listed here.
7.8	**Reporting of results**		
7.8.1	Expanded	**7.8.1** The results shall be reviewed and authorized prior to release	The process of review prior to the authorisation of results has been included. This may or may not be undertaken by the same staff member.
7.8.2.1	Expanded	**7.8.2.1** Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse: c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities. d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; o) identification of the person(s) authorizing the report;	The list includes only those requirements that are expanded or new to reporting. Point c) is not new but has been expanded to clarify what location information needs to be included on the report. Point d) could be pagination of a report or some other way of identifying the information provided is the entire report i.e. as may be needed for electronic data as the report. Point o) has been amended; a signature is no longer required, of the individual authorising the report

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
7.8.2.2	Expanded	**7.8.2.2** The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.	The expanded requirement in this clause covers subcontracted testing which is incorporated into the laboratory's own report. Also now clearly required is a disclaimer where the laboratory report includes customer supplied information such as pH or Chlorine results, for water samples, where the laboratory has not performed the testing but the customer requests all the information be included in the report.
7.8.3.1c) 7.8.4.1a)	Amended	Where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when: • it is relevant to the validity or application of the test results; • a customer's instruction so requires, or • the measurement uncertainty affects conformity to a specification limit;	For both test reports and calibration certificates clarification has been added to state how measurement uncertainty needs to be reported.
7.8.3.2 7.8.4.2	New	Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of the test results / calibration results.	The standard now explicitly calls up sampling as an activity that could be undertaken by the laboratory and therefore include specific reporting requirements associated with sampling activities. The clause for generic reporting of sampling activities has been included with testing and calibration activities in each case referencing 7.8.5.
7.8.5	New	f) information required to evaluate measurement uncertainty for subsequent testing or calibration.	In addition to the requirements for reports on sampling activities which remain as per the 2005 edition, laboratories now need to include information required to evaluate measurement uncertainty, where necessary for the interpretation of the results
7.8.6.1	New	**7.8.6.1** When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule. NOTE Where the decision rule is prescribed by the customer,	No additional comments.

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
		regulations or normative documents, a further consideration of the level of risk is not necessary.	
7.8.6.2	New	**7.8.6.2** The laboratory shall report on the statement of conformity, such that the statement clearly identifies: a) to which results the statement of conformity applies; b) which specifications, standards or parts thereof are met or not met; c) the decision rule applied (unless it is inherent in the requested specification or standard).	No additional comments.
7.8.7.2 7.8.7.3	New	**7.8.7.2** The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such. **7.8.7.3** When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.	In the past IANZ has not permitted opinions and interpretations to be reported under the laboratory's accreditation and this has not changed. However, many laboratories did provide such information to their customers under a separate cover such as a cover letter or email. Note that, even where such information is conveyed verbally, a record needs to be retained.
7.8.8.1	Expanded	**7.8.8.1** When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.	Amended reports now need to contain the reason for the change, where appropriate, which is an expansion on the requirements in the 2005 edition.
7.9 Complaints			
7.9.2 7.9.3 7.9.4 7.9.5 7.9.6 7.9.7	Expanded and new	**7.9.2** A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints. **7.9.6** The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.	The 2005 edition had single requirement to have policies and procedures for the resolution of complaints. The requirements have been expanded to clarify exactly what the policies and procedures need to cover. Of particular note are clauses 7.9.2 and 7.9.6.

Clause No.	Amended / New	Extract from ISO/IEC 17025:2005	IANZ Comment
7.11 Control of data and information management			
7.11.4	New	**7.11.4** When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.	A new requirement for the laboratory to ensure the suitability of off-site service providers. The laboratory will need to have records supporting how they were able to establish that the provider complies with applicable requirements of the standard.
7.11.5	New	**7.11.5** The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.	No additional comments.
Section 8: Management system requirements			
8.1 Options			
8.1 8.2	Amended	**8.1.1 General** The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard and assuring the quality of the laboratory results. In addition to meeting the requirements of clauses 4 to 7 of this International Standard the laboratory shall implement a management system in accordance with option A or option B.	The standard now allows for options with regard to the management system and what was Section 4 of the 2005 edition. Option A is business as usual in terms of the documented management system, with the introduction of the new clauses, such as 8.5.
8.3	New	**8.1.3 Option B** A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9**.**	This is new. Laboratories that choose to implement their management system through an ISO 9001 compliant system will need to ensure that their system supports the laboratory's processes. An ISO 9001 system that makes no reference to the operation and management of the laboratory and its activities will not suffice.
8.3 Control of management system documentation			
8.3.1	Amended	**8.3.1** The laboratory shall control all documents that relate to the fulfilment of this document.	This is an example of a less prescriptive requirement. The standard no longer requires policies and procedures to control document. The requirement is now to control them, and how this

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			is managed is the laboratory's decision. In practice, it is not expected to make a significant change to the laboratory's systems.
8.5 Actions to address risks and opportunities			
8.5.1	New	**8.5.1** The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to: a) give assurance that the management system achieves its intended results; b) enhance opportunities to achieve the purpose and objectives of the laboratory; c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; d) achieve improvement.	While a new requirement, many laboratories have processes as part of their business plan that might prove suitable to support this part of their management system. It is recommended the processes for risk and opportunity management are integrated into the laboratory's system so it is managed on an ongoing basis rather than a periodic event as it is also part of the requirements for impartiality and corrective action.
8.5.2	New	**8.5.2** The laboratory shall plan: a) actions to address these risks and opportunities; b) how to: • integrate and implement the actions into its management system; • evaluate the effectiveness of these actions.	The laboratory will need to have documented a plan as to how identified risks and opportunities are managed, and records to demonstrate the effectiveness of the actions taken.
8.5.3	New	**8.5.3** Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.	The laboratory will need to have records of the actions taken.
8.7 Corrective actions			
8.7	New	**8.7.1** When a nonconformity occurs, the laboratory shall: e) update the risks and opportunities determined during planning, if necessary	The requirement to consider risks which is now throughout the standard is included here, along with opportunities as part of the corrective action process.
8.8 Internal audits			
8.8.1a)	Amended	**8.8.1** The laboratory shall conduct internal audits at planned intervals to provide information on whether the management	The 2017 edition of the standard is now clearer on what the scope of the internal audit programme needs to cover which includes the

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		system; a) conforms to: • the laboratory's own requirements for its management system, including the laboratory activities • the requirements of this document	management system, laboratory activities (testing, sampling, calibration or a combination thereof) and conformance with ISO/IEC 17025.
8.9 Management reviews			
8.9.2	Expanded	**8.9.2** The inputs to management review shall be recorded and shall include information related to the following: m) results of risk identification	The scope of management review has been expanded to include the new requirements for the results of risk identification.