ISO/IEC 17025:2017 Assessment Checklist (b)

Where highlighted (bold) text has been included for clauses identified as a "Major Change", it emphasizes the key change(s) of the requirement (compared to the previous version of the standard).

ISO/IEC 17025:2017 Clause No.	**Emphasis of Change**	**Summary of text/extract from ISO/IEC 17025:2017**	**Action taken with reference to supporting evidence (as necessary)** **(Attach supporting evidence separately and include reference to the clause number)**
1	1	Scope	
2	2	Normative References	
3	3	Terms and definitions	
4		**General requirements**	
4.1		**Impartiality**	
4.1.1	Editorial	Laboratory to manage and structure its activities to safeguard impartiality.	
4.1.2	Editorial	Laboratory management to be committed to impartiality.	
4.1.3	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.	
4.1.5	New	The laboratory must be able to demonstrate how it minimizes or eliminates the risks it identifies.	

4.2		**Confidentiality**	
4.2.1	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.	
4.2.2	New	When the laboratory is required by law or authorized 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**	
	Editorial	The laboratory is to be a legal entity or a defined part of a legally entity and be legally responsible for its activities.	
5.2	Editorial	Management who have overall responsibility for the laboratory need to be identified.	
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	Editorial	Laboratory activities need to meet the requirements of the Standard, its customers, regulatory authorities and organization 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	Editorial	The laboratory must: a) define the organization 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.	
5.6	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 minimize deviations; d) reporting on the management system; e) ensuring the effectiveness of laboratory activities.	
5.7	Editorial	Laboratory management needs to ensure: a) communication on the effectiveness of the management system and customer requirements; b) management system integrity.	
6.0		**Resource Requirements**	

6.1		**General**	
	Editorial	The laboratory to have available the necessary resources to perform its laboratory activities.	
6.2		**Personnel**	
6.2.1	Editorial	All personnel are to act impartially, be competent and adhere to the laboratory's management system.	
6.2.2	Editorial	The competence requirements for each function influencing the results of laboratory activities must be documented.	
6.2.3	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.	
6.2.4	Minor	Duties, responsibilities and authorities shall be communicated to personnel.	
6.2.5	Major	Procedures and records need to be maintained for personnel covering: a) determination of competence requirements; b) to e) selection, training, supervision and authorization; and f) monitoring of competence.	
6.2.6	Major	Personnel must be authorized 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 authorize results.	
6.3		Facilities and Environmental Conditions	

6.3.1	Editorial	The facilities and environmental conditions need to be suitable to the activities performed and not adversely affect the validity of results.	
6.3.2	Editorial	The requirements for suitable facilities and environmental conditions to perform laboratory activities shall be documented.	
6.3.3	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	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.	
6.3.5	Editorial	The requirements related to facilities and environmental conditions also apply to activities performed at facilities outside the laboratory's permanent control.	
6.4		**Equipment**	
6.4.1	Editorial	There must be access to equipment required for the correct performance of the laboratory activities and which can influence the results.	
6.4.2	Editorial	Equipment outside the permanent control of the laboratory shall be capable of satisfying the requirements in the standard.	
6.4.3	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	Editorial	Before being placed in or returned to service, the laboratory shall verify that equipment complies with specified requirements.	
6.4.5	Minor	Equipment shall be capable of achieving the measurement accuracy or measurement uncertainty (MU) required to provide a valid result.	
6.4.6	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.	
6.4.7	Major	A calibration program shall be established, reviewed and adjusted as necessary, to ensure confidence in the status of calibrations.	
6.4.8	Editorial	All equipment which requires calibration or has a defined period of validity must be labelled or otherwise identified.	
6.4.9		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	Editorial	A procedure is to be followed when intermediate equipment checks are necessary.	
6.4.11	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	
6.4.12	Editorial	Practical measures must be taken to prevent unintended adjustments to equipment.	
6.4.13	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.	
6.5		**Metrological Traceability**	
6.5.1	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	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 realization of the SI units.	

6.5.3	Editorial	When metrological traceability is not possible to SI units, traceability is to be demonstrated to an appropriate reference.	
6.6		**Externally provided products and services**	
6.6.1	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	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.	
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.	

7		**Process Requirements**	
7.1		**Review of requests, tenders and contracts**	
7.1.1	Editorial	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	Editorial	The laboratory must inform the customer when the method requested is not considered appropriate or out of date.	
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.	
7.1.4	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.	
7.1.5	No change	Customer must be informed on any deviations to the contract.	
7.1.6	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	Editorial	The laboratory shall cooperate with customers to clarify request and to allow the customer to monitor the laboratory's performance.	
7.1.8	Editorial	Records of contract reviews and significant changes must be kept. Records include pertinent discussions relating to the customer's requirements or results generated.	
7.2		**Selection, verification and validation of methods**	
7.2.1		**Selection and verification of methods**	
7.2.1.1	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.	
7.2.1.2	Editorial	All methods, procedures and supporting documentation shall be kept current and readily available to personnel.	
7.2.1.3	Editorial	Latest versions of methods shall be used unless it is not appropriate or possible. Methods shall be supplemented, where necessary.	
7.2.1.4	Editorial	Appropriate methods shall be selected when the customer does not specify the methods to be used.	
7.2.1.5	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.	

7.2.1.6	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.	
7.2.1.7	Editorial	Deviations from methods shall only occur is the deviation has been documented, technically justified, authorized and accepted by the customer.	
7.2.2		**Validation of methods**	
7.2.2.1	Editorial	Non-standard methods, laboratory-developed methods and standard methods used outside of their scope shall be validated.	
7.2.2.2	Minor	When changes are made to validated methods, the influence of such changes must be determined and validation performed again, if appropriate.	
7.2.2.3	Editorial	The performance characteristics of validated methods must be consistent with specified requirements and relevant to the customers' needs.	
7.2.2.4	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.	
7.3		**Sampling**	
7.3.1	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	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.	
7.3.3	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.	
7.4		**Handling of test or calibration items**	
7.4.1	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.	
7.4.2	Editorial	A system for the unambiguous identification of test and calibration items shall be established.	
7.4.3	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.	
7.4.4	Editorial	When items need to be stored or conditioned, the conditions shall be maintained, monitored and recorded.	
7.5		**Technical Records**	
7.5.1	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	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.	
7.6		**Evaluation of measurement uncertainty**	
7.6.1	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.	
7.6.2	Editorial	The laboratory must evaluate the MU for all calibrations it performs, including of its own equipment.	
7.6.3	Edititorial	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		**Assuring the validity of tests**	
7.7.1	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).	

7.7.2	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.	
7.7.3	Minor	Data from monitoring activities must be analyzed, 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.	
7.8		**Reporting of results**	
7.8.1		**General**	
7.8.1.1	Minor	Results must be reviewed and authorized prior to release.	
7.8.1.2	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	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.	
7.8.2		**Common requirements for reports (test, calibration or sampling)**	

7.8.2.1	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; c) location of the performed activities; d) unique identification that all its components are recognized 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 authorizing the report; p) clear identification when the results are from external providers.	
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		**Specific requirements for test reports**	
7.8.3.1	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	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		**Specific requirements for calibration certificates**	
7.8.4.1	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.	
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.	
7.8.4.3	Editorial	Calibration certificates or labels must not include any recommendation on calibration intervals, unless agreed with the customer.	
7.8.5		**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.	
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.	
7.8.6.2	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).	
7.8.7		**Reporting opinions and interpretations**	
7.8.7.1	Editorial	When opinions and interpretations are provided, it must be ensured that only authorized personnel release the respective statement. The basis upon which the opinions or interpretations have been must be documented.	
7.8.7.2	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.	
7.8.7.3	Minor	When opinions and interpretations are verbally communicated to the customer, a record of the dialogue must to be kept.	
7.8.8		**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.	
7.8.8.2	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	Editorial	When a complete new report is issued, it must be uniquely identified and reference the original report it replaces.	
7.9		**Complaints**	
7.9.1	Editorial	The laboratory must have a documented process for receiving, evaluating and making decisions on complaints.	
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.	
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.	
7.9.7	New	Whenever possible, the laboratory is to give formal notice of the end of the complaint handling to the complainant.	
7.10		**Nonconforming work**	
7.10.1	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 authorizing 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).	
7.10.3	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		**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.	
7.11.2	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 authorized, documented and validated before implementation.	
7.11.3	Editorial	The LIMS must: a) be protected from unauthorized access; b) be safeguarded against tampering and loss; c) be operated in an environment that complies with supplier or laboratory specifications or, for non-computerized 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	Minor	Instructions, manuals and reference data relevant to the LIMS must be readily available to personnel.	
7.11.6	No change	Calculations and data transfers must be checked.	
8		**Management system requirements**	
8.1		**Options**	
8.1.1	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.	
8.1.2		**Option A**	
	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).	
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.	
8.2		**Management system documentation (Option A)**	
8.2.1	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 organization.	
8.2.2	Editorial	The policies and objectives must address the competence, impartiality and consistent operation of the laboratory.	
8.2.3	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	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	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		**Control of management system documents (Option A)**	
8.3.1	Editorial	Documents (both internal and external) that relate to the fulfilment of the requirements in the Standard must be controlled.	
8.3.2	Editorial	It must be ensured that:	

		a) documents are approved prior to issue by authorized 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.	
8.4		**Control of records (Option A)**	
8.4.1	Editorial	Legible documents must be retained to demonstrate fulfilment of the requirements in the Standard.	
8.4.2	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.	

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		**Improvement (Option A)**	
8.6.1	Editorial	Opportunities for improvement must be identified, selected and the necessary actions implemented.	
8.6.2	Editorial	Feedback must be sought from customers, analyzed and used to improve the management system, laboratory activities and customer service.	
8.7		**Corrective action (Option A)**	
8.7.1	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.	

8.7.2	Editorial	Corrective actions are to be appropriate to the effects of the nonconformities encountered.	
8.7.3	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		**Internal audits (Option A)**	
8.8.1	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.	
8.8.2	Editorial	The laboratory must: a) plan, establish, implement and maintain an audit program 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.	
8.9		**Management reviews (Option A)**	
8.9.1	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.	
8.9.2	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.	
8.9.3	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.	
	New	**Annex A (informative) – Metrological traceability**	

	New	**Annex B (informative) Management system**	