Appendix 2 – ISO/IEC 17025:2017 Internal Audit Checklist

Clause	Requirement	YES	NO	Comments
4.0	**GENERAL REQUIREMENTS**			
4.1.1	[illegible]	*x*		*e.g. Management has implemented a suitable program*
4.1.2	Is laboratory management committed to impartiality?			
4.1.3	Does the laboratory prevent [illegible] impartiality?			
4.1.4	Does the laboratory identify risks to its impartiality on an on- going basis?			
4.1.5	[illegible]			
4.2.1	Does the laboratory ensure the [illegible] results?			
4.2.2	Is the laboratory responsible, through legally enforceable [illegible] performance of its activities?			
4.2.3	When legally allowed, does the laboratory notify its customer of any release of confidential information?			
4.2.4	[illegible]			
4.2.5	Do all personnel, including [illegible] required by law?			
5.0	**STRUCTURAL REQUIREMENTS**			
5.1	Is the laboratory a legal entity or a defined part of a legal entity that is responsible for all its activities?			

Commented [170251]: This checklist is to be used for the first internal audit to ensure that all the elements, clauses and issues of standard have been adequately covered during implementation.

1) Note 1: The term "documented information" means that the standard requires the organization to establish, document, implement and maintain a management system.

2) Note 2: To meet the requirements, the laboratory shall implement a QMS in accordance with Option A (8.1.2) or Option B (8.1.3). See also Annex B of standard.

3) Note 3: Documentation can be in any form and any type of medium.

Commented [170252]: These are the requirements of the ISO/IEC 17025:2017 standard; you should also insert the specific requirements from your own documentation.

Note that this is the complete set of requirements and can either be done at one time, several different times, or split throughout the year as per the "Internal Audit Plan." The important thing is that the entire system be audited at least once annually.

Commented [170253]: To be filled in during the audit – fill in Yes or No depending on whether the company is compliant or not.

Commented [170254]: To be filled in during the audit – records, verbal statements, or auditor's personal observations that confirm the finding.

5.2	Has the laboratory identified management who have overall responsibility for the laboratory?			
5.3	Does the laboratory carry out its [illegible] sites and temporary and mobile facilities or customer facilities?			
5.4	Has the laboratory defined and **documented** the range of laboratory activities for which it conforms to this ISO standard?			
5.5	Has the laboratory: a. [illegible] activities?			
	b. Specified the responsibility, [illegible] laboratory activities?			
	c. Documented its [illegible] results?			
5.6	Does the laboratory have [illegible] a. Implementation, maintenance and improvement of the management system?			

Commented [170255]: Look for documentation.

	b. [blurred]			
	c. Initiation of actions to prevent or minimize such deviations?			
	d. Reporting to management [blurred] improvement?			
	e. Ensuring the required validity of laboratory activities?			
5.7	Does laboratory management ensure: a. [blurred] are implemented?			
	b. That communication takes [blurred] requirements?			
6.0	**RESOURCE REQUIREMENTS**			
6.1	In general, does the laboratory [blurred] activities?			
6.2	**Personnel:**			
6.2.1	Do all personnel, internal or external, that could influence [blurred] system?			
6.2.2	Does the laboratory **document** [blurred] requirements for education,			

Commented [170256]: Look for documentation.

	qualification, training, technical knowledge, skills and experience?			
6.2.3	Does the laboratory ensure that [redacted] significance of, and response to deviations in laboratory activities?			
6.2.4	Does the laboratory communicate [redacted] responsibilities and authorities?			
6.2.5	Does the laboratory have **procedures** and maintain **records** for: a. [redacted]			
	b. Selection of personnel?			
	c. Training of personnel?			
	d. Supervision of personnel?			
	e. [redacted]			
	f. [redacted]			
6.2.6	Does the laboratory authorize personnel to: a. [redacted]			
	b. [redacted]			
	c. Report results?			
6.3	**Facilities and environmental conditions:**			
6.3.1	Are the facilities and [redacted] validity of results?			
6.3.2	Are the requirements for facility [redacted]			
6.3.3	Does the laboratory monitor, [redacted] **procedures** or where they influence the validity of results?			

Commented [170257]: Look for a procedure.

Commented [170258]: Look for records.

Commented [170259]: Look for a procedure.

6.3.4	Are measures to control facilities [blurred] to ensure that they do not adversely affect the validity of results, including but not limited to: a. Access to and use of areas affecting laboratory activities?			
	b. [blurred] activities?			
	c. Effective separation [blurred]			
6.3.5	When the laboratory performs [blurred] met?			
6.4	**Equipment:**			
6.4.1	Does the laboratory have access to [blurred] activities: a. Measurement instruments?			
	b. Software?			
	c. Measurement standards?			
	d. Reference materials?			
	e. Reference data?			
	f. [blurred]			
	g. Auxiliary apparatus?			
	h. [blurred]			
6.4.2	When the laboratory uses [blurred] ISO standard are met?			
6.4.3	Does the laboratory have a [blurred] ensure proper functioning and in			

	order to prevent contamination or deterioration?			
6.4.4	Does the laboratory verify that [blurred] into service?			
6.4.5	Is the equipment used for [blurred] to provide a valid result?			
6.4.6	When the measurement accuracy [blurred] result, or metrological traceability is a requirement, is the measuring equipment calibrated?			
6.4.7	Did the laboratory establish a [blurred] maintained?			
	Is the calibration program reviewed and adjusted as necessary in order to maintain confidence in the status of calibration?			
6.4.8	[blurred]			
6.4.9	When equipment is subjected to [blurred] out of service?			
	Is that equipment isolated to prevent its use and/or clearly labeled or marked as being out of service?			
	[blurred]			
6.4.10	When intermediate checks are [blurred] equipment, are these checks			

	carried out according to a **procedure?**			
6.4.11	For calibration and reference [redacted] implemented as appropriate, to meet specified requirements?			
6.4.12	Does the laboratory ensure [redacted] results?			
6.4.13	Are **records** maintained for [redacted] following: a. The identity of equipment, including software?			
	b. [redacted]			
	c. [redacted]			
	d. The current locations, where appropriate?			
	e. Calibration dates, results of [redacted] calibration frequency?			
	f. Dates, results and [redacted] period of validity?			
	g. Maintenance plan and [redacted] equipment?			
	h. Details of any damage, malfunction, modification or repair to the equipment?			

Commented [1702510]: Look for a procedure.

Commented [1702511]: Look for records.

6.5	**Metrological Traceability:**			
6.5.1	Does the laboratory establish and [illegible] uncertainty, linking them to an appropriate reference?			
6.5.2	Does the laboratory ensure that [illegible] a. Calibration?			
	b. Certified values of certified reference materials with stated metrological traceability to the SI?			
	c. [illegible]			
6.5.3	When metrological traceability to [illegible] appropriate reference such as: a. [illegible]			
	b. Results of reference measurement procedures, [illegible] results fit for their intended use and ensured by suitable comparison?			
6.6	**Externally Provided Products and Services:**			

6.6.1	Does the laboratory assure the [illegible] a. Are intended for incorporation into the laboratory's own activities?			
	b. Are provided, in part or in [illegible] from the external supplier?			
	c. [illegible]			
6.6.2	Does the laboratory have a **procedure** and **records** for:			
	a. Defining, reviewing and [illegible] services?			
	b. Defining the criteria for [illegible] external providers?			
	c. Ensuring that externally [illegible] directly provided to the customer?			
	d. Taking any actions arising from evaluations, monitoring and re-evaluations?			
6.6.3	[illegible] requirements for: a. The products and services to be provided?			
	b. The acceptance criteria?			

Commented [1702512]: Look for a procedure and records.

	c. Competence, including any required qualification of personal?			
	d. Activities that the [illegible] premises?			
7.0	**PROCESS REQUIREMENTS**			
7.1	**Review of Requests, Tenders and Contracts:**			
7.1.1.1	Does the laboratory have a **procedure** for the review of requests, tenders and contracts? Does it contain: a. [illegible] understood?			
	b. Does the laboratory have [illegible] used?			
	c. Does the laboratory use [illegible] customer requirements?			
	Does the laboratory have a **procedure** to cover the activities of external providers?			
	Does the laboratory advise the [illegible] provided laboratory activities?			
	Does the laboratory ensure that [illegible] requirements of the standard?			
7.1.1.2	Does the laboratory inform the customer when the method requested by the customer is			

Commented [1702513]: Look for a procedure.

Commented [1702514]: Look for a procedure.

	considered to be inappropriate or out of date?			
7.1.1.3	Are decision rules for conformity to a specification or standard (pass/fail, etc.) clearly defined?			
7.1.1.4	Are differences between requests and contracts resolved before laboratory activities begin? Is each contract accepted by both the customer and the laboratory?			
7.1.1.5	Is the customer informed of any deviation from the contract?			
7.1.1.6	Is the contract review repeated if the contract is amended after work has commenced? Are amendments communicated to all affected personnel?			
7.1.1.7	Does the laboratory cooperate with customers in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed? a. Providing reasonable access to relevant areas of the laboratory? b. Preparation, packaging and dispatch of items needed by the customer for verification purposes?			
7.1.1.8	Are records of reviews, discussions including changes, maintained?			
7.2	**Selection, Verification and Validation of Methods**			
7.2.1	**Selection and verification of methods**			
7.2.1.1	Does the laboratory use appropriate methods and procedures for all laboratory activities?			
7.2.1.2	Are all methods, procedures and supporting documentation kept up to date? Does this include instructions, standards, manuals and reference data?			
7.2.1.3	Are all deviations from methods and procedures documented and technically justified, authorized and accepted by the customer?			

Commented [1702515]: Look for procedures, work instructions, specifications or technique sheets for each test or calibration.

Commented [1702516]: Look for procedures and supporting documentation.

7.2.1.6	Does the laboratory use methods that meet customer requirements? Does the laboratory ensure that it is using the latest edition or a method?			
7.2.1.8	When the customer does not specify a method, does the laboratory select an appropriate method and inform the customer of the method used?			
7.2.1.16	Does the laboratory verify that it can properly perform a method before introducing it?			
7.2.1.7	When method development is required, is it a planned activity assigned to qualified personnel equipped with adequate resources? As method development proceeds, are there periodic reviews to verify that the needs of the customer are being met?			
7.2.2	**Validation of Methods**			
7.2.2.1	Does the laboratory validate non-standard methods, laboratory developed methods and standard methods used outside their intended scope? Is the validation as extensive as necessary to meet requirements? Are the validation results recorded?			
7.2.2.2	When changes are made to validated methods, are the changes documented and a new validation performed?			
7.2.2.3	Are the range and accuracy of values obtained from validated methods assessed to ensure they are relevant to customer requirements?			
7.2.2.4	Does the laboratory record the following as evidence of validation: a. The validation procedure used? b. Specification of the requirements? c. Determination of the performance			

Commented [1702517]: Look for a record for each validation.

Commented [1702518]: If sampling is not done, mark this section as N/A (not applicable).

Commented [1702519]: Look for procedures if sampling is perform in or by a laboratory.

Commented [1702520]: Look for a procedure.

Commented [1702521]: Look for a record.

Commented [1702522]: Look at the records.

	Are original observations, data and calculations recorded at the time they are made?			
7.5.2	Does the laboratory ensure amendments to technical records can be traced back to other previous versions and to original observations? Are the files kept?			
7.6	**Evaluation of Measurement Uncertainty**			
7.6.1	If the laboratory is performing calibrations, including of its own equipment, does it evaluate the measurement uncertainty for all of the calibrations?			
7.6.2	If the laboratory is performing sampling or testing activities, does the laboratory identify all the contributions to measurement uncertainty? Does it make a reasonable estimation of their magnitude?			
7.6.3	When evaluating the measurement uncertainty, are all components of significance identified and taken into account using the appropriate methods of analysis?			
7.7	**Ensuring the Validity of Results**			
7.7.1	Does the laboratory have a procedure for regularly monitoring the validity of laboratory activities and the quality of the laboratory's output?			
	Is the resulting data recorded in such a way that trends are detectable?			
	Is this monitoring planned and reviewed and include where appropriate, but not limited to: a. Regular use of reference materials or quality control materials; b. Regular use of alternative instrumentation that has been calibrated to provide traceable results; c. Functional check of measuring and test equipment;			

Commented [1702523]: Look for the procedure.

Commented [1702524]: Look for the records.

	[illegible]			
	[illegible]			
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	[illegible]			
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[illegible]	[illegible]			
[illegible]	[illegible]			
[illegible]	**[illegible]**			
[illegible]	[illegible]			
[illegible]	**[illegible]**			
[illegible]	[illegible]			
	[illegible]			
	[illegible]			
	[illegible]			

Commented [1702525]: Look for a document.

Commented [1702526]: Look for the procedure.

7.9.2	Does the complaint handling process include: a. A description of the receiving, validating and investigating of the complaint? b. Tracking and recording of the complaints? c. Ensuring that any appropriate action is taken?			
7.9.3	Does the laboratory gather and verify all necessary information to validate the complaint?			
7.9.4	Does the laboratory acknowledge receipt of the complaint and provide progress reports and the outcome?			
7.9.5	Are outcomes reviewed and approved by individuals not involved in the original laboratory activities?			
7.9.6	Does the laboratory give formal notice at the end of the complaint handling?			
7.10	**Nonconforming Work**			
7.10.1	Does the laboratory have a procedure that covers any aspect of laboratory activities that results in nonconforming work? Does the procedure ensure that: a. Responsibilities and authorities for the management of nonconforming work are defined? b. All actions are based upon risk levels established by the laboratory? c. An evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results? d. A decision is taken on the acceptability of the nonconforming work?			

Commented [1702527]: Look for a procedure.

	a. Where necessary, the customer is notified and work is recalled?			
	b. The responsibility for authorizing the resumption of work is defined?			
7.10.2	Does the laboratory retain records of the non-conforming work and actions?			
7.10.3	Where evaluation indicates that nonconforming work could recur or doubt about compliance in laboratory operations, does the laboratory implement corrective action?			
7.11	**Control of Data – Information Management**			
7.11.1	Does the laboratory have access to data and information needed to provide laboratory activities?			
7.11.2	Was the current management information system validated by the laboratory before being introduced? Are changes to the MIS authorized, documented and validated before implementation?			
7.11.3	Does the laboratory MIS: a. Protect from unauthorized access?			
	b. Safeguard against tampering or loss?			
	c. Operates in an environment of compliance with specifications?			
	d. Maintained in a manner that ensures integrity of data and information			
	e. A recording system for failures and for corrective action?			
7.11.4	Is off-site management of the MIS managed and does it comply with the requirements of the ISO 17025 standard?			
7.11.5	Does the laboratory ensure that instructions, manuals and reference data are relevant to the			

	[illegible]			
7.10.8	[illegible]			
8.0	[illegible]			
8.2	[illegible]			
8.2.1	[illegible]			
8.2.2	[illegible]			
8.2.3	[illegible]			
8.2.4	[illegible]			
8.2.5	[illegible]			
8.3	[illegible]			
8.3.1	[illegible]			
8.3.2	[illegible] a. [illegible] b. [illegible]			

Commented [1702528]: Option 'B' Laboratories are usually part of a larger organization that complies to ISO 9001. The following audit items may have been part of the ISO 9001 internal audit. Indicate each section with a note stating the date of that audit.

	c. Changes and current revision status is identified?			
	d. Documents are available at points where there use if necessary and distribution is controlled?			
	e. All documents are uniquely identified?			
	f. Use of obsolete documents is prevented?			
8.4	Control of Records			
8.4.1	Does the laboratory establish and maintain legible records to demonstrate compliance to the ISO 17025 Standard?			
8.4.2	Did the laboratory implement controls for the identification, storage, protection, back-up, retention times and disposal of its records? Is access to these records consistent with confidentiality arrangements?			
8.5	Actions to Address Risks and Opportunities			
8.5.1	Did the laboratory consider risks and opportunities associated with laboratory activities in order to: a. Give assurance that the management system can achieve 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's activities? d. Achieve improvement?			
8.5.2	Does the laboratory planning a. Actions to address these risks and opportunities? b. How to i. Integrate and implement actions into			

	to management system?			
	c) Evaluate the effectiveness of these actions?			
8.5.3	Are actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results?			
8.6	**Improvement**			
8.6.1	Has the laboratory identified and selected opportunities for improvement and implemented necessary actions?			
8.6.2	Does the laboratory seek feedback, both positive and negative, from its customers? Is the feedback analysed and used to improve the management system, laboratory activities and customer service?			
8.7	**Corrective Actions**			
8.7.1	When nonconformity occurs, does the laboratory: a) React to the nonconformity and 1) Take action to control and correct it? 2) Deal with the consequences?			
	b) Evaluate the need for action to eliminate the cause in order that it does not recur or occur elsewhere by 1) Reviewing and analysing the nonconformity? 2) Determining the causes of the nonconformity? 3) Determining if similar nonconformities exist, or could potentially occur?			
	c) Implement any action needed?			
	d) Review the effectiveness of the corrective action?			

Commented [1702529]: Look for records.

	1. Define the audit criteria and scope for each audit?			
	2. Ensure the results of the audits are reported to relevant management?			
	3. Implement appropriate correction and corrective actions without undue delay?			
	4. Retain records as evidence of the implementation of the audit program and the audit results?			
8.9	**Management Reviews**			
8.9.1	Does laboratory management review its management system at planned intervals in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to compliance with the ISO 17025 standard?			
8.9.2	Are inputs to management review recorded and include information related to the following:			
	1. Changes in internal and external issues that are relevant to the laboratory?			
	2. Fulfillment of objectives?			
	3. Suitability of policies and procedures?			
	4. Status of actions from previous management reviews?			
	5. Outcome of recent internal audits?			
	6. Corrective actions?			
	7. Assessments by external bodies?			
	8. Changes in the volume and type of the work or in the range of laboratory activities?			
	9. Customer feedback?			
	10. Complaints?			
	11. Effectiveness of any implemented improvements?			

	[illegible]			
8.8.2	[illegible]			

[job title]
[name]

[signature]

Commented [1702530]: This is only necessary if the document is in paper form.