INSERT COMPANY NAME/LOGO HERE

ISO/IEC 17025:2017 Laboratory Management System - The ISO 17025:2017 – from - ISO 17025:2005 Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating the requirements for the competence of testing and calibration laboratories against the requirements of ISO/IEC 17025:2017 as you transition from ISO/IEC 17025:2005. Each requirement is expressed as a question that the user (auditor / assessor) can ask to evaluate your laboratory capabilities. You will need to have copies of the ISO 17025:2017 and the ISO 17025:2005 standards to use along with this checklist so that you can refer to the requirements if necessary.

While the two versions of the standard do not line up when comparing the requirements:

- New requirements and / or new terminology are highlighted in yellow.
- The intent of the main clauses of the new standard is shown in blue font.
- The 3rd left-hand column in green shade is intended to provide reference / comparison / similarities to and extracts from the ISO 17025:2005 requirements, and to identify and locate where in the new clauses, the former requirements are relevant.
- Comments highlighted in **red font** indicate removed requirements.

After you have prepared an audit schedule and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed. In the space for 'currently in place', list or reference the procedures or other documents, or evidence that you have reviewed and that will provide information for the new laboratory management system. Take notes on the status of the documents, that is, will they need to be revised for the new system, or can they be used as is? Also note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if documented information is in place and if procedures and processes are being complied with, compliance is not your main focus for this audit.

Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with ISO 17025:2017.

Note that the checklist relates to Option A introduced in clause 8.1 of the standard. This option lists the minimum requirements for the implementation of a management system in a laboratory setting and incorporates the requirements of ISO 9001 that are relevant to the scope of laboratory activities covered by the management system. By complying with the requirements of clause 4 through clause 7 and implementing clauses 8.2 through 8.9, laboratories can generally operate in accordance with the ISO 9001:2015 principles.

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4	**GENERAL REQUIREMENTS**		**4 Management requirements**			
Intent of clause	This first clause introduces two sub-clauses as general requirements. First is impartiality, where laboratory activities are undertaken and managed in a structured manner in order to safeguard impartiality and provide presence of objectivity. Second is confidentiality, where responsible management of information obtained or created during the operations of a laboratory is considered and treated as confidential.					
4.1	**Impartiality**		**----**			
4.1.1	As an organization, are your laboratory activities undertaken impartially and structured and managed to safeguard impartiality?	4.1.4 Note 2. A third-party laboratory demonstrates that it is impartial.				
4.1.2	How does the laboratory management demonstrate commitment to impartiality?	4.1.5 d) Laboratory policies to avoid activities that diminish confidence in its impartiality.				
4.1.3	Is the laboratory responsible for the impartiality of its activities and does it disallow commercial, financial, or other pressures to affect impartiality?	4.1.5 b) Ensure that the management and personnel are free from any undue pressures and influences that may adversely affect the quality of their work.				
4.1.4	Has the laboratory identified risks to its impartiality on an on-going basis?					
	Does this include those risks that arise from its activities, relationships, or from the relationships of its personnel?					
With reference to the note in 4.1.4:		----				
	Is a relationship that threatens the	4.1.4 If the laboratory is part of a				

	impartiality of the laboratory based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing, branding, and payment of a sales commission or other inducement for the referral of new customers, etc.?	company performing other than lab services, the responsibilities of key personnel are defined to identify any conflicts of interest.				
4.1.5	When a risk to impartiality is identified, how is the laboratory able to demonstrate that it eliminates or minimizes the risk?					
4.2	**Confidentiality**		**----**			
4.2.1	Is your laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities?					
	• Does the laboratory 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, such as for responding to complaints, is all other information considered proprietary information and handled as confidential?	4.7.1 The laboratory cooperates with customers providing that confidentiality is assured to other customers.				
4.2.2	When the laboratory is required by law or authorized by contractual					

	arrangements to release confidential information, is the customer or individual concerned notified of the information provided?					
4.2.3	Is the information about the customer obtained from sources other than the customer, such as complainant, or regulators, confidential between the customer and the laboratory?					
	• Is the source of this information confidential to the laboratory and not to be shared with the customer, unless agreed by the source?					
4.2.4	Do the personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on behalf of the laboratory, keep confidential all information obtained or created during the laboratory activities?	4.1.5 c) Policies to protect confidential customer information and proprietary rights, including protecting the electronic storage and transmission of results				
5	**STRUCTURAL REQUIREMENTS**		**4.1 Organization**			
	----		**4.2 Management system**			
Intent of clause	This clause looks at your laboratory as a legal entity where overall responsibilities and activities are identified in order to meet all requirements and ensure valid results. This section also asks the laboratory management to ensure that the organizational roles, responsibilities, and authorities for relevant roles are assigned, communicated, and understood.					
5.1	Is the laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for its activities?	4.1.1 The laboratory is an entity that is legally responsible.				
With reference to the note in 5.1:		----				

	Do you consider a government laboratory to be a legal entity based on its governmental status?					
5.2	Is the management with overall responsibility for the laboratory identified?					
		4.1.5 i) Appoint a member of staff as quality manager who, regardless of other duties, has defined responsibility and authority for ensuring that the system related to quality is implemented and followed. The quality manager has direct access to top management where decisions are made on lab policy or resources.				
		4.1.5 j) Appoint deputies for key managerial personnel.				
		4.2.2 The laboratory's management system policies related to quality, includes quality policy statement, defined in a quality manual. The overall objectives are established and reviewed during management review.				
		4.2.2 The quality policy statement issued under the authority of top management includes at least the following: a) The laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers. b) The management's statement of the laboratory's standard of service. c) The purpose of the management system related to quality. d) A requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work. e) The laboratory management's commitment to comply with ISO 17025 and to continually improve the effectiveness of the management system.				
		4.2.5 The quality manual includes or references the supporting procedures including technical procedures and outlines the structure of documentation used.				

		4.2.5 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with ISO 17025 are defined in the quality manual (however named).				
5.3	Has the laboratory defined and documented the range of activities for which it conforms to ISO 17025?	4.2.1 Establish, implement, and maintain a management system appropriate to the scope of the lab activities.				
	• Do you only claim conformity with ISO 17025 for this range of lab activities, which excludes ongoing externally provided lab activities?					
5.4	Are the lab activities carried out to meet the requirements of the ISO standard, along with the requirements of customers, of regulatory authorities and of organizations providing recognition?	4.1.2 It is the lab's responsibility to carry out its activities to meet ISO 17025 requirement and to satisfy the needs of customers, regulatory authorities, or others providing recognition.				
	• Does this include lab activities performed in all permanent facilities, at sites away from permanent facilities, in associated temporary or mobile facilities or at a customer facility?	4.1.3 The lab system covers work carried out in permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.				
5.5	For your laboratory have you:	----				
	• Defined the organizational and management structure, its place in any parent company, and the relationships between management, technical operations, and support services?	4.1.5 e) Define the lab structure, its place in a parent company, and the relationships between quality management, technical operations, and support services.				