INSERT COMPANY NAME/LOGO HERE

ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories
The 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 the international standard ISO/IEC 17025:2017. Each requirement of clauses 4 through 7 along with the management system requirements of clause 8, is expressed as a question that the user (auditor / assessor) can use to evaluate your laboratory capabilities. You will need to have a copy of the standard to use along with this checklist so that you can refer to the requirements. The intent of the main clauses of the new standard is shown in blue font.

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 standard. 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 focus for this audit. Remember that the outcome of this audit should be a list of things that your company needs to do to have a laboratory management system in compliance with the ISO 17025:2017 international standard.

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.

ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories
The Gap Analysis Checklist

---	GENERAL REQUIREMENTS for the COMPETENCE of TESTING and CALIBRATION LABORATORIES	Currently in Place	Compliant YES / NO?	If No - % Completed	Items Needed
4	**GENERAL 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?				
4.1.2	How does the laboratory management demonstrate commitment to 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?				
4.1.4	Has the laboratory identified risks to its impartiality on an on-going basis?				
	• Does this include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel?				
	With reference to the note in 4.1.4:				
	Is a relationship that threatens the 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.?				
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?				
4.2.2	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is the customer or individual involved 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 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?				
5	**STRUCTURAL REQUIREMENTS**				
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?				
	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?				
5.3	Has the laboratory defined and documented the range of activities for which it conforms to ISO 17025?				

	• 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?				
	• 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?				
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?				
	• Specified the responsibility, authority and interrelationship of all personnel who manage, perform, or verify work affecting the results of lab activities?				
	• Documented the procedures needed to ensure the consistent application of the lab activities and the validity of the results?				
5.6	Does your laboratory have personnel who, regardless of other responsibilities, have the authority and resources needed to carry out their duties?				

