INSERT COMPANY NAME/LOGO HERE

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

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This checklist is based on the information from the ISO/IEC 17025:2017 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess the Laboratory Management System (LMS) for the Competence of Testing and Calibration Laboratories requirements based on the standard. You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

The auditors are expected to keep in mind that the standard does not requires mandatory procedures for the various LMS processes; however, the auditors will expect documented information to be available because in the clauses of the standard, the phrase such as 'documented procedures' is used to specify that a process, a method, a system, a work instruction, or an arrangement be documented.

The auditors must use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and titles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right-hand column a:

Yes - for Acceptable Condition or **No -** for Deficient Condition

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4	**GENERAL REQUIREMENTS**		
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?		
	Additional Questions		
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 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 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?		
	Additional Questions		
5	**STRUCTURAL REQUIREMENTS**		
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/IEC 17025?		

	• Do you only claim conformity with ISO/IEC 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?		

	Do the duties of the personnel include:		
	• Implementation, maintenance, and improvement of the management system?		
	• Identification of deviations from the management system or from the procedures for performing lab activities?		
	• Initiation of actions to prevent or minimize any deviations?		
	• Reporting to laboratory management on the performance of the management system and any need for improvement?		
	• Ensuring the effectiveness of lab activities?		
5.7	Does the laboratory management ensure that:		
	• Communication takes place regarding the effectiveness of the management system and the importance of meeting customer and other requirements?		
	• The integrity of the management system is maintained when changes to the management system are planned and implemented?		
	Additional Questions		

6	**RESOURCE REQUIREMENTS**		
6.1	**General**		
	Does the laboratory have available the personnel, facilities, equipment, systems, and support services needed to manage and perform the lab activities?		
	Additional Questions		
6.2	**Personnel**		
6.2.1	Are all internal or external laboratory personnel that could influence the lab activities competent, work in accordance with the management system and act impartially?		
6.2.2	Have you documented the competence requirements for each function influencing the results of lab activities, including requirements for education, qualification, training, technical knowledge, skills, and experience?		
6.2.3	Does the laboratory ensure that the personnel have the competence to perform lab activities for which they are responsible and to evaluate the significance of deviations?		
6.2.4	How does the laboratory management communicate to personnel their duties, responsibilities, and authorities?		

6.2.5	Do you have procedures and retain records for:		
	• Determining the competence requirements?		
	• Selection of personnel?		
	• Training of personnel?		
	• Supervision of personnel?		
	• Authorization of personnel?		
	▪ Monitoring competence of personnel?		
6.2.6	Does the laboratory authorize personnel to perform specific lab activities, such as:		
	• The development, modification, verification, and validation of methods?		
	• The analysis of results, including statements of conformity or opinions and interpretations?		
	• The reporting, review, and authorization of results?		
	Additional Questions		

