INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 – with – ISO/IEC 17025:2017 Management Systems - The Gap Analysis Checklist

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This gap analysis checklist is prepared for use in evaluating your Management System against the requirements of ISO 9001:2015 as you transition from ISO 9001:2015 to include ISO/IEC 17025:2017, the general requirements for the competence of testing and calibration laboratories / Laboratory Management System (LMS). Each requirement of ISO 9001:2015 is expressed as a question that the user (auditor / assessor) can ask to evaluate your QMS-LMS capabilities. You will need to have copies of the ISO 9001:2015 and ISO/IEC 17025:2017 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:

- The right-hand column in green shade is intended to provide correspondence / reference / comparison / similarities to the ISO/IEC 17025:2017 requirements, and to identify and locate where in the requirements are relevant.
- The intent of the main clauses of the ISO 9001:2015 standard is shown in **bold 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, keep in mind the requirements of ISO/IEC 17025 in the right-hand column, 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 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 both ISO/IEC 17025:2017 and ISO 9001:2015.

Note that this checklist relates to Option B introduced in clause 8.1.3 of ISO/IEC 17025:2017, where a laboratory can establish and maintain a management system in accordance with the requirements of ISO 9001:2015 that support and demonstrate the consistent fulfilment of the requirements of ISO/IEC 17025 clause 4 through clause 7 and meets the intent of the requirements specified in clauses 8.2 through 8.9.

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ISO 9001:2015 QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	If NO - % Complete	Items Needed	ISO/IEC 17025:2017 – Reference / Corresponding / Similar Requirements
4 CONTEXT OF THE ORGANIZATION			**4 General requirements**		
This clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the Quality Management System (QMS). In addition, the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.					----
4.1 Understanding the organization and its context			----		
----			**4.1 Impartiality**		
Does your company determine the external and internal issues that are relevant to your purpose and strategic direction?					4.1.1 Laboratory activities are undertaken impartially and structured and managed to safeguard impartiality.
Do you consider the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?					4.1.2 The laboratory management is committed to impartiality. 5.5 a) The laboratory defines the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations, and support services.
Does your company monitor and review the information related to the external and internal issues?					4.1.4 The laboratory identifies risks to its impartiality on an on-going basis, including the risks that arise from lab activities, or from relationships, or from the relationships of personnel.

4.2 Understanding the needs and expectations of interested parties			----		
----					**4.2 Confidentiality**
With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, do you determine:					4.2.1 The laboratory is responsible, through legal commitments, for the management of all information obtained or created during the performance of laboratory activities.
• The interested parties that are relevant to the QMS?					
• The requirements of these interested parties that are relevant to the QMS?					
Does your company monitor and review the information about these interested parties and their relevant requirements?					4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, individuals acting on behalf of the lab, keep confidential all information obtained or created while performing lab activities, except as required by law.
4.3 Determining the scope of the quality management system			**----**		
To establish the scope of the QMS, does your company determine the boundaries and applicability of the QMS?					
When determining the scope of the QMS, do you consider the:					
• External and internal issues (per 4.1)?					

• Requirements of relevant interested parties (per 4.2)?					
• The products and services of your company?					
When a requirement of ISO 9001:2015 can be applied, is the requirement applied by your company?					5.4 Laboratory activities are carried out in such a way as to meet ISO/IEC 17025 requirements, and those of the customers, regulatory authorities, and recognition organizations.
When requirements cannot be applied, and to claim conformity to ISO 9001:2015, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected?					5.3 The laboratory only claims conformity with ISO/IEC 17025:2017 for its identified range of laboratory activities.
Is the scope of the QMS available and maintained as documented information?					
Does the scope state the products and services covered by the QMS?					
Does your company provide justification for any instance where a requirement of the standard cannot be applied?					
----			**8 Management system requirements / 8.1 Options**		
----			**8.1.1 General**. The laboratory establishes, documents, implements, and maintains a management system that can support and demonstrate the consistent achievement of the requirements of ISO/IEC 17025:2017 and assure the quality of the laboratory results. In addition to meeting the requirements of clauses 4 to 7, the laboratory implements a management system in accordance with Option A or Option B.		
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5.2.2 Communicating the quality policy			----		
Is your quality policy:					
• Communicated, understood, and applied within your company?					
• Available as documented information?					
• Available to relevant interested parties?					
5.3 Organizational roles, responsibilities, and authorities			**----**		
Does the top management ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the company?					5.5 a) The laboratory defines the relationships between management, technical operations, and support services. 5.6 The laboratory has personnel who, regardless of other responsibilities, have the authority and resources needed to carry out their duties, and: • Implement, maintain, and improve the management system. • Identify deviations from the system or from the procedures for performing laboratory activities. • Initiate actions to prevent or minimize such deviations. • Report to management on the performance of the system and any need for improvement. • Ensure the effectiveness of laboratory activities.