



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Guide for Preparing Management System Document / Quality Manual

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AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1	01	6,7,8	3	22.07.2019	Deletion of text regarding given format	Typographical error	-Sd-	Sd-
2	02	3	1	05.05.2020	Requirement of 4 days training program is removed	Outcome of Management Review Meeting	-Sd-	-Sd-
3		4	2		Sentence aligned	Internal Review		
4	03	3	1	22.02.2024	As highlighted	i. Internal review ii. Inclusion of year for ISO/IEC 17025: 2017, ISO 15189: 2012 & ISO 17034: 2016	-Sd-	-Sd-
5		4-6,8	2 & 3			iii. Release of ISO 15189: 2022 & ISO/IEC 17043: 2023		
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1. Introduction

Testing and Calibration laboratories are required to comply with the requirements of ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories'; Medical Testing laboratories have to comply with the requirements of ISO 15189 'Medical laboratories - Requirements for quality and competence'; Proficiency Testing Providers have to comply with the requirements of ISO/IEC 17043 'Conformity assessment - General requirements for (the competence of) proficiency testing (providers)'; and Reference Material Producers have to comply with ISO 17034 'General requirements for the competence of reference material producers'.

In preparing the Management System Document / Quality Manual, it should not be restricted to the contents of this guide. However, all elements of ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 as applicable should be addressed in the intended Management System Document / Quality Manual. As an illustration this document provides guidance to CABs for addressing the requirements of relevant ISO/IEC Standards / Guides in their Management System Document / Quality Manual.

The **level** of details to be provided in the document / manual will vary depending upon the size, field of activities, and nature of activities performed by the CAB. The Management System Document / Quality Manual should include or make reference to other documents such as operational procedures, work instructions, forms etc.

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