

NABL 160



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	<ul style="list-style-type: none"> • Internal review • Inclusion of year for ISO/IEC 17025: 2017, ISO 15189: 2012 & ISO 17034: 2016 • Release of ISO 15189: 2022 & ISO/IEC 17043: 2023 	-Sd-	-Sd-
5.		4-6,8	2 & 3					
6.	04	3 to 6, 8, 9	1, 2, 3	12.01.2026	As highlighted, Removal of reference to ISO 15189: 2012	<ul style="list-style-type: none"> • Addition of ISO 20387: 2018 • Withdrawal of ISO 15189: 2012 	-Sd-	-Sd-
7.								
8.								
9.								
10.								

CONTENTS

S. No.	Contents	Page No.
	Amendment Sheet	
	Contents	2
1.	Introduction	3
2.	Process for preparing a Management System Document / Quality Manual	4
3.	Structure and format of Management System Document / Quality Manual	6

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)', Reference Material Producers have to comply with ISO 17034 'General requirements for the competence of reference material producers' and Biobanks have to comply with ISO 20387 'Biotechnology — Biobanking — General requirements for biobanking'.

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: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018 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.

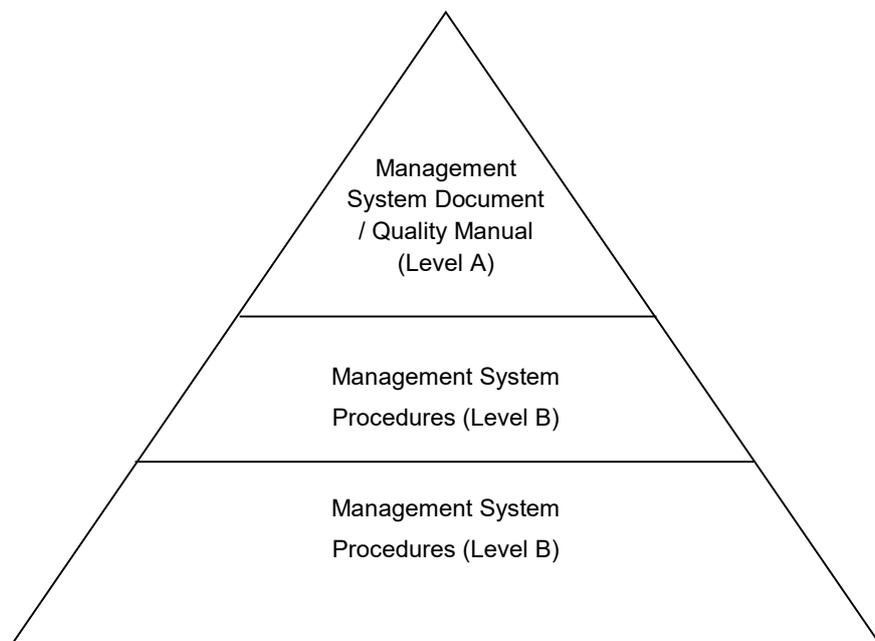
2. Process of preparing a Management System Document / Quality Manual

The management should nominate individuals from one or more functional area / section of the CAB and designate a person responsible for overall quality management system having a background of Management System(s). This group should get fully acquainted with all NABL documents and understand the assessment procedure & methodology of making an application. Relevant requirements for NABL accreditation should be discussed amongst concerned staff of the CAB. The team should collectively make the effort to prepare the Management System Document / Quality Manual.

CAB needs to ascertain the status of its existing management system and its competence. For that all existing policies, objectives, procedures, work instruction whether documented or otherwise are required to be listed and compared with the requirements of ISO/IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 or ISO 20387: 2018 as applicable, relevant NABL Specific criteria (if applicable) and other requirements.

The CAB should examine whether the existing management system is appropriate or it needs modification.

Management System Document / Quality Manual is considered as policy level document, which has to be supplemented by a set of other documents like procedure manuals, work instructions, forms, reports etc. to align the management system in accordance with 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. Therefore, the management system of the CAB can be structured in the following manner:



The order of development of a hierarchy for an individual CAB usually starts with the development of the CAB's Quality Policy & objectives followed by the implementation plan of the various elements of ISO/ IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018 as applicable, in brief. This is the apex document or Level A document termed as the 'Management System Document / Quality Manual'.

The Management System Document / Quality Manual has to be supplemented by a set of management system procedures, Level B documents, which describe the detailed procedures of the activities of individual function units needed to implement the management system. All procedures are cross referred in the Management System Document / Quality Manual.

Management system procedures may further be supplemented with detailed work instructions, forms, reports etc. termed as Level C documents. In some hierarchy systems, forms and reports may be grouped as Level D documents.

The quantity of documented procedures, work instructions, forms, reports etc. and the nature of their format and presentation are to be determined by the individual functional units. However, it is preferred that each of these set of documents are arranged in the same structure and format so that the users become familiar with the consistent approach applied to each requirement and to improve the likelihood of systematic compliance with ISO/ IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018 as applicable.

3. Structure and Format of Management System Document / Quality Manualss

There is no required structure or format for a Management System Document / Quality Manual. However, any such document should convey accurately, completely and concisely the Quality Policy, objectives, address or reference to the next level of documentation and management responsibilities of the CAB. One of the methods of assuring that the subject matter is adequately addressed and located would be to align the sections of the Management System Document / Quality Manual, to the elements of the ISO/ IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018, as applicable. Other approaches, such as structuring the document / manual to reflect the nature of the CAB or nature of work carried out by the CAB, are equally acceptable.

This guide is not intended to define a unique structure, format, content or method of presentation for the Management System Document / Quality Manual, which can be applied to all (or even some) CABs. It is unique to each CAB. However, it is recommended that the first few pages of the Management System Document / Quality Manual, should address the sections of general information like title, authority under which it is issued, scope of the Management System Document / Quality Manual, amendment record of the manual, contents of the manual, references to other documents, definitions and abbreviations used, distribution record, brief description of the CAB and the management system.

After these pages, may place the section on 'Quality Policy and Objectives' of the CAB. It is preferred that it is placed after the introductory pages, since this is the basic objective; the CAB's management system is designed to meet. The remaining sections of the Management System Document / Quality Manual should describe all applicable elements of the ISO/ IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018 as applicable. The description of these sections of the said document should be in a sequence similar to that of ISO/ IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018, as applicable. Other sequencing or cross-referencing, as appropriate to the CAB, is also acceptable.

Thereafter the list of documents, records and forms maintained by the CAB should be placed. Any supportive data, to be provided should be annexed at the end.

A brief explanation of these sections has been given below. These sections, should preferably be sequenced in the manner as given below:

Title

The title of the Management System Document / Quality Manual should clearly indicate the name of the CAB to which the manual belongs. It should also indicate the issue number, issue date, holder's name and the copy number.

Release Authorisation

The section on 'release authorisation' should indicate the authority under which the Management System Document / Quality Manual has been released. The management responsible for the implementation of Management System Document / Quality Manual, normally the Head of the CAB should authorize its release for usage. Each copy should bear evidence of this release.

Table of contents

The table of contents of a Management System Document / Quality Manual should show the titles of the sections within it and how they can be located. The numbering system of sections, subsections, pages, figures, exhibits, diagrams, tables, etc., should be clear and logical.

Scope and field of application

This section of the Management System Document / Quality Manual should clearly mention the compliance to the applicable standard(s) and NABL documents. It should also define the field(s)/ discipline(s)/ area(s) and the section(s)/ division(s) department(s) of the CAB, to which the Management System Document / Quality Manual is applicable. To ensure clarity and avoid confusion, the use of disclaimers (e.g. what is not covered by the Management System Document / Quality Manual and situations where it should not be applied) may also be mentioned.

Use of references

Wherever appropriate, and to avoid unnecessary document volume, reference to existing recognised standards or documents available with the Management System Document / Quality Manual user should be incorporated.

Definitions

Although it is recommended, when practical, to use standard definitions and terms which are referenced in recognised quality terminology documents or in general dictionary usage, this section of the Management System Document / Quality Manual should contain the definitions of terms and concepts that are uniquely used within the Management System Document / Quality Manual.

Abbreviations

Whenever the abbreviations are used, its expanded form should be defined in this section.

Distribution of the document / manual

The method of distribution of the authorised document / manual should provide assurance that all users have appropriate access. Proper distribution and control can be aided, for example, by serialisation of copies for recipients. Management should ensure that individuals are familiar with those contents of the document / manual appropriate to each user within the CAB.

Introduction

The introductory pages of a Management System Document / Quality Manual should provide general information about the CAB concerned and the Management System Document / Quality Manual itself.

The minimum information about the CAB should be its name, location and means of communication. Additional information about the CAB, such as its line of business, a brief description of its background, history or size, may also be included.

The information about the Management System Document / Quality Manual itself should include:

- A. The current issue number, date of issue and identification of amended contents
- B. A brief description of how the Management System Document / Quality Manual is revised and maintained, who reviews its content and how often, who is authorised to change the Management System Document / Quality Manual, and who is authorised to approve it, this information may also be given under the system element concerned; a method for determining the history of any change in procedure may be included, if appropriate.
- C. A brief description of the documented procedures used to identify the status and to control the distribution of the Management System Document / Quality Manual, whether or not it contains confidential information, whether it is used only for the CAB's internal purposes, or whether it can be made available externally.
- D. Evidence of approval by those responsible for authorisation of the contents of the Management System Document / Quality Manual.

Quality Policy and Objectives

This section of a Management System Document / Quality Manual should state the CAB's Quality Policy and objectives, which should be in line with the requirements of ISO/ IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018, as applicable. This is where the CAB commitment to quality is presented and where the CAB's objectives for quality are outlined. This section should also describe how the Quality Policy is made known to, and understood by, all employees and how it is implemented and maintained at all levels.

Elements of the Management system

The subsequent sections of the Management System Document / Quality Manual should describe all the elements of the ISO/ IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018, as applicable.

The format or method of presentation for the description of management system elements, which can be applied, is unique to each CAB. However, it is recommended that the description of the elements of the management system be in a sequence similar to that of ISO/ IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018, as applicable.

Further the description of each element should be divided into logical sub-sections revealing a well-coordinated management system. This may be done by inclusion of policy and objectives with respect to the element or reference to the policy, scope, person(s)/ position responsible for

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 160		Guide for Preparing a Management System Document / Quality Manual		
Issue No.: 07	Issue Date: 11-Sept-2018	Amend. No.: 04	Amend. Date: 12-Jan-2026	Page No.: 8 of 9

executing that policy, documented management system procedures and reference to records for each element.

The management system procedure of each element of Management System Document / Quality Manual, wherever applicable, should be briefly outlined, covering the major aspects of respective clause of ISO/IEC 17025: 2017 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387: 2018, as applicable. The actual process / procedure may be covered in separate procedure document and cross referred in the Management System Document / Quality Manual.

List of documents, records and forms

All documents which are maintained by the CAB and the records & forms, which are used by the CABs, should be listed in these sections. These must find reference in the Management System Document / Quality Manual or the associated document.

Annexure for supportive information

Whenever it appears in this document, that supportive data has to be provided, it should be attached as an annexure at the end.

Page Footer

It is recommended that to facilitate ease of handling and updating of the Management System Document / Quality Manual, each page within the document / manual should have page footer.

Page footer shows the name of CAB, Name of Management System Document / Quality Manual (however named), issue status, amendment status, page no. etc. As and when the manual is amended, the relevant pages where amendment takes place are replaced by new pages and is cross referred in the amendment record.

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Doc. No.: NABL 160		Guide for Preparing a Management System Document / Quality Manual		
Issue No.: 07	Issue Date: 11-Sept-2018	Amend. No.: 04	Amend. Date:12-Jan-2026	Page No.: 9 of 9

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