NABL 160A

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Guide for Preparing Management System Document/Quality Manual for Testing/Calibration Laboratories

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AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature of QA Team	Signature of Competent Authority
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CONTENTS

S. No.	Contents	Page No.
	Amendment Sheet	
	Contents	
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
4.	Sample Quality Manual for Testing/Calibration Laboratories	11

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.

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

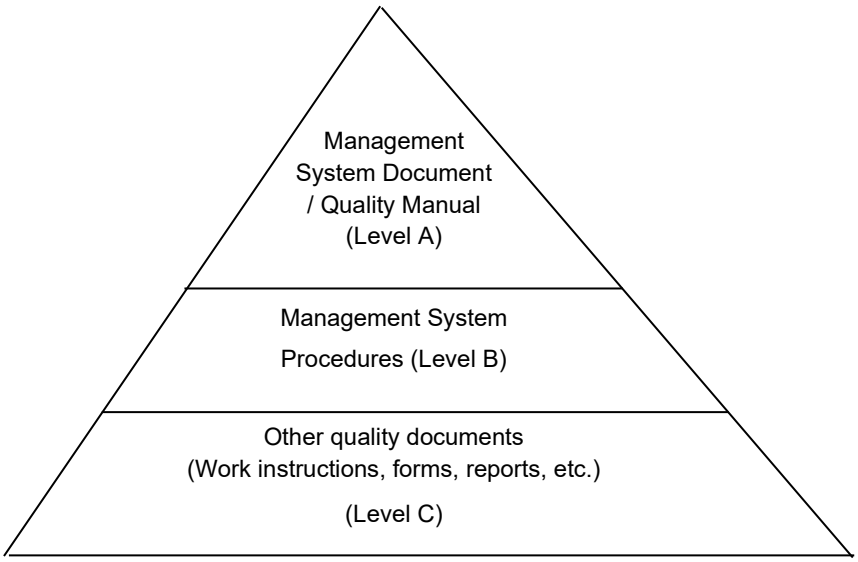
The prime reason for designing the Management System Document is to make the processes clear, more accessible and easily usable. A badly designed and structured documentation will lead to frustration and so the people will try to avoid using it. On the other hand, a well-structured documentation management system will encourage use and help people solve the problems.

As a good practice, standard structure should be used for the Management System document whether it be Quality Manual, Procedures or the instructions.

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

As we know that organization is a team made up of many people, different from each other but with common objectives. Effective people involvement is the key of synchronized team functioning, which helps people give outputs to their maximum potential. So, while developing the management system document, involvement of all people in the organization is utmost important. So, 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). Each section/ area of the laboratory should document the activities what they are doing and the steps followed to do those activities.

The Management system of the CAB can be structured in the following manner:



The order of development of a hierarchy for an individual laboratory usually starts with the development of the laboratory's Quality Policy & objectives followed by the implementation plan of the various elements of ISO/IEC 17025. 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 have to be 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.

While writing the Management System document/ Quality manual, it should be borne in mind that the documents are to be used by different type of users with different levels of technical and functional knowledge. Therefore, it is necessary to write in simple language for the ease of the user as the documentation is basically for them. Many ISO terms are also referred in the document but user should learn to understand these terms and use them. For this, it is essential to explain those terms related to ISO within the documentation itself.

There are some basic rules while writing the documentation as follows but not limited to:

i) Write simple and short sentences
ii) Use common words as far as possible.
iii) Explain technical terms by means of footnotes or by some other means so that user can understand them easily.
iv) Do not write like essay.
v) Do not use passive voice, write active voice.
vi) Match the current practice vs document written keeping in mind the requirement of ISO/IEC 17025.

Following steps would help while writing the Management System Document/ QMS Manual:

i) Collect copy of all documents used in the laboratory and prepare a list.
ii) Open separate file of each clause and place the relevant documents into the respective clause file in which they fit.
iii) Prepare a list of various processes, interlinkages of processes and their application in the laboratory activities.
iv) Study and analyze the processes to ensure whether present work is being performed as per documented process.
v) Revised the process if work is not performed as per documented process.
vi) Prepare the draft of documented management system/quality manual and ensure that all requirements of the standard have been addressed adequately.
vii) Circulate the draft among all staff and seek comments.
viii) Edit the documents by incorporating the comments (if any) keeping in view the alignments of documents in line with requirements of standard.
ix) Read the entire documents for clarity.
x) Release the documented management system for use and revise if any amendment/change is required.

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

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. 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. The description of these sections of the said document should be in a sequence similar to that of ISO/IEC 17025. 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 Authorization

The section on 'release authorization' 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 recognized 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 recognized 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 authorized document / manual should provide assurance that all users have appropriate access. Proper distribution and control can be aided, for example, by

serialization 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 laboratory concerned and the Management System Document/Quality Manual itself.

The minimum information about the laboratory should be its name, location and means of communication. Additional information about the laboratory, 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 authorized to change the Management System Document/Quality Manual, and who is authorized 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 is contains confidential information, whether it is used only for the laboratory's internal purposes, or whether it can be made available externally.
d. Evidence of approval by those responsible for authorization 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 laboratory's Quality Policy and objectives, which should be in line with the requirements of ISO/IEC 17025. This is where the laboratory 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.

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.

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 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. 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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Note:

a) *This document is for guidance purpose only and should not be cross referred at the time of assessment.*

b) *Laboratory is required to mention the actual practice being followed keeping in view the intent of the requirements of ISO/IEC 1025.*

c) *There may be few requirements which are not applicable to testing/Calibration laboratories. So, laboratory may write for those requirements as not applicable*

4. Sample Management System Documents/Quality Manual for Testing/Calibration Laboratories

Name of Laboratory, Place>

Management System Document/Quality Manual

Issue No. **Issue Date:**
Amendment No. **Amendment Date:**

MANAGEMENTS SYSTEM DOCUMENT/QUALITY MANUAL RELEASE AUTHORISATION

RELEASE AUTHORISATION

This Manual has been released under the Authority of

<Name of the Laboratory, Place> **and is the property of** ***<Name of the Laboratory, Place>***

Sd/-
Head of the Laboratory
<Name of the Laboratory, Place>

Amendment Record

S. No	Amendment No.	Page No	Clause No./Section	Date of Amendment	Amendment	Reason	Signature
1.							
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Distribution List:

The following are the authorized holders of the controlled copy of quality manual.

Controlled Copy No	Name/Designation of holder of controlled copy

4. General

4.1. Impartiality

4.1.1. It is the responsibility of the <*Name of the Laboratory, Place*> to structure, manage and carry out activities in a manner so that impartiality is ensured.

4.1.2. Our Laboratory demonstrates commitment to impartiality by:

i) Providing Code of conduct policy to all personnel working in the laboratory.
ii) Ensuring impartiality while performing laboratory activities and evaluation of risk.
iii) Formation of impartiality committee to evaluate risk to impartiality and periodically re-evaluate the risk.
iv) Ensure that all personnel in the laboratory are aware about the risks arises due to violation of code of conduct which in turn affects the impartiality of the laboratory activities.

4.1.3. <*Name of the laboratory, Place*> is fully responsible for the impartiality of activities carried out and not allowing any commercial, financial and other pressures that may compromise the impartiality of the laboratory.

4.1.4. Our laboratory identifies the risk to impartiality on continuous basis and identify the risk arises from the laboratory activities. During identification of risk to impartiality, focus all factors like relationship of personnel with customers are taken into account while identifying risk to impartiality.

4.1.5. Whenever any risk to impartiality is identified, immediate action is being taken to minimize/prevent the risk.

4.2. Confidentiality

4.2.1. <*Name of the laboratory, Place*> is fully responsible for confidentiality of customer information. All personnel working in the laboratory are bound to follow code of conduct policy. <*Name of the laboratory, Place*> is legally bound with its customers by means of non-disclosure agreements.

4.2.2. When customer confidential information is required by law, laboratory will inform the customer for releasing the information. In case, law prohibits not to inform the customer about the released information, laboratory is bound to follow the law.

4.2.3. All information received from any sources other than the customer is kept confidential between the customer and laboratory. Source of the information is also kept confidential until unless it is agreed by the information provider (source) to provide the details of the source to the customer.

4.2.4. All personnel working in the laboratory are signing the code of conduct policy and are all personnel including contractors or any person working on behalf of the laboratory are bound to follow the code of conduct policy.

5. Structural Requirements

5.1. <*Name of the laboratory, place*> is registered as per *(mention the type of registration)* vide registration no…….XXX and is legally responsible for all laboratory activities.

<*Here laboratory may mention the brief introduction of the activities carried out. In case, laboratory is a part of larger organisation performing activities other than testing, a brief introduction of parent organisation as well as laboratory can be mentioned.*>

5.2. Laboratory head (Laboratory may indicate the designation) is responsible for overall activities of the laboratory.

5.3. <*Name of the laboratory, Place*> has defined and documented the range of the laboratory activities as per document no (Mention name of document) and is conforming with requirement of ISO/IEC 17025. Our laboratory is only claiming the conformity of ISO/IEC 17025 as per range of the laboratory defined in document no (mention name of document) and is not including externally provided product and services on ongoing/permanent basis. (Scope should match with application submitted)**.**

5.4. <*Name of the laboratory, Place*> carries out all activities in such a way which meets the requirements of ISO/IEC 17025, our customers, regulatory authorities and NABL requirements that includes laboratory activities performed in permanent facilities, sites away from permanent facilities, associate temporary or mobile facilities or at customer's facility.

5.5. a) Organogram of the laboratory is depicted as below (Laboratory can mention the present organization structure). In case laboratory is part of an organisation performing activities other than testing, laboratory has to mention the organogram of the parent organisation, place of laboratory in parent organisation and organogram of the laboratory.

b) Job Responsibilities, authority and interrelationship of all personnel who manage, perform and verify the work that affects the laboratory activities is mentioned in the document no. (Mention document no.).

c) Laboratory has documented the procedures as identified in successive clauses which ensures the consistent application of laboratory activities and validity of results reported to the customers.

5.6. <*Name of the laboratory, Place*> have (Quality and Technical Manager or whoever *laboratory* has nominated) who irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system
b) identification of deviations from the management system or from the procedures for performing laboratory activities;
c) initiation of actions to prevent or minimize such deviations;
d) reporting to laboratory management on the performance of the management system and any need for improvement;
e) ensuring the effectiveness of laboratory activities

5.7. <*Name of the laboratory, Place*> management ensures that

a) Appropriate communication *(here means of communication followed in the laboratory can be mentioned)* takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;
b) the integrity of the management system is *maintained (laboratory may describe the arrangements done by the management to ensure integrity of the management system)* when changes to the management system are planned and implemented.

6. Resource Requirements

6.1. The laboratory ensures to have necessary personnel, facilities, equipment, systems and support services which are required to manage and perform the laboratory activities as defined in clause 5.3.

6.2. Personnel

6.2.1. The Laboratory ensure that all personnel working in the laboratory (*internal as well as external, external includes contractors, or other personal who are not involved in day to day activities of the laboratory)* are competent and are following our laboratory code of conduct & do not involve in any laboratory activities which compromises the impartiality.

6.2.2. The Laboratory has documented competence requirement of each function that includes requirements for education, qualification, training, technical knowledge, skills and experience. *(refer document no: XXXX)***.**

6.2.3. The Laboratory ensures that personnel are competent to perform the laboratory activities assigned to them and to evaluate the significance of deviations and their impact on laboratory objectives.

6.2.4. Top Management of the laboratory ensures to communicate the duty, responsibilities and authorities as prescribed in Job description (mechanism practised for communication may be described)**.**

6.2.5. The laboratory has procedure and retains records for

a. determining the competence requirements
b. Selection of personnel
c. Training of personnel
d. supervision of personnel
e. authorisation of personnel
f. monitoring competence of personnel.

6.2.6. Laboratory has authorised the following personnel for specific laboratory activities in addition to their current job responsibilities:

Activity	Authorised person
Development, modifications, verifications and validation of methods	XXX
Analysis of results including statement of conformity or opinions and interpretations	XXX
Report, review and authorisation of results	XXX

6.3. Facilities and Environmental Conditions

6.3.1. Laboratory ensure that facilities and environmental conditions are suitable to perform the laboratory activities as defined in range of laboratory activities.

6.3.2. Laboratory has documented the requirements of facilities and environmental conditions as per the scope of laboratory *(Refer Document no: XXX).* This includes the facilities and environmental condition for the activities carried out in the laboratory or at site *(Laboratory can mention as per their range of activities which is applicable and what has been defined in clause 5.3)*.

6.3.3. Laboratory monitors, control and records the environmental conditions as per relevant specification /methods/procedures which influence the validity of results.

6.3.4. Laboratory implements, monitors and periodically reviews the control of the facilities and environmental conditions that includes but not limited to:

a. Restriction to access of specific area which affects laboratory *activities (laboratory may mention the practice followed).*
b. Provision of prevention of cross contamination, interferences or other influences which affect the laboratory activities.
c. effective separation between the areas where the laboratory activities are not compatible to each other. *(Laboratory may mention the arrangements done for effective separation)*.

6.3.5. Laboratory ensures that requirements related to facilities and environmental conditions are met for the activities which are performed at site or activities performed at facilities outside its permanent control.

(Note: In case laboratory is not performing any activities at site or at facilities outside its permanent control, this requirement can be mentioned as not applicable).

6.4. Equipment

6.4.1. Laboratory management ensures that laboratory personnel have access to equipment which are required to perform the laboratory activities as defined in clause 5.3.

6.4.2. Laboratory management ensures that when any equipment used by the laboratory outside of permanent control of the laboratory, all requirements of Clause. no. 6.4 of this document are met. In case, laboratory is not using any equipment outside permanent control of the laboratory, laboratory may mention this clause as not applicable.

6.4.3. Laboratory follows procedure *(Mention procedure no.)* for handling, transport, storage, use and planned maintenance of the equipment to ensure that all equipments are functioning properly and to avoid any cross contamination / deterioration so that the validity of test results is not affected.

6.4.4. Laboratory verifies each equipment as per format no. *(mention format no.)* to ensure that designated equipment is meeting the specified requirements of the laboratory before placing it into service. The records of verification are kept in the laboratory as per control of records procedure.

6.4.5. Laboratory ensures that each equipment used for measurement is capable to achieve the measurement accuracy and /or measurement uncertainty required to provide valid result.

6.4.6. Measurement equipment of the laboratory are calibrated when:

- Measurement accuracy /measurement uncertainty is affecting the validity of test results.
- Calibration of the equipment is required to establish metrological traceability of the reported results

6.4.7. Calibration programme/schedule of all measuring equipment is established and calibration is performed as per defined calibration schedule. This program is reviewed and adjusted depending on the usage of the equipment and to gain confidence in the calibration status of the equipment.

6.4.8. All measuring instruments of the laboratory have calibration label. Calibration label consists of instrument ID, date of calibration and due date of calibration so that the person who is

using the equipment is aware about the calibration status of the equipment. For certain equipments where it is not practically possible to affix the calibration label on the equipment, then calibration label is affixed on the box/container of the equipment.

6.4.9. Laboratory ensure that whenever any equipment gives questionable results due to overloading or mishandling or not meeting the specified requirements, that equipment is taken out of service and out of service label is marked on that particular equipment till the correct performance of that equipment. Respective function head *(or whoever the person designated by the laboratory)* identify the effect of defect or deviation from specified requirements on the validity of test results and initiate the management of non-conformity work as per management of non-conforming work procedure *(Refer procedure no).*

6.4.10. Intermediate checks of the equipments are carried out as per intermediate checks procedure *(Refer Intermediate checks procedure)*.

6.4.11. Laboratory ensures that reference value and correction factors are updated whenever correction factor is required for calibration and reference material data and these correction factors are available at the point of use so that specified requirements are met.

6.4.12. All measuring equipments of the laboratory are safeguarded to prevent unintended adjustment of the equipment and to ensure the validity of test results.

6.4.13. Laboratory maintains following records of the measuring equipment which can influence the laboratory activities:

a) the identity of the equipment including software and firmware version;
b) the manufacturer's name, type identification, and serial number or other unique identification;
c) evidence of verification that equipment conforms with specified requirements
d) the current location;
e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
h) details of any damage, malfunction, modification to, or repair of, the equipment.

6.5. Metrological traceability

6.5.1. Laboratory ensures that metrological traceability of measurement results is established and maintained by means of unbroken chain of calibrations.

6.5.2. Traceability of measurement results to the International System of Units (SI) is maintained through:

a) Calibration provided by a laboratory which is accredited by an accreditation body having MRA from regional co-operation and/or ILAC;
b) certified values of certified reference materials provided by a Reference Material Producer accredited by an accreditation body having MRA from regional co-operation and/or ILAC with stated metrological traceability to the SI;
c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards provided by National Metrological Institute.

6.5.3. When metrological traceability to the SI units is not technically possible, the laboratory demonstrates metrological traceability to an appropriate reference, e.g.

a) certified values of certified reference materials provided by a Reference Material Producer accredited by an accreditation body having MRA from regional co-operation and/or ILAC.
b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.6. Externally provided products and services

6.6.1. Laboratory ensures that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the laboratory's own activities;
b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
c) are used to support the operation of the laboratory.

6.6.2. Laboratory has a procedure *(refer procedure no.)* and retains records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;
b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of ISO/IEC 17025: 2017, before they are used or directly provided to the customer;
d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3. The laboratory communicates the requirements to external customer via email *(or whatever mode of communication laboratory is following may be mentioned)* for:

a) The products and services to be provided;
b) The acceptance criteria;
c) Competence, including any required qualification for personnel;
d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

7. Process Requirements

7.1. Review of request, tender and contracts

7.1.1. The laboratory has procedure *(Refer procedure no.)* for review of request, tender and contracts. This procedure ensures that:

a) the requirements are adequately defined, documented and understood;
b) the laboratory has the capability and resources to meet the requirements:
c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer about the laboratory activities performed by the external provider and gains the customer's approval; *Note: if the laboratory is not using external providers, this cl. is not applicable.*
d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

7.1.2. The laboratory informs the customer when the method requested by the customer is out-dated.

7.1.3. Whenever customer request for statement of conformity as per specification or standard, decision rule is clearly identified and decision rule selected by the customer is communicated to and agreed with the customer in test request itself. In case decision rule is inherent in the specification or standard and customer chooses that specification or standard, then decision rule is communicated accordingly.

7.1.4. Difference between the request or tender and the contract is resolved before starting any testing. Each contract is signed by the laboratory representative and customer. In case any deviation/amendment is requested by the customer, laboratory ensures that integrity of the laboratory is protected and not affecting the validity of test results.

7.1.5. Laboratory informs the customer well in advance if any deviation is there from the contract.

7.1.6. In case contract is amended after starting of testing, the contract review is repeated and is communicated to all internal as well as external personnel involved in that contract.

7.1.7. The laboratory co-operates with the customers to clarify customer request and witnessing of laboratory activities performed by the laboratory related to customer request.

7.1.8. The laboratory retains all the records of reviews that includes any changes requested by customer and any discussion held (telephonically, verbally or via email) with the customer related to customer requirements and results of laboratory activities disclosed to the customer.

7.2. Selection, verification and validation of methods

7.2.1. Selection and Verification of methods

7.2.1.1. The laboratory uses the appropriate method and procedures for all laboratory activities and for evaluation of measurement uncertainty and statistical technique for analysis of data.

7.2.1.2. Laboratory ensures the availability of all valid & updated test methods, procedures and supporting documentation like work instruction, operating manual, reference data for testing activities to the respective personnel.

7.2.1.3. Laboratory ensures to use the latest valid version of the test methods supplemented *(wherever required)* with additional details to ensure consistent application.

7.2.1.4. Whenever customer does not specify test method, the laboratory selects the appropriate method and informs the customer of the method chosen. Laboratory is using the test methods published by the National, International standard writing bodies. *(Here laboratory can mention the method used by the laboratory).*

7.2.1.5. The laboratory verifies all methods before introducing them in the scope of activities to ensure that it can achieve the required performance. Record of verification are maintained. *(mention format no. xxx).* When method is revised by issuing authority, it is verified again for the suitability.

7.2.1.6. When method development is *required (applicable in case methods are developed by the laboratory itself).* These method developments are planned and laboratory head assign the competent personnel to develop the specific method and provides adequate resources. Periodic reviews are conducted during the process of method development to ensure that customer requirements are fulfilled. Any modification in the development plan is approved and authorised by the laboratory head.

Note: For laboratories which use standard test methods this cl.is not applicable.

7.2.1.7. Deviation from the methods occurs only if deviation is documented, technically justified, authorised and accepted by the customer well in advance before starting of laboratory activity.

7.2.2. Validation of methods

Note: Laboratory may write this clause as not applicable if non-standard method/standard testing method outside its scope is not being used by the laboratory

7.2.2.1. Laboratory validates all non-standard test methods, laboratory developed method and standard methods which are used outside their scope. During validation of test method, following one or combination of techniques is used:

a) calibration or evaluation of bias and precision using reference standards or reference materials;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or testing method.

7.2.2.2. Whenever changes are made in the validated test method, the effect of the changes is identified and if the effect of the changes is affecting the validity of test results, laboratory to do revalidation.

7.2.2.3. Laboratory ensures that performance characteristics of the validated method are relevant to customer's needs and are consistent with the specified requirements.

7.2.2.4. Laboratory maintains following records of validation:

a) the validation procedure used;
b) specification of the requirements;
c) determination of the performance characteristics of the method;
d) results obtained;
e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3. Sampling

Note: Laboratory may write this clause as not applicable if laboratory is not involved in sampling activities.

7.3.1. Laboratory follows sampling plan defined in document no. *(mention document no in which sampling plan is mentioned)* and method for carrying out sampling of substances, material or products which is required for subsequent testing in accordance with range of laboratory activities as defined in clause 5.3. Laboratory ensure that sampling plan and method is available at the site of sampling.

7.3.2. Sampling method of the particular product/material/substance consists of

a) the selection of samples or sites.
b) the sampling plan.
c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing.

7.3.3. Laboratory retains following sampling data which forms part of testing performed:

a) reference to the sampling method used;
b) date and time of sampling;
c) data to identify and describe the sample (e.g. number, amount, name);
d) identification of the personnel performing sampling;
e) identification of the equipment used;
f) environmental or transport conditions;
g) diagrams or other equivalent means to identify the sampling location, when appropriate;
h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.4. Handling of test or calibration items

7.4.1. The laboratory follows procedure *(refer procedure no….)* for transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items that includes all provisions necessary to protect the integrity of the test or calibration items, and to protect the interests of the laboratory and the customer. All precautions are taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration.

Handling instructions provided by the customer are followed at all times.

7.4.2. After receipt of test or calibration item in the laboratory, laboratory follows system for the unambiguous identification of test or calibration item. Each test or calibration item is identified as per the laboratory system *(Laboratory can mention the system of identification taken into account the requirements of this clause).* It is ensured that identification of test or calibration item is retained while the item is under the responsibility of the laboratory.

7.4.3. After receipt of test or calibration item, if any deviations are there from specified conditions, the deviations are recorded in the observation sheet. When test items are not suitable for testing, laboratory consults the customer and takes consents from the customer for further processing and records of the discussion are maintained. In case, customer wants to proceed the testing with deviation, laboratory mentions the disclaimer in the reports by indicating that results may be affected due to deviation.

7.4.4. When test or calibration item needs to be stored in the specified environmental conditions, laboratory maintains, monitor and record the environmental conditions required for the test/calibration item as per the specifications provided by the customer.

7.5. Technical Records

7.5.1. Laboratory maintains the technical records of each laboratory activity that contain the results, report and other information required as per laboratory activities. These technical records contain the date and identity of the personnel responsible for a particular laboratory activity. Original observations, data and calculations are recorded at the time of execution of particular activity and are easily traceable/identifiable with the specific task performed.

7.5.2. The laboratory ensures that amendments to technical records is easily tracked to previous versions or to original observations. Both the original and amended data and files are retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.6. Evaluation of measurement uncertainty

7.6.1. Laboratory identifies and takes into account all contributions that are significant including those arising from sampling by using appropriate method *(here laboratory can mention the method chosen).*

7.6.2. Laboratory is evaluating measurement uncertainties of all calibrations including calibration of own equipment. *(This clause is not applicable to testing laboratories).*

7.6.3. Laboratory evaluates the measurement uncertainty of the test performed. Where test method specifies the process of the uncertainty estimation, the same process is followed. In case method precludes rigorous evaluation of measurement uncertainty, estimation is made based on understanding of the theoretical principles or practical experience of the test method.

7.7. Ensuring the validity of results

7.7.1. The laboratory follows procedure *(refer procedure no.)* to monitor the validity of results. Validity of results is monitored as per plan and is reviewed *(review frequency may be mentioned)* that include but not limited to:

a) use of reference materials or quality control materials;
b) use of alternative instrumentation that has been calibrated to provide traceable results;
c) functional check(s) of measuring and testing equipment;
d) use of check or working standards with control charts, where applicable;
e) intermediate checks on measuring equipment;
f) replicate tests using the same or different methods;
g) retesting of retained items;
h) correlation of results for different characteristics of an item;
i) review of reported results;
j) intra-laboratory comparisons;
k) testing of blind sample(s).

7.7.2. The laboratory monitors the performance by comparing the results with other accredited laboratories. PT/ILC plan is prepared by covering the entire scope of accreditation and reviewed that include but not limited to: (Refer NABL 163).

a) Participation in proficiency testing where accredited PT providers are available for the scope of accreditation.
b) participation in inter- laboratory comparison where accredited PT providers are not available.

7.7.3. Data from monitoring activities is analysed and used to control to improve the laboratory activities. Whenever results of the analysis of data from monitoring activities is found outside pre-defined limits as mentioned in the (procedure no…), immediate action is taken so as to avoid reporting of incorrect result.

7.8. Reporting of results

7.8.1. General

7.8.1.1. The results are reviewed and authorized by (designated personnel may be mentioned) prior to release.

7.8.1.2. The results are reported in the form of test report or report of sampling (as applicable to the laboratory). Results includes all information agreed with the customer and information necessary for the interpretation of the results and all information required by the test/sampling method. All reports issued to the customers are retained by the laboratory as technical records.

7.8.1.3. The results are reported in a simplified way if agreed by the customer. However, laboratory ensure that all information listed in 7.8.2 to 7.8.7 that is not reported to the customer is readily available.

7.8.2. Common requirements for reports (test, calibration or sampling)

7.8.2.1. Each report includes the following information:

a) a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”);
b) the name and address of the laboratory;
c) the location of testing that includes testing performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities;
d) Each report is identified as *(method of identification can be mentioned)* and each report page of the report contains the unique identification with page no.
e) the name and contact information of the customer;
f) identification of the method used;
g) a description, unambiguous identification, and, when necessary, the condition of the item;
h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
i) the date(s) of performance of the testing;
j) the date of issue of the report;
k) reference to the sampling plan and sampling method used.
l) statement that the results relate only to the items tested, calibrated or sampled;
m) the results with, the units of measurement;
n) additions to, deviations, or exclusions from the method;
o) identification of the person(s) authorizing the report;
p) clear identification when results are from external providers.

7.8.2.2. The laboratory is responsible for all the information provided in the report, except for the information provided by the customer. Data provided by the customer is clearly

identified. In addition, a disclaimer is put on the report when the information is supplied by the customer and due to that information, validity of results is affected. Where sample has been provided by the customer and laboratory is not involved in the sampling stage, it is stated in the report that results apply to the sample as received.

7.8.3. Specific requirements for test reports

7.8.3.1. In addition to the requirements listed in 7.8.2, test reports include the following:

a) information on specific test conditions, such as environmental conditions;
b) statement of conformity with requirements or specifications *(as decided during the review of request);*
c) the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
   - it is relevant to the validity or application of the test results;
   - a customer's instruction so requires, or
   - the measurement uncertainty affects conformity to a specification limit;
d) opinions and interpretations *(if provided by the laboratory);*
e) additional information that is required by specific methods, authorities, customers or groups of customers.

7.8.3.2. Laboratory is carrying out sampling, test report is complying the requirement mentioned in clause 7.8.5 *(This is not applicable in case laboratory is not involved in sampling activities).*

7.8.4. Specific requirements for calibration certificates

7.8.4.1. In addition to the requirements mentioned in clause 7.8.2, calibration certificate has following information:

a) the measurement uncertainty of the measurement result is reported in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);
b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
c) statement identifying that the measurements are metrologically traceable.
d) the results before and after any adjustment or repair, if available;
e) statement of conformity with requirements or specifications;
f) opinions and interpretations *(if laboratory is providing opinions and interpretations).*

7.8.4.2. In case laboratory is involved in sampling activities, calibration certificate meets the requirements mentioned in clause 7.8.5.

7.8.4.3. Calibration certificate and calibration label does not have recommendation on the calibration interval. However, if the customer wants to mention calibration interval on the calibration certificate and label, same is provided as per agreement with customer.

7.8.5. Reporting sampling – specific requirements

In case, laboratory is involved in sampling activity, the report includes the following information in addition to the requirements listed in 7.8.2: [This is not applicable in case laboratory is not involved in sampling activities (Cl. 7.3)]

a) the date of sampling;

b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate); (clause to be reviewed in terms of testing laboratories)

c) the location of sampling, including any diagrams, sketches or photographs;

d) a reference to the sampling plan and sampling method;

e) details of any environmental conditions during sampling that affect the interpretation of the results;

f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.6. Reporting statement of conformity

7.8.6.1. Laboratory documents the decision rule employed wherever statement of conformity (pass/fail) to a specification or standard is provided to the customer. Level of risk is also taken into account associated with the decision rule. In case, decision rule is employed by the customer, laboratory is not considering the risk associated with the decision rule.

7.8.6.2. When laboratory provides statement of conformity, it ensures that statement is clearly identified for the following:

a) results to which statement of conformity applies.
b) Specification, standards or parts are met or not met
c) decision rule applied. Decision rule applied is not mentioned when decision rule is inherent in the specification or standard.

7.8.7. Reporting Opinions and Interpretations (not applicable for those laboratories which does not provide Opinions and Interpretations)

7.8.7.1. Laboratory provides opinions and interpretations for the test results reported. Laboratory ensures that authorized person release the statement of opinions and interpretations. Laboratory document the basis on which opinion and interpretations are made.

7.8.7.2. The opinions and interpretations expressed in reports are based on the results obtained from the tested or calibrated item and are clearly identified as such.

7.8.7.3. When opinions and interpretations are directly communicated by dialogue (via telephone or in person meeting) with the customer, record of such dialogues is maintained.

7.8.8. Amendment to reports

7.8.8.1. In case, an issued report needs to changed, amended or reissued, any change of information is clearly identified and reason of change is also included in the revised, amended or re-issued report.

7.8.8.2. Amendments to a report is issued only in the form of a new report that includes the statement “Amendment to Report, serial number. Laboratory ensure that amendment report meet all the requirements of clause 7.8.

7.8.8.3. In case, it is necessary to issue a completely new report, this new report is uniquely identified and contain reference of previous report (original report) that it replaces.

7.9. Complaints

7.9.1. Laboratory have documented process (mention document no in which process is defined) to received, evaluate and to make decision on complaints.

7.9.2. Complaint handling process is made available to all interested parties based on the request. After receipt of the compliant, laboratory scrutinises the complaint and ascertain that the complaint is related to laboratory activities. If the compliant is not related to laboratory activities, laboratory does not deal with the same. Laboratory is responsible for all decision at all levels of the handling process of complaints.

7.9.3. The process for handling complaints includes the following elements and methods:

a) Description of the process for receiving, validation, investigating the compliant and deciding the actions to be taken in response of the complaint.
b) Tracking and recording complaints including actions undertaken to resolve complaints.
c) Ensure that appropriate action is taken.

7.9.4. After receipt of the complaint, laboratory gathers and verify all information to validate the complaint.

7.9.5. After receipt of the complaint, laboratory acknowledge the receipt of the complaint. Progress report with outcome of the complaint is also shared with the complainant.

7.9.6. Final outcome of the complaint is communicated to the complainant. Laboratory ensures that outcome of complaint is reviewed, approved and communicated by the person who is not involved in laboratory activities for which complaint has lodged.

7.9.7. Whenever possible, laboratory gives formal notice of the end of complaint to the complainant.

7.10. Nonconforming work

7.10.1. When any aspect of the laboratory activities does not conform to laid down procedures or agreed requirement of the customer, management of non-conformity work procedure *(mention procedure no. here)* is implemented. Management of non-conformity work procedure ensure that.

a) the responsibilities and authorities for the management of nonconforming work are defined;
b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
d) a decision is taken on the acceptability of the nonconforming work;
e) where necessary, the customer is notified and work is recalled;
f) the responsibility for authorizing the resumption of work is defined.

7.10.2. The laboratory retains records of non-conforming work and actions taken as per clause 7.10.1 (b to f)

7.10.3. After evaluation of non-conforming work, if it appears that non-conforming work can happen again, laboratory do the corrective action.

7.11. Control of data and information management

7.11.1. The laboratory ensures the access to data and information which is required to perform laboratory activities.

7.11.2. The laboratory follows laboratory information management system which is used for collection, processing, recording, reporting, storage and retrieval of data. Laboratory information management system is validated to ensure proper functioning before implementation. In case of changes in LIMS, they are authorised by the designated person, documented and validated before implementation.

Note: Laboratory information management system(s) includes the management of data and information contained in both computerized and non-computerized systems. Laboratory has to mention the actual practice followed in the laboratory.

7.11.3. Laboratory ensures that Laboratory information management system (LIMS) is

a) protected from unauthorized access;
b) safeguarded against tampering and loss;
c) operated in an environment that complies with provider or laboratory specifications (applicable for computerized systems), in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; (It depends on the laboratory which system they are using in their laboratory)
d) maintained in a manner that ensures the integrity of the data and information;
e) recording system failures and the appropriate immediate and corrective actions.

7.11.4. In case, laboratory information management system is managed and maintained off site or through an external service provider, laboratory ensure that service provider or operator of the system is complying with the confidentiality, impartiality and other applicable requirement of ISO/IEC 17025.

7.11.5. Laboratory management ensures that instructions, manuals, procedures and other reference data related to laboratory information management system is readily available to laboratory personnel.

7.11.6. Laboratory ensures that calculations and data transfers are checked before releasing the report to the customer. (Practice followed in the laboratory may be mentioned)

8. Management System Requirements

8.1. Options

8.1.1. General

Laboratory has established, implemented and maintained a management system which is capable to support and demonstrate the consistent achievement of the requirements of ISO/IEC 17025 and to assure the quality of laboratory results.

In addition to meet the requirements of clause 4 to 7, laboratory has implemented management system in accordance with Option A or Option B (laboratory has to mention the option followed in the laboratory).

8.1.2. Option A

Management system of the laboratory addresses the following:

- Management system documentation (Clause 8.2)
- Control of management system documents (clause 8.3)
- Control of records (Clause 8.4)
- Actions to address risks and opportunities (Clause 8.5)
- Improvement (Clause 8.6)
- Corrective actions (Clause 8.7)
- Internal Audits (Cause 8.8)
- Management reviews (Clause 8.9)

8.1.3. Option B

Laboratory has established and maintained management system in accordance with the requirements of ISO 9001 and is capable to support and demonstrate the consistent requirements of clause 4 to 7 of ISO/IEC 17025 and also fulfils the intent of management system requirements mentioned in 8.2 to 8.9.

Note: There may be few laboratories which are part of organisation performing activities other than testing and have implemented the Quality Management system in accordance with ISO 9001, they can opt for the Option B keeping in mind that at least intent of management system requirements (clause 8.2 to 8.9 of ISO 17025) are addressed in their existing documented management system.

8.2. Management system documentation (Option A)

8.2.1. Laboratory management has established, documented and maintained policies and objectives that fulfils the purpose of ISO/IEC 17025 and ensure that policies and objectives are acknowledged and implemented at all levels of the laboratory.

8.2.2. The Policies and Objectives of the laboratory addresses the competence, impartiality and consistent operations of the laboratory.

8.2.3. The Laboratory management demonstrates the commitment to the development and implementation of the management system and to continually improving effectiveness.

8.2.4. All documentation, processes, systems, records which are related to fulfil the requirements of ISO/IEC 17025 are included in and linked to the documented management system of the laboratory.

8.2.5. Laboratory ensures that all personnel involved in laboratory activities have access to the parts of the management system documentation and the information required to carry out the job responsibilities of their respective area.

8.3. Control of management system documents (Option A)

8.3.1. The laboratory controls all the documents (internal as well as external) that are required to perform the laboratory activities and to fulfil the requirements of ISO/IEC 17025.

8.3.2. The laboratory ensures that

a) documents are approved for adequacy prior to issue by authorized personnel.

b) documents are periodically reviewed and updated as necessary

c) changes and current revision of documents are identified.

d) relevant versions of applicable documents are available at point of use and their distribution is controlled.

e) all documents are uniquely identified.

f) The unintended use of obsolete documents is prevented by using stamp of obsolete on the documents which has been obsolete. (Laboratory may write the actual practice followed for prevention of use of obsolete documents)

8.4. Control of records (Option A)

8.4.1. The laboratory has established and retained legible records that demonstrate the fulfilment of requirements mentioned in ISO/IEC 17025.

8.4.2. The laboratory has implemented the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time and disposal of records. The laboratory retains the record for a period (period may be defined as per laboratory policy) keeping in view legal, regulatory and contractual obligations. Laboratory ensures that all records are easily available and confidentiality commitments is ensured at all times.

8.5. Actions to address risks and opportunities (Option A)

8.5.1. The laboratory considers the risks and opportunities that are associated with the laboratory activities in order to:

a) give assurance that the management system achieves its intended results.

b) enhance opportunities to achieve the purpose and objectives of the laboratory;

c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;

d) achieve improvement.

8.5.2. The laboratory plans:

a) Actions to address these risks and opportunities associated with the laboratory activities;

b) How to integrate and implement these actions into laboratory management system;

c) How to evaluate the effectiveness of these actions.

Note: Laboratory may mention the actual practice followed in the laboratory for the above-mentioned points.

8.6. Improvement (Option A)

8.6.1. The laboratory identifies and select opportunities for improvement and implement the necessary actions arising from identification.

Note: Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results. (Laboratory has to mention the actual practice being followed in the laboratory for improvement.

8.6.2. The laboratory seeks feedback (both positive and negative) from all customer. Customer feedback form is used for seeking the feedback. The feedback received is analysed and used to improve the management system, laboratory activities and customer service.

Note: Few laboratories may have the practice of seeking the feedback of customer by sending the customer feedback form along with test report to customer. There may be similar other good practices which are being followed by various laboratories. Laboratory has to mention the actual practice being followed to seek customer feedback.

8.7. Corrective actions (Option A)

8.7.1 When any non-conformity occurs in the laboratory, laboratory

a) react to the non-conformity

- takes action to control and correct the non-conformity
- the consequences on the laboratory activities due to non-conformity.

b) evaluate the need for action to eliminate the cause of the non-conformity so as to avoid its reoccurrence or occur elsewhere by following means:

- Each non-conformity is reviewed and analysed.
- Cause of the non-conformity is determined.
- Determine whether similar non-conformity exists or could potentially occur.

c) Implement the actions identified from cause of the non-conformity.

d) Review the effectiveness of the corrective action taken.

e) Update risk and opportunities determined during planning

f) Makes necessary changes to management system.

8.7.2 Laboratory ensures that corrective actions taken is appropriate to the effects of the non-conformities occurred.

8.7.3 The laboratory retains records of

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

8.8. Internal Audits (Option A)

8.8.1. The laboratory conducts internal audits once in a …….. (frequency may be mentioned as per laboratory policy) to ensure that laboratory's documented management system conforms to laboratory requirements including laboratory activities and is effectively implemented and maintained.

8.8.2. a) Before conducting the internal audit, laboratory plans, establish, implement and maintain audit programme that includes the frequency, methods, responsibilities, planning requirements and reporting by taking into consideration the importance of the laboratory activities, changes that affects the laboratory and results of previous audits. Audit criteria and scope for each audit is defined during the planning of internal audit.

b) Laboratory ensure that results of audit are reported to laboratory management.

c) Laboratory ensure to implement appropriate correction and corrective actions without undue delay.

d) Laboratory retains record of evidence of implementation of audit programme and the audit results.

8.9. Management Reviews (Option A)

8.9.1. The laboratory management reviews the management system of the laboratory once in____ (frequency may be mentioned as per laboratory policy) to ensure that management system is suitable, adequate and effective including the documented policies and objective related to the fulfilment of ISO/IEC 17025.

8.9.2. The Inputs to the management review is recorded and includes information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;

b) fulfilment of objectives;

c) suitability of policies and procedures;

d) status of actions from previous management reviews;

e) outcome of recent internal audits;

f) corrective actions;

g) assessments by external bodies;

h) changes in the volume and type of the work or in the range of laboratory activities;

i) customer and personnel feedback;

j) complaints;

k) effectiveness of any implemented improvements;

l) adequacy of resources;

m) results of risk identification;

n) outcomes of the assurance of the validity of results; and

o) other relevant factors, such as monitoring activities and training.

8.9.3. The outputs from the management review is recorded that includes all decisions and actions related to

a) the effectiveness of the management system and its processes

b) Improvement of the laboratory activities related to the fulfilment of the requirements of ISO/IEC 17025.

c) provision of required resources

d) any need for change.

National Accreditation Board for Testing and Calibration Laboratories (NABL)
J200, World Trade Centre,
Nauroji Nagar, New Delhi-110029
Website: www.nabl-india.org
Tel. No.: +91-11-40032400 (30 lines)