



**National Accreditation Board for
Testing and Calibration Laboratories
(NABL)**



**NABL's Policies for Accreditation
(as per ISO/IEC 17025:2017)**

AMENDMENT SHEET

Sl.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QM	Signature CEO
1.	6/10	6 (Table-1-Note)	16.07.2018	Note added as highlighted	Internal review	-Sd-	-Sd-
2.	--	--	08.10.2018	CAB word is replaced by Laboratory wherever given	Internal review	Sd-	-Sd-
3.	4/10	4 & 4(a)		Existing paragraph on impartiality is reframed			
4.	7/10	6		Inclusion of policy externally provided products & services (testing & calibration)			
5.	8/10	8		NABL 133 is referred for use of NABL symbol / claim of accreditation			
6.	3/10	--		Reference of NABL 120 as a document			
7.	5/10	5	As highlighted	Internal review			
8.	6/10	6	As highlighted	Regulatory requirement			
9.							
10.							
11.							

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Introduction

ISO/IEC 17025:2017 is an international standard which sets out the general requirements for the competence of testing & calibration laboratories.

The purpose of this document is to enable the laboratories about the NABL's Policies for accreditation as per ISO/IEC 17025:2017.

This document follows the numbering system of ISO/IEC 17025:2017 for the clauses. It does not reproduce the text of the standard but elaborates only those requirements, wherein, further elucidation is required.

In addition to the requirements of ISO/IEC 17025:2017, the laboratory shall also meet the mandatory requirements as elucidated in this document. The policies contained herein, shall be adopted for use within the NABL accreditation program.

In this document, the term “shall” denotes a mandatory requirement and the term “should” / “may” denotes a guidelines or recommendations.

Mandatory requirements are those requirements against which the assessment team shall raise non-conformity, whereas guidelines or recommendations are the ones which is for the interpretations or expectations from the laboratory w.r.t. the compliance to the requirements of ISO/IEC 17025:2017. Moreover guidelines or recommendations are also supplemented by examples in this document for the ease of understanding and implementation of the requirement.

Note: For categorization of product groupings while applying towards accreditation as per ISO/IEC 17025:2017, testing & calibration laboratories should refer document NABL 120; Guidance for Classification of Product Groups in Testing & Calibration fields, available on website www.nabl-india.org.

4. General Requirements (Clause No. 4 of ISO/IEC 17025: 2017)

Impartiality

Laboratory activities shall be undertaken impartially and structured so as to safeguard impartiality: the organizational structure shall be such that there is no conflict of interest with other activities, defining the responsibilities: this may be seen where organization defines the structure particularly in case of In-house laboratories or where the laboratories are the part of larger organization.

For being impartial, laboratory shall conduct its activities without any bias. Results of the laboratory should not be compromised due to being influenced by any relationships of the laboratory's personnel involved in the activities of the laboratory, with its customer.

To safeguard the impartiality in an organization wherein there are other activities in addition to the testing/ calibration, laboratory shall clearly define the segregation of the other activities in its organization which may be vulnerable to risks to impartiality.

Risks to impartiality may also arise within the laboratory itself by means of creating undue pressure on the analysts/ technicians to skip the test/ calibration procedural steps for faster results delivery or to overlook the adverse results which will distress a customer. Further undue pressure may also include offering monetary incentives to the employees for the number of tests/ calibration conducted or the results of test/ calibration. It is suggested that the identification of risks to impartiality should be carried out on an on-going basis or at a regular interval.

Also, looking at the external risks to impartiality, there are following possibilities as given below which may cause the bias:

- Business relationships between the laboratory and the customer;
- Family or personal relationships between persons of the laboratory who is involved in laboratory activities and the customer

It is worth mentioning that simply by having a relationship with a customer does not necessarily lead to a risk to impartiality, however, the laboratory is required to identify the potential risk and thereafter demonstrate that the risk has been eliminated or mitigated.

Confidentiality

Legally enforceable commitments may be in the form of contract / agreement / work order between the laboratory and its customer.

5. Structural Requirements (Clause No. 5 of ISO/IEC 17025: 2017)

Laboratory shall provide one of the following documents in support of its legal status claimed:

- i. Proprietorship firm (Bank passbook, Account statement, ID of the Proprietor)
- ii. Partnership (Copy of Registration under 1932 Act)
- iii. Company Act (Copy of Registration under 1956 Act)
- iv. Societies Registration Act (Copy of Registration under 1860 Act)
- v. Indian Trust Registration Act (Copy of Registration under 1882 Act)
- vi. **Limited Liability Partnership (Limited Liability Partnership Act, 2008)**
- vii. Government (Copy of Government Notification / Declaration etc.)

Permanent Laboratory: A testing or calibration laboratory set up in a dedicated location for an indeterminate amount of time.

Note: This is the laboratory location and address denoted on the certificate of accreditation

Entity: Company, Consultancy, Partnership or other body who does not necessarily have a permanent laboratory but who performs tests or calibrations at site.

Note: This definition may be read only in connection with the purpose of this document.

Site Testing / Calibration Facility: Testing / Calibration performed by staff of a laboratory or entity at the customer premises or location outside of a permanent laboratory.

Note:

1. Temporary facility created for a defined period is considered as site calibration / testing facility
2. Site Tests or Calibrations are normally performed:
 - i. by an accredited, permanent laboratory
 - ii. by an entity that does not have a permanent laboratory

Mobile Facility: Fully equipped, self-contained, transportable testing or calibration facility capable of performing tests / calibrations under controlled environmental conditions.

The organization and management structure of the laboratory can be in various forms i.e. individual laboratory at single location, laboratory being part of larger organization, laboratory with multiple locations, laboratory in Public Private Partnership (PPP) mode etc. For Public Private Partnership (PPP), accountability of test reports / calibration certificate issued, shall lie with the laboratory as per the contractual agreement, albeit, such agreement shall be devised on long term basis (Minimum 02 years).

The designated personnel (howsoever named), responsible for implementation, maintenance and improvement of the management system of laboratory, shall have successfully undergone 4-days training on ISO/IEC 17025 from a reputed institute **Or any other equivalent training on ISO/IEC 17025 in case of overseas laboratories.**

Laboratory personnel trained on previous edition of ISO/IEC 17025 are required to be familiar with requirements of new edition i.e. ISO/IEC 17025: 2017. The competence shall be verified by NABL assessment team.

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6. Resource Requirements (Clause No. 6 of ISO/IEC 17025: 2017)

Personnel

Laboratory's personnel (employed or on contract basis including third party contract) shall not work in another laboratory which falls under the different legal identity. However, the manpower resources may be shared with the laboratories under the same legal identity provided the laboratories' activities are not compromised. The minimum period of contract for the personnel shall be of minimum one year

Personnel authorized by the laboratory to report, review and authorization of results shall be "Authorized Signatory".

The technical competence of proposed Authorized Signatories for issue / release of test reports shall be verified by NABL assessment team however such Authorized Signatories shall meet the minimum qualification and experience requirements of NABL as defined in **Table-1** of this document.

NABL approved authorized signatory(s) in a laboratory, shall not be an authorized signatory in another laboratory which falls under the different legal identity. However, in case of multiple locations, a person shall be approved as an authorized signatory (ies) at different laboratory's location under the same legal identity, provided, there is one alternate permanent approved authorized signatory available at each location.

The personnel performing Radiological calibration activity shall have training from an agency recognized by BARC/AERB covering the aspects of calibration of radiation monitoring instruments and radiation safety aspects.

Table -1

Qualification & Experience Requirements for Authorized Signatory in Testing & Calibration Fields:

S. No	Minimum Qualifications	Minimum Years of Relevant hands on Experience
1.	Bachelor degree in Engg / Technology or Post Graduate in Science in the same field of testing / calibration	Two Year experience
2.	Bachelor degree in Engg / Technology or Post Graduate in Science in the Similar* field of testing / calibration	Three Years experience
3.	Diploma in Engg. / Technology or Graduate in Science in the same field of testing / calibration	Three Years experience
4.	Diploma in Engg. / Technology or Graduate in Science in the Similar* field of testing / calibration	Five Years experience
5.	ITI / Equivalent	Ten Years experience.
6.	Irrespective of the qualifications and experience, an authorized signatory accepted by a regulator, shall be considered eligible for those testing activities.	
<i>Note -</i>		
(a)	<i>*Similar field may be considered when that particular subject is covered in the said qualification.</i>	
(b)	<i>Qualification with specialized field like food, pharma, civil etc. shall be considered eligible for groups falling under more than one discipline of testing / calibration;</i>	
(c)	<i>In addition to the above requirements, the authorized signatory in NDT (Metal testing) shall have ASNT Level 2/ ISNT level 2 certifications.</i>	
(d)	<i>In each case, merely requisite qualifications and experience is not sufficient to become the Authorized signatory; the technical competence shall be verified by NABL assessment team before recommending as authorized signatory</i>	

Equipment

Laboratory shall have access to the equipment for its dedicated use only either by ownership or by long term contract / lease. Such contract shall be of minimum of 02 years. The control of such equipment shall lie with the laboratory under the contractual agreement.

In exceptional case, where the test facility is unique in nature and is the only facility available in the country, the laboratory may use the test facility without owning it but with proper justification and agreement.

Laboratories operating under same legal identity / ownership / organization, purchasing of external services such as consumable, Reference Materials (RM) or Certified Reference Materials (CRMs) from a central procurement point and its distribution amongst the laboratories for usage in testing, shall be acceptable, provided, the integrity of the procured material is not compromised.

Metrological Traceability

Laboratory shall comply with requirements of **NABL 142** 'Policy on Traceability of Measurement Results'

Calibration laboratory shall refer **NABL 143** "Policy on Calibration and Measurement Capability (CMC) and Uncertainty in Calibration".

Externally Provided Products and Services

Laboratory shall use only suitable externally provided services (testing & calibration) which affect laboratory activities. The services (testing & calibration) from External service provider (sub-contractor) is permitted only in the case of unforeseen reasons e.g. sudden breakdown of the working instrument or lack of man power or excess work load. However such external service providers shall be accredited by an Accreditation Body under APLAC/ILAC MRA signatory status for the services availed.

7. Process Requirements (Clause No. 7 of ISO/IEC 17025: 2017)

Handling of test or Calibration items

The laboratory shall ensure any anomalies and deficiencies are recorded, upon receipt of the sample. These anomalies and deficiencies may vary from:

- i. Damaged sample,
- ii. Insufficient sample for testing &
- iii. Deficiencies pertaining to filtration, chemical preservation, sample container, temperature on arrival, elapsed time subsequent to sampling, etc.

If the sample deficiencies may affect the validity of the result, the customer shall be informed in advance.

Evaluation of Measurements Uncertainty

Laboratory shall retain the records for the compliance

Ensuring the Validity of Results

Laboratory shall refer **NABL 163** "Policy for Participation in Proficiency Testing Activities" for the minimum requirements of PT participation during accreditation process of the laboratory.

Reporting of Results

For use of NABL symbol/ claim of accreditation, laboratory shall refer **NABL 133: NABL Policy for Use of NABL Symbol/ Claim of Accreditation by Accredited Conformity Assessment Bodies & NABL Accredited CAB Combined ILAC MRA Mark.**

NABL approved authorized signatories shall sign on test/ calibration reports or certificates. However, if the laboratory wishes to have an option of using electronic, photographic and mechanical means of reproducing signatures, the laboratory shall demonstrate that such system is safeguarded and the identity of the responsible person for such report shall be clearly identified.

Laboratory shall document the decision rule used while making statements of conformity.

A laboratory is considered to make statement of conformity when a result is identified as meeting or exceeding a specification or standard, the requirements regarding statements of conformity and decision rules will apply. 'NOTE' in this clause refers where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary. Laboratory shall document the decision rule used while making statements of conformity (refer ILAC G8-Guidelines on the reporting of compliance with specification & EURACHEM/ CITAC 2007- Use of Uncertainty Information in Compliance Assessment for more details).

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8. Management System Requirements (Clause No. 8 of ISO/IEC 17025: 2017)

ISO/IEC 17025:2017 describes two options for fulfilling the management system requirements, Option A & Option B. Besides meeting the requirements of Clause 4 to clause7 of ISO/IEC 17025:2017, the laboratory shall also implement a management system according to Option A or B.

Option A

Laboratory shall address the requirements of clause 8.2 to 8.9 as a bare minimum.

Option B

If a laboratory has established and maintains management system in accordance with the requirements of ISO 9001:2015, these may be referred against the requirements of clause 8.2 to 8.9 of ISO/IEC 17025:2017 in the laboratory's quality management system. Compliance to these requirements shall be verified during on-site assessment by NABL.

Management System Documentation (Option A)

Laboratory management shall establish, document, and maintain policies and objectives for the fulfillment of the purposes of ISO/IEC 17025: 2017 and shall ensure that the policies and objectives are documented, acknowledged and implemented at all levels of the organization. Laboratory shall have a management system document / Manual (howsoever named) for the purpose of compliance to ISO/IEC 17025: 2017.

Laboratory shall control the documents that fulfills the requirements of this Clause (Refer Cl. No. 5.5 (c))

Laboratory should be able to explain in detail how it addresses risk in carrying out its activities, albeit, standard ISO/IEC 17025:2017 does not define any standard method or risk management process, but it may be more difficult to demonstrate compliance without risk management approach (Appendix A).

Internal audit

Laboratory shall conduct internal audit at least once in a year covering all elements of ISO/IEC 17025: 2017. This may be done all at once or scheduled throughout the year depending on the scope and size of the laboratory.

Internal auditor shall be well conversant with Laboratory's operations / activities and the requirements of ISO/IEC 17025:2017.

Management Reviews

Laboratory shall review its management system at least once in a year. This may be carried out in a series of meetings throughout the year.

Records shall be retained by laboratory to demonstrate the compliance of inclusion of all the inputs in its management review meetings.

Appendix A

Guidance on Risk – based Approach in Laboratory

ISO/IEC 17025:2017 necessitates the laboratory to plan and implement actions to address risks and opportunities. This approach will be a vital tool to enhance the effectiveness of the management system, achieving improved results and preventing the adverse effects. Here laboratory has to determine which risks and opportunities are to be addressed. However, ISO/IEC 17025:2017 do not prescribe any formal Risk Management system

Following clauses of ISO/IEC 17025:2017 explicitly refer the term 'Risk':

- ✓ Clause 4.1.4 & 4.1.5 on impartiality,
- ✓ Clause 7.8.6.1 considering the risk in terms of decision rules used in reports,
- ✓ Clause 7.10.1 related to management of nonconforming work,
- ✓ Clause 8.5 on actions to be implemented to address risks & opportunities
- ✓ Clause 8.6 on improvement
- ✓ Clause 8.7 on corrective action
- ✓ Clause 8.9 on management reviews

How to do Risk Management in Laboratory:

Followings are the sequential step to manage the risk:

1. **Identify**- what can happen, when , where, why & how
2. **Assess**- determine existing control, determine likelihood, and consequences leading to estimate level of risk
3. **Evaluate**- compare against criteria, identify and weigh options, decide on response and establish priorities
4. **Control & Monitor**- mitigate by modifying process, document outcomes

This is pertinent to mention that there should be a thorough analysis of risks which a laboratory faces to address the risks in the laboratory adequately. The influences and causes are analyzed based on the risk scenario. Further, a classification and evaluation of risks must be carried out. This assessment can either lead to the initiation of measures or the acceptance of the risk as such. If measures are taken, their effectiveness shall also be examined. It is possible that a risk is acceptable.

A risk assessment can be conducted for example by a three-stage rating system:

- a) Low Impact, which is easy to correct. Probability of the same is very rare. The lowest risk can be an acceptable risk, however, it is necessary to decide whether it is still acceptable or if measures need to be taken.
- b) Moderate, which is errors occurring again but already clear (e.g. credibility loss). The probability of such risk is rare.
- c) High, which is serious error with possibly irreparable consequences (upto danger for life and health). The probability of occurrence is very frequent but it requires immediate measures to mitigate or eliminate.

When is Risk Assessment desirable?

Whenever it is necessary (e.g. customer requirements or ISO/IEC 17025) or if it helps to achieve the objectives of the management system. This may be regular or occasional in case of abnormalities or changes in the laboratory procedures.

Indeed, the laboratory should face risks for instance, to its existence, to its impartiality, to the validity of its results, etc., that may lead to failure, loss, damage or others and act against them in an appropriate manner to mitigate or eliminate them.

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