

NABL 210



National Accreditation Board for Testing and Calibration Laboratories (NABL)

ASSESSOR GUIDE

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AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1.	5	2.2	18-Jul-2020	Inclusion of following text 'The compliance of all shall requirements are to be verified for compliance'	Internal review	-Sd-	-Sd-
2.	14	6.3.7i		Reference to NABL 165 removed and reference to application form included.	NABL 165 is withdrawn by NABL.		
3.	5	2.2	05-Jul-2021	The sentence "The compliance of all shall requirements are to be verified for compliance" is revised as "The compliance of all shall requirements are to be verified".	Repeated word deleted.	-Sd-	-Sd-
4.	8	2.14.1		Reference to NABL 215 'Assessment Forms & Checklists (based on ISO/ IEC 17025:2005) is deleted.	NABL 215 document is withdrawn in view of transition deadline.		
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CONTENTS

S. No.	Title	Page No.
	Amendment Sheet	1
	Contents	2
1.	Introduction	3
2.	Assessor's Role and Responsibility	5
3.	Assessor Assignment Procedure	9
4.	Procedure for Assessment of CAB	10
5.	Pre-Assessment	12
6.	On-site Assessment	13
7.	Guide to Formulate Recommendations	19
8.	Procedure for Conducting Closing Meeting	20
9.	Scope of Accreditation	21
10.	Procedure for Handling the Management System Document/ Quality Manual and other Documents after Assessment	22
11.	On-site Surveillance and Re-assessment	23

1. INTRODUCTION

National Accreditation Board for Testing and Calibration Laboratories (NABL) provides third-party accreditation to Conformity Assessment Bodies {Testing Laboratories/ Calibration Laboratories / Medical Testing Laboratories / Proficiency Testing Provider (PTP) / Reference Material Producers (RMP)} according to international standards. The liberalization (of trade and industry) policy of Government of India provides greater thrust for exports. This makes it imperative for the Conformity Assessment Bodies (CABs), where the products are assessed, to be at international level of competence. NABL is, therefore, committed to ensure that the accreditation requirements and assessment system for CABs are in line with international norms and practices.

NABL assures itself of the competence of the CAB it accredits through a system of assessment in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories- Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 - General Requirements for the Competence of Reference Material Producers, whichever is applicable. The assessment is carried out by a team of Assessors, led by a Lead Assessor, empanelled by NABL.

The assessment is carried out systematically on all aspects of technical competence and of CAB's management system. The objective evidence so collected forms the basis:

- for arriving at a judgement for recommendation of the team on grant, continuation or renewal of accreditation,
- to specify the competence of CAB in terms of its capability to perform the activities for which it is seeking accreditation or holds accreditation

The objective of the assessment, however, is not to compile non-conformities as an evidence to justify denial of accreditation in case of negative recommendation.

This Guide has been published in order to provide assistance to NABL Assessor in conducting assessments for NABL. It describes the role of an Assessor in conducting the Assessment-related activities for NABL. The methodologies being described are basically

National Accreditation Board for Testing and Calibration Laboratories			
Doc. No.: NABL 210	Assessor Guide		
Issue No.: 07	Issue Date: 22-Jan-2020	Amend. No.: 02	Amend. Date: 05-Jul-2021

to help an Assessor to be able to discharge his / her responsibilities effectively. Since an Assessor would be representing NABL during the assessment of a Conformity Assessment Bodies {Testing Laboratories/ Calibration Laboratories / Medical Testing Laboratories / Proficiency Testing Provider (PTP) / Reference Material Producers (RMP)}, (s)he should understand NABL and its accreditation process, its objectives, mission as well as the assessment methodology.

This guide has been prepared based on the general practices followed by international bodies and the experience of experts of the country. This document accordingly aims to:

- a. provides guidance to the Assessors for conducting assessment of a CAB;
- b. ensures uniformity of assessment and reporting; and

2. ASSESSOR'S ROLE AND RESPONSIBILITY

- 2.1. The objective of any on-site assessment is to obtain evidence on compliance with respect to the ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 - General Requirements for the Competence of Reference Material Producers, whichever is applicable. Basically, the NABL Assessor's role is to conduct assessment of CAB to adjudge the compliance to above Standards.
- 2.2. The Assessor shall also check that the CAB meets other requirements of NABL including the NABL's Specific Criteria for the relevant field and / or discipline (wherever applicable) and has competence to perform the specific test(s)/ calibration(s) / PT scheme or Production of RM/ CRM. **The compliance of all shall requirements are to be verified.** The Assessor shall ensure that (s)he is using the latest documents which are available on the NABL web-site for each assessment. The Assessor shall also pay attention to the specific announcements on web-site pertaining to policy decisions and its transition period (if any) before proceeding with the assessment.
- 2.3. Since CAB accreditation requires formal recognition of competence to carry out specific test(s)/ calibration(s) / PT scheme or Production of RM/CRM by a CAB, an Assessor has also to consider conformities against these aspects in the assessment. Thus, an Assessor would be required to exercise his scientific & technical judgement and form his opinion regarding extent of conformity with respect to accreditation criteria.
- 2.4. Assessors are required to maintain the confidentiality on the matters / subjects related to CAB.
- 2.5. Notwithstanding the strength of the NABL system, the success of the accreditation scheme depends on the Assessors who conduct assessment. Thus, the Assessors play a vital role in determining the credibility and value of the accreditation.
- 2.6. In case the assessment team members observe gross non-conformities in the documents and their implementation, the Lead Assessor shall consult with NABL for abandoning the assessment process.
- 2.7. The Lead Assessor is also required to monitor the performance of Technical Assessor(s), Expert(s) and the Observer(s). The lead assessor shall also recommend whether the Observer is capable to perform the role of a Technical Assessor in future, if asked by NABL, The Lead assessor's comments / rating for each Technical Assessor shall be enclosed with the report in Form 45(c).

National Accreditation Board for Testing and Calibration Laboratories			
Doc. No.: NABL 210	Assessor Guide		
Issue No.: 07	Issue Date: 22-Jan-2020	Amend. No.: 02	Amend. Date: 05-Jul-2020

- 2.8. The Technical Assessor should clearly understand the areas / activities to be assessed by him. He must review the Laboratory's documented system to verify compliance with the requirements of ISO/IEC 17025/ ISO 15189 / ISO/IEC 17043 or ISO 17034, related NABL Specific Criteria and other policies/ guidelines of NABL. (S)he should assess to verify that the documented SOPs, test methods, records are indeed implemented & effective, and record observations. (S)he should also complete Checklist 2 related to the requirements of respective clauses and using NAF(XX) 3 and NAF(XX) 3A for witness done by him. The Technical Assessor must review and endorse the Measurement Uncertainty / % CV calculations for each test/ parameter witnessed. In case a Technical Expert is a member of the team, the Technical Assessor has to provide information to the Technical Expert regarding NABL forms and policies and guide him during the assessment. NC identified by the Technical Expert will however, be raised by the Lead Assessor.
- 2.9. The role of Technical Expert is same as that of Technical Assessor, except that he will seek guidance of Technical assessor in filling the relevant forms, checklist etc. Technical expert is not allowed to raise any NC. In case NC is identified during an assessment by TE, it has to be raised by the Lead Assessor (using his checklist in case of assessments conducted through portal).
- 2.10. The Observer (Potential Assessor) will be assigned to accompany the Lead Assessor and Technical Assessor(s) as per the schedule provided. (S)he shall be guided by the Lead Assessor and the Technical Assessor(s). (S)he is not required to submit any report however his/ her TA / DA form shall be submitted to the Lead Assessor. (S)he is not entitled for payment of any honorarium.
- 2.11. An Assessor must ensure that (s)he is well versed with:
- 2.11.1. Assessment principles including risk-based assessment principles, practices and techniques,
- 2.11.2. General management system principles and tools,
- 2.11.3. Applicable standard (ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 'General Requirements for the Competence of Reference Material Producers'),
- 2.11.4. Other relevant Specific criteria documents, and
- 2.11.5. NABL policy documents prior to the visit to Conformity Assessment Bodies (CABs).

National Accreditation Board for Testing and Calibration Laboratories			
Doc. No.: NABL 210	Assessor Guide		
Issue No.: 07	Issue Date: 22-Jan-2020	Amend. No.: 02	Amend. Date: 05-Jul-2021

2.12. Considering improvement as a continuous process, the assessor is required to enhance following knowledge and skills on an on-going basis:

2.12.1. Understanding the knowledge of practices and processes of the Conformity Assessment Body business environment,

2.12.2. Communication skills,

2.12.3. Note-taking and report-writing skills,

2.12.4. Opening and closing meeting skills,

2.12.5. Interviewing skills,

2.12.6. Assessment management skills

2.13. The detailed requirements of knowledge and skills are mentioned below:

Knowledge and Skills	Accreditation Activities	
	Document Review	Assessment
Knowledge of Applicable Standard	√	√
Knowledge of relevant guidance and applicable documents	√	√
Knowledge of NABL Policies and Procedures	√	√
Knowledge of general regulatory requirements	√	√
Knowledge of assessment principles, practices and techniques	√	√
Knowledge of General management system principles and tools	√	√
Note-taking and report-writing skills	√	√
Knowledge of risk-based assessment principles		√
knowledge of practices and processes of the Conformity Assessment Body business environment		√
Communication skills		√
Interviewing skills		√
Opening and Closing meeting skills (including information to CAB about complaint and appeal mechanism of NABL in closing meeting)		√
Assessment Management Skills		√

2.14. The supplementary documents to this guide are as follows:

National Accreditation Board for Testing and Calibration Laboratories			
Doc. No.: NABL 210	Assessor Guide		
Issue No.: 07	Issue Date: 22-Jan-2020	Amend. No.: 02	Amend. Date: 05-Jul-2021

Documents

Page No: 7 of 24
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