



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Terms & Conditions for Obtaining and Maintaining NABL Accreditation

ISSUE NO.: 08
ISSUE DATE: 16-Jul-2020

AMENDMENT NO.: 02
AMENDMENT DATE: 11-Sept-2023

AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.	01	2	1	10.07.2023	Inclusion of text	Internal Review	-Sd/-	-Sd/-
2.		2	5					
3.		4	14, 15, 17, 19					
4.		6	41, 42, 43, 44					
5.		7	45					
6.		2 to 7	----		As highlighted			
7.	02	2, 3, 4, 7, 8, 9	5, 14-17, 45-48, 50-54, 56, 57, 58	11.09.2023	As highlighted	Comment from Stakeholders	-Sd/-	-Sd/-
8.								
9.								
10.								
11.								
12.								

Terms & Conditions for Obtaining and Maintaining NABL Accreditation (To be submitted to NABL along with the application form)

The terms and conditions mentioned in this document are considered as accreditation agreement between NABL and Conformity Assessment Body (CAB). By accepting these terms and conditions, it is implied that a CAB as an applicant and after obtaining accreditation agrees to comply at all times with all the Terms and Conditions for maintaining NABL Accreditation. Any violation of any one or more of these terms and conditions (accreditation agreement) shall result in adverse decision as per NABL 216 'Procedures for Dealing with Adverse Decisions', including legal action.

The Conformity Assessment Body {Testing Laboratory/ Calibration Laboratory/ Medical Testing Laboratory/ Proficiency Testing Provider (PTP)/ Reference Material Producer (RMP)} that are applicant or accredited by NABL shall be required to fulfill the following terms and conditions:

1. The Conformity Assessment Body (CAB) shall carry out its Testing / Calibration / Medical/ PTP / RMP activities in such a way as to meet the requirements of relevant standard (eg. ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034, whichever is applicable), appropriate NABL specific criteria/application documents (wherever applicable) and other policies of NABL, as relevant to the accredited scope **at all times**.
2. CAB shall ensure that the latest versions of NABL documents are available with **it** and are effectively implemented.
3. CAB shall familiarize **itself** with all relevant standards, NABL documents etc. applicable for particular accreditation scheme.
4. The CAB shall have a valid legal entity status as given below:

Type of Legal Entity	Document to be submitted
One Person Company	Registration certificate under The Companies Act, 2013
Limited Liability Partnership	Registration certificate under The Limited Liability Partnership Act, 2008
Company	Registration certificate under The Companies Act, 1956 or 2013
Societies / Trust	Registration certificate under Societies Registration Act, 1860/ Registration under The Indian Trusts Act, 1882
Government	Gazette or Government Notification or self-Declaration on Letter head by Head of the organization

5. CAB (Conformity Assessment Body) shall provide all necessary information about its antecedents as required by NABL which shall include but not limited to its background information i.e. history, establishment, ownership, and organizational structure, Key Personnel, Previous Experience, Legal Compliance, Disputes and Complaints if any, Quality Management System, Financial Information if required, Conflict of Interest, Accreditations and Certifications from any other body or Any other information, deemed necessary by NABL to analyse and evaluate the CAB's eligibility for accreditation. By submitting the application for accreditation, the CAB expressly consents to the collection, use, and disclosure to NABL of the provided information for the purpose of evaluating the

accreditation application and ensuring compliance with accreditation standards. NABL reserves the right to verify the accuracy and authenticity of the provided information. Failure to provide accurate and complete information or any attempt to withhold relevant details shall result in the rejection of the accreditation application.

6. It is the responsibility of CAB to abide by the National/ Regional/ State/ Local regulatory requirements/ Acts/ Rules/ Legal orders/ Court Decisions/ Orders issued by Government/ Statutory Bodies as applicable and effective from time to time.
7. The CAB shall identify and define various activities which they are involved in, and ensure that it does not lead to any potential conflict of interest.
8. The CAB shall have available qualified and trained personnel for applied and/or accredited scope including sampling (wherever applicable).
9. Wherever applicable, the CAB shall follow the test methods as mentioned in the current National or International standards and/or as stipulated by regulatory bodies. Where such methods do not exist, other validated methods may be followed. In case CAB uses in-house validated methods, the validation data should be submitted along with the application.
10. CAB shall ensure the capability with respect to applied scope of accreditation (availability of resources not limited to personnel, equipment, CRM, method validation etc.) before applying to NABL and thereafter at all times during the accredited period.
11. The CAB shall promptly inform NABL of any changes in its organization, personnel, facilities, scope of services, or any other significant factors that may impact its accreditation status.
12. Applicant CAB shall successfully participate in at least one Proficiency Testing (PT) program prior to gaining accreditation in each discipline applied. There may be situation where PT is not available. Requirements are specified in NABL 163 and the same shall be followed for PT participation or otherwise.
13. CAB shall submit the completed application for renewal of accreditation well in advance (give sufficient time to process) prior to the expiry of accreditation and also agree to undergo assessment as per the schedule proposed by NABL to maintain continuity in accreditation cycle. Application submitted after expiry of accreditation will be considered as fresh application. The assessment (onsite) interval shall not exceed 24 months and in case if exceeds, then it will be treated afresh.
14. The CAB shall offer full cooperation to NABL or its representative or member of team evaluating/assessing during the conduct of assessments (including onsite surveillance), any additional assessments, such as additional surveillance assessments based on risk, unannounced assessment/visit (including visit for investigation of complaints related to NABL accreditation against the CAB). The cooperation by the CAB shall include access to, but not limited to, the following activities:
 - a. Undergoing assessments in stipulated time intervals / whenever NABL considered it as required.