

NABL 131



National Accreditation Board for Testing and Calibration Laboratories (NABL)



Terms & Conditions for Obtaining and Maintaining NABL Accreditation

ISSUE NO. : 07
ISSUE DATE : 19-Apr-2016

AMENDMENT NO. : 01
AMENDMENT DATE : 11-Sept-2018

National Accreditation Board for Testing and Calibration Laboratories				
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AMENDMENT SHEET

Sl.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QM	Signature CEO
1.	2 & 3 of 5	5 & 9 (i)	11.09.2018	Inclusion of authorized qualified personnel for review, evaluation & release of reports	New CEA amendment under MoHFW	-Sd-	-Sd-
2.	4 & 5 of 5	16 (f) & 26		Inclusion of Sample Collection Facility/ centre	Recognition of SCFs declared by medical lab		
3.	4 of 5	12		Inclusion of compliance to NABL 165 for CABs	New NABL Policies Document; NABL 165		
4.	3 of 5	11		Inclusion of NABL Accredited CAB Combined ILAC MRA Mark under NABL 133	Policy development for the use of NABL Accredited CAB Combined ILAC MRA Mark		
5.							
6.							
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10.							

Terms & Conditions for Obtaining and Maintaining NABL Accreditation

(To be submitted to NABL along with the application form)

The Conformity Assessment Bodies (Testing including Medical / Calibration Laboratories / Proficiency Testing Providers-PTP / Reference Material Producers-RMP) that are applicant / accredited by NABL shall be required to fulfill the following terms and conditions:

1. The Conformity Assessment Bodies (CABs) shall carry out its testing / calibration / medical / PTP / RMP activities in such a way as to meet the requirements of ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 whichever are applicable, relevant NABL specific criteria (wherever applicable) and other policies of NABL.
2. The CAB shall have a valid legal identity.
3. The CAB shall meet the requirements of regulators in relevant field.
4. 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.
5. The CAB shall have adequate qualified and trained manpower for stated scope including NABL approved authorized signatory(s) who is responsible for authenticity and issue of test / calibration / PTP / RMP reports or authorized qualified personnel for review, evaluation & release of results, as applicable who meets the requirements of relevant NABL specific criteria (wherever applicable) for each field / discipline of accreditation.
6. The designated Quality Manager / designated personnel (howsoever named), responsible for implementation, maintenance and improvement of the management system of CAB, shall successfully undergo 4 days training on ISO/IEC 17025 (CAB personnel trained on previous edition of ISO/IEC 17025 is required to be familiar with requirements of latest edition i.e. ISO/IEC 17025) or ISO 15189 whichever is relevant from a reputed training institute. For PTP / RMP, the Quality Manager shall preferably undergo either 4-days training on ISO/IEC 17043 / ISO 17034 or at least 4 days training on ISO/IEC 17025 (CAB personnel trained on previous edition of ISO/IEC 17025 are required to be familiar with requirements of new edition i.e. ISO/IEC 17025) or ISO 15189 as the case may be.

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7. The CAB, where applicable, shall participate in one inter laboratory comparison / proficiency Testing program in at least one parameter / type of test per discipline prior to gaining accreditation and after obtaining accreditation for all groups included in the accredited scope of each discipline at least once every four years. Requirements specified in NABL 163 shall be followed for PT participation.
8. CAB shall submit the completed application for renewal of accreditation six months 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.
9. The CAB shall offer cooperation to NABL or its representative in:
 - a. Undergoing assessments in stipulated time intervals / whenever NABL considered it as required.
 - b. Access to all CAB areas of operations including subcontractor premises, wherever relevant and applicable.
 - c. Undertaking any check / inspection to verify the capability of the CAB for the applied / accredited scope.
 - d. Witnessing the activities being performed relevant to accreditation.
 - e. Assessing the competence of the staff (including staff working in shift operations / at site) during assessment.
 - f. Access to all relevant information and documentation.
 - g. Access to those documents that provide insight into the level of independence and impartiality to the CAB from its related bodies, if applicable.
 - h. Access to all records pertaining to relevant personnel.
 - i. Providing names of all authorized signatory (s) who are responsible for authenticity and issue of test / calibration / PTP / RMP reports or list of authorized qualified personnel for review, evaluation & release of results (Medical testing), as applicable.
 - j. Investigating any complaints against the CAB.
10. On grant of accreditation, the CAB shall claim accreditation in only those premises, fields, facilities, disciplines, tests / calibrations / PT Schemes / Production of Reference Materials for which it has been accredited (as stated in Accreditation Certificate).
11. Accredited CAB shall adhere to 'NABL 133' for the use of NABL symbol, use of NABL Accredited CAB Combined ILAC MRA Mark as well as any claim of accreditation of the CAB.

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12. CAB applying for accreditation and accredited as per new version of ISO/IEC 17025 shall comply with the requirements of 'NABL 165: NABL's Policies for Accreditation as per ISO/IEC 17025:2017, wherever applicable.

13. Accredited CAB shall make it clear in all its contracts with customers that its activities falling under accredited scope in no way imply that the product so tested or equipment calibrated is approved by NABL.

14. CAB shall ensure that its customers are made clear that accreditation in no way implies that its process system or person is approved by NABL.

15. The CAB shall pay application fees for accreditation, re-accreditation; expenses towards travel, boarding & lodging for any kind of assessment including supplementary visit , surveillance, desktop surveillance, re-assessment and annual accreditation fees as shall be from time to time determined by NABL.

16. The CAB shall inform NABL within 15 days of significant changes affecting the CAB's activities and operations relevant to accreditation, such as:

- a. its legal, commercial, ownership or organizational status
- b. the organization, top management and key personnel including authorized signatories*
- c. main policies
- d. resources and premises
- e. other such matter that may affect the ability of the laboratory to fulfill the requirements of ISO/ IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 whichever is applicable.
- f. any change in the Sample Collection Centre/ Facility (ies) to NABL.

17. The CAB shall continuously keep in touch with NABL to keep itself updated with the latest versions of NABL documents and national and international standards.

18. The CAB shall unambiguously declare the name of any individual or organization that has provided consultancy for preparing towards NABL accreditation.

19. The accredited CAB shall itself normally perform the activities which is covered under scope of accreditation. Where a CAB subcontracts a substantial or critical part of the accredited activities that work shall be placed with another accredited CAB only.

20. The accredited CAB shall respond promptly to the changes initiated by NABL in its accreditation criteria, policies and procedures. The CAB shall inform NABL when such alterations under the agreed time frame have been completed.
21. CAB shall take corrective actions to close all the non conformities raised during the assessment within 30 days time to avoid any adverse decisions against it as detailed in 'NABL 216'.
22. CAB shall not involve in any kind of Activity(s) which may bring NABL to disrepute.
23. The accredited CAB upon suspension or withdrawal of its accreditation (however determined) or expiry of validity of accreditation shall forthwith discontinue its use of all advertising matter that contain any reference to the accreditation status and return the certificates of accreditation to NABL.
24. The accredited CAB can relinquish accreditation by giving notice in writing to NABL by surrendering the certificates of accreditation.
25. The CAB shall inform NABL Secretariat, if any of the proposed assessor(s) happens to be their Consultant or associated with the CAB in any other capacity,
26. NABL absolves itself of any legal or financial liability arising out of activities of any of its accredited CAB/ Sample Collection Centre/ Facility (ies) declared by medical CAB involving any accidental or consequential damages to personnel / equipment / products at any time.

By signing this document, it is implied that a CAB/ Sample Collection Centre/ Facility (ies) declared by medical CAB as an applicant and after obtaining accreditation agrees to comply at all times with all Terms and Conditions for NABL Accreditation. Any violation of this terms and conditions shall result in adverse decision such as abeyance, suspension, forced withdrawal etc against the CAB as specified in 'NABL 216'.

All disputes, if any, arising out of NABL decisions that remain unresolved through mechanism provided by NABL are subject to the exclusive jurisdiction of the Courts at New Delhi and none other.

Signature of Chief Executive or his Authorized Representative _____

Name, Designation of Chief Executive or his Authorized Representative _____

CAB Name _____

Date & Place _____

Signature of NABL official & Date of Receipt _____

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