

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Terms & Conditions for Obtaining and Maintaining NABL Accreditation

ISSUE NO.: 08 AMENDMENT NO.: 02

ISSUE DATE: 16-Jul-2020 AMENDMENT DATE: 11-Sept-2023

AMENDMENT SHEET

| S. No | Amendme nt No. | Pag e No. | Claus e No. | Date of Amendmen t | Amendme nt | Reasons | Signatu re QA Team | Signatur e Compete nt 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 Stakeholde rs | -Sd/- | -Sd/- |
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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

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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.

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- b. Providing access to all areas of operations related to CAB including site, mobile / temporary, subcontractor / external provider premises, wherever relevant and applicable.
- c. Undertaking any check / inspection to verify the capability of the CAB for the applied and/or 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, at mobile facility) during assessment.
- f. Access to all relevant information and documentation and records.
- g. Access to those documents that provide insight into the level of independence and impartiality of the CAB from its own activities and its related bodies, if applicable.
- h. Access to all records pertaining to competence of the CAB personnel.
- i. Assessing the competence of the persons who are responsible to report, review and authorization of the results,
- j. Assessing the competence of the persons who are responsible for opinion and interpretation
- 15. The CAB shall maintain the highest level of impartiality, integrity, and professionalism throughout the accreditation process as well as accreditation period. It shall avoid any actions or relationships that could compromise its independence or objectivity.
- 16. The CAB shall establish and maintain an effective management system, adhering to recognized international or any other standards by NABL, to ensure consistent and reliable conformity assessment services.
- 17. The CAB shall cooperate fully with NABL during assessments, audits, investigations, and any other activities related to the accreditation process. It shall provide all necessary information and access required by NABL to evaluate its compliance with accreditation standards.
- 18. The CAB shall have, where applicable, legally enforceable arrangements with their customer/client that commit the customers/clients to provide, on request, access to NABL assessment team to assess the CAB's performance when carrying out conformity assessment activities at the customer/client's site.
- 19. An accredited CAB shall also demonstrate the following during the validity period of its accreditation:
 - a) compliance with the terms of this agreement
 - continuing conformity with the relevant standard (eg. ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034, whichever is applicable) and appropriate NABL specific criteria/application documents (wherever applicable)
 - c) continuing competence within the scope of its accreditation
 - d) willingness to give such undertakings as NABL may reasonably require
- 20. During the accreditation period, the CAB shall claim accreditation for only those premises, and scope for which it has been accredited (as stated in Accreditation Certificate and scope of Accreditation).

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- 21. Applicant CABs shall not claim to be NABL Accredited or use NABL symbol/logo before receiving the communication regarding grant of accreditation from NABL. In case it is found that CAB is claiming to be NABL Accredited or using NABL symbol/logo in applicant stage or misleading customers about its accreditation status in any way, this may lead to rejection of application or termination of the assessment process or denial of accreditation. Legal action may also be initiated.
- 22. 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. CAB shall ensure that it fully conforms to the requirements of NABL and ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 (as applicable) for claiming accreditation status while making references of its NABL accreditation in communication media. During the period of suspension or after withdrawal of accreditation, suitable legal action may be taken by NABL in case CAB falsely claims to be NABL accredited.
- 23. Accredited CAB shall ensure that the copy of the test report/certificate, medical test report/certificate, calibration certificate/report, PT report and RM document stored/retained shall be an exact replica of the report issued to the customer including the format of the test report/certificate, medical test report/certificate, calibration certificate/report, PT report and RM document header & footer, and NABL symbol.
- 24. CAB shall use NABL accredited CAB Combined ILAC MRA Mark only after obtaining written permission from NABL and the usage shall be restricted to the period of validity of the permission as informed by NABL.
- 25. Accredited CAB shall make it clear to its customer that its activities falling under accredited scope in no way imply that the product so tested or equipment calibrated or PT scheme offered or Reference Material (RM) produced is approved by NABL.
- 26. The accredited CAB is neither allowed to make misleading / unauthorized statement regarding its accreditation nor refer to accreditation in such a way so as to imply that a product, process, service, management system or person is approved by NABL.
- 27. The CAB shall pay application fees for accreditation, renewal of accreditation, expenses towards travel, boarding & lodging for any kind of assessment including supplementary visit, on-site surveillance, desktop surveillance, re-assessment and annual accreditation fees as determined from time to time, by NABL.
- 28. The CAB shall inform NABL without delay (within 15 days) of significant changes relevant to accreditation, such as:
 - a. its legal, commercial, ownership or organizational status,
 - b. its resources not limited to personnel, facilities, equipment to manage and perform its activities, authorized personnel responsible to report, review and authorization of the results.
 - c. premises,
 - d. scope of accreditation,
 - e. sub-contractor addition (RMP),

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- f. Major changes in the operation of the CAB, for example, closure of the CAB for long duration, say more than 6 months;
- g. any other factor that may affect the ability of the CAB to fulfill the requirements of NABL accreditation including policies & ISO/IEC 17025, ISO 15189 or ISO/IEC 17043 or ISO 17034 as applicable.
- h. any other change in information submitted in application.
- 29. The CAB shall regularly visit NABL website to keep itself updated with the latest versions of NABL documents as well as the NABL newsletter or any other relevant information concerning accreditation provided on the NABL website.
- 30. CAB shall always have a dedicated person responsible for implementation of Management System.
- 31. The CAB shall unambiguously and truthfully declare the name of any individual and organization that has provided consultancy for preparing towards NABL accreditation, at the relevant section in the application form.
- 32. Where a CAB subcontracts a substantial or critical part of the accredited activities that work shall be placed with another CAB that is accredited by NABL.
- 33. The accredited CAB shall commit to comply with 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.
- 34. The CAB shall take all necessary actions and discharge all non- conformities raised during the assessment within 30 days to avoid any adverse decisions against it as detailed in 'NABL 216'. The same shall be verified to the satisfaction of NABL. The final decision on accreditation shall rest with NABL.
- 35. CAB shall not use its NABL accreditation in such a manner as to bring NABL into disrepute.
- 36. At any point in the application or initial process, if there is evidence of fraudulent behavior and/ or if the CAB has intentionally provided false information or conceals information, NABL shall reject the application or terminate the assessment process or denial of accreditation.
- 37. If evidence is found of fraudulent behaviour or the CAB intentionally provides false information or conceals information, NABL shall initiate adverse action as per NABL 216.
- 38. The accredited CAB upon suspension, withdrawal of accreditation or debar from reapplying (however determined) shall forthwith discontinue claim of accreditation in any form in all advertising material and return the accreditation certificates to NABL, if applicable.
- 39. CAB shall inform its affected clients of the suspension, scope reduction, withdrawal of accreditation (and debar from reapplying, if applicable) and the associated consequences, without undue delay.
- 40. Accredited CAB can voluntarily withdraw accreditation by giving notice in writing to NABL (and by surrendering the accreditation certificates, applicable) after clearing the outstanding amount, if any.
- 41. The CAB shall inform NABL, if any of the proposed assessor(s) happens to be their consultant or associated with the CAB in any other capacity (personal or professional).

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- 42. NABL shall not be held responsible for any legal or financial liability arising out of activities of any of its accredited CAB involving in any accidental or consequential damages to personnel / equipment / products at any time.
- 43. CAB shall not offer inducement of any kind such as any gifts or any kind of payments in cash or any undue favour to the assessment team members. In case of any violation, NABL shall initiate adverse action as per NABL 216.
- 44. All information obtained by NABL and its personnel in NABL's direct dealing with the accredited CABs in all stages from application onwards, other than the information in public domain shall be treated as confidential. When NABL is required by law or authorized by contractual arrangements to release the confidential information, the CAB shall be notified unless prohibited by law.
- 45. CABs acknowledges and agrees to maintain strict confidentiality with regard to all sensitive information, records, data, and proprietary materials obtained or accessed during the accreditation process. CABs shall not disclose, share, or disseminate any confidential information obtained from NABL or any other CABs, clients, or stakeholders participating in the accreditation process. This includes, but is not limited to, information related to assessment methodologies, assessment outcomes, accreditation decisions, and any other sensitive or proprietary information.
- 46. If the CAB engages subcontractors, consultants, or third-party service providers to assist in the accreditation process, the CAB shall declare these to NABL and ensure that such entities/individuals also comply with the same level of confidentiality and other obligations as set forth herein.
- 47. The CAB shall implement appropriate measures to protect the confidentiality and security of any personal data or sensitive information received or processed during the accreditation process. The CAB acknowledges that any breach of the confidentiality obligations outlined in this clause may result in the termination of the accreditation process, and may also give rise to legal liabilities.
- 48. The confidentiality obligations outlined in this clause shall continue to apply even after the conclusion of the accreditation process, regardless of whether accreditation is granted or not, except as required by law.
- 49. Information about the conformity assessment body obtained from sources other than the conformity assessment body (e.g. complainant, regulators) shall be confidential between the conformity assessment body and the NABL. The provider (source) of this information is confidential to NABL and is not be shared with the conformity assessment body, unless agreed by the source.
- 50. The CAB shall indemnify, defend, and hold harmless NABL, its officers, directors, employees, agents, and representatives from any and all claims, demands, suits, or actions brought against them by any third party, arising from the CAB's accreditation application or accreditation status, including but not limited to claims related to errors, omissions, negligence, non-compliance, or any other alleged misconduct on the part of the CAB.
- 51. The CAB agrees that NABL shall not be liable for any damages, losses, or expenses incurred by the CAB due to the rejection or withdrawal of its accreditation application or accreditation status, regardless of the reasons for such rejection or withdrawal.

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- 52. NABL shall not be liable for any failure or delay in performing its obligations under the accreditation process due to force majeure events or circumstances beyond its reasonable control.
- 53. The CAB shall maintain adequate and appropriate insurance coverage to protect itself against any liabilities, claims, or damages that may arise during the accreditation process.
- 54. The CAB seeking accreditation hereby agrees to abide by all applicable rules, regulations, guidelines, and standards set forth by NABL and other relevant authorities throughout the accreditation process and the provision of conformity assessment services.
- 55. The CAB shall ensure strict compliance with the accreditation criteria, policies, procedures, and guidelines issued by NABL. The CAB shall implement any necessary corrective actions to address any non-conformities identified during assessments or audits.
- 56. After exhausting all remedies provided by NABL to resolve any issue, the CAB may approach courts at New Delhi and none other and shall be governed by the laws of India.
- 57. If the acts of the CAB is violative to the terms and conditions of NABL policy, rules, regulations or CAB is found indulged into some fraudulent and unethical activities or any such activities which may adversely affect to the integrity of NABL or is in violation of the accreditation terms, then the NABL shall be at liberty to take appropriate action against the CAB as per its policy, rules and regulations which may extend to the removal of CABs from the NABL website. In case a CAB has approached the court against the decision or action of NABL, the accreditation certificate (related to the legal entity), and if there are multiple CABs accredited by NABL at different locations belonging to the same legal entity, then each one of the accredited CABs shall be remain removed from the NABL website.

The existing activities of all CABs (linked to that legal entity which has approached court) shall be put on hold till the pendency or resolution of the matter and considering the gravity of the matter. CAB shall not submit any application during the pendency of the court proceeding and any such application if submitted shall not be entertained by NABL till the outcome of the court proceedings and the application if any submitted by CAB during such period shall stand rejected by NABL.

- 58. NABL reserves the right to take appropriate adverse action against the CAB in the event of non-compliance with the accreditation criteria, rules, regulations, or any other contractual obligations outlined in the accreditation agreement. NABL reserves the right to take legal action against the CAB for any breach of contract, negligence, or misconduct that results in harm to NABL or other stakeholders.
- 59. Repeat violation of terms & conditions and commitments given by CAB to NABL shall be dealt strictly as per NABL 216.
- 60. The existing CAB owner(s) shall be responsible for all the related compliances and violations (if any) for the previous and current CAB application(s) processed by NABL.

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 Terms and Conditions for Obtaining and Maintaining NABL Accreditation. Any violation of this terms and conditions (arrangement) shall result in adverse

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decision as per NABL 216 'Procedures for Dealing with Adverse Decisions' including legal action. NABL reserves the right to suspend or withdraw accreditation in case of established irregularities without show cause notice or opportunity for hearing under exceptional circumstances and for the reasons including but not limited to the non-compliance, misconduct, non- remedial action, non- payment of fee, legal and regulatory compliance, emergencies and public interest. NABL shall notify the CAB promptly of such decision and provide reasons for the suspension, or withdrawal, The CAB shall have the right to appeal the decision of suspension, or withdrawal, in accordance with the established appeal mechanism and procedures prescribed by NABL.

| 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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