

Quality and Accreditation Institute
Centre for Laboratory Accreditation



Change Adapt Improve

**TERMS AND CONDITIONS FOR MAINTAINING
QAI ACCREDITATION**

Issue No.: 05

Issue Date: February 2022

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CHANGE HISTORY

| Sl. No. | Doc No. | Current Issue No. | Revised Issue No. | Date of Issue | Reasons |
|---------|---------|-------------------|-------------------|-------------------------------------|---|
| 1. | CLA 002 | 01 | 02 | August 2019 (10 August 2019) | Certification included, font modified and more terms and conditions added. |
| 2 | CLA 002 | 02 | 03 | February 2020 (01 February 2020) | There is a change in policy of Assessment, Surveillance and Reassessment i.e. no onsite surveillance will be held therefore, in Clause no. 5, 9b & 9c surveillance term is removed. |
| 3 | CLA 002 | 03 | 04 | April 2021 (13 April 2021) | Laboratory replaced with Conformity Assessment Body (CAB). |
| 4 | CLA 002 | 04 | 05 | February 2022 (14 February 2022) | Certification removed |
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Terms & Conditions for Maintaining QAI Accreditation

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

Applicant/ Accredited Conformity Assessment Bodies (CAB) shall be required to fulfill the following terms and conditions. The Conformity Assessment Bodies would include Testing Laboratories, Medical Laboratories and Biobanks.

1. The Conformity Assessment Body (CAB) should provide its services and carry out its functions in such a way as to meet the requirements of Accreditation Standards.
2. The accreditation shall be granted for a defined period of time.
3. The CAB shall offer to QAI or its representative cooperation in:
 - a. Access to all service areas provided by the CAB.
 - b. Access to various patient care areas and other departments.
 - c. Access of all relevant information and documentation.
 - d. Access to those documents that provide insight into the level of independence and impartiality to the CAB from its related bodies, if applicable.
 - e. Access to all records and relevant personnel.
4. On grant of accreditation, the CAB shall:
 - a. claim accreditation in only those premises, services, for which it has been accredited (applicable for CAB) having more than one branch or part of large organisation
 - b. not state its accreditation in a manner as to be considered misleading or unauthorised and bring QAI to disrepute
 - c. not use QAI accreditation symbol or certificate for promotional or publicity purposes in any way that QAI may consider to be misleading
 - d. use accreditation only to indicate that it has met the relevant QAI standards and does not imply that a product or service is approved by QAI
 - e. make reference to accreditation in its documents, brochures or advertising only in compliance with the requirements of QAI.
5. The accredited CAB shall pay all the applicable dues such as application fees for renewal; annual accreditation fees; expenses towards travel, hotel and meals of assessment team for assessment, re-assessment, verification etc. as shall be determined by QAI from time to time.
6. The CAB shall inform QAI within 15 days of significant changes affecting the operation of the CAB relevant to accreditation, such as:
 - a. its legal/ commercial ownership or organisational status
 - b. senior management and key personnel
 - c. main policies
 - d. resources and premises
 - e. scope of accreditation and
 - f. the CAB shall continuously keep in touch with QAI to keep itself updated with the latest versions of QAI documents. However, QAI shall publish such information on its website.

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7. The accredited CAB shall respond promptly to the changes initiated by QAI in its accreditation criteria, policies and procedures. The CAB shall be given sufficient notice and time, as in the opinion of QAI is found reasonable, to carry out adjustments in its system. The CAB shall inform QAI when such adjustments have been completed.
8. QAI may occasionally give provisional extension of accreditation beyond the normal cycle of defined time period where:
 - a. Re-assessment has been completed but the decision is pending.
 - b. There is delay in conducting re-assessment for reasons beyond control of QAI.
 - c. Any other reason leading to delay in decision beyond control of QAI.
9. QAI may suspend or withdraw accreditation of an accredited CAB / stop processing application of an applicant CAB, as per QAI policy, on one or more of the following grounds:
 - a. an applicant CAB claiming to be QAI accredited organisation
 - b. during re-assessment, CAB does not comply with the accreditation requirements
 - c. non-payment of accreditation expenses like assessment or re-assessment charges and annual accreditation fees
 - d. not applied six months before the expiry of accreditation and QAI has not been able to take a decision for renewal of accreditation
 - e. non-cooperation with QAI
 - f. refusal to allow examination of relevant documents and records by QAI & its assessors
 - g. denial of access to QAI & its assessor to its services and patient care areas
 - h. wrong representation of scope of accreditation
 - i. misuse of QAI logo/ accreditation symbol or its use after expiry of accreditation
 - j. misleading reporting of facts
 - k. activity bringing disrepute to QAI
 - l. result of complaint analysis or any other information, which indicates that the CAB no longer complies with requirements of QAI.
10. 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.
11. The accredited CAB can relinquish accreditation by giving three months notice in writing to QAI.
12. The CAB is required to inform QAI Secretariat, if any of the proposed assessor(s) happens to be their consultant for accreditation activities or associated with the CAB in any other capacity, since QAI cannot appoint these consultants as assessors.
13. The CAB shall ensure that all the systems and processes are in place for patient safety. Further, the CAB shall be committed to maintain, continuously review and improve the performance of its services, against these standards.
14. Compliances to all applicable regulatory/ statutory/ legal requirements is the sole responsibility of the CAB and we undertake to comply with these at all times.

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15. Quality and Accreditation Institute Pvt. Ltd. (QAI) is not liable for damage the CAB undergoes if any by participating in the accreditation programme.
16. The CAB safeguards the QAI from all agreements with third parties which stem from the participation of the CAB in the accreditation programme and the decisions which the QAI takes in this context.
17. The assessment and judgment of QAI do not exclude incidents with regard to the quality of healthcare/ allied services. For any adverse events/ incidents occurring in CAB, QAI shall not bear any responsibility in whatsoever manner.
18. QAI is not liable for any damages in the CAB which might incur/ occur during the assessment process unless in the case of deliberate intent or gross negligence on the part of persons designated by QAI.
19. QAI is not liable for any damages the CAB might incur because of participating in the accreditation programme, or by any decision of QAI regarding the awarding or not awarding of accreditation or the temporary or indefinite suspension of accreditation status or the discontinuation on the side of QAI of the Terms and Conditions for Maintaining Accreditation.
20. QAI absolves itself of any legal or financial liability arising out of any act involving any accidental or consequential damages to personnel/ equipment at any time.
21. All disputes, if any, arising out of QAI decisions that remain unresolved through mechanism provided by QAI are subject to the exclusive jurisdiction of the Courts at New Delhi, India and none other.

By signing this document, it is implied that a CAB as an applicant and after accreditation agrees to comply at all times with all Terms and Conditions for Maintaining QAI Accreditation.

Name & Signature of Chief Executive or
his/her Authorised Representative - _____

Name of the CAB _____

Date & Place _____

Signature of QAI official & Date of receipt _____

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Quality and Accreditation Institute

Centre for Laboratory Accreditation
A-34, Sector 48, Noida-201304, India
Website: www.qai.org.in
Twitter: @QAI2017

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