

**Quality and Accreditation Institute**  
**Centre for Laboratory Accreditation**



*Change Adapt Improve*

**TERMS AND CONDITIONS FOR MAINTAINING  
QAI CLA ACCREDITATION**

Issue No.: 07

Issue Date: June 2022

|                                     |  |               |
|-------------------------------------|--|---------------|
| Quality and Accreditation Institute |  |               |
| Centre for Laboratory Accreditation |  |               |
| Doc. No.: QAI CLA 002               | Terms and Conditions for Maintaining QAI CLA Accreditation |               |
| Issue No.: 07                       | Issue Date: June 2022                                      | Page No.: 1/6 |

## CHANGE HISTORY

| Sl. No. | Doc No. | Current Issue No. | Revised Issue No. | Date of Issue                       | Reasons  |
|---------|---------|-------------------|-------------------|-------------------------------------|--|
| 1.      | CLA 002 | 01                | 02                | August 2019<br>(10 August 2019)     | Certification included, font modified and more terms and conditions added.   |
| 2       | CLA 002 | 02                | 03                | February 2020<br>(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<br>(13 April 2021)       | Laboratory replaced with Conformity Assessment Body (CAB).   |
| 4       | CLA 002 | 04                | 05                | February 2022<br>(14 February 2022) | Certification removed  |
| 5       | CLA 002 | 05                | 06                | June 2022<br>(04 June 2022)         | Following additions/modifications done for clarity and due to APAC Evaluation 3.f added, 9.b modified 11 & 12 added  |
| 6       | CLA 002 | 06                | 07                | June 2022<br>(28 June 2022)         | APAC evaluation cl. 2-information about 2-year accreditation cycle added<br>3.g & 3.h added<br>Internal review: new programme will be starting.<br>Calibration labs added to list of CAB, QAI changed to QAI CLA |
|         |         |                   |                   |                                     |  |

|  |  |   |                      |
|--|--|---|----------------------|
| <b>Quality and Accreditation Institute</b> |  |   |                      |
| <b>Centre for Laboratory Accreditation</b> |  |   |                      |
| <b>Doc. No.: QAI CLA 002</b>               |  | <b>Terms and Conditions for Maintaining QAI CLA Accreditation</b> |                      |
| <b>Issue No.: 07</b>                       |  | <b>Issue Date: June 2022</b>                                      | <b>Page No.: 2/7</b> |

## **Terms & Conditions for Maintaining QAI CLA Accreditation**

(To be submitted to QAI CLA 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, Calibration 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. Currently, accreditation is granted for a two-year accreditation cycle.
3. The CAB shall offer to QAI CLA or its representative cooperation by providing:
  - a. Access to all service areas/ locations 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.
  - f. Access for unannounced visit
  - g. Access to equipment including examination
  - h. Access for witnessing by peer evaluators and other personnel as required
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 CLA to disrepute
  - c. not use QAI CLA accreditation symbol or certificate for promotional or publicity purposes in any way that QAI CLA may consider to be misleading
  - d. use accreditation only to indicate that it has met the relevant QAI CLA standards and does not imply that a product or service is approved by QAI CLA
  - e. make reference to accreditation in its documents, brochures or advertising only in compliance with the requirements of QAI CLA.
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 CLA from time to time.
6. The CAB shall inform QAI CLA 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

|  |   |                      |
|--|---|----------------------|
| <b>Quality and Accreditation Institute</b> |   |                      |
| <b>Centre for Laboratory Accreditation</b> |   |                      |
| <b>Doc. No.: QAI CLA 002</b>               | <b>Terms and Conditions for Maintaining QAI CLA Accreditation</b> |                      |
| <b>Issue No.: 07</b>                       | <b>Issue Date: June 2022</b>                                      | <b>Page No.: 3/7</b> |

- d. resources and premises
  - e. scope of accreditation and
  - f. the CAB shall continuously keep in touch with QAI CLA to keep itself updated with the latest versions of QAI CLA documents. However, QAI CLA shall publish such information on its website.
7. The accredited CAB shall respond promptly to the changes initiated by QAI CLA in its accreditation criteria, policies and procedures. The CAB shall be given sufficient notice and time, as in the opinion of QAI CLA is found reasonable, to carry out adjustments in its system. The CAB shall inform QAI CLA when such adjustments have been completed.
  8. QAI CLA may occasionally give 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 CLA.
    - c. Any other reason leading to delay in decision beyond control of QAI CLA.
  9. QAI CLA may suspend or withdraw accreditation of an accredited CAB / stop processing application of an applicant CAB, as per QAI CLA policy, on one or more of the following grounds:
    - a. an applicant CAB claiming to be QAI CLA accredited
    - b. if it is found that CAB does not comply with the accreditation requirements and does not take satisfactory corrective actions for non-conformities raised during re-assessment
    - 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 CLA has not been able to take a decision for renewal of accreditation
    - e. non-cooperation with QAI CLA
    - f. refusal to allow examination of relevant documents and records by QAI CLA & its assessors
    - g. denial of access to QAI CLA & its assessor to its services and patient care areas
    - h. wrong representation of scope of accreditation
    - i. misuse of QAI CLA logo/ accreditation symbol or its use after expiry of accreditation
    - j. misleading reporting of facts
    - k. activity bringing disrepute to QAI CLA
    - l. result of complaint analysis or any other information, which indicates that the CAB no longer complies with requirements of QAI CLA.
  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 informs its affected clients of the suspension, reduction or withdrawal of its accreditation and the associated consequences without undue delay.
  12. The CAB shall assist in the investigation and resolution of any accreditation-related complaints about the conformity assessment body referred to it by the accreditation body.

|  |   |                      |
|--|---|----------------------|
| <b>Quality and Accreditation Institute</b> |   |                      |
| <b>Centre for Laboratory Accreditation</b> |   |                      |
| <b>Doc. No.: QAI CLA 002</b>               | <b>Terms and Conditions for Maintaining QAI CLA Accreditation</b> |                      |
| <b>Issue No.: 07</b>                       | <b>Issue Date: June 2022</b>                                      | <b>Page No.: 4/7</b> |

13. The accredited CAB can relinquish accreditation by giving three months notice in writing to QAI CLA.
14. The CAB is required to inform QAI CLA 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 CLA cannot appoint these consultants as assessors.
15. 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.
16. 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.
17. Quality and Accreditation Institute Pvt. Ltd., Centre for Laboratory Accreditation (QAI CLA) is not liable for damage the CAB undergoes if any by participating in the accreditation programme.
18. The CAB safeguards the QAI CLA from all agreements with third parties which stem from the participation of the CAB in the accreditation programme and the decisions which the QAI CLA takes in this context.
19. The assessment and judgment of QAI CLA do not exclude incidents with regard to the quality of healthcare/ allied services. For any adverse events/ incidents occurring in CAB, QAI CLA shall not bear any responsibility in whatsoever manner.
20. QAI CLA 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 CLA.
21. QAI CLA is not liable for any damages the CAB might incur because of participating in the accreditation programme, or by any decision of QAI CLA 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 CLA of the Terms and Conditions for Maintaining Accreditation.
22. QAI CLA 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.
23. All disputes, if any, arising out of QAI CLA decisions that remain unresolved through mechanism provided by QAI CLA are subject to the exclusive jurisdiction of the Courts at New Delhi, India and none other.

|  |  |   |                      |
|--|--|---|----------------------|
| <b>Quality and Accreditation Institute</b> |  |   |                      |
| <b>Centre for Laboratory Accreditation</b> |  |   |                      |
| <b>Doc. No.: QAI CLA 002</b>               |  | <b>Terms and Conditions for Maintaining QAI CLA Accreditation</b> |                      |
| <b>Issue No.: 07</b>                       |  | <b>Issue Date: June 2022</b>                                      | <b>Page No.: 5/7</b> |

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

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

\_\_\_\_\_

Name of the CAB \_\_\_\_\_

Date & Place \_\_\_\_\_

Signature of QAI CLA official & Date of receipt \_\_\_\_\_

|  |   |                      |
|--|---|----------------------|
| <b>Quality and Accreditation Institute</b> |   |                      |
| <b>Centre for Laboratory Accreditation</b> |   |                      |
| <b>Doc. No.: QAI CLA 002</b>               | <b>Terms and Conditions for Maintaining QAI CLA Accreditation</b> |                      |
| <b>Issue No.: 07</b>                       | <b>Issue Date: June 2022</b>                                      | <b>Page No.: 6/7</b> |

**Quality and Accreditation Institute**

Centre for Laboratory Accreditation  
A-34, Sector 48, Noida-201304, India  
Website: [www.qai.org.in](http://www.qai.org.in)  
Twitter: @QAI2017

|  |   |                      |
|--|---|----------------------|
| <b>Quality and Accreditation Institute</b> |   |                      |
| <b>Centre for Laboratory Accreditation</b> |   |                      |
| <b>Doc. No.: QAI CLA 002</b>               | <b>Terms and Conditions for Maintaining QAI CLA Accreditation</b> |                      |
| <b>Issue No.: 07</b>                       | <b>Issue Date: June 2022</b>                                      | <b>Page No.: 7/7</b> |