QAI CIA 002

Quality and Accreditation Institute

Centre for International Accreditation



TERMS AND CONDITIONS FOR MAINTAINING QAI CIA ACCREDITATION

Issue No.: 08 Issue Date: December 2023

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CHANGE HISTORY

| SI. No. | Doc No. | Current Issue No. | Revised Issue No. | Date of Issue | Reasons |
|------------|-------------|----------------------|----------------------|--|--|
| 1 | QAI CLA 002 | 01 | 02 | August 2019 (10 August 2019) | Certification included, font modified and more terms and conditions added. |
| 2 | QAI 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 | QAI CLA 002 | 03 | 04 | April 2021 (13 April 2021) | Laboratory replaced with Conformity Assessment Body (CAB). |
| 4 | QAI CLA 002 | 04 | 05 | February 2022 (14 February 2022) | Certification removed |
| 5 | QAI CLA 002 | 05 | 06 | June 2022 (04 June 2022) | Following additions/ modifications done for clarity and due to APAC Evaluation 3.f added, 9.b modified 11 & 12 added |
| 6 | QAI CLA 002 | 06 | 07 | June 2022 (28 June 2022) | APAC evaluation cl. 2-information about 2-year accreditation cycle added 3.g & 3.h added Internal review: new programme will be starting. Calibration labs added to list of CAB, QAI changed to QAI CLA |
| 7 | QAI CIA 002 | 07 | 08 | December 2023 (15 December 2023) | Centre for Laboratory Accreditation (CLA) changed to Centre for International Accreditation (CIA) Changed office address from A-34, Sector 48, Noida-201304 to 709, Wave Silver Tower, Sector 18, Noida-201301 Point 4. And 5 added Added QAI logo in header and borders and Changed office address |

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Terms & Conditions for Maintaining QAI CIA Accreditation

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

The terms and conditions mentioned in this document are considered as accreditation agreement between QAI 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 QAI Accreditation. Any violation of any one or more of these terms and conditions (accreditation agreement) shall result in adverse decision as per QAI 022 'Policies and Procedures for Dealing with Adverse and Other Decisions', including legal action.

Applicant/ Accredited CAB shall be required to fulfill the following terms and conditions. The Conformity Assessment Bodies would include Testing Laboratories, Calibration Laboratories, Medical Laboratories, Biobanks, Proficiency Testing Providers, Inspection Bodies and Reference Material Producers.

- 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 relevant Accreditation Standards (e.g., ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 or ISO/IEC 17020, whichever is applicable).
- **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 CIA or its representative cooperation by providing:
 - a. Access to all service areas/ locations related to CAB including site, mobile / temporary, subcontractor / external provider premises, wherever relevant and applicable.
 - b. Access of all relevant information and documentation.
 - c. Access to those documents that provide insight into the level of independence and impartiality to the CAB from its related bodies, if applicable.
 - d. Access to all records and relevant personnel.
 - e. Access for unannounced/ special visit
 - f. Access to equipment including examination
 - g. Access for witnessing by peer evaluators and other personnel as required
- **4.** At any point during the application process, if there is evidence of fraudulent behaviour and/ or if the CAB has provided false information or conceals information, QAI shall terminate the application/assessment process or deny accreditation. In such cases, QAI shall initiate adverse action as per QAI CIA 022.
- **5.** 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 CIA to disrepute
 - c. not use QAI CIA accreditation mark or certificate for promotional or publicity purposes in

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- any way that QAI CIA may consider to be misleading
- d. use accreditation only to indicate that it has met the relevant QAI CIA standards and does not imply that a product or service is approved by QAI CIA
- e. make reference to accreditation in its documents, brochures or advertising only in compliance with the requirements of QAI CIA.
- **6.** QAI shall only grant permission to use 'QAI Accredited CAB Combined ILAC MRA Mark' to QAI accredited CABs established in economies where the ILAC MRA Mark is registered, or where an application for registration has been lodged and registration is pending.
- 7. 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 CIA from time to time.
- **8.** The CAB shall inform QAI CIA 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 CIA to keep itself updated with the latest versions of QAI CIA documents. However, QAI CIA shall publish such information on its website.
- **9.** The accredited CAB shall respond promptly to the changes initiated by QAI CIA in its accreditation criteria, policies and procedures. The CAB shall be given sufficient notice and time, as in the opinion of QAI CIA is found reasonable, to carry out adjustments in its system. The CAB shall inform QAI CIA when such adjustments have been completed.
- **10.** QAI CIA 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 CIA.
 - c. Any other reason leading to delay in decision beyond control of QAI CIA.
- **11.** QAI CIA may suspend or withdraw accreditation of an accredited CAB / stop processing application of an applicant CAB, as per QAI CIA policy, on one or more of the following grounds:
 - a. an applicant CAB claiming to be QAI CIA 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 CIA has not been able to

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take a decision for renewal of accreditation

- e. non-cooperation with QAI CIA
- f. refusal to allow examination of relevant documents and records by QAI CIA & its assessors
- g. wrong representation of scope of accreditation
- h. misuse of QAI CIA logo/ accreditation mark or its use after expiry of accreditation
- i. misleading reporting of facts/ fraudulent activities
- j. activity bringing disrepute to QAI CIA
- k. result of complaint analysis or any other information, which indicates that the CAB no longer complies with requirements of QAI CIA.
- **12.** 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.
- **13.** CAB shall not offer any inducement or any other benefit to the assessment team under assessment which can be seen/ construed as a favour to the CAB in any manner.
- **14.** The accredited CAB informs its affected clients of the suspension, reduction or withdrawal of its accreditation and the associated consequences without undue delay.
- **15.** 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.
- **16.** QAI reserves the right to take legal action against the CAB for any breach of contract, negligence, or misconduct that results in harm to QAI or other stakeholders.
- **17.** The accredited CAB can relinquish accreditation by giving three months notice in writing to QAI CIA.
- **18.** The CAB is required to inform QAI CIA 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 CIA cannot appoint these consultants as assessors.
- **19.** The CAB shall ensure that all the systems and processes are in place for safety. Further, the CAB shall be committed to maintain, continuously review and improve the performance of its services, against these standards.
- **20.** Compliances to all applicable National/International regulatory/ statutory/ legal requirements is the sole responsibility of the CAB and the CAB undertake to comply with these at all times.
- **21.** Quality and Accreditation Institute Pvt. Ltd., Centre for International Accreditation (QAI CIA) is not liable for damage the CAB undergoes if any by participating in the accreditation programme.
- **22.** The CAB safeguards the QAI CIA from all agreements with third parties which stem from the participation of the CAB in the accreditation programme and the decisions which the QAI CIA takes in this context.

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- **23.** The assessment and judgment of QAI CIA do not exclude incidents with regard to the quality of healthcare/ allied services. For any adverse events/ incidents occurring in CAB, QAI CIA shall not bear any responsibility in whatsoever manner.
- **24.** QAI CIA 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 CIA.
- **25.** QAI CIA is not liable for any damages the CAB might incur because of participating in the accreditation programme, or by any decision of QAI CIA 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 CIA of the Terms and Conditions for Maintaining Accreditation.
- **26.** QAI CIA 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.
- **27.** All disputes, if any, arising out of QAI CIA decisions that remain unresolved through mechanism provided by QAI CIA 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 as an accredited CAB agrees to comply at all times with all Terms and Conditions for Maintaining QAI CIA Accreditation mentioned in this document. Any violation of this terms and conditions shall result in adverse decision as per QAI CIA 022 'Policy and Procedures for Dealing with Adverse and Other Decisions' including legal action.

| Name & Signature of Chief Executive or his/her Authorised Representative - | | | | |
|--|--|--|--|--|
| | | | | |
| Name of the CAB | | | | |
| Date & Place | | | | |
| Signature of QAI CIA official & Date of receipt | | | | |

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