

Quality and Accreditation Institute

Centre for Laboratory Accreditation



Change Adapt Improve

TERMS AND CONDITIONS FOR MAINTAINING QAI ACCREDITATION/ CERTIFICATION

Issue No.: 02

Issue Date: August 2019

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Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 002	Terms and Conditions for Maintaining QAI Accreditation/Certification	
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CHANGE HISTORY

Sl. No.	Doc No.	Current Issue No.	Revised Issue No.	Date of Issue	Reasons
1.	QAI CLA 002	01	02	10 August 2019	Certification included, font modified and more terms and conditions added.

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Terms & Conditions for Maintaining QAI Accreditation/ Certification

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

Applicant/ Accredited/ Certified Laboratory shall be required to fulfill the following terms and conditions:

1. The Laboratory should provide its services and carry out its functions in such a way as to meet the requirements of QAI Standards.
2. The accreditation/ certification shall be granted for a defined period of time.
3. The Laboratory shall offer to QAI or its representative cooperation in:
 - a. Access to all service areas provided by Laboratory.
 - 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 Laboratory from its related bodies, if applicable.
 - e. Access to all records and relevant personnel.
4. On grant of accreditation/ certification, the Laboratory shall:
 - a. claim accreditation/ certification in only those premises, services, for which it has been accredited/ certified (applicable for Laboratory having more than one branch or part of large organisation)
 - b. not state its accreditation/ certification in a manner as to be considered misleading or unauthorized and bring QAI to disrepute
 - c. not use QAI accreditation/ certification symbol or certificate for promotional or publicity purposes in any way that QAI may consider to be misleading
 - d. use accreditation/ certification 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/ certification in its documents, brochures or advertising only in compliance with the requirements of QAI.
5. The accredited/ certified Laboratory shall pay all the applicable dues such as application fees for renewal; annual accreditation/ certification fees; expenses towards travel, hotel and meals of assessment team for assessment, surveillance in case of accreditation, re-assessment, verification etc. as shall be determined by QAI from time to time.
6. The Laboratory shall inform QAI within 15 days of significant changes affecting the operation of the Laboratory relevant to accreditation/ certification, such as:
 - a. its legal/ commercial ownership or organizational status
 - b. senior management and key personnel
 - c. main policies

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- d. resources and premises
 - e. scope of accreditation/ certification and
 - f. the Laboratory 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.
7. The accredited/ certified Laboratory shall respond promptly to the changes initiated by QAI in its accreditation/ certification criteria, policies and procedures. The Laboratory shall be given sufficient notice and time, as in the opinion of QAI is found reasonable, to carry out adjustments in its system. The Laboratory shall inform QAI when such adjustments have been completed.
 8. QAI may occasionally give provisional extension of accreditation/ certification 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/ certification of an accredited/ certified Laboratory / stop processing application of an applicant Laboratory, as per QAI policy, on one or more of the following grounds:
 - a. an applicant Laboratory claiming to be QAI accredited/ certified organization
 - b. during a surveillance or re-assessment, Laboratory does not comply with the accreditation/ certification requirements
 - c. non-payment of accreditation/ certification expenses like assessment or surveillance or re-assessment charges and annual accreditation/ certification fees
 - d. not applied six months before the expiry of accreditation/ certification and QAI has not been able to take a decision for renewal of accreditation/ certification
 - 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/ certification
 - i. misuse of QAI logo/ accreditation/ certification symbol or its use after expiry of accreditation/ certification
 - j. misleading reporting of facts
 - k. activity bringing disrepute to QAI
 - l. result of complaint analysis or any other information, which indicates that the Laboratory no longer complies with requirements of QAI.
 10. The accredited/ certified Laboratory upon suspension or withdrawal of its accreditation/ certification (however determined) or expiry of validity of accreditation/ certification shall forthwith discontinue its use of all advertising matter that contain any reference to the accreditation/ certification status.
 11. The accredited/ certified Laboratory can relinquish accreditation/ certification by giving three months notice in writing to QAI.

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12. The Laboratory is required to inform QAI Secretariat, if any of the proposed assessor(s) happens to be their consultant for accreditation/ certification activities or associated with the Laboratory in any other capacity, since QAI cannot appoint these consultants as assessors.
13. The Laboratory shall ensure that all the systems and processes are in place for patient safety. Further, the Laboratory 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 Laboratory and we undertake to comply with these at all times.
15. Quality and Accreditation Institute Pvt. Ltd. (QAI) is not liable for damage the Laboratory undergoes if any by participating in the accreditation/ certification program.
16. The Laboratory safeguards the QAI from all agreements with third parties which stem from the participation of the Laboratory in the accreditation/ certification program 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 Laboratory, QAI shall not bear any responsibility in whatsoever manner.
18. QAI is not liable for any damages in the Laboratory 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 Laboratory might incur because of participating in the accreditation/ certification program, or by any decision of QAI regarding the awarding or not awarding of accreditation/ certification or the temporary or indefinite suspension of accreditation/ certification status or the discontinuation on the side of QAI of the Terms and Conditions for Maintaining Accreditation/ Certification.
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.

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

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

Name of the Laboratory _____

Date & Place _____

Signature of QAI official & Date of receipt _____

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