

Quality and Accreditation Institute

Centre for Laboratory Accreditation



Change Adapt Improve

Information Brochure for QAI Certification of Basic Composite Medical Laboratory (QCBCML)

Issue No. 02

Issue Date: March 2019

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Centre for Laboratory Accreditation		
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CHANGE HISTORY

Sl. No.	Doc. No.	Current Issue No.	Revised Issue No.	Date of Issue	Reasons
1	CLA 111	01 Nov. 2018	02	March 2019 (11.03.2019)	QAI Certification mark added
2					
3					
4					
5					

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1. QAI Certification for Basic Composite Medical Laboratories (QCBCML)

Quality and Patient Safety are the words we keep hearing every now and then. However, as a healthcare system, have we reached out to healthcare facilities those are providing services to patients but may not have an opportunity to check on how they are doing in terms of quality and patient safety. Moreover, they may not have even exposed to the concept of quality and patient safety. Many such healthcare facilities are medical laboratories both based in a hospital and standalone. Several hundred medical laboratories operating in India for several years were never exposed to this concept of quality and patient safety. It is high time to reach out to these laboratories to support them through education and capacity building to make them competent to just ensure reliability of test results they are producing.

To steer this agenda forward, QAI has initiated a certification program- QAI Certification for Basic Composite Medical Laboratories (QCBCML). This certification program is based on the (1) requirements prescribed in Gazette Notification G.S.R.468 (E) dated 18th May, 2018 by Ministry of Health and Family Welfare, Government of India related to Clinical Establishments (Central Government) Rules, 2012 and (2) certain quality improvement principles. This program is likely to serve several important underline purposes including encouragement to labs to meet minimum regulatory requirements, adopt quality & patient safety as core element of the business.

Labs would be encouraged to adopt ISO 15189 as they move forward in their quality journey.

2. Benefits of Certification

• Benefits for Users/ Patients

Users/ patients are the biggest beneficiary among all the stakeholders. Test results are crucial for the management of a patient. Any error in the test results may lead to wrong diagnosis and thus wrong treatment. Certification results in improving the quality of test results and patient safety.

• Benefits for Laboratories

Certification to a medical laboratory stimulates continuous improvement. It enables laboratories in demonstrating commitment to quality. It raises community confidence in the services provided by them.

• Benefits for Staff

The staff in a certified laboratory is satisfied lot as it provides for continuous learning, good working environment and leadership. It improves overall professional development of all the staff including medical and para medical staff.

3. About Quality and Accreditation Institute (QAI)

Quality and Accreditation Institute is a private limited company incorporated by Registrar of Companies under the Companies Act 1956. QAI was set up to create an ecosystem of education, training, quality improvement and accreditation. It is believed that this organisation would provide a platform to stakeholders including professionals and organisations, associated with quality in any way, to share their wisdom and knowledge in order to make its Vision realised. This will further provide tremendous opportunities to all concerned to learn and contribute in improving organisations

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engaged with QAI. Different activities would be initiated under different verticals in a manner that they remain independent of each other. QAI aims to operate globally.

Vision: Nurturing the largest global pool of organisations and people through quality and accreditation framework.

Mission: To conceive and deliver education, training, accreditation and related programs in partnership with stakeholders using an approach of co-design and co-creation.

Values:

Listener: Seek continuous feedback from stakeholders to address their concerns

Competitive: Look for viable options to benefit users of our services

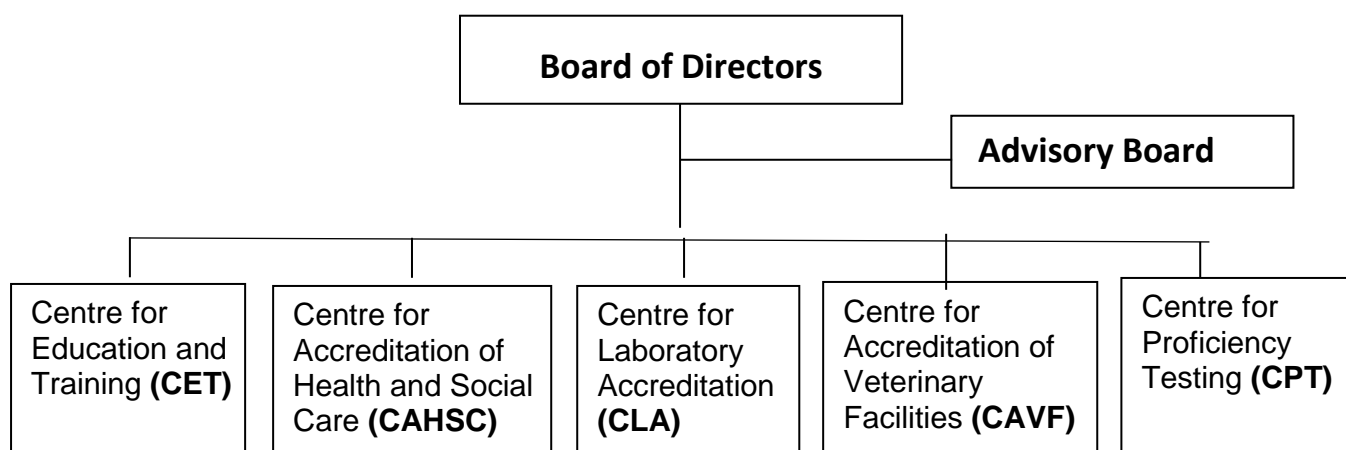
Transparency: Clearly defined policies made available in public domain

Innovation: Continuously evolve using co-design and co-creation

4. Organization Structure

The organization structure of QAI's Centre for Laboratory Accreditation has been designed to meet the requirements of an effective and efficient accreditation/certification system. The Centre is governed by a Board. The Board frames and approve policies and guidelines, and provide direction to QAI's CLA. CEO, QAI is the Member Secretary of the Board. CLA operates its accreditation/certification process through a structured framework of competent staff and pool of empanelled assessors covering all fields and disciplines as specified in the scope of accreditation. All assessors are personnel having considerable experience in related activities. They are trained by CLA as per the relevant accreditation criteria and subsequently empanelled as assessors/ lead assessors through defined contractual agreements.

Organisation Structure of QAI



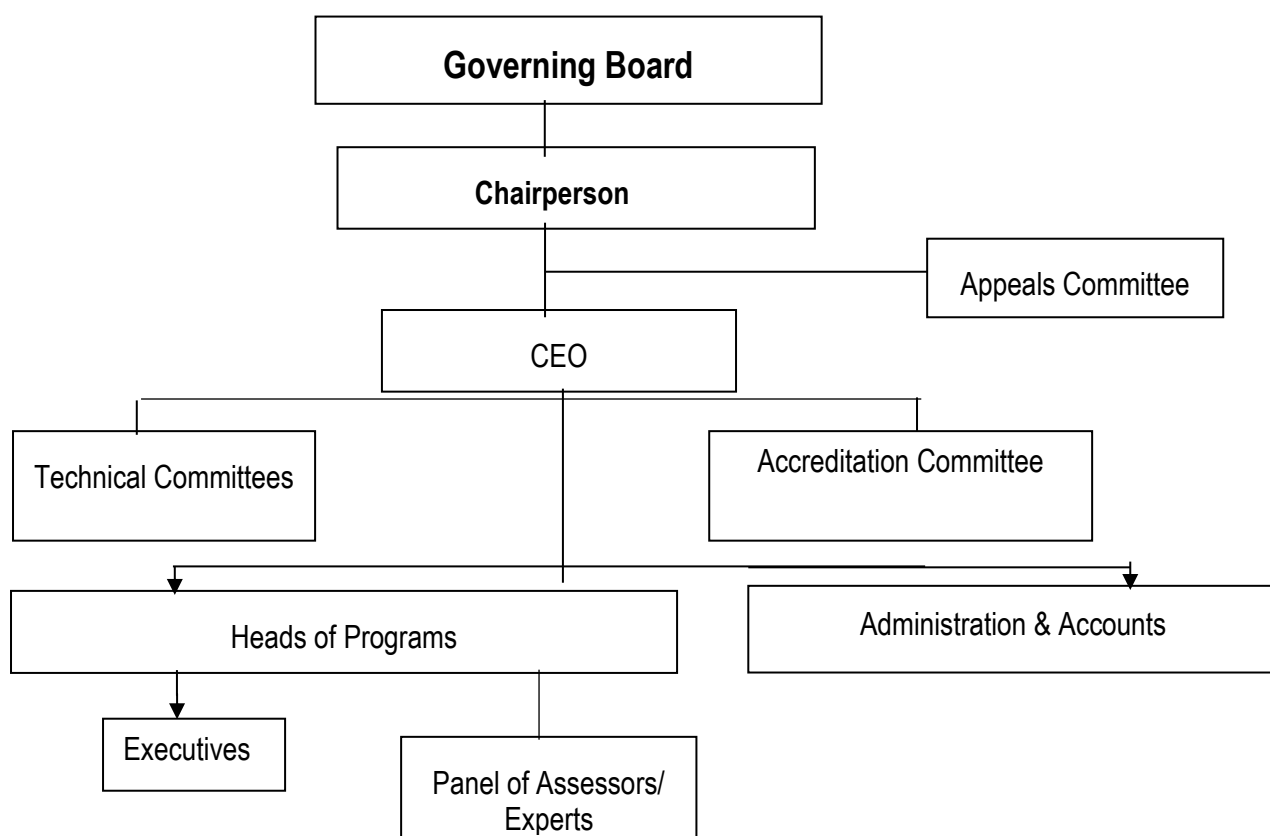
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5. Centre for Laboratory Accreditation (CLA)

It is set up to operate laboratory accreditation/certification for:

- medical as per ISO 15189
- testing & calibration laboratories as per ISO/IEC 17025
- **QAI Certification of Basic Composite Medical Laboratory**

Structure of CLA



The long-term goal is to attain signatory status of Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Program (ILAC) Mutual Recognition Arrangements (MRA). This information brochure is specifically prepared to give information about laboratory certification program- QCBCML.

6. Eligibility Conditions for Medical Laboratories

A laboratory performing the tests covered (given below) under Basic Composite Medical Laboratory (BCML) in Gazette notification G.S.R. 468 (E) dated 18th May, 2018 by MOHFW regarding Clinical Establishments (Central Government) Rules, 2012 is eligible to apply under this program of Certification of BCML. A laboratory performing tests outside BCML scope can also apply subject to availability of required authorised signatory as per applicable regulation. **(Refer document CLA- 113).**

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Biochemistry: Routine Biochemistry tests like Blood Sugar, Renal Function Tests, Liver Function Tests, Amylase, Lipase, Lipid profile, Cerebro-Spinal Fluid (CSF) and other biological fluids (glucose and protein), Oral Glucose Tolerance Test, Electrolytes, Calcium or Phosphate, HbA1c, any bio chemistry based rapid test.

Haematology: Haemogram (CBC, Hb, TLC, DLC, Platelet Count, RBC Count, HCT, MCV, MCH, MCHC, ESR), Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching.

Medical Microbiology & Immunology: Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio Cholerae, Stool for ova, cyst. All HIV positive rapid assays need to be confirmed from the next level diagnostic laboratory using confirmatory tests.

7. Value Proposition for Laboratories

- **Increased Reliability of Laboratory Results**
Through adherence to the BCML Standards, laboratory testing errors are reduced, processes are improved and thereby reliability of test results increase.
- **Earn a Certification Mark**
Laboratory will earn a certification mark on compliance with the standards.
- **Self-assessment**
Self-Assessment provides an opportunity to fix issues before they go out of control.
- **Competitive Advantage and Public Recognition**
Certification would increase competitive advantage and public recognition resulting into increased revenue.
- **Government / Regulator and Insurance Companies Can Rely on Certification**
Government/ Regulator can rely on certification for registration under Clinical Establishment Act and insurance companies can recognise for incentives.

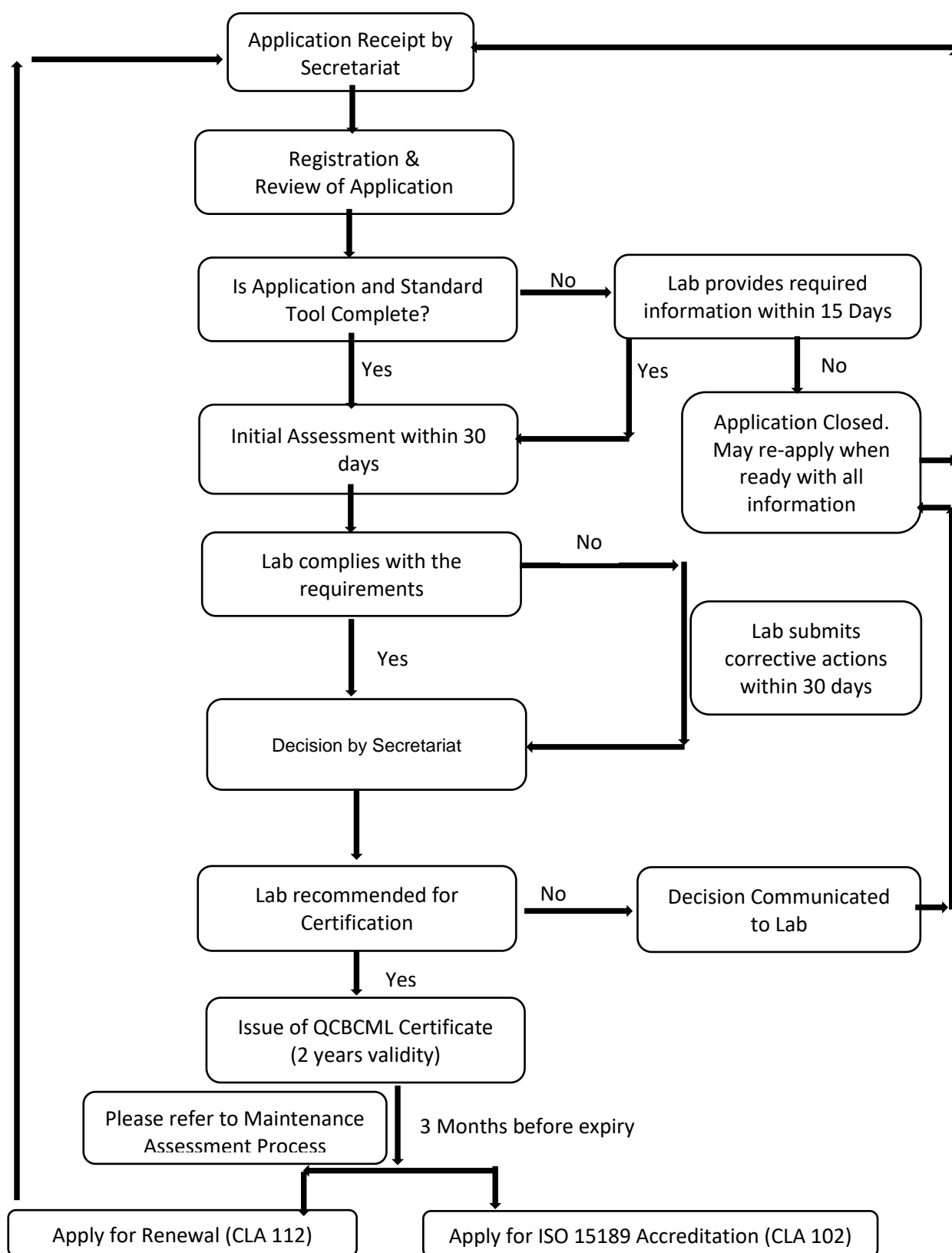
8. Application Process

Interested laboratory is required to submit following:

- a. application form (CLA 112)
- b. standard tool for QCBCML (CLA 113) duly filled-in column- Evaluation by Lab', and
- c. a non-refundable fee of Rs. 12000. This fee include application fee (Rs. 2000) and assessment charges (Rs. 10000).

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Initial Assessment/ Renewal Assessment Process



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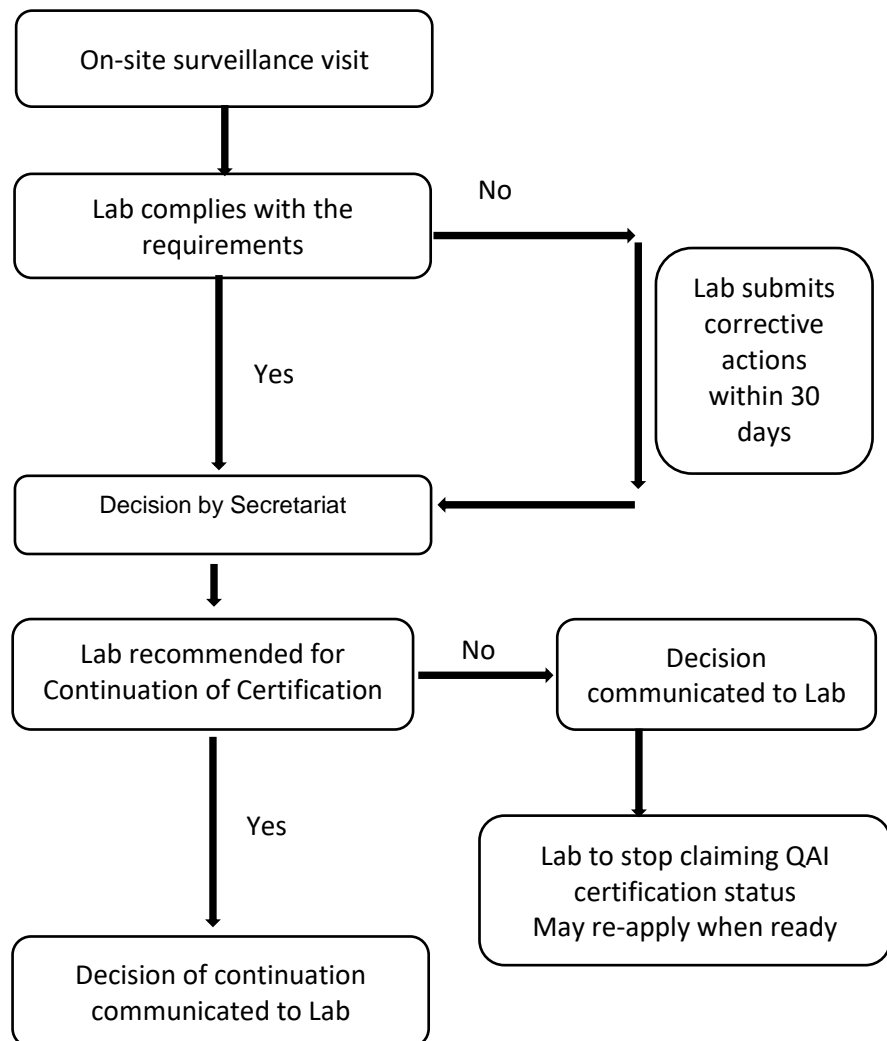
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9. Maintenance Assessment (Surprise Surveillance) Process

QAI may conduct a surprise on-site surveillance (maintenance assessment) at any time during 2 years of the certification cycle to ensure continued compliance of the standards.

Process of Surprise On-Site Surveillance



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10. Certification Mark

A certificate will be issued to the laboratory upon grant of certification. Certified lab will be provided following certification mark to be used on test reports, stationary and promotional materials as per policy on use of the certification mark.



11. Terms and Conditions for Applicant & Certified BCML

The laboratories that are applicant/ have achieved certificate under BCML shall be required to fulfill the following terms & conditions:

- 11.1** Lab agree to comply fully with the requirements of QAI Certification for Basic
- 11.2** Composite medical laboratory.
- 11.3** We agree to comply with certification procedures and pay all costs for any assessment carried out irrespective of the result.
- 11.4** We agree to co-operate with the assessment team appointed by QAI CLA for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of certification.
- 11.5** On grant of certification, the laboratory shall:
 - a. claim certification in only those premises, services, tests for which it has been certified
 - b. not state its certification in a manner as to be considered misleading or unauthorized and bring QAI to disrepute
 - c. not use QAI certification mark or certificate for promotional or publicity purposes in a way that QAI may consider to be misleading
 - d. use certification only to indicate that it has met the relevant standards and does not imply that a product or service is approved by QAI
 - e. make reference to certification in its documents, brochures or advertising only in compliance with the requirements of QAI.
- 11.6** QAI may suspend or withdraw certification of 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 certified
 - b. during a surveillance (surprise check) or re-assessment, laboratory does not comply with the certification requirements
 - c. non-payment of certification expenses like assessment or surveillance or re-assessment charges and certification fees
 - d. not applied three months before the expiry of certification and QAI has not been able to take a decision for renewal of certification

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- 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 premises under application/ certification
 - h. wrong representation of scope of certification
 - i. misuse of QAI logo/ certification mark or its use after expiry of 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.
- 11.7** We undertake to satisfy all national, regional and local regulatory requirements for operating the laboratory.
- 11.8** 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.
- 11.9** 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 and none other.

12. Procedure for Adverse Decisions

12.1 Closure of Application

- 12.1.1** When the lab's application is incomplete and it fails to complete the same within 15 days.
- 12.1.2** When the lab shows unwillingness to undergo initial assessment within 30 days from the date of completion of application.
- 12.1.3** When the lab voluntarily withdraws application for BCML.
- 12.1.4** When the lab relinquishes/withdraws by giving notice in writing to QAI.

Procedure for re-application

The lab can apply afresh with relevant application form and applicable fee.

12.2 Denial of QAI Certification to BCML

- 12.2.1** When the lab has not been recommended during the initial assessment
- 12.2.2** When the lab has not been recommended during the on-site surprise surveillance assessment.

Procedure for re-application

The lab can apply afresh with relevant application form and applicable fee.

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