

QAI CLA 101

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



*Change Adapt Improve*

**INFORMATION BROCHURE**  
**FOR**  
**MEDICAL LABORATORIES**

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## 1. **Laboratory Accreditation**

Accreditation is the third-party attestation related to a laboratory conveying the formal demonstration of its competence to carry out specific conformity assessment task. Laboratory is an organisation providing the following conformity services: testing including medical, calibration, inspection, proficiency testing, management system certification, personnel certification, and product certification.

Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence for specific tests/ measurements, based on third party assessment and following international standard. The general requirements for laboratories or other organisations, to be considered competent to carry out testing (other than medical) and calibration are specified in the International Standard ISO/IEC 17025 and for medical are specified in the International Standard ISO 15189. Accreditation is considered as the first step for facilitating mutual acceptance of test results and measurement data. Confidence in accreditation is obtained by a transparent system of control over the accredited laboratories and an assurance given by the accreditation body that the accredited laboratory fulfils the accreditation criteria. Accredited laboratories can objectively state conformance of product or service to specified requirements. It is important for the consumer, purchaser, regulator, government, and the public to be able to identify accredited laboratories which is generally through the mark of accreditation issued by an Accreditation Body.

## 2. **Benefits of Accreditation**

- Increased confidence in Testing/ Calibration Reports issued by the laboratory.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- Potential increase in business due to enhanced customer confidence and satisfaction.
- Accredited laboratories are publicised by the Accreditation Body by putting their name on its website.
- Users of accredited laboratories enjoy greater access for their products, in both domestic and international markets.
- Time and money are saved due to reduction or elimination of the need for retesting of product.
- Global recognition as it is based on International Standard ISO:15189.
- Potential of empanelment by government/ regulator/ insurance companies.

## 3. **About Quality & 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 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 programmes 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

## **QAI has set up following Centres of Excellence:**

- Centre for Education & Training (CET)
- Centre for Accreditation of Health & Social Care (CAHSC)
- Centre for Laboratory Accreditation (CLA)
- Centre for Accreditation of Veterinary Facilities (CAVF)

### **4. QAI's Centre for Laboratory Accreditation (CLA)**

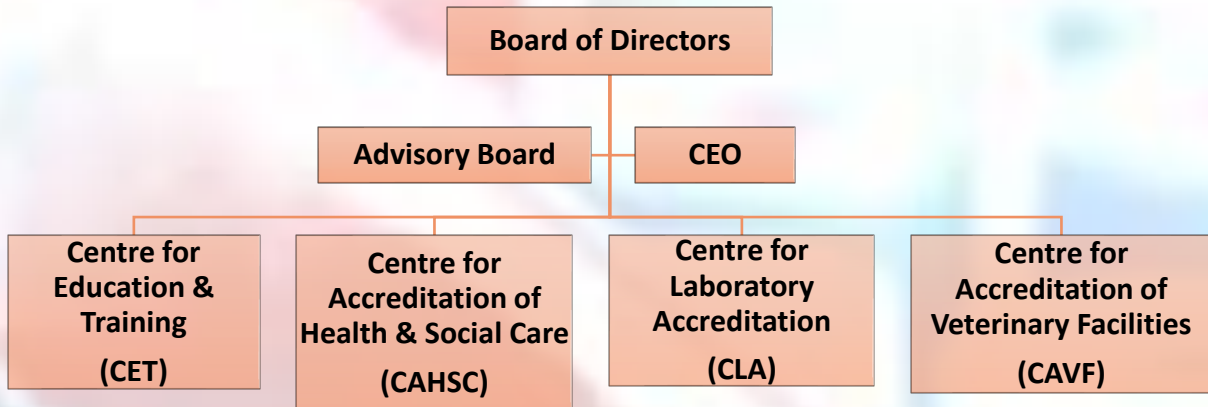
QAI's CLA has been established with the objective of providing Government, Industry Associations and Industry in general with a scheme of accreditation of laboratories including medical, testing and calibration laboratories. The laboratory accreditation services to testing and calibration laboratories are provided in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' and ISO 15189 'Medical laboratories -- Requirements for Quality and Competence'. The Scope of accreditation is listed in the application form as well under scope in this document. We offer accreditation services in a non-discriminatory manner. These services are accessible to all testing including medical and calibration laboratories in India and other countries regardless of the size of the applicant laboratory or its membership of any association or group. QAI-CLA will establish its accreditation system in accordance with ISO/IEC 17011 'Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies'. Our accreditation system also takes note of the requirements of Mutual Recognition Arrangements (MRAs). We shall make relevant documents for laboratories, assessors and stakeholders on the website. It is set up to operate laboratory accreditation for medical as per ISO 15189 and other testing & calibration laboratories as per ISO/IEC 17025. The long-term goal is to attain signatory status of Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Programme (ILAC) Mutual Recognition Arrangement (MRA).

### **5. Organisation Structure**

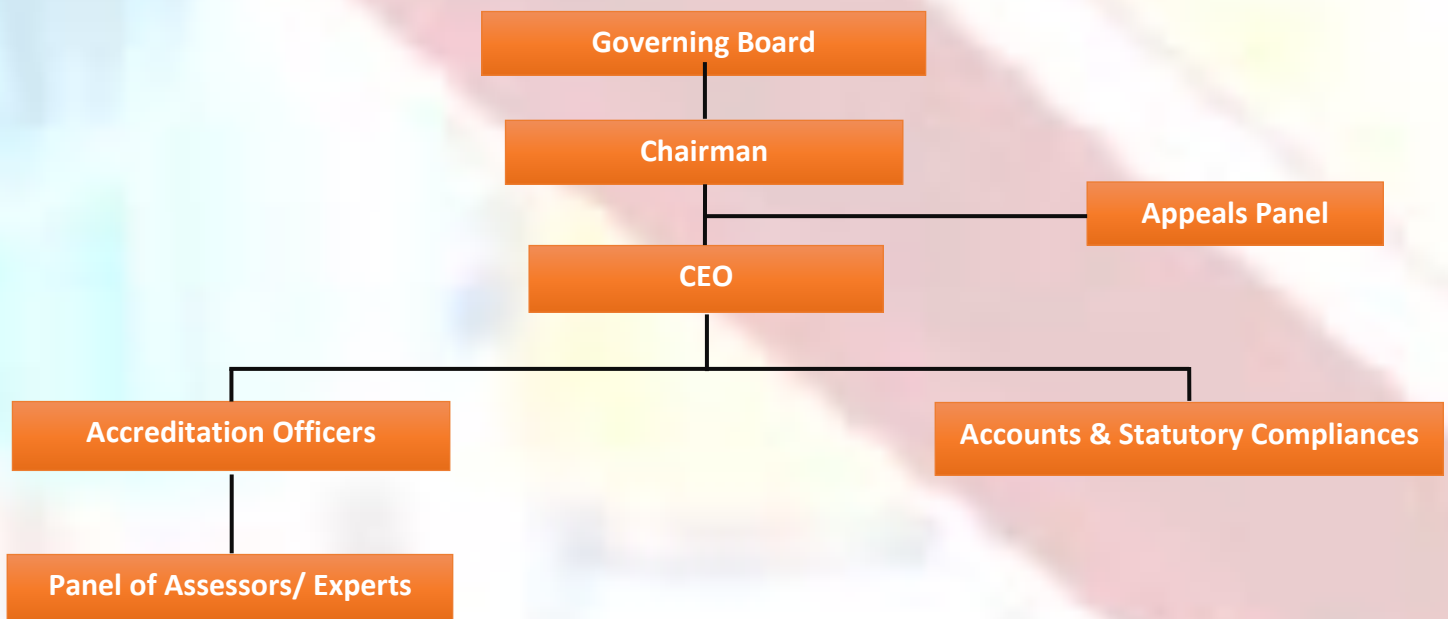
The organisation structure of QAI's Centre for Laboratory Accreditation has been designed to meet the requirements of an effective and efficient accreditation system. The Centre is governed by a Board. The Board frames and approve policies and guidelines, and provide direction to QAI's CLA. CEO is the Member Secretary of the Board.

CLA operates its accreditation process through a structured framework of competent staff and pool of empanelled Lead Assessors and Technical Assessors covering all fields and disciplines as specified in the scope of accreditation. All Lead Assessor and Technical Assessors are personnel having considerable experience in related activities. They are trained by CLA as per the relevant international accreditation criteria and subsequently empanelled as assessors/ lead assessors through defined contractual agreements. Membership of various committees

is drawn from reputed organisations, experts in the field, experienced assessors, academic institutions, important professional bodies, regulatory agencies/ bodies etc.



**Organogram of CLA**



## 6. International Linkages

QAI's Centre for Laboratory Accreditation is an associate member of APAC. In order to achieve the objectives of WTO-TBT i.e., the acceptance of test/ calibration data across the borders, CLA operates and is committed to update its accreditation system as per the requirements of international standard ISO/ IEC 17011.



## 7. Special Features of Laboratory Accreditation Programme:

- Comprehensive Assessment Management System to allow quick turnaround time for the accreditation process as each step is linked to a defined period.
- Endorsement of quality and competence of a laboratory as per the intent of the standard.
- No pre-assessment to reduce cost and time.
- Introducing a new concept of self-assessment and document review replacing pre-assessment and providing opportunity to labs for a thorough review of their documentation and implementation of requirements of ISO 15189.
- Our process ensures continuous support to our clients in handling their queries as each lab is unique in itself.
- We facilitate quality improvement journey on an ongoing basis.
- Rigorous Assessor Management System including a transparent monitoring and evaluation mechanism.
- Open to hear the voice of all keeping 'Client First'.
- Harmonising local, national, regional and global framework.
- Blend of global strategy, experience and leadership.
- Labs in SAARC nations to enjoy same fee structure as for labs in India.
- Consolidated fee structure reducing number of transactions and cost effective compared to other accreditation bodies.
- Compliance to ISO/IEC 17011.
- Economic yet global model.

## 8. Scope of Accreditation

Accreditation is currently given in the following disciplines.

### Medical Laboratory

Clinical Biochemistry	Point-of-Care Testing (POCT) (ISO 22870)
Clinical Pathology	Cytopathology
Haematology & Immunohematology	Genetics including Molecular Diagnostics
Histopathology	Nuclear Medicine ( <i>in-vitro</i> tests only)
Microbiology and Serology	

## 9. Medical Laboratory Accreditation Programme

### 9.1 Preparing for Accreditation

Management of the laboratory shall first decide about getting accreditation from QAI. It is important for the laboratory to make a definite plan of action for obtaining accreditation and nominate a person to co-ordinate all activities related to seeking accreditation. An official nominated should be familiar with existing laboratory quality management system.

Laboratory must procure a copy of the relevant standard (ISO 15189 or ISO/IEC 17025). The laboratory looking for accreditation shall understand the QAI assessment process. The laboratory shall ensure that all the requirements of the standard are implemented. For preparing the quality manual or verifying its contents, the laboratory may get its personnel trained in a training programmes on quality management system organised by various

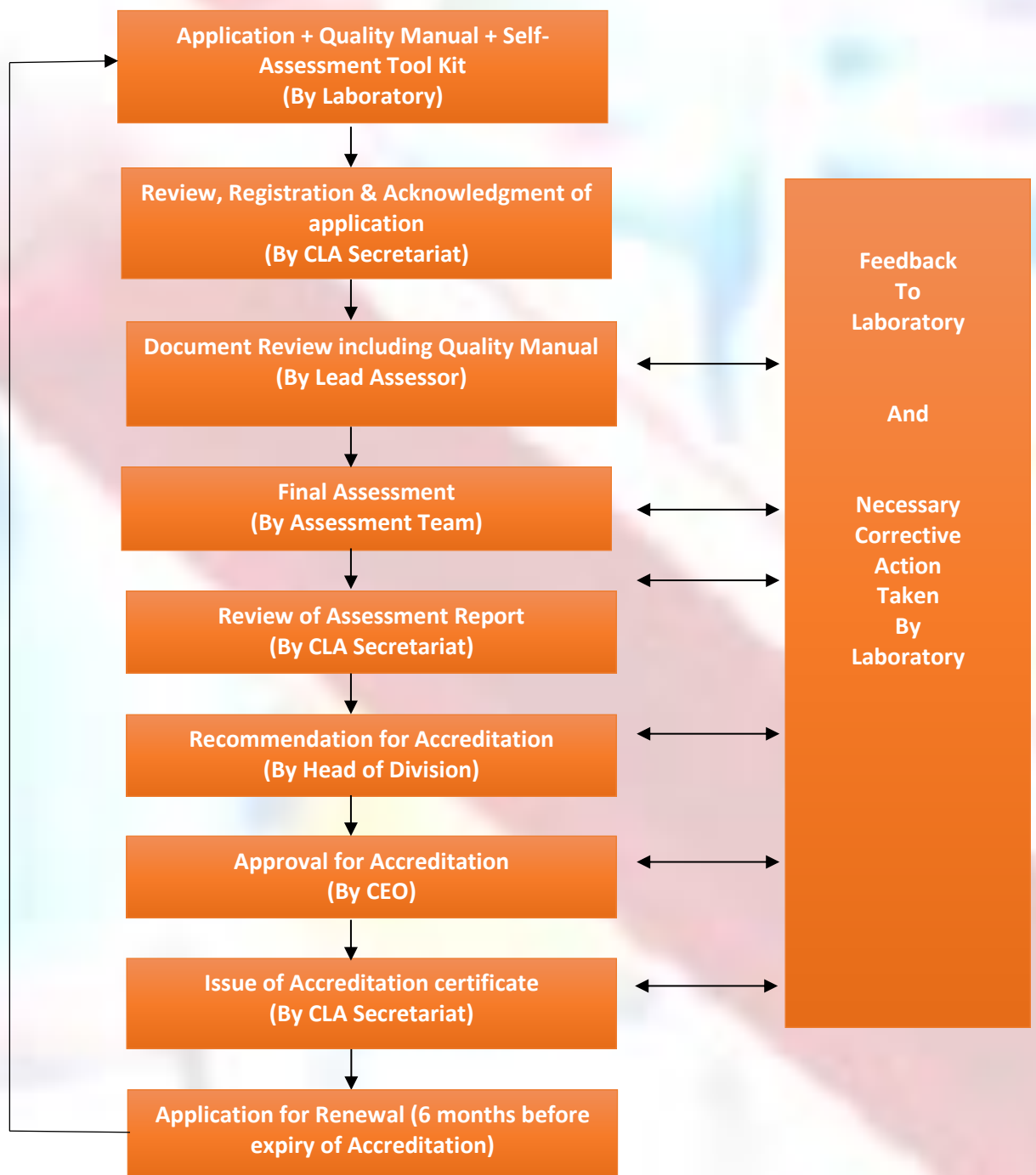
institutes including QAI's Centre for Education and Training. The proposed Quality manager shall have undergone a formal training on management system and internal audit based on relevant standard.

## **9.2 Eligibility for Accreditation**

The applicant laboratory must comply with all clauses of ISO 15189 whichever is applicable. The applicant laboratory must have participated satisfactorily in the proficiency testing programme, wherever applicable, conducted by QAI's CPT/ APAC or any other national or international accredited/ recognised PT provider. If no suitable PT programme is available the laboratory can initiate an inter-laboratory comparison with adequate number of accredited laboratories or engage into other types of internal quality control checks. The minimum stipulated participation for laboratories is one parameter/ type of test/ calibration per discipline, prior to grant of accreditation and covers its scope in phase manner. The applicant laboratory must have conducted at least one internal audit and a management review before the submission of application.

## 10. Accreditation Process

Conceptualised an accreditation process which is simple and efficient as shown below:





## 10.1 Application for Accreditation

Applicant laboratory is requested to submit the following:

- Soft copy of completed application form (available on website)
- Soft copy of Self-assessment tool kit along with referenced documents
- Soft copy of Quality Manual
- Prescribed application fees
- Soft copy of signed QAI CLA 002 'Terms and Conditions for Obtaining and Maintaining Accreditation/ Certification'

Laboratory first carry out Self-assessment tool kit which is based on the requirements of the accreditation standards (ISO 15189). It gives an opportunity to the laboratory to examine all its documentation and their implementation. It will also give a comprehensive view of its documentation to the Lead Assessor.

## 10.2 Review, Registration and Acknowledgement of Application

CLA Secretariat on receipt of application form, self-assessment tool kit, referenced documents, quality manual and the fees review the application for its completeness, and a unique ID number is allocated which is used for correspondence with the laboratory. Secretariat may ask for additional information/ clarification(s) at this stage, if found necessary.

## 10.3 Appointment of Lead Assessor for document review and adequacy of Quality manual

Secretariat appoints a Lead assessor from the list of empanelled assessors. The lead assessor carries out document review by going through the self-assessment tool kit and quality manual in accordance with the relevant standard and submits the report to Secretariat. The lead assessor gives a report to CLA regarding the adequacy of the documentation including quality manual, indicating inadequacies (if any). The report is sent to the laboratory for taking action to amend the manual and also implements the management system accordingly. In case there are no inadequacies in the documentation or after satisfactory corrective action by the laboratory, final on-site assessment visit is organised.

## 10.4 Final on-site/ remote/ hybrid Assessment

CLA constitutes an assessment team. The team includes the lead assessor (generally same who is already appointed for carrying out document review), the technical assessor(s)/ expert(s) in order to cover various fields within the scope of accreditation sought. CLA may also nominate an observer which is either an assessor-in-training or a Secretariat staff. CLA seeks laboratory's acceptance for the proposed assessment team and dates for assessment. The laboratory can refuse any member of the proposed assessment team by giving specific reason(s) for their non-acceptance. Once the team and dates are finalised, lead assessor takes over to initiate the further process. **The assessment team keeps the secretariat in loop for any communication with the laboratory.** During on-site visit, the assessment team reviews the documented management system and verifies its compliance with the requirements of ISO 15189 whichever is applicable and other relevant policies. The documented Management system, SOPs, work instructions, test methods and technical competence etc. are assessed for their implementation. The assessment report contains the evaluation of technical resources, all relevant material examined, test witnessed including those of replicate testing/ measurement. The nonconformities, if identified are reported in the assessment report. It also provides a recommendation towards grant of accreditation or otherwise. The report is endorsed by the authorised signatory of the laboratory. The report prepared by the assessment team is sent to CLA Secretariat. A copy of summary of assessment report and

copies of non-conformities, if any, are provided to the laboratory at the end of the assessment visit.

#### **10.5 Review of Assessment Report**

The assessment report is examined by the Secretariat and follow up action as required is initiated. Laboratory has to take necessary corrective action on non - conformities/ concerns and submit a satisfactory report to the Secretariat within 30 days. Which means that submission of corrective actions and acceptance by the assessment team should be completed within 30 days.

#### **10.6 Decision Making**

After satisfactory corrective action submitted by the laboratory and accepted by the assessment team, the assessment report is submitted to the Head of Division which examines the report and comments of the assessment team and may seek clarification from the Lead Assessor/ Assessor/ Laboratory concerned. In case requirements are in order, the Head of Division makes appropriate recommendations regarding accreditation to the CEO. All decisions taken by CLA regarding grant of accreditation are open to appeal by the laboratory as per laid down appeal process.

#### **10.7 Issue of Accreditation Certificate**

When the recommendation of the Head of Division results in the grant of accreditation, QAI-CLA issues an accreditation certificate which has a unique number, discipline, date of validity along with the scope of accreditation.

### **Accreditation Mark**

Accredited Laboratory is authorised to use following accreditation mark subject to requirements specified in QAI CLA-Policy for use of QAI Accreditation/ Certification mark.



**ISO 15189:2012**

**Certificate No.**

**Example: QAI/CLA/ML/2020/0000**

#### **10.8 Maintaining Accreditation**

##### **Conformance to applicable standards and other requirements**

The accredited laboratory at all times shall conform to the requirements of ISO 15189 as well as any other laid down requirements.

##### **Terms and Conditions**

The accredited laboratory is required to comply at all times with the terms and conditions given in CLA 002 'Terms & Conditions for Obtaining and Maintaining Accreditation/ Certification'. The laboratory is required to submit a signed soft copy of the same before issue of the accreditation certificate.

### **Modifications to the Accreditation Criteria**

If the accreditation criteria are modified by ISO/ ILAC/ APAC/ QAI-CLA/ Regulator, the laboratory is informed of this giving an appropriate transition period to align its operations in accordance with the modified criteria.

### **Adverse decision against the laboratories**

If the laboratory at any point of time does not conform to the applicable standards and/ or does not maintain the terms and conditions; or is not able to align itself to the modified criteria, CLA may take adverse decision against the laboratory like abeyance, scope reduction, denial of accreditation, suspension or forced withdrawal as per laid down policy.

### **Ongoing Monitoring**

Accredited laboratory is required to submit following information/documents/ records every year in the middle of the accreditation cycle. This is to ensure that the accredited laboratory is continuously complying with the requirements of the applicable standard (ISO 15189:2012) and any other requirements stipulated from time to time.

#### **A. Internal Audit**

- A.1 Internal audit plan
- A.2 Date of last internal audit
- A.3 Summary of findings of last internal audit

#### **B. Management Review**

- B.1 Management review plan
- B.2 Date of last management review
- B.3 Minutes of the last review

#### **C. Proficiency Testing/ External Quality Assessment Schemes/ Inter-laboratory comparisons (ILC)/ Any other method (e.g. use of CRMs)**

- C.1 Proficiency testing plan to cover the accredited scope in a period of four years
- C.2 Details of participation in last one year
- C.3 Details of action taken for any unsatisfactory results

#### **D. Major Changes, if any**

Any major changes in last one year (e.g. change in legal status, change in management and senior staff, change in testing scope etc.)

#### **E. Declaration by the Management (on the letter head)**

A statement "This is to declare that that the laboratory has been complying to the requirements of ISO 15189:2012 and any other requirements prescribed by the QAI CLA since last on-site assessment"

## **10.9 Reassessment**

QAI CLA accreditation cycle will be of two years. There will be an on-site/ remote/ hybrid reassessment conducted before the expiry of accreditation within 24 months from the date of accreditation. An accredited laboratory has to apply six months before the expiry of accreditation in order to complete all formalities for renewal of accreditation before the expiry of the current accreditation cycle so that continuity of the accreditation is maintained.

***This is in full compliance with the Clause 7.9.3 of ISO/IEC 17011:2017 which states "A sample of the scope of accreditation shall be assessed at least every two years. The time between consecutive on-site/ remote/ hybrid assessments shall not exceed two years."***

The renewal application is submitted in the prescribed form (QAI CLA 102). The laboratory will have an opportunity of requesting for an extension to the scope of accreditation, which should explicitly be mentioned in the application form. Rest of the process is same as for initial on-

site/ remote/ hybrid assessment except there will be no adequacy of quality manual. However, there will be adequacy check if there is a change in accreditation standard.

## **11. Complaints and Appeals**

### **Complaints**

QAI-CLA is open to receiving complaints for any of the activities performed by its officials, assessors and the accredited laboratories. The details are provided in 'Policy and Procedure for Dealing with Complaints and Appeals'.

### **Appeals**

QAI-CLA is open to appeals from the applicant/ accredited laboratories against its decisions. The decisions against which appeals are entertained relate to adverse decisions like denial of accreditation, reduction of scope of accreditation or abeyance/ suspension/ forced withdrawal of accreditation. The details are provided in a separate document 'Policy and Procedure for Dealing with Complaints and Appeals'.

## **12. Rights and Obligations of Laboratories**

### **Rights of Laboratories**

Laboratories are entitled to receive information related to laboratory accreditation. They can access our website [www.qai.org.in](http://www.qai.org.in) which gives information necessary for accreditation. QAI-CLA is obliged to make available information on scope of accreditation and validity dates for its accreditation certificate(s). The laboratory has the right to object to appointment of specific member(s) of assessment team by giving valid reasons. QAI-CLA accredited laboratory has the right to use 'QAI Accreditation Mark' on the test/ calibration reports issued by it as long as the test/ calibration is included in its scope of accreditation as per laid down policy. Detailed requirements governing use of 'QAI Accreditation Mark' have been stated in a separate document.

### **Obligations of the Laboratories**

An accredited laboratory is obliged to fulfil requirements of relevant standard and any other requirements set by QAI-CLA at all times. The laboratory is expected to provide access to all premises where key activities are performed and allow access to all relevant information, documents and records necessary to assess compliance to the relevant requirements. An accredited laboratory can claim accreditation only for the scope for which it has been granted accreditation and not claim accreditation in a manner which can bring disrepute to QAI or misrepresent the facts. The laboratory is required to notify QAI of any change that may affect accreditation status, within 15 days. The laboratory is required to pay necessary fees as determined by QAI from time to time.

## **13. Rights and Responsibilities of QAI-CLA**

### **Rights**

- QAI-CLA requires that all laboratories will conform to ISO 15189 and any other requirement specified by QAI-CLA from time to time to maintain accreditation.
- QAI-CLA requires that all accredited labs abide by 'Terms and Conditions for Obtaining and Maintaining Accreditation/ Certification'.
- QAI-CLA has the right to:

- ❖ effect changes in standards on which laboratory accreditation is based in accordance with international norms
- ❖ decide on policies related to accreditation in consultation with stakeholders
- ❖ appoint assessment teams in consultation with lab and the assessors
- ❖ take appropriate action including adverse decisions against a lab giving valid reasons for the same

#### **Duties**

- QAI-CLA is obliged to make available relevant information to its applicant and accredited labs. This information is provided on our website [www.qai.org.in](http://www.qai.org.in).
- QAI-CLA will communicate changes to the requirements of accreditation such as ISO 15189 through website.

## **14. Finance and Fee Structure**

### **Finance**

QAI derives its funds from the revenue generated through accreditation and training activities.

### **Fee Structure**

A uniform fee structure is maintained for all laboratories and the charges are maintained at a reasonable level so that laboratories are not denied participation in the accreditation process because of unreasonable financial conditions. The fee structure is kept simple and economical to facilitate maximum number of participations, less invoices and bank transactions. The information about the fee structure for various field(s)/ discipline(s) is given below.

### Fee Structure for Accreditation of Medical Laboratories within India

Type of laboratories	No. of patients/ day/ locations	Application fee (non-refundable, to be paid along with the application)	Accreditation Fee (per year from the date of accreditation)
<b>Very Small Laboratories</b>	Below 30 patients/day/ location	Rs. 20,000/-	Rs. 30,000/-
<b>Small Laboratories</b>	31-100 patients/day/ location	Rs. 25,000/-	Rs. 35,000/-
<b>Medium</b>	101 – 400 patients/ day/ location	Rs. 40,000/-	Rs. 55,000/-
<b>Large Laboratories</b>	401 – 1000 patients/ day/ location	Rs. 100,000/-	Rs. 125,000/-
<b>Very Large Laboratories / Laboratories operating from multiple locations (more than one location in the same city)</b>	Above 1000 patients/ day/ location or Laboratories operating from multiple locations (more than one location in the same city)	Rs. 2,00,000/-	Rs. 2,20,000/-
<b>Charges for Collection Centres attached to the laboratory</b>			
<b>Number of Collection Centres</b>	up to 10	Rs. 3,000/-	Rs. 3,000/-
	>10 – 50	Rs. 6,500/-	Rs. 6,500/-
	> 50 – 100	Rs. 13, 000/-	Rs. 13, 000/-
	More than 100	Rs. 25,500/-	Rs. 25,500/-

In addition to the above-mentioned fee, GST @18.0 % or as applicable from time to time to be paid.

**Fee Structure for Accreditation of Medical Laboratories Outside India operating within SAARC countries (Afghanistan, Bangladesh, Bhutan, Nepal, the Maldives, Pakistan & Sri Lanka)**

Type of Laboratory	No. of patients/ day/ locations	Application fee (non-refundable, to be paid along with the application)	Accreditation Fee (per year from the date of accreditation)
<b>Very Small Laboratories</b>	Below 30 patients/day/ location	\$350	\$500
<b>Small Laboratories</b>	31-100 patients/day/ location	\$400	\$550
<b>Medium</b>	101 – 400 patients/ day/ location	\$650	\$900
<b>Large Laboratories</b>	401 – 1000 patients/ day/ location	\$1600	\$2000
<b>Very Large Laboratories / Laboratories operating from multiple locations (more than one location in the same city)</b>	Above 1000 patients/ day/location or Laboratories operating from multiple locations (more than one location in the same city)	\$3200	\$3500
<b>Charges for Collection Centres attached to the laboratory</b>			
<b>Number of Collection Centres</b>	up to 10	\$75	\$75
	>10 – 50	\$150	\$150
	> 50 – 100	\$250	\$250
	More than 100	\$400	\$400

In addition to the above-mentioned fee, GST @18.0 % or as applicable from time to time to be paid.

**Assessment Charges:** In addition to the above fee, laboratory shall bear the cost of following (In case of On-site/ hybrid Assessment):

- a. Travel of the assessment team
- b. Accommodation and meals

**Guidelines for Travel and Lodging:**

- a. Travel to be made by Air in economy class (Apex fare) or by train in 2<sup>nd</sup> AC Class or by AC Bus.
- b. The laboratory will provide the tickets for travel as per above guidelines. If the journey is made by own car, the re-imburement will be as per company's rules or restricted to 2<sup>nd</sup> AC Class fare by train.
- c. The laboratory shall also make arrangements for boarding & lodging for the Assessment team. A single occupancy AC accommodation may be provided for each Assessor/ Observer in a reasonably good hotel/ guesthouse and arrangement for local transportation from temporary residence to the laboratory site and airport/ railway station/ bus stand.

**Fee Payment:**

All payments through Demand Draft/ Check/ Bank Transfer shall be made in favour of 'Quality and Accreditation Institute Pvt. Ltd.' payable at Noida/ New Delhi.

**Bank Transfer details are:**

Beneficiary name: Quality and Accreditation Institute Pvt. Ltd.

Bank Account number: 003105031612

Bank Details: ICICI Bank Limited, K-1, Senior Mall, Sector 18, Noida-201301, India

Bank IFSC Code: ICIC0000031

Bank Swift Code: ICICINBBNRI

PAN No.: AADCI3230L

GSTIN: 09AADCI3230L1ZK

**Note: Any bank charges for transfer of fee is to be paid by the Laboratory.**

**15. QAI-CLA Publications**

All relevant publications (policy/ procedure/ document) are available on our website [www.qai.org.in](http://www.qai.org.in).



# Quality and Accreditation Institute

Centre for Laboratory Accreditation

Email: [info@qai.org.in](mailto:info@qai.org.in) Website: [www.qai.org.in](http://www.qai.org.in)

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