

Quality and Accreditation Institute

Centre for Laboratory Accreditation



Change Adapt Improve

INFORMATION BROCHURE MEDICAL LABORATORIES

Issue No.: 03

Issue Date: May 2019

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CHANGE HISTORY

| Sl. No. | Doc No. | Current Issue No. | Revised Issue No. | Date of Issue | Reasons |
|---------|---------|-------------------|-------------------|-----------------------------|---|
| 1. | CLA-101 | 01 | 02 | August 2018 (27.08.2018) | Font changed |
| 2. | CLA-101 | 02 | 03 | June 2019 (17.07.2019) | APLAC changed to APAC, Fee structure of outside India added |
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Quality and Accreditation Institute
Centre for Laboratory Accreditation

Doc. No.: QAI CLA 101

Information Brochure for Medical Laboratories

Issue No.: 01

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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

Accredited laboratories with international criteria have following advantages:

- 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 is saved due to reduction or elimination of the need for retesting of products.

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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 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

QAI has set up following Centres of Excellence:

- 3.1 Centre for Education & Training (CET)
- 3.2 Centre for Accreditation of Health & Social Care (CAHSC)
- 3.3 Centre for Laboratory Accreditation (CLA)
- 3.4 Centre for Accreditation of Veterinary Facilities (CAVF)
- 3.5 Centre for Proficiency Testing (CPT)

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4. QAI' 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 Program (ILAC) Mutual Recognition Arrangement (MRA)

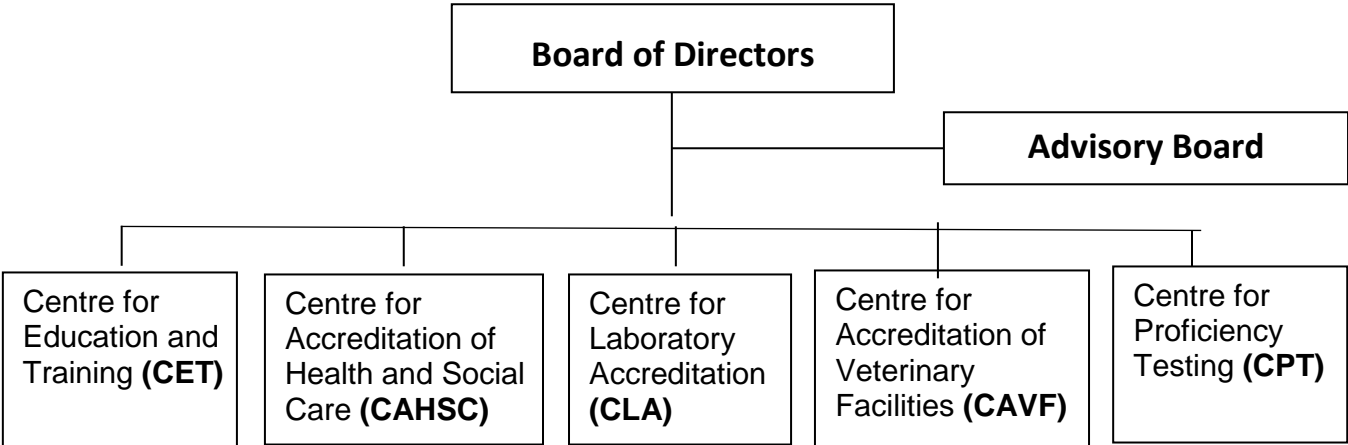
Organization Structure

The organization structure of QAI's Centre for Laboratory Accreditation has been designed to meet the requirements of an effective and efficient accreditation 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.

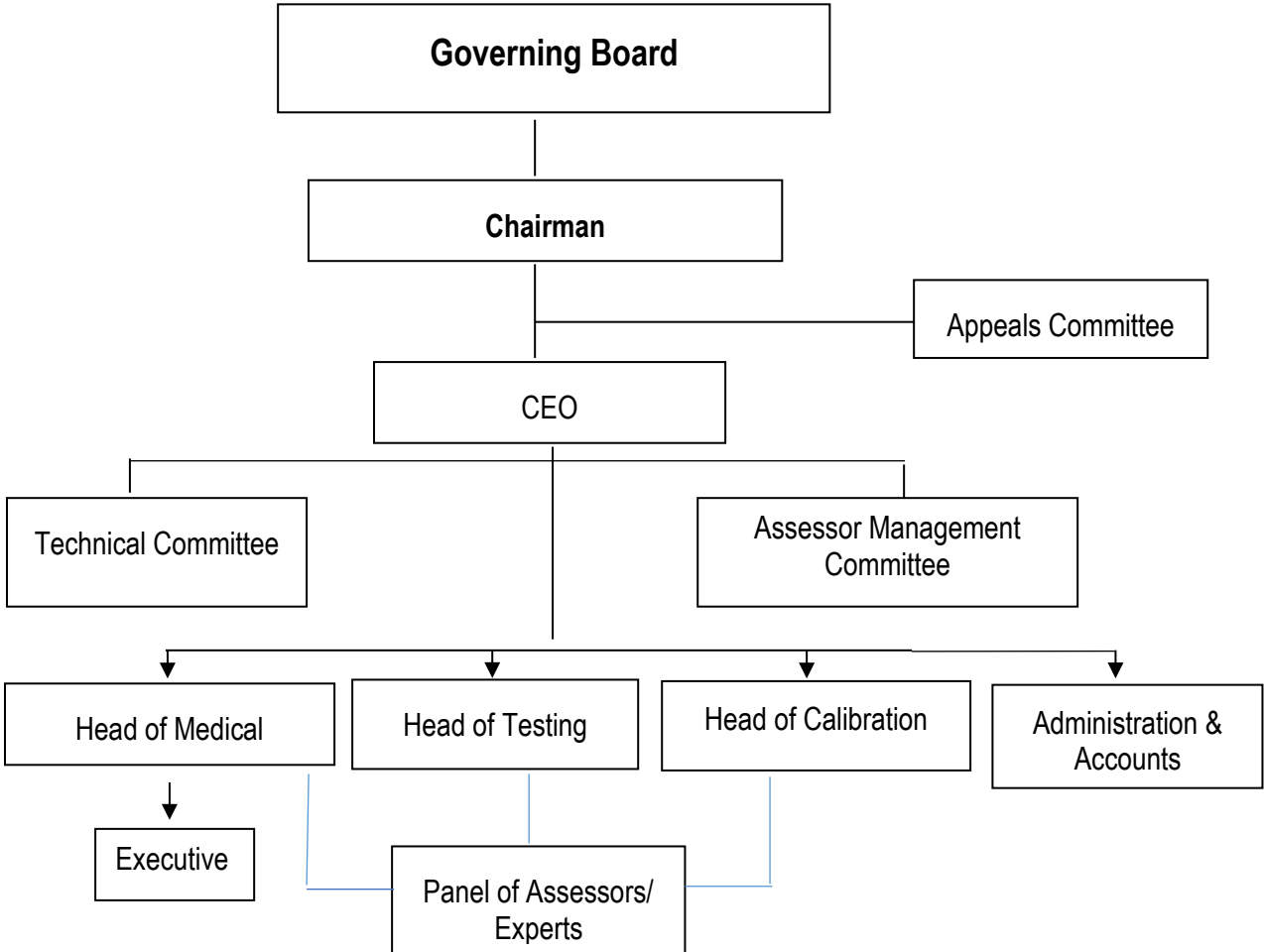
CLA operates its accreditation process through a structured framework of competent staff and pool of empanelled Lead Assessors and Technical Assessors covering all fields and disciplines as specified in the scope of accreditation. All Lead Assessor and Technical Assessors are personnel having considerable 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.

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Organisation Structure of QAI



Structure of CLA



5. International Linkages

QAI's Centre for Laboratory Accreditation is in the process of joining APAC and ILAC membership. 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. Eventually it must gain MRA of APAC and ILAC.

6. Special Features of Laboratory Accreditation Program:

- 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 and ISO/IEC 17025.
- Rigorous Assessor Management System including a transparent monitoring and evaluation mechanism.
- 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.
- Compliance to ISO/IEC 17011.
- Economic yet global model.

7. Scope of CLA Accreditation for Medical Laboratories

Accreditation is currently given in the following disciplines.

Medical Laboratory

- Clinical Biochemistry
- Clinical Pathology
- Haematology & Immunohematology
- Microbiology and Serology
- Histopathology

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- Cytopathology
- Genetics
- Molecular Diagnostics
- Nuclear Medicine
- Point-of-Care Testing (POCT) (ISO 22870)

8. Medical Laboratory Accreditation Program

8.1 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 programs 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.

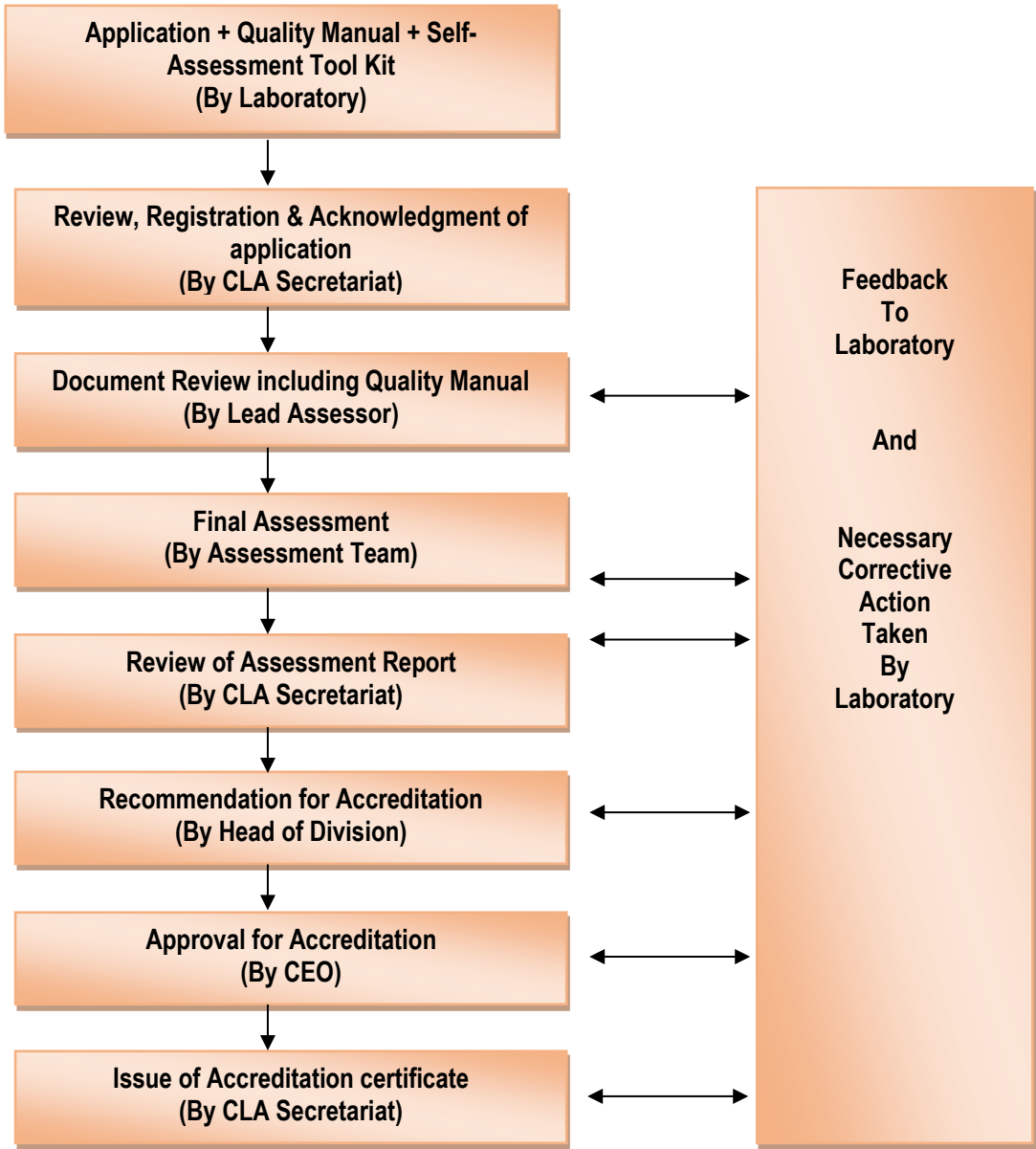
8.2 Eligibility for Accreditation

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 program, wherever applicable, conducted by QAI's CPT/ APAC or any other national or international accredited/ recognized PT provider. If no suitable PT program 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.

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9. Accreditation Process

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



9.1 Application for Accreditation

Applicant laboratory is requested to submit the following:

- Three copies of completed application forms
- One copy of self-assessment tool kit along with referenced documents (**soft copy**)
- Two copies of Quality Manual
- Prescribed application fees
- Signed copy of QAI CLA 001 'Terms and Conditions for Obtaining and Maintaining Accreditation'

Self-assessment tool kit 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.

9.2 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.

9.3 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.

9.4 Final on-site 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**

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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.

9.5 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.

9.6 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.

9.7 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.

9.8 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.

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Terms and Conditions

The accredited laboratory is required to comply at all times with the terms and conditions given in CLA 001 'Terms & Conditions for Obtaining and Maintaining Accreditation'. The laboratory is required to submit a signed 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.

9.9 Surveillance and Re-assessment

The accreditation certificate is valid for a period of two years. CLA conducts annual surveillance which is aimed at evaluating continued compliance with the applicable standards and other requirements stipulated from time to time.

9.10 Reassessment

The accredited laboratory is subjected to re-assessment every 2 years for renewal of accreditation. The 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 so that continuity of the accreditation is maintained. 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 assessment except there will be no adequacy of quality manual. However, there will be adequacy check if there is a change in accreditation standard.

10 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'.

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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'.

11 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 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.

12 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.

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- QAI-CLA requires that all accredited labs abide by ‘Terms and conditions for obtaining and maintaining accreditation’.
- 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 web –site www.qai.org.in.
- QAI-CLA will communicate changes to the requirements of accreditation such as ISO 15189 through website.

13 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:

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Medical Laboratory Fee Structure:

| 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) |
|--|--|---|---|
| Very Small Laboratories | Below 30 patients/day/ location | Rs. 20,000/- | Rs. 30,000/- |
| Small Laboratories | 31-100 patients/day/ location | Rs. 25,000/- | Rs. 35,000/- |
| Medium | 101 – 400 patients/ day/ location | Rs. 40,000/- | Rs. 55,000/- |
| Large Laboratories | 401 – 1000 patients/ day/ location | Rs. 100,000/- | Rs. 125,000/- |
| Very Large Laboratories / Laboratories operating from multiple locations (more than one location in the same city) | 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/- |
| Charges For Collection Centres/ Number of Collection Centres | 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.

Assessment Charges: In addition to the above fee, laboratory shall bear the cost of following:

- a) Travel of the assessment team
- b) Boarding & Lodging

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No other overhead charges**Guidelines for Travel, Boarding and Lodging:**

- a. Travel to be made by Air in economy class (Apex fare) or by train in 2nd 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-imbursment will be as per company's rules or restricted to 2nd 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.

Beneficiary Address: 416, Krishna Apra Plaza, Sector 18, Noida-201301, India

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

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FEE STRUCTURE FOR ACCREDITATION OF LABORATORIES OUTSIDE INDIA

Fee structure for Medical Laboratories (covering all disciplines) 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) |
|--|---|---|---|
| Very Small Laboratories | Below 30 patients/day/ location | \$350 | \$500 |
| Small Laboratories | 31-100 patients/day/ location | \$400 | \$550 |
| Medium | 101 – 400 patients/ day/ location | \$650 | \$900 |
| Large Laboratories | 401 – 1000 patients/ day/ location | \$1600 | \$2000 |
| Very Large Laboratories / Laboratories operating from multiple locations (more than one location in the same city) | Above 1000 patients/ day/location or Laboratories operating from multiple locations (more than one location in the same city) | \$3200 | \$3500 |
| Charges For Collection Centres attached to the laboratory | | | |
| Number of Collection Centres | up to 10 | \$75 | \$75 |
| | >10 – 50 | \$150 | \$150 |
| | > 50 – 100 | \$250 | \$250 |
| | More than 100 | \$400 | \$400 |

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In addition to the above mentioned fee applicable tax, if any to be paid.

Assessment Charges: In addition to the above fee, laboratory shall bear the cost of following:

- a) Travel of the assessment team
- b) Boarding & Lodging

Guidelines for Travel, Boarding and Lodging:

- a) Inter-country travel to be made by air in economy class (Apex fare) and intra-country travel by air or by train or by AC bus or by taxi, as available.
- b) The laboratory will provide the tickets for travel as per above guidelines.
- 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.

Fee payment:

All payments through Bank Transfer shall be made as per following details:

Beneficiary name: Quality and Accreditation Institute Pvt. Ltd.

Beneficiary Address: 416, Krishna Apra Plaza, Sector 18, Noida-201301, India

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

Note:

Any bank charges for transfer of fee is to be paid by the laboratory.

14 QAI-CLA Publications

All relevant publications (policy/procedure/document) are available on our website

www.qai.org.in.

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