

QAI CLA 301

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



Change Adapt Improve

**INFORMATION BROCHURE
FOR
BIOBANK ACCREDITATION PROGRAMME**

Issue No.: 01

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1. Introduction

Accreditation is a procedure wherein an Accreditation Body gives formal recognition of technical competence for specific activities, based on third party assessment and following international standard.

Accreditation requirements for biobanking are specified in the International Standard ISO 20387:2018. This standard specifies general requirements for the competence, impartiality and consistent operation of biobanks including quality control requirements to ensure biological material and data collections of appropriate quality.

Biobank is a legal entity or part of a legal entity that performs biobanking i.e., processes such as collecting/procuring and/or acquiring and receiving, tagging, accessioning/logging, cataloguing/classifying, examining, preparing, preserving, storing, managing data, destroying, packaging as well as safeguarding, distributing and transporting defined biological material as well as related information and data.

Accreditation is considered a mechanism to enable biobanks to demonstrate competent biobank operation and the ability to provide biological material and associated data of appropriate quality for research and development. This is intended to be achieved by the planning and implementation of policies, processes and procedures covering the life cycle of biological materials and their associated data. The use of ISO 20387 facilitates cooperation, fosters exchange, and assists in the harmonization of practices among biobanks, researchers and other parties.

ISO 20387 is applicable to all organizations performing biobanking, including biobanking of biological material from multicellular organisms (e.g., human, animal, fungus and plant) and microorganisms for research and development.

Please note that this standard does not apply to biological material intended for food/feed production, laboratories undertaking analysis for food/feed production, and/or therapeutic use.

2. Benefits of Accreditation

Accredited biobank with international standards has following advantages:

- Increased confidence in Biobanks;
- Ensure biological material and associated data is of appropriate quality.
- Biobank users and regulatory authorities can rely on accreditation as a measure of competence compliance to the regulatory requirements;
- Facilitate cooperation, fosters exchange, and assists in the harmonization of practices among biobanks, researchers and other parties.
- Potential increase in business due to enhanced user confidence and satisfaction.
- Accredited biobanks are publicised by the Accreditation Body by putting their name on its website.
- Global recognition and networking as accreditation is granted in accordance with International Standard ISO 20387.

3. About Quality & Accreditation Institute (QAI)

Quality and Accreditation Institute was set up to create an ecosystem of accreditation, education, training and quality improvement. We would like to provide a platform to stakeholders including professionals and organisations, associated with quality in any way, to share their wisdom and

knowledge in order to place quality at the core of any business. 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)

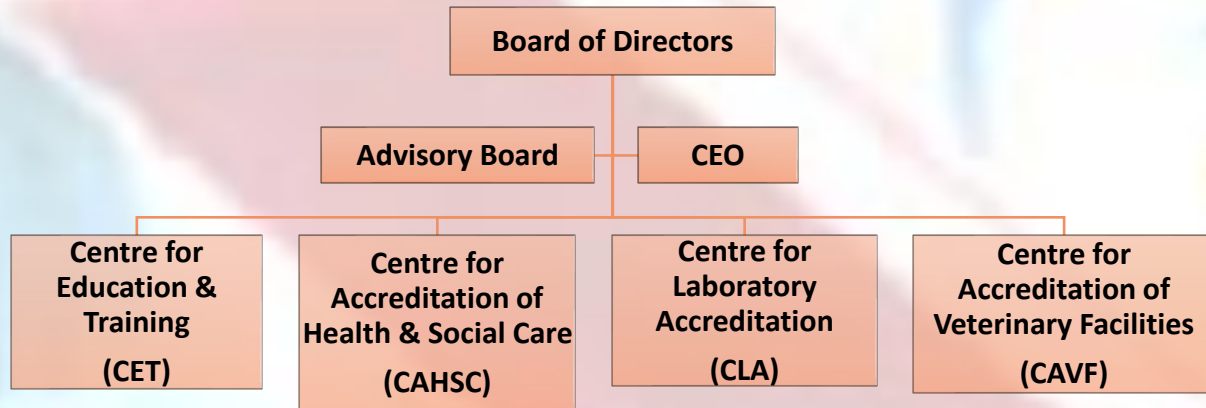
QAI's CLA has been established with the objective of providing Government, Industry Associations and Industry in general with a scheme of accreditation of laboratories including medical, testing, and calibration laboratories and biobanks. The laboratory accreditation services to testing and calibration laboratories are provided in accordance with ISO/ IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories', ISO 15189 'Medical laboratories -- Requirements for Quality and Competence' and ISO 20387 'Biobanking - General requirements for biobanking'. 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 and biobanks in India and other countries regardless of the size, affiliation and types. QAI-CLA has established 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) of the Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Programme (ILAC) Mutual Recognition Arrangement (MRA). We shall make available relevant documents for laboratories, biobanks, assessors and stakeholders on the website. We aim to attain signatory status of Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Programme (ILAC).

5. Organisation Structure

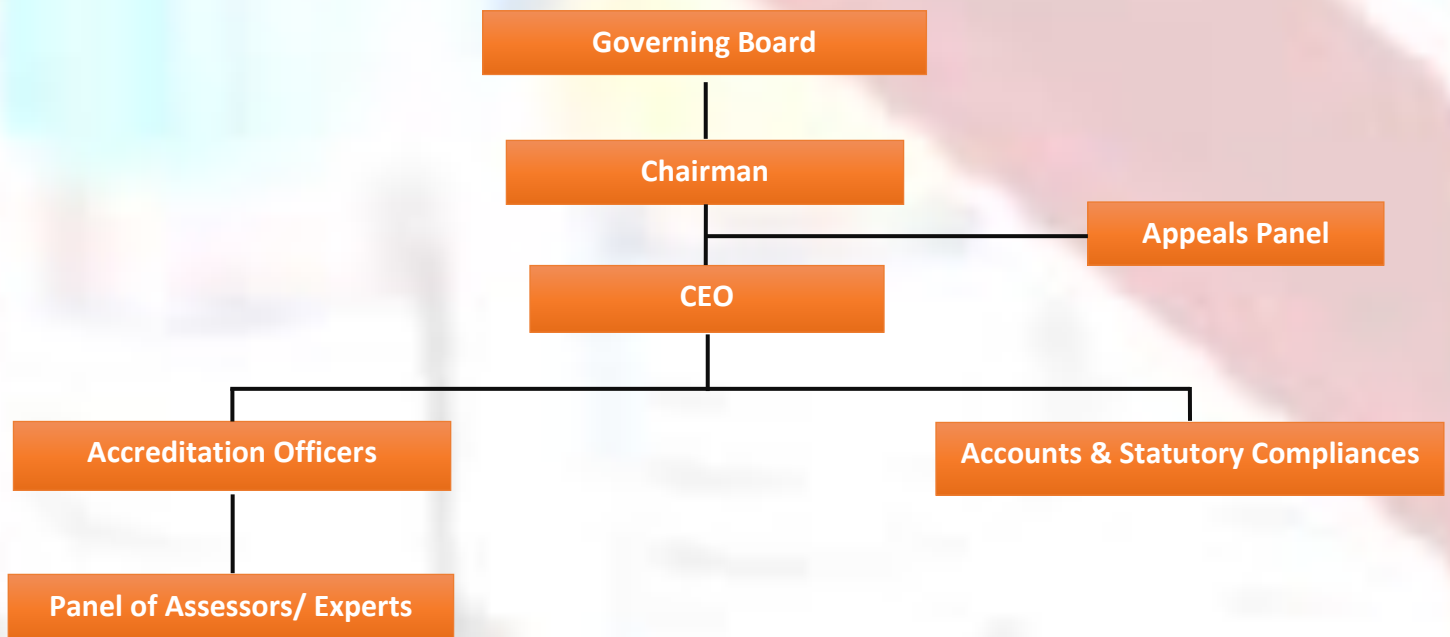
The organisation structure of QAI's Centre for Laboratory Accreditation has been designed to meet the requirements of an effective and efficient accreditation system. The Centre is governed by an

independent Board comprise of professionals and in a manner that no single interest predominates. 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 (Team Leaders) and Assessors. All Lead Assessor and Assessors are personnel having considerable experience in related activities. They are trained by CLA as per the relevant international accreditation standard 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 Biobank 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 biobank as per the intent of the standard
- Introducing a new concept of self-assessment and document review enabling Biobanks for a thorough review of their documentation and implementation of requirements of ISO 20387.
- Assessment process ensures continuous support to our clients in handling their queries in timely manner.
- Rigorous Assessor Management System including a transparent monitoring and evaluation mechanism for all empanelled assessors.
- Harmonising local, national, regional and global framework.
- Blend of global strategy, experience and leadership.
- Consolidated fee structure reducing number of financial transactions
- Economic yet global model.

8. Scope of Accreditation

Accreditation is currently given for the following scope:

Source and Type of Biological Material & Associated Data	Activities	Procedure(s)	Method to Carry out the Procedure
A. Human (blood products/ components, tissues, body fluids, cell lines, gametes, genetic material, waste products etc.)	Acquisition/ Collection/ Procurement	Receiving Tagging Accessioning/ Logging Examining	e.g., SOP-1
	Preparation/ Processing	Labelling	e.g., SOP-2
	Testing/ Analysis	Inoculation Sequencing Microscopy	e.g., SOP-3
B. Animal (blood, tissue, body fluids, gametes, cell lines, genetic materials etc.)	Preservation	Liquid Nitrogen Flash Freezing Freeze drying Ultra-low temperature Formalin	

C. Plant (tissue, genetic materials etc.)	Storage		
D. Microorganism (culture, genetic materials etc.)	Distribution/ Transportation of material (alongwith related information and data)		
E. Multicellular organism neither animal nor plant e.g., Fungi, Brown Seaweed (culture, genetic materials etc.)	Disposal (of material beyond a defined storage period, if any)		

9. Biobank Accreditation Programme

9.1. Preparing for Accreditation

Management of the biobank shall first decide to get its Biobank accredited. It is important for the biobank to make a definite plan of action for obtaining accreditation and nominate a person to coordinate all activities related to seeking accreditation. An official nominated should be familiar with existing activities and quality management system as per ISO 20387.

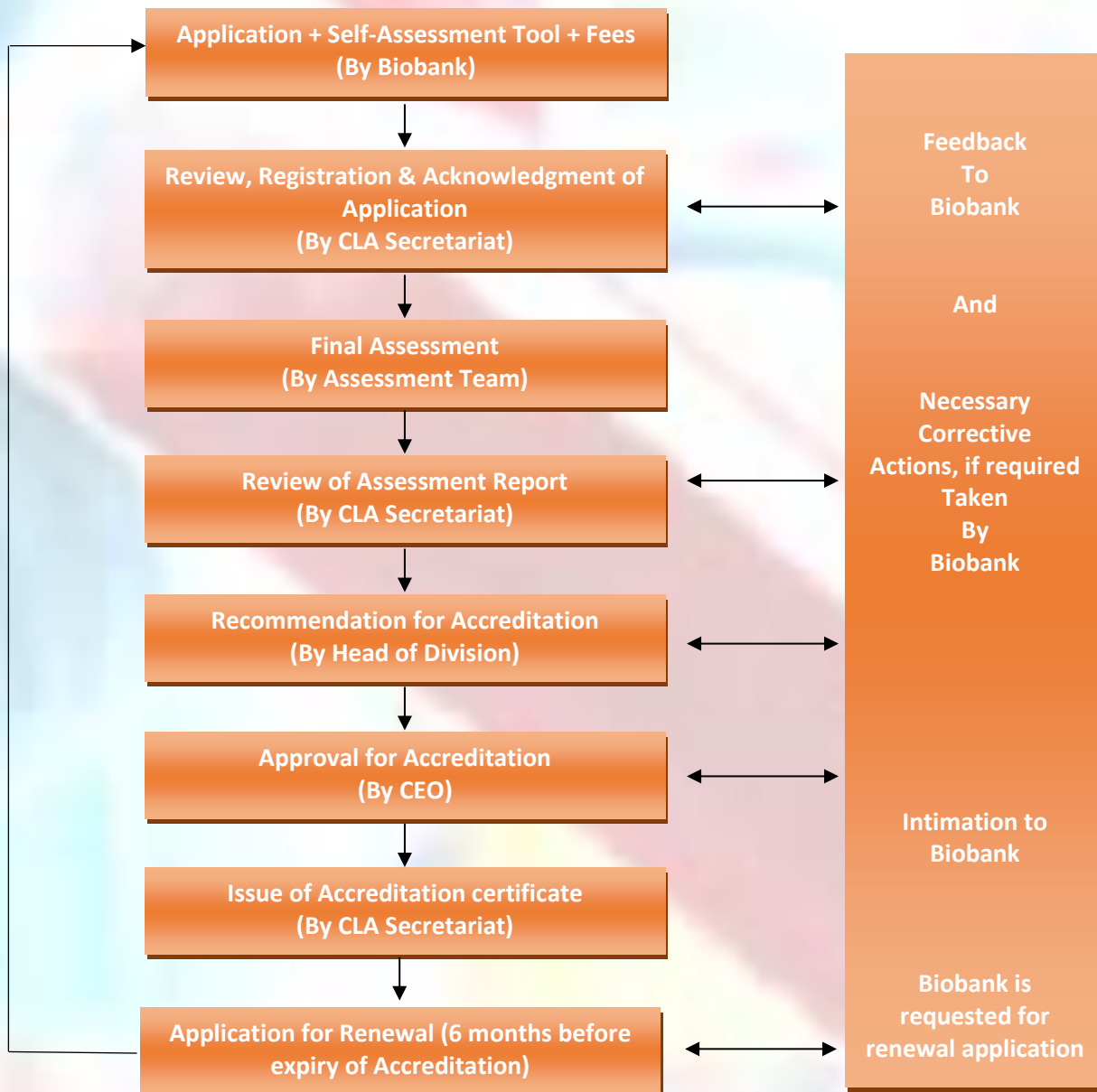
Biobanks must procure a copy of the standard ISO 20387:2018. The biobank seeking accreditation shall understand the QAI assessment process. The biobank shall ensure that all the requirements of the standard are implemented. It is advised that biobank may get its personnel trained in a training programme on current ISO 20387. Biobank may find it useful to get its staff responsible for maintaining the Quality Management System trained in a formal and relevant internal auditor training programme.

9.2. Eligibility for Accreditation

The applicant biobank must comply with all requirements of ISO 20387:2018. The applicant biobank must attempt to participate in a proficiency testing programme, wherever applicable, conducted by APAC or any other national or international accredited/ recognised PT provider. If no suitable PT programme is available, the biobank can initiate an inter-laboratory comparison with adequate number of biobanks or develop other approaches as given in the standard. The applicant biobank must have conducted at least one internal audit and a management review before the submission of application.

10. Accreditation Process

Accreditation process is developed in a manner which provide clear guidance to applicant biobank at each stage of processing. The process is transparent and a two-way communication channel works to support the applicant biobank for addressing queries, if any.



10.1 Application for Accreditation

Applicant biobank is requested to submit the following:

- Soft copy of completed application form (available on website)
- Soft copy of self-assessment tool along with referenced documents
- Prescribed application fee
- Signed copy of QAI CLA 002 'Terms and Conditions for Obtaining and Maintaining Accreditation/Certification'

Self-assessment tool is based on the requirements of the accreditation standard ISO 20387:2018. It gives an opportunity to the biobank to examine all its documentation and their implementation. It will also give a comprehensive view of its documentation to the assessment team.

10.2 Review, Registration and Acknowledgement of Application

CLA Secretariat on receipt of application form, self-assessment tool, referenced documents and the fees reviews the application for its completeness, and a unique ID number is allocated which is used for correspondence with the biobank. Additional information/ clarification(s) may be sought, if required.

10.3 Assessment (On-site/ Remote/ Hybrid)

Secretariat constitutes an assessment team. The team includes team leader and technical assessor(s)/ expert(s) in order to cover various fields within the scope of accreditation sought. Secretariat may also nominate an observer which is either an assessor-in-training or a Secretariat staff. Secretariat will seek biobank's acceptance for the proposed assessment team and dates for assessment. The biobank 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, team leader/lead assessor takes over to initiate the further process. The assessment team keeps the secretariat in loop for any communication with the biobank. During assessment visit, the assessment team reviews the documented management system and verifies its compliance with the requirements of ISO 20387:2018 and other relevant policies. The assessment report contains the evaluation of technical resources, all relevant material examined, activity and procedure witnessed. 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 biobank. The report prepared by the assessment team is sent to CLA Secretariat. A copy of summary of the assessment report and copies of nonconformities, if any, are provided to the biobank at the end of the assessment visit.

10.4 Review of Assessment Report

The assessment report is examined by the Secretariat and follow up action as required is initiated. Biobank has to take necessary corrective action on nonconformities and submit a satisfactory report giving evidences to the Secretariat within 30 days.

10.5 Decision Making

After satisfactory corrective action submitted by the biobank and accepted by the assessment team, Lead Assessor submits its recommendation to the Secretariat which examines the report and comments of the assessment team and may seek clarification from the Lead Assessor/ Assessor/ biobank concerned. In case requirements are in order, decision regarding grant of accreditation is taken by Secretariat. All decision regarding grant of accreditation are open to appeal by the biobank as per laid down appeal process.

10.6 Issue of Accreditation Certificate

When the decision results into grant of accreditation, Secretariat issues an accreditation certificate which has a unique number, discipline, date of validity along with the scope of accreditation.

Accreditation Mark/ Symbol

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



ISO 20387:2018

Certificate No.

Example: QAI/CLA/BB/2020/0000

10.7 Maintaining Accreditation

Conformance to applicable standards and other requirements

The accredited biobank at all times shall conform to the requirements of ISO 20387 as well as any other laid down requirements.

Terms and Conditions

The accredited biobank 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 biobank 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 biobank is informed of this giving an appropriate transition period to align its operations in accordance with the modified criteria.

Adverse decision against the biobank

If the biobank 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 biobank like abeyance, scope reduction, denial of accreditation, suspension or forced withdrawal as per laid down policy.

Ongoing Monitoring

Accredited biobank is required to submit following information/documents/ records every year in the middle of the accreditation cycle. This is to ensure that the accredited biobank is continuously complying with the requirements of the applicable standard (ISO 20387:2018) and any other requirements stipulated from time to time.

A. Internal Audit

- A.1 Internal audit plan
- A.2 Copy of last internal audit

B. Management Review

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

C. Proficiency Testing/ External Quality Assessment Schemes/ Inter-laboratory comparisons (ILC)/ Any other approach provided in the ISO 20387 (e.g., use of CRMs)

- C.1 Proficiency testing (or any other approach) 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 scope etc.)

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

A statement "This is to declare that that the biobank has been complying to the requirements of ISO 20387:2018 and any other requirements prescribed by the QAI CLA since last assessment"

10.8 Re-assessment

Accreditation cycle will be of two years. Reassessment will be conducted before the expiry of accreditation. An accredited biobank is required 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 assessments shall not exceed two years."

The renewal application is submitted in the prescribed form (QAI CLA 302). The biobank 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.

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 biobanks. 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 biobanks against its decisions. The decisions against which appeals are entertained relate to adverse decisions like non-acceptance of application, 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 Biobanks

Rights of Biobank

Biobanks are entitled to receive information related to biobank accreditation. They can access our website www.qai.org.in which gives information necessary for accreditation. The biobank has the right to object to appointment of specific member(s) of assessment team by giving valid reasons. QAI-CLA accredited biobank has a right to use 'QAI Accreditation Mark' on the publicity material and reports as long as such use is as per laid down policy.

Obligations of the Biobanks

An accredited biobank is obliged to fulfil requirements of relevant standard and any other requirements set by QAI-CLA. The biobank 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 biobank can claim accreditation only for the scope for which it has been granted accreditation and shall not claim accreditation in a manner which can bring disrepute to QAI or misrepresent the facts. The biobank is required to notify QAI of any change that may affect accreditation status, within 15 days of such change. The biobank 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 biobanks will conform to ISO 20387:2018 and any other requirement specified by QAI-CLA from time to time to maintain accreditation.
- QAI-CLA requires that all accredited biobanks abide by 'Terms and conditions for obtaining and maintaining accreditation/certification'.
- QAI-CLA has the right to:
 - ❖ effect changes in standards on which biobank accreditation is based in accordance with international norms
 - ❖ decide on policies related to accreditation
 - ❖ appoint assessment teams in consultation with biobank and the assessors
 - ❖ take appropriate action including adverse decisions against a biobank giving valid reasons for the same

Duties

- QAI-CLA is obliged to make available relevant information to its applicant and accredited biobanks. This information is provided on our web site www.qai.org.in.
- QAI-CLA is obliged to make available information on scope of accreditation, validity dates for accreditation certificate(s) and contact details to users of the biobank.
- QAI-CLA will communicate changes to the requirements of accreditation such as ISO 20387 through website.

14. Finance and Fee Structure

Finance

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

Fee Structure

A uniform fee structure is maintained for all biobanks and the charges are maintained at a reasonable level so that biobanks 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. Information about the fee structure for various field(s)/ discipline(s) is given below:

Fee structure for Biobanks operating within India

Sl. No.	Type of Biobank	Application fee (non-refundable, to be paid along with the application)	Annual Accreditation Fee (from the date of accreditation)
1.	For one source and one type of biological material	Rs. 25000/-	Rs. 75000/-
	For each additional type of biological material from same source	Rs. 10000/-	
2.	For each additional source of biological material	Rs. 25000/-	

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, biobank shall bear the cost of following (applicable for onsite visit)

- 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 2nd AC Class or by AC Bus.
- b. The biobank 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 2nd AC Class fare by train.
- c. The biobank 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 biobank site and airport/ railway station/ bus stand.

Fee Payment:

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

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 are to be paid by the Biobank.

15. QAI-CLA Publications

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



Quality and Accreditation Institute

Centre for Laboratory Accreditation

Email: info@qai.org.in Website: www.qai.org.in

Twitter: [@QAI2017](https://twitter.com/QAI2017)